U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
April 13, 1998

Guidance for Industry

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

Draft Guidance

This guidance document is being distributed for comment purposes only.

Draft released for comment on April 13, 1998.

Comments and suggestions regarding this draft document should be submitted by June 26, 1998 to Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. All comments should be identified with the Docket number 97N-0451. For questions regarding this draft document contact Joyce Saltsman, (202) 205-5916, or Michelle Smith, (202) 205-2975.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
April 13, 1998

GUIDANCE FOR INDUSTRY[1]

GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS FOR FRESH FRUITS AND VEGETABLES

PREFACE

American consumers enjoy one of the safest food supplies in the world. However, over the last several years, there has been an increase in reported outbreaks of foodborne illness associated with both domestic and imported fresh fruits and vegetables. 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 to provide further assurance that fruits and vegetables consumed by Americans,

including fruits and vegetables imported from other countries meet the highest health and safety standards (Ref 3). The plan, entitled "Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables," is geared towards increasing assurances that fruits and vegetables, whether produced domestically or imported, are safe. 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 document ("the guide") addresses microbial food safety hazards and good agricultural practices common to the growing, harvesting, packing, and transporting of most fruits and vegetables that are sold to consumers in an unprocessed or minimally processed (raw) form.

The guide is intended to be guidance only, to assist growers and packers in continuing to improve the safety of domestic and imported produce. Alternative approaches may also be applied if they minimize food safety hazards. Growers and packers should use the general recommendations in this guide to tailor food safety practices appropriate to their particular operations. Moreover, the recommendations in this guide do not supercede applicable Federal, State, or local laws or regulations.

The guide is one of the first steps under the President's initiative to improve the safety of fresh produce from the farm to the table. The produce food safety initiative is not limited to the farm. As part of the President's total food safety initiative, educational outreach programs (such as the recently initiated "Fight Bac" campaign to improve safe food handling by consumers) will be targeted to everyone along the farm to table chain. FDA's Food Code provides advice to State and local agencies about safe food handling practices at grocery stores, restaurants, and other retail establishments (Ref 4). FDA is 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 at the retail level that might effectively reduce or eliminate microbial contamination of fresh produce.

The food safety initiative is also focused on scientific research, identifying and supporting research priorities designed to help fill the gaps in our knowledge of food safety, and assisting in assessing risks and in developing cost-effective interventions to prevent, control, or eliminate microbial pathogens on fresh produce.

Growers are urged to take a proactive role in minimizing the food safety risks from fruits and vegetables. 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, growers should encourage the adoption of safe practices by their partners along the farm to table pathway, including those involved in the packing and transport of produce, distributors and retailers, food service operators, and consumers, to assure that each individual effort will be enhanced.

INTRODUCTION

The importance and influence of the diet on health is undisputed. Several chronic diseases, such as coronary heart disease and some types of cancer are associated with dietary excess and imbalance and are a major public health concern in the United States. 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.

While the health benefits associated with regular consumption of fresh fruits and vegetables have been clearly demonstrated, some data suggest that the proportion of outbreaks associated with fresh produce compared to other foods may be increasing. Estimates of the incidence and prevalence of foodborne infection from fresh produce are unavailable.

Several recent outbreaks of illness associated with produce (*E. coli O*157:H7 and mesclun mix lettuce, *Cyclospora* and imported raspberries) have raised concerns regarding the safety of fruits and vegetables that are not processed to reduce or eliminate pathogens. These organisms are found in the feces of humans and animals, including birds. Growers and packers, in order to ensure the marketability of their products, need to assess their individual operations and implement steps to reduce the risk of microbial contamination of raw produce.

Use of This Guide

> ***Because of the diversity of agricultural practices and commodities, practices to minimize microbial contamination will be most effective when these general concepts are adapted to specific operations.***

This guide is intended to assist the produce industry in enhancing the safety of domestic and imported produce by addressing common areas of concern in the growing, production, and distribution of fresh fruits and vegetables. The guide will identify the broad microbial hazards associated with each area of concern, the scientific basis of that concern, and present good agricultural practices for reducing the risk of microbial contamination in fresh produce.

It is important to note that there are a number of missing pieces of information in the scientific basis for reducing or eliminating pathogens in an agricultural setting. Thus, the examples of good agricultural practices and good management practices presented in the guide are not intended to be required of all industry operators. Rather, the examples are intended to build broad industry understanding and awareness of those practices that individual growers and packers may find useful to address in their own operations. Because of the diversity of agricultural practices and commodities, practices to minimize microbial contamination will be most effective when these general concepts are adapted to specific operations.

The agencies recognize that the agricultural community has made a significant effort in the past few years to adjust practices to help minimize microbial food safety hazards in produce. Several organizations in the fresh fruit and vegetable industry, universities, State and local government agencies, and countries exporting produce to the United States have taken strong leadership roles in assisting growers in identifying potential hazards associated with their operations. These efforts have included the development of quality assurance programs, good manufacturing practices and good agricultural practices guidance documents; funding of agriculture research studies; and sponsoring educational initiatives. The intent of the guide is to build on those earlier 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 and USDA. It was developed in cooperation with experts from several Federal and State government agencies. The guide cannot adequately 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 reviewing this guide.

1) The guide focuses on risk reduction not risk elimination. In many cases, current technologies cannot eliminate all potential food safety risks associated with fresh produce.

2) The guide provides broad, scientifically based principles. Producers should use the guide to help assess microbiological risks within the context of the specific conditions (climatic, geographical, cultural, economic) that apply to their own operation and implement appropriate cost effective risk reduction strategies.

3) 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.

4) The guide focuses on microbial hazards for fresh produce. The guide does not specifically address other hazards to the food supply or environment (such as pesticides or chemical contaminants). In evaluating the recommendations in this guide that are most appropriate for reducing microbial hazards in their individual operations, growers and packers should strive to establish practices that do not increase other risks to the food supply or the environment (e.g., excessive packaging or improper use and disposal of antimicrobial chemicals.

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 practices for your operation.

This guidance document is based upon certain basic principles associated with minimizing microbial food safety hazards from the field through distribution of fresh fruits and vegetables. The broad categories of these basic principles include water, manure/municipal biosolids, worker hygiene, field and facility sanitation, and transportation.

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

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

Principle 2. To minimize microbial food safety hazards in fresh produce, growers or packers should use good agricultural practices in those areas over which they have some degree of control while not increasing other risks to the food supply or the environment.

Principle 3. Anything that comes in contact with fresh produce has the potential of contaminating it. For most foodborne pathogens associated with produce, the major source of contamination is associated with human or animal feces.

Principle 4. Whenever water comes in contact with produce, its source and quality dictate the potential for contamination. Good agricultural and manufacturing practices must be considered to minimize the risk of contamination from water used for agricultural and processing purposes.

Principle 5. Practices using manure or municipal biosolids should be closely managed to minimize the potential for contamination.

Principle 6. Worker hygiene and sanitation practices along the production cycle play a critical role in minimizing the potential for microbial contamination of fresh produce.

Principle 7. It is important to understand and follow all local, State, and Federal government regulations relative to established agricultural practices.

Principle 8. Establish a system for accountability at all levels of your agricultural environment (farm, packing facility, distribution center, and transport operation). A successful food safety program should include provisions for qualified personnel and effective monitoring and maintenance to ensure that all elements of the program are functioning 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 generally to water used in the growing environment (e.g., field or orchard) for agronomic reasons, such as irrigation, transpiration control (cooling), frost protection, and as a carrier for pesticides. Occasionally a more specific term may be used, such as "irrigation water."

Adequate means that which is needed to accomplish the intended purpose in keeping with good practice.

Composting refers to a managed process in which organic materials are digested aerobically or anaerobically by microbial action.

Control means (a) to manage the conditions of an operation to maintain consistency with established criteria, and (b) to follow correct procedures and meet established criteria.

Control measure means any action or activity that can be used to prevent, reduce, or eliminate a hazard.

Facility means the sites and buildings used for or in connection with the harvesting, storage, processing,

packaging, labeling, or holding of fruits and vegetables.

Food-contact surfaces 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 used in agricultural practice.

Fresh fruits and vegetables refers to produce that are likely to be sold to consumers in an unprocessed or minimally processed (i.e., raw) form. Such produce may be intact (e.g., strawberries, raspberries, fresh market tomatoes) or cut during harvesting (e.g., celery). The guidance in this document is also applicable to "fresh cut" produce (e.g., 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 those covered in this broadscope guidance document.[2]

Food safety control operation means a planned and systematic procedure for taking all actions necessary to prevent food from becoming unsafe for the consumer.

Good management practices refers to general practices to reduce microbial food safety hazards. The term may include both "good agricultural practices" employed in the growing environment and "good manufacturing practices" employed in the processing/packing environment.

Microorganisms means yeasts, molds, bacteria, protozoans, and viruses. Occasionally, the term "microbe" or "microbial" is used instead of the term "microorganism."

Microbial hazard means microorganisms that are reasonably likely to cause illness or injury. This includes the specific bacterial, fungal, and viral pathogens, and other microorganisms, that cause food to become a public health hazard.

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

Operator means the person or persons who have day to day responsibility for the production, harvesting, processing, or distribution of fresh fruits and vegetables, and responsibility for management of all employees who are involved in these activities.

Pathogen means a microorganism capable of causing disease or injury.

Pest 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.

Sanitize means to treat produce by a process that is effective in destroying or substantially reducing the numbers of vegetative cells of microorganisms of public health concern, and other undesirable microorganisms, without adversely affecting the quality of the product or its safety for the consumer. For food-contact surfaces, sanitize means the application of cumulative heat or chemicals on cleaned surfaces sufficient to reduce populations of representative microorganisms by 5 log or 99.999%.

Surfactant means any substance that when dissolved in water or an aqueous solution reduces its surface tension or the interfacial tension between it and another liquid.

II. WATER

> ***Wherever water comes in contact with fresh produce, its source and quality dictate the potential for pathogen contamination.***

Water use in crop production involves numerous field operations including irrigation, applications of pesticides and fertilizers, and produce rinsing, cooling, washing, waxing, and transport. Water 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 source and quality dictate 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 certain microorganisms including pathogenic strains of *Escherichia coli*, *Salmonella* spp., *Vibrio cholerae*, *Shigella* spp., *Cryptosporidium parvum*, *Giardia lamblia*, *Cyclospora cayetanensis*, and the Norwalk and hepatitis A viruses. Even small amounts of contamination with some of these organisms can result in foodborne illness. Research has shown that the use of contaminated irrigation water can increase the frequency of pathogen isolation from harvested produce (Refs 5 and 6). For example, in 1995, an outbreak of *E. coli* O157:H7 infections involving at least 29 people was linked to leaf lettuce (Ref 7). While it is not known where the lettuce became contaminated, investigators noted that the lettuce was irrigated with surface water, which may be vulnerable to contamination (such as through runoff). 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 8 and 9). Tomatoes from both outbreaks were traced back to a single packinghouse where a water-bath appeared to be the likely source of contamination.

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 known what proportion of produce may become contaminated by water used in agricultural or packinghouse operations. However, 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 produce may need to be of better quality compared to uses where there is minimal contact with the edible portion of the plant.***

The source 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 produce may need to be of better quality compared to uses where there is minimal water-to-produce contact. An example of this is that water quality needs may be higher for overhead spray irrigation where water is more likely to have significant, direct contact with the edible portion of the plant compared to drip irrigation which can avoid such contact for many crops. Produce that has a large surface area and those with topographical features that foster pathogen attachment or entrapment may be at greater risk from

contaminants in irrigation water, especially if applied from above (e.g., overhead spray irrigation) and when contact occurs close to harvest.

Some sectors of the produce industry use water containing sanitizers to minimize potential surface contamination, such as during washing and rinsing to clean produce and harvest and transportation equipment. Operators should consider the following issues and practices when assessing water quality in their own operations and in applying controls to minimize microbial food safety hazards.

1.0 Agriculture Water

> ***Water quality should be adequate for its intended use.***

Agricultural water quality will vary, particularly from surface waters that may be subject to intermittent, temporary contamination, such as 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 ensure that the water quality is adequate for its intended use may include ensuring that wells are properly constructed and protected, treating water to reduce microbial loads, or using alternative application methods (such as drip irrigation) that reduce or avoid water-to-produce contact. The feasibility of these and other practices will depend on the intended water use and the needs and resources of the particular farming 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 agriculture water include flowing surface waters from rivers, streams, irrigation ditches, and open canals; impoundments such as ponds, reservoirs, and lakes; and ground water from wells and municipal supplies. It is generally assumed that groundwater is less likely to be exposed to 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. 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 possible contamination, may want to have their well examined by a water quality expert. The Extension Service Farm*A*Syst program available from County Extension Offices may help determine the condition of the well.

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

  Agriculture 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. On-farm sources of contamination from animal waste include manure storage near crop fields, leaking or overflowing manure lagoons, uncontrolled livestock access to surface waters 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.**

  Because agricultural water is frequently a shared resource, operators should consider factors that impact their portion of the watershed. For example, the topography of the field, and current and historical use of adjacent lands all affect the potential for irrigation water to serve as a mechanism for spreading contaminants. Growers should evaluate their crop fields in terms of their proximity to surrounding land uses that pose a potential for polluted runoff from heavy rainfall. While growers may not have control over all factors that impact the watershed, awareness of potential problems will help determine which control options are most feasible. 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 produce crops.

- **Consider testing water quality.**

  As discussed below, there are a number of significant gaps in the science upon which to base a microbial testing program for agricultural water.[3] Thus, microbial testing of agricultural water may not be useful for all growers. 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[4], using standard indicators of fecal pollution, such as *E. coli* tests, which may be performed by private, State, or local government laboratories. 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.

  - Examples of factors that have been shown to increase the likelihood of contamination include presence of wastewater discharges upstream, significant urban runoff, combined sewer overflows, and areas heavily impacted by livestock production.

  - Testing water may not reveal specific pathogens if they are present in low numbers. Further, water quality, especially surface water quality, can vary seasonally (or even hourly), and a single test may not indicate the potential for water to be contaminated.

1.2 Irrigation Water

Irrigation water is a potential source of contamination of produce by pathogens, if the water is exposed to pollution. Irrigation practices that expose the edible portion of plants to direct contact with contaminated water increase microbial food safety hazards. Thus, for many crops, spray irrigation has a greater potential for spreading contamination than drip irrigation. Depending on specific crop needs and the potential for source water contamination, growers may consider using a drip irrigation type water delivery system to minimize direct water-to-produce contact. To the extent feasible, growers should follow good agricultural practices that minimize the potential for contaminated water contact with the edible portion of produce. This becomes increasingly important the closer irrigation applications are made in relation to harvest.

- **Be aware of risk factors.**

The potential for irrigation water to contaminate fresh produce depends on many interrelated factors, such as the presence of pathogens in the water, the method of water delivery (drip station, overhead spray, etc.), the time interval between last irrigation and harvest, and the physical characteristics of the crop (such as, orchard fruit or low growing, leafy vegetables). In general, as water-to-produce contact increases, microbiological water quality needs to be better, especially close to harvest.

- **Consider practices that will protect irrigation water quality.**

  Growers should consider practices, where feasible, to protect the quality of water used for irrigation, such as protecting wells and pump areas from uncontrolled livestock or wildlife access to limit the extent of fecal contamination.

1.3 Non-irrigation Water Uses

Water for non-irrigation agricultural uses, such as for cooling crops, frost protection, or pesticide applications may also be a potential source of microbial contamination and should be considered in the same manner as irrigation water.

- **Be aware of risk factors.**

  The potential for non-irrigation water to contaminate fresh produce depends on factors such as the physical characteristics of the crop, the amount of water contacting produce, frequency of water use, and when it is applied. The presence of surfactants, powders, or debris in crop protection sprays, and the biological characteristics of microorganisms, may also influence the potential for microbial contaminants in non-irrigation water to contaminate produce.

2.0 Processing Water

The quality of processing water should be compatible with its intended use.

Water used during the processing of fruits and vegetables often involves a high degree of intimate 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. Therefore, operators need to institute practices to ensure that the quality of processing water is compatible with its intended use.

Good Manufacturing Practices (GMPs) for water used for food and food contact surfaces in processing facilities are set out in Title 21 CFR 110.37(a) and 110.8(a)(1). Operators using water for processing operations in the field, such as cooling and washing, may want to consider these good manufacturing practices.

2.1 General Considerations

- **Follow good management practices to minimize microbial contamination from processing water.**

  - Water quality needs may vary depending on where a particular operation falls within the series of

processes that are applied to fresh produce. For example, water quality needs for a dump tank receiving produce from the field may not be as great as for water used for later washing and rinsing treatments. Use higher quality water for treatments towards the end of processing, such as a final rinse before consumer packaging. Exercise care to ensure that water used in washing, or other food processing operations, does not contribute to food safety concerns.

- Water that meets the microbial standards for drinking water is considered "safe and sanitary."

- Where water is reused for a series of processes, use a counter current water flow to the movement of produce through the different unit operations. For example, water might be used first in a final rinse, reused in an earlier unit operation, such as a chlorine dip, and finally, used in processes such as dump tanks or flume operations where water quality needs are not as great.

- **Consider practices that will ensure and maintain water quality.**

  The quality of water, including recycled water, should be appropriate for its intended use at the start of any process, and remain adequate throughout the process. Consider management practices that will ensure and maintain water quality. Such practices include:

  - Periodic water sampling and testing,

  - Monitoring pH and sanitizer levels (such as available chlorine) in the water,

  - Changing water as necessary to maintain sanitary conditions, adding sufficient make-up or overflow water during processing to compensate for the potential build-up of organic materials,

  - Water contact surfaces, such as dump tanks, flumes, wash tanks, and hydrocoolers, should be maintained in a clean and sanitary condition (e.g., daily cleaning and sanitizing), 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 chemical sanitizers after contamination occurs.

2.2 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 significant proportion of the produce

- **Use appropriate wash methods.**

  - Consider washing produce in hot water or water containing a surfactant or wetting agent then washing again or rinsing with clean water.

- Vigorous washing may increase the likelihood of pathogen removal for some crops.

- As water-to-produce contact increases, the potential for contamination also increases. Spray wash treatments may be less likely to directly spread microbial contaminants, if they are present, from one produce item to another compared to submersion wash treatments. However, spray wash treatments may spread pathogens by splashing or by aerosol, or on food contact surfaces, such as brushes. Further, if water is contaminated during washing and then reused, it can still 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.

- **Consider the use of sanitizers or antimicrobials in wash water.[5]**

  Sanitizers or antimicrobials in wash water and other processing water may be useful in reducing pathogens on the surface of produce and/or reducing pathogen build-up in water. The effectiveness of a sanitizer depends on its chemical and physical nature, treatment conditions (such as water temperature, pH, and contact time), resistance of pathogens, and the nature of the fruit or vegetable surface. Chlorine is a commonly used antimicrobial.[6] Chlorine dioxide,[7] trisodium phosphate,[8] organic acids,[9] and ozone[10] have also been studied for use as antimicrobials in produce wash water. All chemical substances that contact food must be used in accordance with FDA and EPA regulations.

  - Follow manufacturer's directions for correct mixing of sanitizers or antimicrobials for food processing uses to obtain effective chlorine concentrations.

  -Surface treatments with antimicrobials (such as washes, dips, or spray treatments) should be followed by a clean water rinse to remove any residues.

  - Monitor chlorine levels during washing and other operations to ensure that they are maintained at an effective level. For some operations, a swimming pool test kit may be a simple but adequate method for monitoring chlorine levels. Levels should be routinely monitored and recorded.

- **Maintain the efficacy of wash treatments.**

  Wash water, even with antimicrobial chemicals, will likely reduce but not necessarily eliminate pathogens on the surface of produce. Antimicrobial washes generally reduce microbial populations by 10– to 100-fold. As organic materials and microbial load increases in wash water, the efficacy of antimicrobials decreases.[11] Operators should adopt practices to maintain the efficacy of wash treatments.[12] Such practices may include an initial wash treatment to remove the bulk of field soil from produce followed by a sanitizing dip and a rinse, and adding additional sanitizer to processing water as the sanitizer is depleted.

- **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, there is some evidence to suggest that submerging warm tomatoes in colder water may create a pressure differential, causing pathogens that may be present on the surface of tomatoes or in the water to be internalized or pulled into the tomatoes. If pathogens are

internalized, washing is unlikely to address this food safety hazard. Findings that Salmonella in a water bath can enter the flesh of tomatoes through the stem scar when the water bath temperature is colder than the tomatoes have led to the recommendation that wash water for tomatoes be hyperchlorinated and 10 degrees F warmer than the tomatoes (Ref 12).

- Research may show that the above recommendation could have application to other produce items with internal airspace (such as celery and apples). Denser products (such as carrots) do not appear to be affected. For products that may be susceptible to internalization of pathogens, the recommended temperature differential may be achieved either by heating water or by cooling produce before immersion. When it is not practical to expose produce to warmer temperatures, good management practices to minimize pathogens in the water or on the surface of produce are especially important. Such practices may include using sanitizers 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.

  - Several alternative disinfectant treatments are under study, including ultraviolet (UV) radiation, low-dose ionizing radiation ($\leq$ 1 kGy), ozone, and gas-based disinfectants.

2.3 Cooling Operations

A variety of methods are available for cooling produce. Water, ice, or forced air may be used to cool produce. The method used will depend on the needs of the crop and the resources of the operator. In most instances, cooling with air (such as vacuum coolers or fans) will pose the lowest risk. However, air cooling equipment and cooling areas should be periodically cleaned and inspected. Further, potential sources of contamination should not be located near air intakes.

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 carton going through a cooling process may result in the build-up of pathogens over time in the cooling water supply. The use of sanitizers in cooling water may reduce the potential for microbial contamination of produce. Use of contaminated cooling water has the potential to expose subsequent cartons of produce to contamination. An outbreak of *Shigella sonnei* foodborne infection or illness associated with iceberg lettuce is believed to have resulted from the use of fecally contaminated water, used either for irrigation or in cooling after packing (Ref 13).

- **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. There is general agreement that good quality intact produce is most resistant to microbial contamination and growth. Thus, an overriding concern should be with maintaining temperatures that maintain optimum product quality. Operators should follow good management practices to ensure that chilling does not introduce food safety hazards.

- **Keep water and ice clean and sanitary.**

  Consider periodic 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.

- **Ice should be manufactured, transported, and stored 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. To the extent practical, field soil should be removed 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 manure or biosolids to minimize microbial hazards.***

Properly treated manure or biosolids can be an effective and safe fertilizer. Untreated or improperly treated manure or biosolids used as a fertilizer, used to improve soil structure, or that enters surface or ground waters through run off, may contain pathogens of human health significance that can contaminate produce. Growers need to follow good agricultural practices for handling manure or biosolids to minimize microbial hazards.

Growers also need to critically 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 manure or biosolids in the production of fresh produce 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 or deer in fields).

B. Control of Potential Hazards

Good agricultural practices for the use of manure or biosolids include treatments to reduce pathogens and maximizing the time between application to crop fields 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. 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 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.

The use of biosolids on fields used to produce food crops involves a number of concerns in addition to microbial risk factors (e.g., potential heavy metals and toxic 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 Resource Conservation Service (NRCS) (formerly the Soil Conservation Service), and Cooperative State Research, Education, and Extension Service. 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 manure to reduce the potential for introducing microbial hazards to produce. Such practices may include processes, such as composting, that are designed to reduce possible levels of pathogens in manure. Good agricultural practices may also include minimizing, to the extent feasible, 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 third party (e.g., 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.

- **Passive treatments**.

  Passive treatments rely primarily on the passage of time, in conjunction with environmental factors, such as natural temperature and moisture fluctuations and 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. However, as an example, Cornell Cooperative Extension recommends that manure slurry be stored for 60 days in summer and 90 days in the winter prior to field application (Ref 15).

- **Active treatments.**

  Active treatments include pasteurization, heat drying, anaerobic digestion, alkali stabilization, aerobic digestion, or combinations of these. Composting is a controlled and monitored process, commonly used to reduce the microbial hazards of raw manure.

2.1.1 Composting

Composting is a common treatment to reduce the microbial hazards of raw manure.

The high temperature generated during composting can kill most pathogens in a number of days. Thus, the risk of microbial contamination from composted manure is reduced compared to untreated manure. However, 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, such as the hepatitis A virus, have a higher thermal threshold than others. In addition, the time and temperature required to eliminate or reduce microbial hazards in manure or other organic materials may vary depending on regional climate and 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 cross-contamination from manure to fresh produce.

2.2 Handling and Application

> ***Growers should review existing practices and conditions to identify potential sources of contamination.***

- Minimize contamination of produce from manure in open fields, compost piles, or storage areas onto nearby maturing crops. Manure storage or treatment sites close to fresh produce fields or packinghouses increase the risk of microbial contamination.

- Consider barriers or physical containment to secure manure storage or treatment areas where cross-contamination from runoff, leaching, or wind spread is a concern.

- 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).

- 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 to the use of manure that has been treated to reduce pathogens. Growers using untreated manure may need to consider the following good agricultural practices:

- Competition with soil microorganisms may reduce pathogens. Incorporating manure into the soil (e.g., prior to planting) may reduce microbial hazards.

- Applying raw manure to produce fields during the growing season (e.g., broadcasting or sidedressing crops) is not recommended.

- Growers may reduce the risk of contamination from manure by maximizing the time between application of manure to a field and harvest. The National Organic Standards Board, formed under the Organic Food Production Act of 1990, following the guidance of the act, recommended that raw (untreated) manure should not be applied within 60 days of harvest of organic crops intended for human consumption.

- Because most annual fruit and vegetable crops take more than 60 days to reach harvest maturity, this recommended 60 day minimum may be relatively easily achieved (or exceeded) by pre-plant incorporation of manure. However, no one knows for sure how long pathogens can survive in the field or on produce or how pathogen survival may be influenced by environmental conditions.[13] Thus, to the extent feasible, growers using untreated manure may want to choose longer intervals between application and harvest.

- Other good agricultural practices to maximize the time between manure application and harvest of produce for the fresh market include 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 to crops that are to be cooked or properly heat processed prior to being delivered to consumers.

- Growers should contact State or local manure handling experts for advice specific to their individual operations and regions. As more research becomes available, growers may need to further modify their manure handling practices.

- Additional research is also needed to determine how pathogens in manure may spread in the field. However, for some operations, drift and 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.

2.2.2 Treatments to Reduce Microbial Hazards in Manure

Natural fertilizers, such as composted manure, and fertilizers containing natural components, need to be processed in a manner to reduce the likelihood of introducing pathogens. Care should be taken to avoid contamination of fresh produce from manure that is in the process of being composted or otherwise treated. Growers using treated manure should consider the following good agricultural practices:

- Composting 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 composted manure that is stored before use. Therefore, to the extent feasible, growers using treated manure may want to consider some of the recommendations made for untreated manure, such as maximizing time between application and harvest.

- The specific requirements of any treatment to reduce pathogens will 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 turning outside edges into the center of a compost pile or containment.

- As more data become available on the viability of microorganisms in manure, and on treatments that most effectively reduce microbial hazards, growers and manure suppliers may need to adjust practices accordingly.

3.0 Animal Feces

> ***Animal feces are a known source of pathogens that can cause foodborne illness.***

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 include:

- Domestic animals, such as cows or sheep, 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.

- 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 will not cross-contaminate the crop during heavy rains, especially if fresh produce is grown in low-lying fields. Measures might include physical barriers, such as ditches, mounds,

grass/sod waterways, diversion berms, and vegetative buffer areas.

- 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. In addition, Federal, State, or local animal protection requirements must be considered. However, high concentrations of wildlife (such as deer or waterfowl in a field) may increase the potential for microbial contamination. 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, to the extent possible. Options may include visual, auditory, or physical deterrents and border crops or buffer areas between fields growing fresh market produce and areas frequented by wildlife.

Helpful Resources:

The NRCS Conservation Practice Standard 317, "Composting Facility" sets out standards for on-farm composting (USDA, SCS, December 1990).

NRCS AWMFH 651.1004(F), Rynk et al., "On Farm Composting Handbook," NRAES-54 North Regional Agricultural Engineering Svc, Cooperative Extension, and 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. SANITATION AND HYGIENE

> ***Good sanitation and hygiene are essential for reducing microbial hazards in fresh produce.***

This section of the guide focuses on how operators can use proven sanitation and hygiene principles to reduce the risk of fresh produce becoming contaminated with disease-causing microorganisms. Because different levels of sanitary controls are achievable at each level of production (such as an agricultural field compared to the packinghouse), the discussion is organized by production segment: field environments, packing facilities, and transport operations. A general discussion of the role of the agricultural worker in maintaining good sanitation programs is also included. At every phase of the food chain, from the field to the table, good sanitation and hygiene practices are essential for reducing microbial hazards in fresh fruits and vegetables.

A. Worker

Be aware of existing State and Federal regulations regarding standards for worker hygiene and sanitation practices during the manufacturing, packing, or holding of human food.

The U.S. Code of Federal Regulations 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 in the agricultural environment (field and packinghouse). In addition, operators should be aware of and follow applicable standards for protecting worker health established under the Occupational Safety and Health Act.

1.0 Microbial Hazard

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

Past outbreaks of foodborne illness associated with fresh fruits and vegetables are usually the result of produce becoming contaminated with fecal material. Therefore, operators should place a high priority on ensuring the use of agricultural practices that minimize the potential for direct or indirect contact between fecal material and fresh fruits and vegetables. Infectious diseases, ill health accompanied by diarrhea, open lesions (including boils, sores, or infected wounds), or other ailments are a source of disease-causing microorganisms. Workers can unintentionally contaminate fresh produce, water supplies, and other workers, and transmit foodborne illness if they do not know and follow hygienic principles.

2.0 Control of Potential Hazards

Train all employees to follow good hygienic practices.

2.1 Personal Health and Hygiene

It is important to ensure that all personnel, including those indirectly involved in fresh produce operations (such as 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 varies among operations and between workers. Growers or packers will need to determine the most effective way of communicating these principles. A formalized training program, coupled with periodic evaluation by supervisors of sanitary conditions, has proven to be effective in other segments of the food industry. Depending on the workers' job requirements, periodic refresher or follow-up training sessions may be needed. (Also, see section 2.2 below on training.)

- **Become familiar with typical signs and symptoms of infectious diseases.**

Because of the high infectivity (ability to invade and multiply in the body) and virulence (ability to produce severe disease) of *Salmonella typhi*, *Shigella* species, *E. coli* O157:H7, or hepatitis A virus, any worker diagnosed with an active case of illness caused by any of these pathogens should be excused from work assignments that involve contact with fresh produce or produce processing equipment. Workers with diarrheal disease and symptoms of other infectious diseases should not work with fresh produce or produce equipment. To become more familiar with symptoms of infectious diseases that can contaminate food, operators should consult FDA's Food Code (Ref. 4).

- **Provide protection for a worker who has 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 equipment, increases the risk of contaminating fresh produce. If a lesion cannot be covered in such a way that it will not have contact with produce or harvesting equipment, the employee should not be working with fresh produce.

- **Consider alternative good hygienic practices.**

  Gloves can be an important hygienic practice in combination with handwashing in some circumstances. If gloves are considered, be sure they are used properly and do not become another vehicle for spreading pathogens.

- **Assure that visitors to the farm, processing, or transport facilities follow good hygienic practices.**

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

2.2 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. 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, when 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:

  - 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.

- **The importance of using toilet facilities.**

  All employees should be encouraged to use toilet facilities connected to a sewage disposal system, or properly constructed on-site sanitary pit, privies, or latrines to reduce the potential for cross-contaminating fields, produce, other workers, and water supplies. See section B. (Sanitary Facility) for additional information about toilet facilities.

B. Sanitary Facilities

1.0 Microbial Hazards

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

2.0 Control of Potential Hazards

Operators should become familiar with laws and regulations that describe appropriate field and facility sanitation practices. Field sanitation laws, such as those under the Occupational Safety and Health Act 29 CFR 1928.110, outline the appropriate number of toilet facilities to the number of workers, describe proper handwashing facilities, the maximum worker-to-restroom distance, and how often such facilities should be cleaned. Good field sanitation not only helps reduce the potential for contaminating produce, but it also ensures that employees and consumers are protected from foodborne diseases.

The U.S. Code of Federal Regulations prescribes current good manufacturing practices for buildings and facilities, equipment, and production and process controls (21 CFR 110.20 to 110.93), and is a good resource to guide the development of mitigation programs. OSHA standards under 29 CFR 1910.141, subpart J, provide regulations relative to toilet facilities and other sanitation issues. Enclosed packinghouse facilities come under these regulations. Packers should also consider application of food service type standards, such as found in FDA's Food Code (Ref. 4), in the packinghouse and processing environments.

2.1 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 will help 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, if in the field, should not be 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 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 and sanitary.**

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

2.2 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 and 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." Examples of good practices to consider are as follows:

- **Use caution when servicing portable toilets.**

  Waste water from portable toilet facilities that drains into a field can contaminate produce. Dispose of wastes through a municipal sewage system, a sub-surface septic tank system, a properly constructed and located pit, privy, or latrine away from field; or collect waste water in a drainage tank to be correctly disposed of at a remote site. Sewage transport trucks should have access to toilet facilities.

- **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.

C. Field

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

1.0 Microbial Hazards

Microbial contamination or cross-contamination of produce during pre-harvest and harvest activities may result from contact with soils, fertilizers, water, workers, and growing and harvesting equipment. Any of these may be a source of pathogenic microorganisms. Sections II. and III. in this guidance document address the concerns associated with water quality and use of manure and municipal biosolids. Sections IV.A. and B. above address the importance of worker hygiene and good sanitation practices. Section IV.D. provides general guidance for packinghouses.

2.0 Control of Potential Hazards

2.1 General Harvest Considerations

- **Clean harvest storage facilities prior to use.**

  Produce storage facilities should be cleaned and, as necessary, disinfected prior to harvest. Also inspect storage facilities for evidence of pests, such as rodents.

- **Repair or discard damaged cartons in an effort to reduce possible microbial contamination of fresh produce.**

- **Clean muddy containers or bins before using to transport fresh produce.**

  Clean containers for whole fruits and vegetables that are intended for hulling, husking, peeling, or washing prior to consumption. Clean and sanitize containers used for ready-to-eat produce, such as raspberries.

- **Ensure that produce that is harvested, washed, cooled, and 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 produce with pathogenic microorganisms.

- **Remove as much dirt and mud as practicable from the produce before it leaves the field.**

  At certain times, such as when fields are muddy, removing mud from the produce may not be practical; such mud would have to be removed at the packing stage. It is important to try to eliminate, as much as possible, the potential sources of microbial contamination of produce during the harvesting and packing operations.

2.2 Equipment Maintenance

Field equipment, such as harvesting machinery, cartons, tables, baskets, packaging materials, brushes, buckets, etc., can easily spread germs to fresh produce. Growers and operators should consider the

following guidelines:

- **Use harvesting and processing equipment appropriately and keep as clean as practicable.**

  Any equipment used to haul garbage, manure, or other debris should not be used to haul fresh produce or have contact with cartons or pallets that are used in contact with fresh produce without first being carefully cleaned and disinfected.

- **Assign responsibility for equipment to the person in charge.**

The person in charge should be aware of how equipment is being used during the day, ensure that it is functioning properly, and take steps to ensure proper cleaning of equipment when needed.

D. Packing Facility

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

1.0 Microbial Hazard

Operations with poor sanitation in the packinghouse environment can significantly increase the risk of contaminating fresh produce and water. Pathogenic microorganisms may be found on the floors and in the drains in the packinghouse and on the surfaces of processing equipment. In the absence of good sanitary practices, any of these surfaces that come in contact with food could be a potential source of microbial contamination. Good sanitation practices should be employed throughout the packinghouse environment and should include routine scrutiny of produce contact surfaces.

2.0 Control of Potential Hazards

2.1 General Packing Considerations

- **Remove as much dirt and mud as practicable from the produce outside of packinghouses or packing areas.**

  Take additional care to protect produce from possible contamination when it is packed in the field 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 air-borne contaminants from any nearby livestock or poultry areas or manure storage or treatment facilities.

- **Repair or discard damaged cartons.**

  Inspect cartons for damage on a regular schedule. Because damaged carton surfaces may harbor pathogenic microorganisms and cause damage to the surface of the produce, they should not be used.

- **Clean muddy pallets, containers or bins before using to transport fresh produce.**

Operators might set aside an area in the receiving yard for treatment of pallets and containers. Pallets should be clean. Clean containers used for whole fruits and vegetables that are intended for hulling, husking, peeling, or washing prior to consumption. Clean and sanitize containers used for ready-to-eat produce, such as raspberries. Care must be taken when packing produce in the field not to contaminate containers or bins by exposure to soil and manure.

2.2 General Considerations for Facility Maintenance

Equipment used in packing fresh fruits and vegetables 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 principles:

- **Keep equipment or machinery that comes in contact with fresh produce as clean as practicable.**

  All processing 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.

- **Use equipment appropriately.**

  To reduce potential cross-contamination of equipment, personnel should not use packing equipment or machinery that has contact with fresh produce for carrying other materials (for example, lunches, tools, etc.).

- **Clean packing areas at end of each day.**

  Clean and disinfect, as necessary, packing areas, including the washing and packing lines, to reduce the potential for microbial contamination of produce.

- **Maintain the cooling system to ensure proper functioning of the equipment.**

  Inspect all pre-cooling equipment daily, remove all debris, and clean as necessary.

- **Clean product storage areas regularly.**

  Remove all visible debris, soil, dirt, and unnecessary items from product storage areas on an ongoing basis. Clean on a regularly scheduled and "as needed" basis. Free floating dust and other airborne contaminants should be kept to a minimum.

2.3 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*. Pest problems can be minimized by taking precautions, such as:

- **Establish a pest control system.**

  For all facilities, a pest control program is essential for reducing the risk of contamination by rodents and other animals.

- **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 equipment that is no longer used, to eliminate areas where rodents and insects can harbor.

  - Clean daily to remove product or product remnants that attract pests in and around the packinghouse 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. Strive to 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 preclude exacerbating the situation by allowing carcasses to attract other pests.

  - Ensure that all 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.**

  Strive to 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 as needed.

- **Consider use of a pest control log.**

  Maintain a pest control log to include dates of inspection, inspection report, and steps taken to eliminate any problems. A pest control program should also include frequent monitoring of affected and treated areas to determine the effectiveness of the treatment applied.

E. Customer-Pick Operations and Road-Side Produce Stands

Operators who invite the public to pick their own fruits or vegetables in the field or who sell their own produce directly to customers should consider opportunities to educate consumers on good produce handling techniques.

- **Promote good hygienic practices.**

  - Encourage customers to wash hands. Provide convenient, properly equipped handwashing stations in the field.

- **Provide clean, properly supplied, and convenient restrooms for customer use.**

- **Promote good handling/processing practices.**

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

Helpful Resources:

USDA Agriculture Marketing Service, "Selling the best at the Farmers Market: Good Handling Practices for Direct Marketers.

F. Transportation

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

Operators are encouraged to pay particular attention to the product as it is transported between the field and the cooler, packinghouse, processing facility, distribution and retail centers. The proper transport of fresh fruits and vegetables will help reduce the potential for microbial contamination. An active and ongoing discussion with personnel responsible for transportation is essential for assuring the success of any management program designed to deliver safe foods to the consumer.

1.0 Microbial Hazard

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

2.0 Control of Potential Hazards

Wherever produce is transported and handled, the sanitation conditions should be evaluated, especially between links in the distribution chain. Fresh produce should be segregated from other food and nonfood sources of pathogens in order to prevent contamination of the produce.

2.1 General Considerations

- **Workers involved in the loading and unloading of produce during transport should practice good hygiene (e.g., proper handwashing).**

  See section IV.A.2. 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.

2.2 General Transport Considerations

Operators should strive to assure that sanitation requirements for trucks or other carriers are met before loading produce to help reduce the likelihood for microbial contamination. Some specifics to consider are:

- **Inspect trucks or transport cartons for cleanliness, odors, obvious dirt or debris before loading produce.**

- **Keep transportation vehicles clean to help reduce the risk of microbial contamination or cross-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 disinfection methods for individual operations.

- **Maintain proper storage temperatures to help ensure both the quality and safety of fresh produce.**

- **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.

V. TRACEBACK

> ***The ability to identify the source of a product can serve as an important complement to good 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 product cannot prevent the occurrence of a microbiological hazard that may lead to an outbreak of foodborne disease. However, the ability to identify the source of a product (i.e., traceback) can serve as an important complement to good management practices intended to prevent the occurrence of food safety problems. Information gained from traceback capabilities will assist in identifying and eliminating a hazardous pathway and will help avoid affecting unassociated produce or farms. In general, reliable traceback systems can help to prevent food scares.

Overview of traceback inspection 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, health officials attempt to obtain the following information:

1. Point of service establishment (where the food causing the outbreak was served or sold) and its method of preparation.

2. Pertinent product identifying information from point of service, including product type, packaging, labeling, and lot numbers, if applicable.

3. Identification and documentation of suspect shipments of the implicated product from its original source up to the point of service are typically obtained in one of two ways:

    a. By tracing lot numbers, if they are available, or

    b. By knowing the period of time that the implicated product would be salable and usable as it relates to the infection period, and by using delivery information obtained from record review and interviewing employees at the point of service. Interviews must also be conducted for all possible distributors throughout the traceback chain.

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 used or recorded on receipt/shipping records. Public health inspectors 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 practices in the fresh produce 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 (e.g., a field or packinghouse) 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, which can be very costly. The economic burden is especially troublesome for those industry segments that may later be proven not to have been involved in the actual outbreak. In 1996, a series of outbreaks of a protozoan parasite, *Cyclospora cayatanensis*, were erroneously linked to fresh strawberries, which reportedly cost domestic strawberry producers over $40,000,000.

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 inspectors clues that may lead to a specific region, packinghouse, even field, rather than an entire commodity.

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.

Limiting the potential scope of an outbreak lessens the economic burden on those industry operators not responsible for the problem. Improving the speed and accuracy of tracing implicated food items back to their source may also improve the ability of public health officials to determine potential causes of contamination, thereby providing data for growers, operators, and others for identifying and minimizing risk factors.

Instituting effective traceback systems

Because of the diversity of handling practices throughout the produce distribution 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, ideally, 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 cooler to receiver.

Many farmers, especially those from small farms, have little control over what happens to produce after it leaves their property. Therefore, it is critical that farmers and packers work with their partners in transportation, distribution, and retail to develop technologies that allow grower/packinghouse identification to follow produce from the farm to the retailer. 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.

VI. CONCLUSION

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

Protecting the safety of our nation's food supply takes a comprehensive and coordinated effort throughout the food system. The responsibility to safeguard our food supply is shared by everyone involved, from the farm to the table. This includes farmers, farm workers, packers, processors, 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 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 some control. Operators are encouraged to utilize this guide to evaluate their own operations and assess site-specific risks so they can develop and implement reasonable and cost effective alternative management practices.

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. Individual growers and packers will need to consider the variety of physical characteristics and agricultural practices that impact the potential sources of contamination associated with their farm, packing, or transport operation, and decide on which combination of good agricultural practices likely to achieve food safety goals 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. Owner/operators should follow-up with supervisors or the person in charge to be sure that regular monitoring takes place, equipment is working, and good agricultural practices are being followed. Without accountability to ensure the process is working, the best attempts to minimize the risk of microbial contamination of fresh fruits and vegetables are subject to failure.

VII. REFERENCES

1. The White House. Office of the Press Secretary. "Radio Address of the President to the Nation." January 25, 1997.

2. U.S. Environmental Protection Agency, Department of Health and Human Services, and U.S. Department of Agriculture. "Food Safety from Farm to Table: A National Food-Safety Initiative -- A Report to the President," May 1997.

3. The White House. "Memorandum for the Secretary of Health and Human Services, The Secretary of Agriculture," October 2, 1997.

4. U.S. Public Health Service, FDA. 1997 Food Code, U.S. Department of Health and Human Services, Food and Drug Administration, Washington, DC 20204.

5. Norman, N.N. and P.W. Kabler, Bacteriological Study of Irrigated Vegetables. *Sewage and Industrial Wastes* 25:605-609, 1953.

6. Dunlop, S.G. and W.L.L. Wang. Studies on the Use of Sewage Effluent for Irrigation of Truck Crops. *Journal of Milk Food Technology* 24:44-47, 1961.

7. CDC. Outbreak of E. coli O157:H7, Northwest Montana. EPI-AID 95-68, 1995.

8. Wood, R.C., C. Hedburg, and K. White. A multistate outbreak of Salmonella javiana associated with raw tomatoes. Abstract. Epidemic Intelligence Service 40th Ann. Conference, CDC, Atlanta, GA, 1991.

9. CDC. Multistate outbreak of Salmonella serotype Montevideo infections. EPI-AID 93-79, 1993.

10. U.S. EPA. Ambient Water Quality Criteria for Bacteria, EPA Office of Water Regulations and Standards, EPA 832-B-92-005, January 1986.

11. USDA. List of Proprietary Substances and Nonfood Compounds Authorized for Use Under USDA Inspection and Grading Programs.

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

13. Frost, J.A., M.B. McEvoy, C.A. Bentley, Y. Anderson, and B. Rowe. An outbreak of Shigella sonnei infection associated with consumption of iceburg lettuce. *Emerging Infectious Diseases* 1:26-28, 1995.

14. U.S. EPA. Domestic Septage Regulatory Guidance, A Guide to the EPA 503 Rule. EPA, Office of Water Regulations and Standards, 832-B-92-005, September 1993.

15. Reiners, S., A. Rangarajan, M. Pritts, L. Pedersen, and A. Shelton. "Prevention of Foodborne Illness Begins on the Farm." Cornell Cooperative Extension, Cornell University, Ithaca, NY.

16. Wang, W., Zhao, and M.P. Doyle. Fate of enterohemorrhagic Escherichia coli O157:H7 in bovine feces. *Journal of Applied and Environmental Microbiology* 62: No. 7, 1996.

17. Bohach, C.H., Personal communication regarding survival of E. coli in sheep manure. December 1, 1997.

ADDENDUM

Additional Information on the Development Process and Response to Comments on the November 25, 1997 Working Draft Guide

A. Development of the Proposed Guide.

The proposed guide on reducing food safety hazards in fresh fruits and vegetables was developed in accordance with FDA's policy set out in the **Federal Register** of February 27, 1997 (62 FR 8961), known as Good Guidance Practices. Under that policy, guidance must be developed with appropriate public participation and the resulting guidance document must be readily available to the public. FDA is also required to review periodically and update guidance document as science and existing policies evolve. Most importantly, the policy recognized clearly that guidance documents do not themselves establish legally enforceable rights or responsibilities and are not legally binding on the public.

In keeping with this policy and the President's Directive, FDA sought participation not only from local, State and Federal health and agricultural agencies but also from the public at large, particularly growers and their trade associations. On November 17, 1997, at a public meeting in Washington, DC, representatives from USDA, FDA, and EPA presented the elements of a draft of proposed guidance on ways to minimize microbial contamination of fresh produce. The Fresh Produce Subcommittee of the

National Advisory Committee for Microbiological Criteria for Food also reviewed and commented on sections of a working draft at the November meeting. Broad areas covered by the working draft included water quality, manure and municipal biosolids, worker hygiene, field and packinghouse sanitation, transportation and traceback. FDA based the working draft, in part, on trade association guidance documents. The agency also received valuable input from USDA, EPA, Occupational Safety and Health Administration (OSHA), and the Centers for Disease Control and Prevention (CDC), as well as other government agencies. On November 25, 1997, FDA made a draft of the proposed guide available on its World Wide Web home page (http://www.fda.gov) under the title "Working Draft -- Guide to Minimize Microbial Safety Hazards for Fresh Fruits and Vegetables."

To obtain wide participation in the development of the draft guide for fresh produce, FDA, in cooperation with USDA, held six grassroots meetings between December 1 and December 12, 1997. The grassroots meetings were held in Grand Rapids, MI, Geneva, NY, West Palm Beach, FL, Helotes, TX, Salinas, CA, and Portland, OR, and focused primarily on domestic produce. In addition, on December 8, 1997, in Washington, DC, FDA held a meeting for representatives of foreign countries that focused on imported produce. The purpose of the meetings was threefold: (1) to introduce the working draft of the guide early in its developmental stage; (2) to solicit input for the guide and other pertinent comments from the agricultural community, industry, consumers, academia and other interested parties; and (3) to address an apparently common misunderstanding that FDA intends to impose additional regulations on the farming industry through issuance of the guide.

A total of more than 400 registered participants attended the various grassroots meetings. Participants included representatives from small and mid-sized farms, food companies, trade associations, retailers, agricultural consultants, academia, consumer and labor organizations, dietitians, home economists, and consulting engineers, as well as representatives of county, state, and federal government agencies. An additional 100 or more individuals, reflecting representation from at least 32 foreign governments, as well as trade and consumer organizations, Congressional staff, and the press, participated in the December 8th meeting. Transcripts of these meetings and all comments received on the working draft of the proposed guide are on file in the Dockets Management Branch (address above) under the docket number appearing above and are accessible via the FDA home page on the World Wide Web (http://www.fda.gov/dockets/dockets.htm).

B. Comments on the Working Draft of the Proposed Guide.

FDA received 55 letters containing one or more comments on the working draft of the proposed guide in addition to many oral comments at the various public meetings. FDA has reviewed the comments and has modified the proposed draft in light of those comments. A discussion of several comments that are beyond the specific content of the proposed guide follows:

1. Many comments stated that the time projected for completing Federal guidance on GAPs and GMPs for fresh and minimally processed fruits and vegetables is too compressed.

The agency has listened to comments about the timeline and has revised it to allow for additional industry input before the final guidance document is published in October of this year.

FDA believes that the timeline is justified by the need to improve current agricultural and distribution practices for fresh produce and to increase the awareness of potential microbial hazards involved in the processing and handling of these foods. Moreover, as noted, despite the fast pace, the agency has provided and is providing significant opportunities for public participation and comment.

2. Many comments expressed concern that the proposed guidance for industry would become de facto regulations.

FDA pointed out in each of its public meetings that the guide is intended to be used as guidance which, if applied as appropriate and feasible to individual operations, will minimize risks associated with microbial contamination of fresh produce. FDA anticipates that the proposed guide will serve as a basis for operators on practical ways to apply good agricultural and management practices to the production and packing of fresh produce. Thus, FDA is again emphasizing that the proposed guide is not a regulation and, therefore, does not have the force and effect of law. The proposed guide will not bind FDA, USDA, or the public, nor will it create or confer any rights, privileges, or benefits for, or on, any person.

The agency notes that several trade associations, such as the United Fresh Fruit and Vegetable Association and Western Growers Association and the International Fresh-Cut Produce Association, have already established guidance for their members that is designed to minimize food safety risks associated with fresh produce. The proposed guide incorporates many of the concepts of such industry guidance. When issued in final form, the guide will serve as FDA's and USDA's current advice on ways to minimize microbial hazards in fresh fruits and vegetables.

The agency recognizes that some of the recommendations in the proposed guide may, if adopted, require financial or other investments on the part of the operator. As noted in the proposed guide, producers should use the guide to help assess microbiological risks within the context of the specific conditions that apply to their own operation and implement appropriate cost effective risk reduction strategies.

3. A number of comments expressed the need for a sound scientific basis for the proposed guide before the agency issues the guide in final. Several comments suggested that research should be conducted to establish expected outcomes or specific values that can be included in the guide, such as the length of time untreated manure must be held prior to use in growing areas.

The overall research goal of the fresh produce initiative is development of cost-effective intervention and prevention strategies to reduce the incidence of foodborne illness. FDA acknowledges that in a number of instances research is needed to identify more clearly possible sources of contamination along the food chain. There is also a need for research focused on the development of rapid and accurate testing procedures to identify and characterize pathogens on fruits and vegetables and on improved technologies that can be used to eliminate or reduce pathogen levels on fresh produce. These methods will be used to support long-term surveillance and monitoring of both domestic and imported produce at the point of production and harvest and to support development and control and prevention strategies to augment use of general guidance.

FDA does not believe, however, that it can or should wait, as the comments suggest, until additional research addresses the safety issues delineated in the proposed guide because significant food safety concerns are raised by some of the emerging pathogens. Several new foodborne pathogens have emerged over the past ten years. Other microorganisms, once thought to be innocuous, have been linked to life-threatening diseases after acquiring new virulence genes and antimicrobial resistance. FDA plans to work cooperatively with other agencies of DHHS, the USDA, and EPA on methods development, as well as on physiological, genetic, and other factors that contribute to or cause foodborne-disease causing microorganisms to develop resistance to preservation technologies. The agency points out that the guide will not be a static document. It can and will be revised as new and improved strategies for detecting, minimizing, or eliminating microbial hazards associated with fresh produce become available.

FDA has requested and received information from a number of relevant trade associations and has incorporated into the proposed guide much of the information supplied by industry. The agency believes that many of the practices that are already being used by some segments of industry may be generally applicable to other segments. Establishment of specific values or outcomes may not be practicable in light of the broad range of products, and variations in characteristics of the products, covered by the proposed guide. In addition, variations in growing and harvesting conditions, climatic conditions, and geographical locations militate against establishment of specific values. For these reasons, the proposed guide is based on general principles and is written in general terms.

The guide represents the current thinking of FDA and USDA on a number of microbial food safety hazards and on good agricultural practices and good manufacturing practices common to the growing and packing of most fresh fruits and vegetables. FDA believes that operators can best use the general recommendations in the guide as a basis to assess and tailor individual food safety practices that are appropriate and feasible for their particular operations. Growers, packers, and other operators must continue to comply with any applicable local, State, and Federal regulations. The guide will not supersede any of those requirements.

4. Several comments argued that the guidance document was a "top-down" document that does not reflect grower input. These participants requested that trade associations and other relevant parties be fully included in the development of any guidance.

The agency is making every effort to obtain broad public participation and input. Concepts obtained from industry and trade association guidance documents were included in the initial draft of the guide. The grassroots meetings in December were specifically intended to solicit comments from growers and other interested individuals in the principal produce-growing regions around the United States. As a result of these efforts and the public meetings, the agency received 55 letters from growers, packers, produce industry trade associations, and other interested parties. FDA notes that, with publication of this notice and request for comments, trade associations, growers, consumers, and any other interested parties will have another opportunity to make their concerns known and to comment on the content of the document. FDA and USDA are also working cooperatively with other agencies that have programs operating at the growers' level, such the Cooperative State Research, Education, and Extension Service, to increase the awareness of the proposed guide and to solicit comments.

5. Several comments raised questions about the international implications of the food safety initiative and the development of the proposed guide. The comments asserted the need for a "level playing field" with respect to the treatment of foreign and domestic fresh produce and the need to promote fair trade in both directions.

The agency agrees there should be a level playing field between domestic and foreign producers. Consistent with this view, the guide is intended to assist both foreign and domestic growers and packers to produce safer fresh produce and to enhance the ability of both groups to comply with existing U.S. food safety laws and regulations. These requirements will not change as a result of this guidance. FDA notes that agencies of DHHS, USDA, and EPA work directly with many foreign countries to enhance the food production system and regulatory oversight infrastructure to better ensure that foreign exports meet U.S. standards. As resources permit, these agencies also provide technical assistance to help correct deficiencies in production practices and foreign monitoring and enforcement programs.

C. The Proposed Guide and Next Steps.

FDA prepared the proposed guide in cooperation with the USDA. In addition to comments from the public, it incorporates comments from several other Federal and State agencies. Agriculture and health officials from the States of California, Florida, and Michigan also contributed significantly to the development of the proposed guide through the Association of Food and Drug Officials and the National Association of State Departments of Agriculture. The agency anticipates that as new information and technologies improve our understanding of the factors associated with identifying and reducing microbial food safety hazards, the recommendations and information contained in the guide will be revised.

FDA plans to continue its information exchange with growers, packers, consumers, trade associations, and other interested persons during the comment period on the proposed guide. In the near future, FDA and USDA plan to hold additional meetings at the grower level to discuss the applicability and practicality of the guide. Notices announcing the dates and locations will be published in the **Federal Register** and on the agency's home page on the World Wide Web. FDA is requesting comment on whether the advice in the proposed guide is practicable, whether additional recommendations are needed at this time, and whether the proposed recommendations should to be modified and, if so, how and why they should be changed.

The proposed guide represents the agencies' current thinking on strategies to minimize microbial hazards for fresh fruits and vegetables. It does not create or confer any rights for or on any person and does not operate to bind FDA, USDA, or the public. An alternative approach may be used if such approach would effectively serve to reduce the microbial contaminants that could result in foodborne illnesses and if such approach satisfies applicable statutes, regulations, or both. The proposed guide is being distributed for comment purposes, in accordance with the FDA's policy for Level 1 Good Guidance Practices documents as set out in the Federal Register of February 27, 1997 (62 FR 8961).

Footnotes

[1] 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 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 strongly encourage growers and packers 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 contaminants that could result in foodborne illness and if such approach satisfies applicable statutes, regulations, or both.

[2] Operators may wish to refer to programs such as the USDA Agricultural Marketing Service's voluntary program entitles "Qualified Through Verification fro Fresh Cut Produce" for additional assistance.

[3] We are not aware of existing microbial standards for agricultural water use in the United States. EPA standards for recreational waters specify that mean bacterial densities should not exceed 126 per ml for *E. coli* or 33 per ml for enterococci (Ref 10). It may be possible to modify these standards to develop workable testing strategies for growers.

[4] The frequency of testing depends on the water source. Properly constructed closed, underground, or capped well systems are much less susceptible to surface contamination, therefore, annual testing, during the irrigation season, may be appropriate. Water quality from surface sources tends to fluctuate due to environmental influences, like runoff events, so it may be appropriate to test these sources more frequently.

[5] FDA regulations for the use of sanitizing solutions for food processing equipment and other food contact articles are set out in 21 CFR 173.315 "Chemicals used in washing or to assist in the lye peeling of fruits and vegetables" and in 21 CFR 110.80(b)(1). The "List of Proprietary Substances and Nonfood Compounds Authorized for Use Under USDA Inspection and Grading Programs" (Ref 11) lists sanitizers and other substances approved for use in slaughtering and processing plants operating under the USDA poultry, meat, rabbit, shell egg grading, and egg products inspection programs. Technical advice may be available from sanitizer manufacturers and trade associations.

[6] There are three major groups of chlorine compounds, i.e., liquid chlorine, hypochlorites, and chlorine dioxide, which exhibit various degrees of antimicrobial activity. Chlorine is commonly used at concentrations of 50 - 200 ppm (total chlorine) with contact time of 1 - 2 minutes. A pH of 6.0 - 7.5 is most appropriate for effective sanitizing activity while minimizing damage to equipment.

[7] Chlorine dioxide may prove to be useful for washing intact fruits and vegetables at a concentration not to exceed 5 ppm. Its antimicrobial activity is less affected by pH and organic load compared to chlorine. A disadvantage of chlorine dioxide is that it is unstable and can explode when concentrated. Additional research is needed to determine its effectiveness against specific pathogens.

[8] Trisodium phosphate (TSP) in washing and chilling water is effective in killing *Salmonella* on poultry. It may have potential for fresh produce but more research is needed.

[9] Organic acids, especially lactic acid, have been successfully used to sanitize beef, lamb, and poultry carcasses. Vinegar (acetic acid) and lemon juice (contains citric acid) have been shown to reduce populations of some types of pathogens under household use. The commercial use of organic acids to reduce pathogens on produce, and their impact on the sensory qualities of different types of produce, need more research.

[10] Ozone treatment of wash and flume waters holds promise as a treatment to control microbial build-up, especially in recycled water.

[11] Fruit and vegetable tissue components and other organic matter neutralize chlorine rendering it inactive against microorganisms.

[12] The use of surfactants and other agents that may increase the effectiveness of sanitizers, and their effect on the sensory qualities of different types of produce, is also being researched. Operators should keep up-to-date with the latest recommendations on the use of sanitizers and surfactants by contacting their State and local Environmental and Protection and Public Health agencies, extension agents, trade associations, and other waer treatment experts. Operators should also discuss appropriate safe handling considerations for specific sanitizers.

[13] Some researchers have found that *E. coli* O157:H7 may survive in dairy cattle manure for at least 70 days, depending on temperature and, perhaps, moisture conditions (Ref 16). Other researchers have

found that *E. coli* O157:H7 may survive in sheep manure for more than a year (Ref 17).

Draft Guidance: April 13, 1998

April 13, 1998 Federal Register Notice

November 25, 1997 Working Draft Guide

Food Safety Initiative

Hypertext updated by dms 1998-APR-13