Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain

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COMMODITY SPECIFIC FOOD SAFETY GUIDELINES FOR THE LETTUCE AND LEAFY GREENS SUPPLY CHAIN • 1ST Edition

This document was prepared by members of the lettuce/leafy greens industry from farm to table.

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User's Note

This document provides voluntary recommended guidelines on food safety practices that are intended to minimize the microbiological hazards associated with fresh and fresh-cut lettuce/leafy greens products. The intent of drafting this document is to provide currently available information on food safety and handling in a manner consistent with existing applicable regulations, standards and guidelines. The information provided herein is offered in good faith and believed to be reliable, but is made without warranty, express or implied, as to merchantability, fitness for a particular purpose, or any other matter. These recommended guidelines were not designed to apply to any specific operation. It is the responsibility of the user of this document to verify that these guidelines are appropriate for its operation. The publishing trade associations, their members and contributors do not assume any responsibility for compliance with applicable laws and regulations, and recommend that users consult with their own legal and technical advisers to be sure that their own procedures meet with applicable requirements.

Foreword

The diversity of production and processing methods in the lettuce/leafy greens industry makes a single, universally applicable approach to food safety planning complicated. It is important that each firm assess its operations and implement methods that meet its individual needs. What is most important is that basic food safety program components are implemented by producers to ensure lettuce/leafy greens product safety for consumers. Whatever the preferred production and processing method may be for a single producer, the lettuce/leafy greens industry recognizes the following basic principles that serve as the foundation for all food safety programs found within the industry:

- The lettuce/leafy greens industry recognizes that once lettuce/leafy greens are contaminated, removing or killing pathogens is difficult. Therefore, prevention of microbial contamination at all steps from production to distribution is strongly favored over treatments to eliminate contamination after it has occurred.

- The lettuce/leafy greens industry supports implementation and documentation of food safety programs that utilize risk assessment techniques that identify significant risks and use a preventive approach to ensure safe food products.

- The lettuce/leafy greens industry also supports and encourages routine and regularly scheduled food safety awareness training for all persons who grow, handle, distribute, process, prepare and/or serve lettuce/leafy greens products.

- The human pathogens most often associated with produce (*Salmonella* and *E. coli* O157:H7) cause infection and illness by the fecal-oral route of food contamination. Therefore, lettuce/leafy greens food safety programs should pay special attention to controlling, reducing and eliminating potential fecal contamination from people and domestic and wild animals through the most likely conduits, that being human hands, water and soil.

In the sections that follow, the lettuce/leafy greens field to fork supply chain has been broken down into the following unit operations: production and harvesting, postharvest handling, fresh-cut/value-added operations, distribution and end-user handling (retail, foodservice and consumer). Experts from industry and academia were solicited to identify, in the unit operations that they were intimately familiar with, microbial food safety issues that are found to be common to but not necessarily exclusive to lettuce/leafy greens. For each identified potential food safety issue, a list of "things to consider" about the issue was developed to raise awareness and offer possible mitigation steps or practices as means to address the issue. However, it is the responsibility of individuals and companies involved in the field to fork lettuce/leafy greens supply chain to determine what actions are appropriate in their individual operations. The potential food safety issues identified in each unit operation section are focused only on lettuce/leafy greens and may or may not apply to other specialty crops. Particular recommendations put forward to address any identified issue are not the only means by which the issue may be addressed. Individuals and companies are encouraged to use this document to evaluate, develop and enhance their own food safety programs.

At the end of each section and this document there are lists of required reference documents that offer detailed and important background information for individuals and companies that are engaged in the various aspects of the lettuce/leafy greens field to fork supply chain. These required reference documents provide detailed information regarding how to develop food safety programs for specific segments of the fresh produce industry from field to fork supply chain. Each company's comprehensive food safety program and its various components (e.g. employee training, sanitation, etc.) must be developed based upon an analysis of the potential hazards in that specific company's operations. This guidance document, as presented, is not sufficient to serve as an action plan for any specific operation but should be viewed as a starting point. This guidance document is intended to supplement, not replace, already established food safety program components such as Good Agricultural Practices (GAPs), current Good Manufacturing Practices (cGMPs), Hazard Analysis Critical Control Point (HACCP), etc., for the fresh fruit and vegetable industry.

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Introduction

In 1998, the U.S. Food and Drug Administration (FDA) issued its "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." The practices outlined in this and other industry documents are collectively known as Good Agricultural Practices or GAPs. GAPs provide general food safety guidance on critical production steps where food safety might be compromised during the growing, harvesting, transportation, cooling, packing and storage of fresh produce. More specifically, GAP guidance alerts fruit and vegetable growers, shippers, packers and processors to the potential microbiological hazards associated with various aspects of the production chain including: land history, adjacent land use, water quality, worker hygiene, pesticide and fertilizer use, equipment sanitation and product transportation. The vast majority of the lettuce/leafy greens industry has adopted GAPs as part of normal production operations. Indeed the majority of lettuce/leafy greens producers undergo either internal or external third-party GAP audits on a regular basis to monitor and verify adherence to their GAPs programs. These audit results are often shared with customers as verification of the producer's commitment to food safety and GAPs.

While the produce industry has an admirable record of providing the general public with safe, nutritious fruits and vegetables, it remains committed to continuous improvement with regard to food safety. In 2004, the FDA published a food safety action plan that specifically requested produce industry leadership in developing the next generation of food safety guidance for fruit and vegetable production. These new commodity-specific guidelines focus on providing guidance that enhances the safe growing, processing, distribution and handling of commodities from the field to the end user.

In the last 10 years, the focus of food safety efforts has been on the farm, initial cooling and distribution points and value-added processing operations. Fruit and vegetable processing operations have developed sophisticated food safety programs largely centered on current Good Manufacturing Practices (cGMPs) and the principles of Hazard Analysis Critical Control Point (HACCP) programs. As we develop a greater understanding of food safety issues relative to the full spectrum of supply and distribution channels for fruits and vegetables it has become clear that the next generation of food safety guidance needs to encompass the entire supply chain.

Scope

The scope of this document pertains only to fresh and fresh-cut lettuce and leafy greens products, and does not include products commingled with non-produce ingredients (e.g. salad kits which may contains meat, cheese, and/or dressings). Examples of "lettuce/leafy greens" include, but are not limited to, iceberg lettuce, romaine lettuce, green leaf lettuce, red leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix and spinach. These crops are typically considered lettuce and leafy greens by FDA but may not be similarly defined by other state or federal regulatory bodies. This document is also limited to offering food safety guidance for crops grown under outdoor field growing practices and may not address food safety issues related to hydroponic and/or soil-less media production techniques for lettuce/leafy greens.

Lettuce/leafy greens may be harvested mechanically or by hand and are almost always consumed uncooked or raw. Because lettuce/leafy greens may be hand-harvested and hand-sorted for quality, there are numerous "touch points" early in the supply chain and a similar number of "touch points" later in the supply chain as the products are used in foodservice or retail operations. Each of these "touch points" represents a potential opportunity for cross-contamination. For purposes of this document, a "touch point" is any occasion when the food is handled by a worker or contacts an equipment food contact surface.

Lettuce/leafy greens present multiple opportunities to employ food safety risk management practices to enhance the safety of lettuce/leafy greens. It should be noted that processed or value-added versions of lettuce/leafy greens packaged products are also commonly found in the marketplace in both retail and food-

service stores. These products are generally considered to be “ready-to-eat” (RTE) owing to the wash process used in their manufacturing and protective packaging employed in their distribution and marketing. In a processing operation, the basic principles of cGMPs, HACCP, sanitation and documented operating procedures are commonly employed to ensure production of the safest products possible. Lettuce/leafy greens raw agricultural commodities and fresh-cut/value added products are highly perishable and it is (strongly) recommended that they be distributed, stored and displayed under refrigeration to maintain product quality. Further, it should be understood that this recommendation is for product quality reasons only, and not for food safety reasons. Raw agricultural commodities do not require refrigeration for food safety.

Safe production, packing, processing, distribution and handling of lettuce/leafy greens depends upon a myriad of factors and the diligent efforts and food safety commitment of many parties throughout the distribution chain. No single resource document can anticipate every food safety issue or provide answers to all food safety questions. These guidelines focus on minimizing only the microbial food safety hazards by providing suggested potential actions to reduce, control or eliminate microbial contamination of lettuce/leafy greens in the field to fork distribution supply chain.

It is suggested that all companies involved in the lettuce/leafy greens farm to table supply chain consider the recommendations contained within these guidelines to ensure the safe production and handling of lettuce/leafy greens products from field to fork. Every effort to provide food safety education to supply chain partners should be made as well. Together with the commitment of each party along the supply chain to review and implement these guidelines, the fresh produce industry is doing its part to provide a consistent, safe supply of produce to the market.

Figure 1. General Supply Chain Flow for Lettuce/Leafy Greens

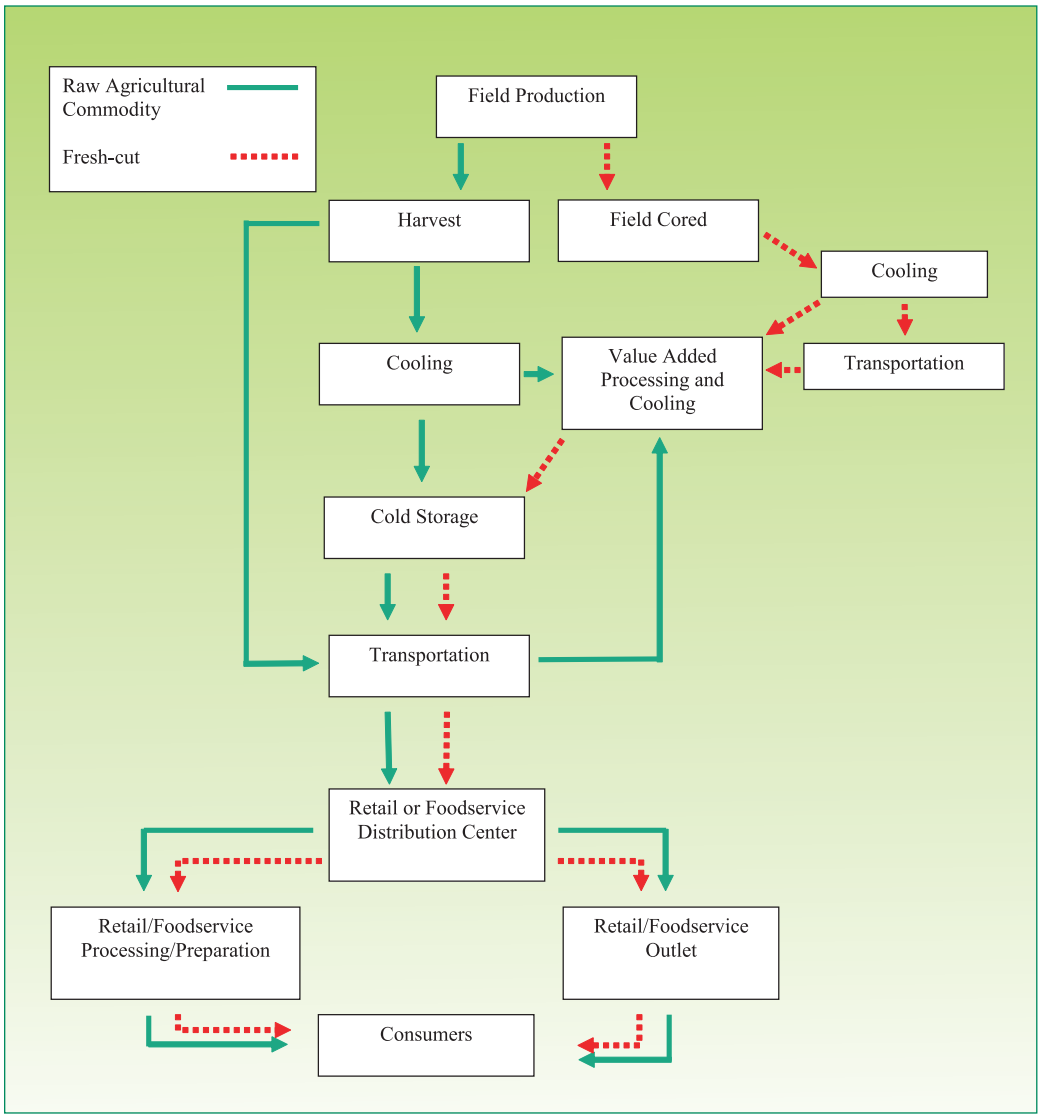
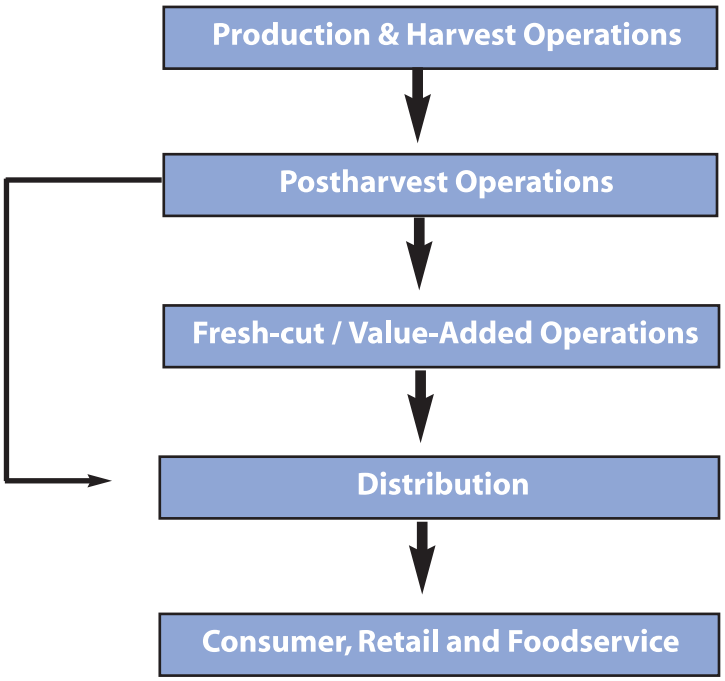


Figure 2. Lettuce/ Leafy Greens Unit Operations



Lettuce/Leafy Greens Commodity Specific Guidance

I. Production & Harvest Unit Operations

Issue: Water

Water used for in production and harvest operations may contaminate lettuce and leafy greens if there is direct contact of water containing human pathogens with edible portions of lettuce/leafy greens or by means of water-to-soil and soil-to-lettuce/leafy greens contact (Solomon *et al.,* 2003). In addition, irrigation methods vary and each may have varying potential to introduce human pathogens or promote human pathogen growth on lettuce and leafy greens.

Things to Consider:

- Assuring that irrigation water and water used in harvest operations is of appropriate microbial quality for its intended use.
- Reducing human pathogen contamination of soil which may in turn contaminate water and/or edible portions of lettuce and leafy greens (e.g., solarization, fumigation, etc.).
- Evaluating irrigation methods (drip irrigation, overhead sprinkler, furrow, etc.) for their potential to introduce, support or promote the growth of human pathogens on lettuce and leafy greens. Considerations include the potential for depositing soil on the crop, pooled or standing water that attracts animals, etc.
- Evaluating irrigation water reservoir conditions and means of reducing, controlling or eliminating potential contamination with human pathogens.
- Evaluating risks of using tail water and/or reclaimed (primary or secondary) water, including use in operations such as road dust abatement.
- When waters from various sources are combined, consider the potential for pathogen growth.
- Using procedures for storing irrigation pipes and drip tape that reduce potential pest infestations. Developing procedures to assure safe use of irrigation pipes and drip tape if a pest infestation does occur.
- Water used for direct or indirect application to edible portions of lettuce/leafy greens such as spraying and mixing pesticides should be of appropriate microbial quality for its intended purpose. Water may be tested on a regular basis, treated or drawn from an appropriate source as a means of assuring it is appropriate for its intended purpose.
- Water used on harvesting equipment or during harvesting should be of appropriate microbial quality for its intended use (e.g., meets U.S. EPA or WHO microbial standards for drinking water). The water source should be tested periodically to assure that it is of appropriate microbial quality for its intended purpose.

Issue: Soil Amendments

Soil amendments are commonly but not always incorporated into agricultural soils used for lettuce/leafy greens production to add organic and inorganic nutrients to the soil as well as to reduce soil compaction. Human pathogens may persist in animal manures for weeks or even months (Fukushima *et al.,* 1999;

Gagliardi and Karns, 2000). Proper composting of animal manures via thermal treatment will reduce the risk of potential human pathogen survival. However, the persistence of many human pathogens in untreated agricultural soils is currently unknown and under extensive investigation (Jiang *et al.,* 2003a; Jiang *et al.,* 2003b; Islam *et al.,* 2004). Field soil contaminated with human pathogens may provide a means of lettuce and leafy greens contamination. Studies conducted in cultivated field vegetable production models, in controlled environment and open-field, point towards a rapid initial die-off from high populations but a characteristic and prolonged low level survival. Readily detectable survival is typically less than 8 weeks following incorporation but has been documented to exceed 12 weeks. Recoverable populations, using highly sensitive techniques, have been reported to persist beyond this period under some test conditions. The detection of introduced pathogens on mature lettuce plants, from these low levels of surviving pathogens was not possible and the risk was concluded to be negligible. Human pathogens do not persist for long periods of time in high UV index, low relative humidity conditions but may persist for longer periods of time within aged manure or inadequately composted soil amendments. Therefore, establishing suitably conservative pre-plant intervals, appropriate for specific regional and field conditions, is an effective step towards minimizing risk (Suslow, 2005).

Things to Consider:

- Do not use raw animal manure with any lettuce/leafy greens crop.
- Implementing management plans that assure that the use of soil amendments does not pose a significant potential human pathogens hazard (e.g. timing of applications, storage location, source and quality, transport, etc.).
- Verifying the time and temperature process used during the composting process to assure that the potential of human pathogens being carried in the composted materials is reduced, controlled or eliminated as applicable to regulatory requirements.
- Maximizing the time interval between the soil amendment application and time to harvest.
- Implementing practices that control, reduce or eliminate likely contamination of lettuce/leafy green fields that may be in close proximity to on-farm stacking of manure.
- Using soil amendment application techniques that control, reduce or eliminate the likely contamination of surface water and/or edible crops being grown in adjacent fields.
- Minimizing the proximity of wind-dispersed or aerosolized sources of contamination (e.g., water and manure piles) that may potentially contact growing lettuce/leafy greens or adjacent edible crops.
- Segregating equipment used for soil amendment applications such as compost or use effective means of equipment sanitation before subsequent use.

Issue: Machine Harvest

This section addresses harvest and harvest aid equipment used for lettuce/leafy greens that will be further processed into a ready-to-eat (RTE) product. Mechanical or machine harvest has become increasingly prevalent and provides opportunity for increased surface contact exposure. This includes field cored lettuce operations that use various harvest equipment and aids.

Things to Consider:

- Establishing appropriate measures that reduce, control or eliminate the potential introduction of human pathogens at the cut surface during and after mechanical harvest operations.
- If re-circulated rinse or antioxidant solutions are used on the cut surface, ensure that they do not become a source of contamination.

- Designing equipment to facilitate cleaning by use of materials and construction that facilitates cleaning and sanitation of equipment food contact surfaces.
- Establishing the frequency of equipment cleaning and sanitation by development of Sanitation Standard Operating Procedures (SSOPs) and a sanitation schedule for machine harvest operations.
- Evaluating the use of cleaning verification methods for harvesting equipment (e.g. ATP test methods).
- Locating equipment cleaning and sanitizing operations away from product and other equipment to reduce the potential for cross contamination.
- Establishing equipment storage and control procedures that minimize the potential for contamination when not in use. Establishing policies and sanitary design options that facilitate frequent and thorough cleaning and sanitizing of food contact surfaces.
- Developing and implementing appropriate cleaning, sanitizing, storage and handling procedures of all food contact surfaces to reduce, control or eliminate the potential for microbial cross contamination (e.g., food contact surfaces may include transportation tarps, conveyor belts, etc.).

Issue: Hand Harvest - Direct Contact with Soil During Harvest

After manual harvest of lettuce/leafy greens, placing or stacking product on soil before the product is placed into a container may expose the product to human pathogens if the soil is contaminated. Research has demonstrated that microbes, including human pathogens, can readily attach to cut lettuce/leafy green surfaces (Takeuchi and Frank, 2001a).

Things to Consider:

- Evaluating appropriate measures that reduce, control or eliminate the potential introduction of human pathogens through soil contact at the cut surface after harvest (e.g. frequency of knife sanitation, no placement of cut surfaces of harvested product on the soil, container sanitation, single use container lining, etc.).
- Avoiding stacking soiled bins on top of each other.

Issue: Hand Harvest - Transfer of Human Pathogens by Field Workers

Lettuce/leafy greens are handled by harvest crews during harvest, in that each lettuce/leafy greens plant is touched/handled as part of the harvest process. It is possible that persons working with produce in the field may transfer microorganisms of significant public health concern. Workers may be asymptomatic.

Things to Consider:

- Using appropriate preventive measures outlined in GAPs such as training in appropriate and effective hand washing, glove use and replacement and mandatory use of sanitary field latrines to reduce, control or eliminate potential contamination.
- Establishing programs that can be used to verify employee compliance to company food safety policies.
- Eating, drinking or smoking in close proximity to unharvested product should be prohibited to reduce the potential for product contamination.
- Optimizing the location and sanitary design of field latrines and hand wash facilities to facilitate the control, reduction and elimination of human pathogens from employee hands. Evaluate the location

of field sanitation and worker hygiene facilities to maximize accessibility and use, while minimizing the potential for the facility to serve as a source of contamination.

- Establishing the frequency of facility maintenance/sanitation.
- Establishing equipment storage and control procedures when not in use.
- Establishing policies and sanitary design options that facilitate frequent and thorough cleaning and sanitizing of food contact surfaces (e.g., policies that prohibit employees from taking tools such as knives from the work area and require the use of knife scabbards that can be easily cleaned and sanitized).
- Minimizing the harvest of lettuce/leafy greens that have visible signs of decay due to the possible increased risk of the presence of human pathogens associated with decay or damage. Either remove the decayed portions or do not use it at all.

Issue: Equipment Facilitated Cross Contamination

Farm equipment that has direct contact with soil, soil amendments, or water that is likely to contain microorganisms of significant concern to public health may spread microbial contamination to other production lands or water sources. Of particular attention is equipment that may come into contact with raw untreated manure, untreated compost, waters of unknown quality, wildlife or domestic animals and other potential human pathogen reservoirs. Higher risk activities may entail the use of this equipment in proximity to, or in areas where it may contact edible portions of lettuce / leafy greens.

Things to Consider:

- Identifying any field operations that may pose a risk for cross-contamination.
- Segregating equipment that is used in high-risk operations.
- Using effective means of equipment cleaning and sanitation before subsequent equipment use in lettuce/leafy greens production, if it was previously used in a high-risk operation.
- Developing appropriate means of reducing, controlling or eliminating the possible transfer of human pathogens to soil and water that may directly contact edible lettuce/leafy green tissues through use of equipment.

Issue: Flooding

Flooding for purposes of this document is defined as the flowing or overflowing of a field with water outside a grower's control, that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of the edible portions of fresh produce in that field.

Pooled water (e.g. after rainfall) that is not reasonably likely to contain microorganisms of significant public health concern and is not reasonably likely to cause adulteration of the edible portions of fresh produce should not be considered flooding.

If flood waters contain microorganisms of significant public health concern, crops in close proximity to soil such as lettuce/leafy greens may be contaminated if there is direct contact between flood water or contaminated soil and the edible portions of lettuce/leafy greens (Wachtel *et al.,* 2002a and Wachtel *et al.,* 2002b).

In the November 4, 2005 FDA "Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce/leafy greens" the agency stated that it "considers ready to eat crops (such as lettuce/leafy greens) that have been in contact with flood waters to be adulterated due to potential exposure to sewage, animal waste, heavy metals, pathogenic microorganisms, or other contaminants. FDA is not aware of any method of reconditioning these crops that will provide a reasonable assurance of safety for human food use or otherwise bring them into compliance with the law. Therefore, FDA recommends that such crops be excluded from the human food supply and disposed of in a manner that ensures they do not contaminate unaffected crops during harvesting, storage or distribution.

Adulterated food may be subject to seizure under the Federal Food, Drug, and Cosmetic Act, and those responsible for its introduction or delivery for introduction into interstate commerce may be enjoined from continuing to do so or prosecuted for having done so. Food produced under insanitary conditions whereby it may be rendered injurious to health is adulterated under § 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a) (4))."

Areas that have been flooded can be separated into three groups: 1) product that has come into contact with flood water, 2) product that is in proximity to a flooded area but has not been contacted by flood water, and 3) production ground which was partially or completely flooded in the past, before a crop was planted. The considerations for each situation are separated below.

Things To Consider For Product That Has Come Into Contact With Flood Water:

- FDA considers any crop that has come into contact with floodwater to be an “adulterated” commodity that cannot be sold for human consumption.

Things To Consider For Product That Is In Proximity To A Flooded Area But Has Not Been Contacted By Flood Water:

- Preventing cross contamination between flooded and non-flooded areas (e.g. cleaning equipment, eliminating contact of any farming or harvesting equipment or personnel with the flooded area during growth and harvest of non-flooded areas).

Things To Consider For Formerly Flooded Production Ground

- Field history and crop selection on formerly flooded production ground.
- Assessing the time interval between the flooding event, crop planting and crop harvest. Comparative soil samples may be utilized to assess relative risk if significant reductions in indicator microorganisms have occurred within this time interval.
- Determining the source of flood waters (drainage canal, river, irrigation canal, etc.) as to whether there are significant upstream potential contributors of human pathogens at levels that pose a significant threat to human health.
- Allowing soils to dry sufficiently and be reworked prior to planting subsequent crops on formerly flooded production ground.
- Sampling previously flooded soil for the presence of microorganisms of significant public health concern or appropriate indicator microorganisms. Microbial soil sampling can provide valuable information regarding relative risks, however sampling by itself does not guarantee that all raw agricultural commodities grown within the formerly flooded production area are free of the presence of human pathogens.

Issue: Water Usage to Prevent Product Dehydration

Lettuce/leafy greens may be sprayed with small amounts of water during machine harvest or in the field container just after harvest to reduce water loss. Water used in harvest operations may contaminate lettuce and leafy greens if there is direct contact of water containing human pathogens with edible portions of lettuce/leafy greens.

Things to Consider:

- Due to the timing of this application of water that directly contacts edible portions of lettuce/leafy greens, this water should be of appropriate microbial quality for this purpose (e.g., meets U.S. EPA or WHO microbial standards for drinking water).
- Testing periodically to assure that it is of appropriate microbial quality for its intended purpose (e.g., meets U.S. EPA or WHO microbial standards for drinking water).
- Establishing and implementing cleaning and sanitation schedules for containers and equipment that will be used in hydration.
- Establishing policies for the storage and control of water tanks and equipment used for hydration operations when not in use.

Issue: Production Locations - Climatic Conditions and Environment

Lettuce/leafy greens are grown in varying regions but generally in moderate weather conditions. Cool, humid conditions favor human pathogen persistence (Takeuchi and Frank, 2000; Takeuchi *et al.,* 2000) while drier climates may present other problems such as requirements for additional water which may increase the potential for introduction of human pathogens. Heavy rains in certain areas may also cause lettuce/leafy greens to be exposed to contaminated soil due to rain splashing. It is important to tailor practices and procedures designed to promote food safety to the unique environment in which each crop may be produced.

Things to Consider:

- Heavy rains or irrigation practices may increase the likelihood of soil-to-lettuce/leafy greens contamination. Consider harvest practices such as removing soiled leaves, not harvesting soiled heads, etc., when excessive soil or mud builds up on lettuce/leafy greens.
- Care should be taken to reduce the potential for windborne soil, water or other media that may be a source of contamination to come into direct contact with the edible portions of lettuce and leafy greens.
- When soil has accumulated on plants, remove soil during the harvest or further processing.

Issue: Production Locations - Encroachment by Animals and Urban Settings

Lettuce/leafy greens are generally grown in rural areas that may have adjacent wetlands, wildlands and/or parks harboring wildlife. Many wildlife species (deer, pigs, birds, insects, amphibians and snakes) are known to be potential carriers of human pathogens (Fenlon, 1985). Extensive development in certain farming communities has also created situations with urban encroachment and unintentional access by domestic animals.

Things to Consider:

- Monitoring and minimizing domestic animal and wildlife activity in lettuce/leafy greens fields and production environments (e.g. reduce potential cover, harborage, standing water and utilize animal repellants and attractants).
- Evaluating the risk to subsequent crop production on production acreage that has experienced recent postharvest grazing of domesticated animals, using field culls as a source of animal feed.
- Locating production blocks (to the degree feasible) to minimize potential access by wildlife. For example, consider the proximity to, water, wildlife harborage, open range lands, non-contiguous blocks, urban centers, etc.
- Considering production field locations and proximity to wildlife especially if the production block location is isolated from other non-contiguous production areas, for example in foothill locations adjacent to open lands.
- If unusually heavy wildlife pest activity or evidence of wildlife pest activity occurs (e.g. presence of wildlife feces), consider whether or not to harvest affected portions of the field.
- Harvest employees should be trained to recognize and report for appropriate actions the evidence (e.g. feces) of wildlife activity or infestations.
- Consider controlling risks associated with production fields that are encroached upon by urban development. Risk factors that warrant consideration may include, but are not limited to, septic tank leaching and domestic animal fecal contamination of production fields and harvest equipment.

Detailed Background Guidance Information

Required Reference Documents

1. *FDA Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (www.foodsafety.gov/~dms/prodguid.html)*
2. *UFFVA Food Safety Auditing Guidelines: Core Elements of Good Agricultural Practices for Fresh Fruits and Vegetables*
3. *UFFVA Food Safety Questionnaire for Fresh Fruits and Vegetables*
4. *National GAPs Program Cornell University: Food Safety Begins on the Farm: A Grower Self Assessment of Food Safety Risks*

Lettuce/Leafy Greens Commodity Specific Guidance

II. Postharvest Unit Operations

Issue: Cooling

Lettuce/leafy greens are routinely cooled immediately after harvest by either forced-air cooling, vacuum cooling (iceberg lettuce) or spray-vacuum (hydrovac) cooling (leaf lettuce/leafy greens, romaine lettuce, spring mix, spinach). Water used in postharvest operations may contaminate lettuce and leafy greens if there is direct contact of water containing human pathogens with edible portions of lettuce/leafy greens.

Things to Consider:

- Water used to hydrovac cool lettuce/leafy greens should be free from human pathogens.
- Single-pass or one-use cooling water may be used in hydrovac cooling of lettuce/leafy greens.
- If lettuce/leafy greens hydrovac cooling water is re-circulated, water disinfectant should be present at sufficient levels and the levels monitored to reduce the potential risk of cross-contamination.
- Cooling equipment should be cleaned and sanitized on a regular basis to assure that the potential for cross contamination is minimized.
- Developing and implementing appropriate cleaning and sanitizing procedures for all food contact surfaces to reduce, control or eliminate the potential for microbial cross-contamination.
- Developing SSOPs for equipment including procedures and a schedule for the sanitation of cooling facilities.
- Establishing policies and sanitary design options that facilitate frequent and thorough cleaning of equipment and cleaning and sanitizing of food contact surfaces.
- Evaluating layout and drainage issues associated with the cooling facility to prevent cross-contamination of equipment that may be returned to the field.
- Pest control procedures should be implemented to minimize potential for introduction of human pathogens.
- Product placement and storage should not facilitate cross-contamination (e.g., pallets placed on top of bins, iced containers placed above containers with non-iced product, etc.).
- Take appropriate actions to ensure that adjacent land use does not pose a significant risk of product cross-contamination.
- Ensuring employees are trained regularly regarding food safety and hygiene.

Issue: Water

Water used in postharvest operations may contaminate lettuce and leafy greens if there is direct contact of water containing microorganisms of significant public health concern with edible portions of lettuce/leafy

greens. Consider all uses of water including ice where it directly contacts lettuce and leafy greens; for example, when water is used as a lubricant to facilitate packing whole leaf lettuces or romaine hearts into plastic bags, sleeves or wraps on field packing machines or in packinghouses or similar operations.

Things to Consider:

- Assuring that water that directly contacts edible portions of lettuce/leafy greens during postharvest operations is of appropriate microbial quality (e.g., meets U.S. EPA or WHO microbial standards for drinking water).
- Testing the water source periodically at a frequency sufficient to assure that it is of appropriate microbial quality for its intended purpose.
- Tanks that hold or store water used in packing operations should be included in relevant sanitation schedules.

Issue: Field Containers

Packaging materials such as field bins or totes should be clean and handled in a clean manner. Re-use of field bins or totes provides the potential for product cross contamination if, after use, field bins or totes are not stored, transported and re-used in a sanitary manner.

Things to Consider:

- Developing appropriate cleaning, storage and handling procedures (e.g., SOPs) for re-usable field containers to reduce, control or eliminate the potential for microbial cross-contamination and assure that they are stored, transported and re-used in a sanitary manner.
- Single-use liners should be used with containers that cannot be sanitized. Liners should not be re-used.
- Using procedures for storing and handling single use containers such as corrugated boxes and pallets that reduce, control or eliminate the potential for pest infestation. Prevent the use of containers that have or show evidence that they have been infested by pests.

Issue: Bulk Bin Modified Atmosphere Process

Lettuce may be packed in bulk bins and placed under a modified atmosphere (e.g., reduced oxygen atmosphere) for shipment to processing plants. Equipment and handling procedures employed in MAP bins have the potential for introducing human pathogens.

Things to Consider:

- See Appendix 4: "IFPA/NFPA/UFFVA Field Cored Lettuce Best Practices" for detailed information regarding appropriate procedures for handling bulk bin MAP lettuce/leafy greens.

Issue: Condition and Sanitation of Transportation Vehicles

Whole and fresh-cut lettuce/leafy greens products may be transported to the cooling and cold storage facilities by numerous modes of transportation. Transportation of lettuce/leafy greens should be managed to reduce, control or eliminate the risk of contamination.

Things to Consider:

- Lettuce and fresh-cut lettuce products should be transported in shipping containers and vehicles that are clean and sanitary.
- Implementing inspection/evaluation management programs of shipping containers/trailers to verify that food safety needs are being met. Items that may be evaluated include but are not limited to, the container/trailer condition, overall cleanliness, good structural condition, etc.

Issue: Employee Hygiene

Lettuce/leafy greens are rarely handled by employees at the cooling and cold storage facility. But it is possible that persons working with produce at the cooler of cold storage facility may transfer microorganisms of significant public health concern, therefore employee hygiene and sanitary procedures are appropriate in all environments where produce and people are in proximity.

Things to Consider:

- Using appropriate preventive measures outlined in GAPs such as training in appropriate and effective handwashing, glove use and replacement and mandatory use of sanitary facilities to reduce, control or eliminate potential contamination.
- Eating, drinking or smoking outside of designated areas at the cooler or in cold storage facilities should be prohibited to reduce the potential for product contamination.
- Optimizing the location and sanitary design of toilets and hand wash facilities to facilitate the control, reduction and elimination of human pathogens from employee hands. Evaluating the location of worker hygiene facilities to maximize accessibility and use, while minimizing the potential for the facility to serve as a source of contamination.
- Establishing the frequency of toilet and handwashing facility maintenance/sanitation.
- Establishing equipment and supply storage and control procedures when not in use.
- Establishing equipment storage and control procedures when not in use. Establishing policies and sanitary design options that facilitate frequent and thorough cleaning and sanitizing of food contact surfaces.

Detailed Background Guidance Information

Required Reference Documents

1. *FDA Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (www.foodsafety.gov/~dms/prodguid.html)*
2. *UFFVA Food Safety Auditing Guidelines: Core Elements of Good Agricultural Practices for Fresh Fruits and Vegetables*
3. *UFFVA Food Safety Questionnaire for Fresh Fruits and Vegetables*
4. *National GAPs Program Cornell University: Food Safety Begins on the Farm: A Grower Self Assessment of Food Safety Risks*
5. *IFPA/NFPA/UFFVA Field Cored Lettuce Best Practices*

Lettuce/Leafy Greens Commodity Specific Guidance

III. Fresh-cut / Value Added Unit Operations

While not specifically stated in the following issues and considerations, fresh-cut processors are reminded that it is important to follow applicable federal regulations, such as current Good Manufacturing Practices, which can help minimize the potential for product contamination.

Issue: Wash Water

Fresh-cut lettuce and leafy greens go through one or more vigorous washing processes before they are packaged and sold to consumers. Wash water disinfectants can be very effective in eliminating free-floating or exposed microorganisms. However, chlorine and other wash water disinfectants are used in wash systems to prevent the potential for cross contamination, NOT to surface sanitize produce. Washing ready-to-eat lettuce and leafy greens products during fresh-cut processing is necessary but does not imply that fresh-cut produce is free of microbes. In fact, fresh-cut produce should be expected to have a normal population of harmless microorganisms associated with it.

Scientific studies have demonstrated that washing produce in cold, chlorinated water will reduce microbial populations by only 90 - 99 percent. Microbial reduction on lettuce/leafy greens surfaces is a disinfectant concentration-by-time dependent relationship and it must be remembered that human pathogens, if present on the surface of lettuce/leafy greens, may not be completely eliminated by washing. This is because microorganisms adhere to the surface of produce and may be present in nooks and crannies where water and wash water disinfectants cannot penetrate. Microorganisms, including human pathogens, have a greater affinity to adhere to cut surfaces than uncut surfaces.

Water used in the washing of fresh-cut lettuce/leafy greens may become a source of contamination if the wash water contains human pathogens and if there is insufficient wash water disinfectant present. When lettuce/leafy greens are fully submerged in water, for washing or as a means of cooling, they are more likely to have wash water infiltration into the tissues. Growing conditions, particularly conditions such as soil type (sand, muck, etc.), may have a profound effect on wash water disinfectant efficacy as well as the potential for removal of soil particles (e.g., difficulty in removing sand particles from crinkly leaf spinach products).

Things to Consider:

- Ensuring that single-pass water used to wash lettuce/leafy greens after cutting is of sufficient microbial quality for its intended use (e.g., meets U.S. EPA or WHO microbial standards for drinking water).
- When water used to wash lettuce/leafy greens after cutting is re-circulated and/or reused, ensure that sufficient concentrations of approved water disinfectant are present to reduce the potential for lettuce/leafy greens-to-water-to-lettuce/leafy greens cross-contamination. Monitor the disinfectant level in the water at a frequency sufficient to assure that it is of appropriate microbial quality for its intended use.
- Minimizing use for fresh-cut production of lettuce/leafy greens that have visible signs of decay due to the possible increased risk of the presence of human pathogens associated with decay or damage. Either remove the decayed portions or do not use it at all.
- Evaluating water quality variables such as pH, organic load, turbidity, soil, product throughput capacity, etc., to assure that the wash water disinfectant of choice is effective in reducing the potential for water-to-lettuce cross-contamination.

- Evaluating process design to accommodate raw product variability (e.g., variations in soil and weather conditions) that may affect wash water efficacy. For example, evaluating specific product wash water disinfectant demand, product-to-water volume ratio; assess use of filtration systems to remove sand or soil from water during processing; or assess when water should be changed or added.

Issue: Labeling of Raw Agricultural Commodity (RAC) versus Ready-To-Eat (RTE) Products

End-users, including consumers, may have difficulty in quickly and easily differentiating a RAC which should be washed before consumption from an RTE food product that need not be washed again before consumption.

Things to Consider:

- Clearly label products to avoid end-user confusion regarding whether or not a product needs to be washed before consumption. For example, label fresh-cut products as "washed," "triple washed" or "ready-to-eat" on the package, to indicate that there is no need to wash product again.

Issue: New Technologies

New technologies that enhance production, quality or commercial distribution may have unforeseen consequences for food safety. For example, technologies that significantly extend product shelf-life may allow extra time for the survival, persistence and slow growth of human pathogens from very low (undetectable) levels to levels that may be capable of causing disease, particularly if temperature abuse occurs.

Things to Consider:

- Determining the impact on food safety when evaluating new technologies, e.g. shelf-life extenders.

Issue: Finished Product Packaging

Appropriate primary and secondary packaging is the last protection of ready-to-eat products against subsequent contamination with undesirable microorganisms.

Things to Consider:

- Determining whether the primary and secondary packaging and packaging operation are sufficient to prevent subsequent contamination.
- Determining whether the packaging manufacturer understands the ultimate use of the package.
- Appropriately label packages that do not provide a barrier to potential external microbial contamination.

Detailed Background Guidance Information

Required Reference Documents

6. *IFPA Food Safety Guidelines for the Fresh-Cut Produce Industry*

7. *Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food 21 CFR 110 (www.access.gpo.gov/nara/cfr/waisidx_04/21cfr110_04.html)*

8. *DRAFT Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables (www.cfsan.fda.gov/~dms/prodgui2.html)*

Lettuce/Leafy Greens Commodity Specific Guidance

IV. Distribution Unit Operations

Issue: Conditions and Sanitation of Transportation Vehicles

Whole and fresh-cut lettuce/leafy greens products can take many routes to the end user, including direct or indirect shipments through intermediate distributors and warehouses. Each step of each route must be managed to reduce, control or eliminate the risk of contamination.

Things to Consider:

- Transport lettuce and fresh-cut lettuce products in shipping containers and trailers that are clean and sanitary.
- Implementing inspection/evaluation management programs of shipping containers/trailers to verify that food safety needs are being met. Items that may be evaluated include, but are not limited to, the container/trailer condition, overall cleanliness of the walls and floor, good structural condition (free from damage to walls and floor or ceiling, such as exposed insulation and holes), absence of off-odors or unusual smells and functional chilled air delivery chute.
- Addressing food safety requirements for the sanitary transportation of lettuce/leafy greens products in contracts with transportation companies. For example, establish restrictions on previous cargoes to avoid the possibility of cross contamination.

NOTE: The Sanitary Food Transportation Act of 2005 has amended the Federal Food Drug and Cosmetic Act to define adulterated food to include food transported or offered for transportation under conditions not in compliance with 21 U.S.C. § 342 (i). The FDA is currently developing regulations requiring shippers, motor and rail carriers, receivers and other persons engaged in the transportation of food to use sanitary transportation practices. These regulations will pertain to but are not limited to: sanitation, packaging, isolation and other protective measures, limitations on the use of vehicles, recordkeeping, and nonfood products that the agency determines may, if transported in bulk or non-bulk equipment, adulterate food if simultaneously or subsequently transported in the same vehicle.

Issue: Conditions and Sanitation of Distribution/Cooler Facilities

Cooler facilities used to hold product during distribution may serve as a point of contamination if appropriate practices are not followed.

Things to Consider:

- Establishing and implementing GAP or cGMP procedures as appropriate to the product and stage of distribution; e.g. written sanitation, pest control, food safety training for workers, etc.

Issue: Techniques for Temperature Measurement of Product

These are perishable products and proper temperature control during distribution is critical for optimal shelf-life and product quality. Monitoring product temperature by invasive techniques (i.e., puncturing the package with a temperature probe) can be a source of product contamination.

Things to Consider:

- Using non-invasive techniques for monitoring product temperature, e.g., “pillowing” the temperature probe between two packages.
- If an invasive technique is used, discard any product or package that is penetrated.

Detailed Background Guidance Information:

Required Reference Documents

1. *FDA Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (www.foodsafety.gov/~dms/prodguid.html)*
2. *UFFVA Food Safety Auditing Guidelines: Core Elements of Good Agricultural Practices for Fresh Fruits and Vegetables*
4. *IFPA Food Safety Guidelines for the Fresh-Cut Produce Industry 4th Edition*
9. *IFPA/PMA Fresh-cut Produce Handling Guidelines*
10. *FMI Total Food Safety Management Guide: A Model Program for Raw Ready-To-Eat Fresh-cut Produce*
11. *AFDO Guidance for Processing Fresh-cut Produce in Retail Operations*
12. *FMI SuperSafeMark: Retail Best Practices and Guide to Food Safety and Sanitation*
13. *National Restaurant Association Education Foundation ServSafe® Food Safety Program*

Lettuce/Leafy Greens Commodity Specific Guidance

V. End-user Handling (Retail, Foodservice and Consumer) Unit Operations

Specific procedures for storing or displaying food, for excluding or restricting ill employees, for washing hands, date marking, and for washing and sanitizing equipment can be found in the FDA Model Food Code. Further considerations for lettuce/leafy greens are found below. In addition, handlers of lettuce/leafy greens should be aware of and follow all federal, state, or local rules and regulations. Lettuce/leafy greens may be handled extensively at retail or in food service operations, therefore it is of particular importance, to wash hands thoroughly with soap and water before cutting or handling lettuce/leafy greens. Rewash as necessary.

This document provides information unique to lettuce/leafy greens safety, and it supplements other food safety advice found in the required reference documents that offer detailed and important background information for individuals and companies that are engaged in the various aspects of the lettuce/leafy greens field to fork supply chain. It is essential that retail and foodservice companies develop comprehensive food safety programs that include robust employee training and hygiene components as well as facility sanitation. Each company's comprehensive food safety program and its various components (e.g. employee training, sanitation, etc.) must be developed based upon an analysis of the potential hazards in that specific company's operations. This guidance document, as presented, is not sufficient to serve as an action plan for any specific operation but should be viewed as a starting point.

Issue: In recent years there have been foodborne illness outbreaks and product recalls associated with lettuce/leafy greens due to inadvertent contamination with human pathogens. Edible portions of the lettuce/leafy greens flesh may be contaminated by numerous means in the field to fork supply chain. Important considerations are excluding or restricting ill food workers, employee hygiene/handling, water quality, and cross-contamination.

Things to Consider: (Retail and Foodservice)

- Decayed lettuce/leafy greens and lesions caused by plant pathogens may act as harborage for human pathogens (Wells and Butterfield, 1997). If lettuce/leafy greens have visible signs of decay do not use them due to the possible increased risk of the presence of human pathogens associated with decay or damage. When in doubt about the use of decayed or distressed product, either remove the unusable portions or do not use it at all.

- For retail and foodservice establishments, the U.S. FDA 2005 Model Food Code Section 3-302.15 specifies: "Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form." Packaged produce labeled “ready-to-eat,” “washed” or “triple washed” need not be washed.

- Ensuring water used to wash lettuce/leafy greens is of sufficient microbial quality for its intended purpose (e.g. meets U.S. EPA or WHO microbial standards for drinking water).

- After cutting, rewash the lettuce/leafy greens in a clean and sanitized sink or container. Immerse and agitate the cut lettuce/leafy greens, then remove from water avoiding contact with any dirt or debris that may settle out. Repeat the cleaning process as needed with a clean and sanitized basin/sink/bowl and fresh water.

- Cleaning and sanitizing all food-contact equipment and utensils that contact cut lettuce/leafy greens (cutting boards, knives, etc.) with the following steps: wash thoroughly with hot soapy water, rinse, sanitize, and air-dry.
- Washing hands thoroughly with soap and water before cutting or handling lettuce/leafy greens. Rewash as necessary.
- Using a barrier such as gloves and/or an appropriate utensil (changed with sufficient frequency to prevent cross-contamination) to touch fresh-cut lettuce/leafy greens. This does not alleviate the need for proper hand-washing.
- For optimal quality, store and display fresh-cut lettuce/leafy greens under refrigeration throughout distribution.
- Uncut whole lettuce/leafy greens do not require refrigeration for safety.
- Fresh-cut lettuce may deteriorate more quickly than uncut product and should be stored and displayed under refrigeration. For fresh-cut lettuce/leafy greens that are prepared on the retail/foodservice premises, establish a policy for how long fresh-cut lettuce can be displayed and offered for sale. Mark the product with a "prepared on" or "best if used by date." The manufacturer may label fresh-cut lettuce/leafy greens "Keep Refrigerated." Follow the manufacturer's recommendation for this product.
- Develop training programs that will educate all potential handlers of lettuce and leafy greens regarding the importance of food safety and the specific guidance issues and considerations.

Issue: Raw Agricultural Commodity (RAC) versus Ready-To-Eat (RTE) Product labeling

End-users may have difficulty in quickly and easily differentiating a raw agricultural commodity that should be washed before consumption from a ready-to-eat food product that does not need to be washed again before consumption. In addition, end-users should note that RAC's including lettuce/leafy green products shipped often have little protection from cross contamination because they are simply packed in a primary container such as a box.

Things to Consider (Retail and Foodservice):

- End-users should carefully read labels to determine whether a product is a RAC (e.g. hearts of romaine) that should be washed before consumption or an RTE food product (e.g. fresh-cut salad) that does not need to be washed again before consumption.
- Raw agricultural commodities (fruits and vegetables) should be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form.
- If fresh-cut lettuce/leafy greens are labeled as "washed," "triple washed" or "ready-to-eat" on the package, there is no need to wash them again. Although not recommended, if end-users do re-wash ready-to-eat fresh-cut lettuce/leafy greens, they must have appropriate sanitary washing and drying conditions in the foodservice, retail or in-home food preparation environment to reduce the potential for cross contamination of fresh-cut ready-to-eat produce with human pathogens. Produce washing must occur in food preparation areas that have: clean and sanitary food contact surfaces (e.g. colanders, knives, drying cloths, etc.), clean and sanitary preparer hands and an environment clearly segregated from other food items (e.g. raw meat, poultry, etc.) that may harbor human pathogens.
- Because whole lettuce/leafy greens shipping containers do not provide a sufficient barrier to cross contamination, ensure that storage practices do not subject the product to potential cross contamination (e.g., do not store raw meats above lettuce/leafy greens cartons).

Issue: Lettuce Re-Crisping

Lettuce may be re-crisped by placing fresh-cut lettuce/leafy greens in containers with tap water. The small amounts of chlorine present in the re-crisping tap water may be quickly inactivated by the organic load presented by lettuce/leafy greens. This may increase the potential for lettuce/leafy greens cross contamination particularly if additional lettuce/leafy greens are added to the re-crisping container (Wachtel and Charkowski, 2002).

Things to Consider (Retail and Foodservice):

- When re-crisping whole lettuce, reduce the potential for water and utensils to contaminate lettuce/leafy greens. Clean and sanitize the sink or container first and use water supplies that meet drinking water standards for re-crisping. The water should be changed at a frequency sufficient to ensure that it is of appropriate microbial quality for its intended use.
- Evaluate use of running water to re-crisp lettuce as needed, in lieu of re-crisping by water soaking, to reduce the potential for cross contamination.

Issue: Cross-contamination (Consumers)

Six percent of consumers in a recent survey responded that they never or seldom wash fresh produce before consumption (Li-Cohen and Bruhn, 2002). This survey also found that many consumer respondents did not separate produce from raw meat, poultry or fish in their refrigerators. These limited observations clearly indicate the need for educational outreach to emphasize safe handling practices of produce from purchase to consumption.

Information from the Partnership for Food Safety Education - Produce Handling Education Campaign (http://portal.fightbac.org/pfse/toolsyoucanuse/phec/), recommends the following steps for consumers to help reduce the risk of foodborne illness from fresh produce.

Things to Consider: (Consumers)

Check

- Check to be sure that the fresh vegetables you buy are not bruised or damaged.
- Check that fresh-cut vegetables like packaged salads are refrigerated at the store before buying. Do not buy fresh cut items that are not refrigerated.

Clean

- Wash hands with warm water and soap for at least 20 seconds before and after handling fresh fruits and vegetables.
- Clean all surfaces and utensils with hot water and soap, including cutting boards, counter tops, peelers and knives that will touch fresh vegetables before and after food preparation.
- Rinse fresh vegetables under running tap water, including those with skins and rinds that are not eaten. Packaged vegetables labeled “ready-to-eat,” “washed” or “triple washed” need not be washed.
- Rub firm-skin vegetables under running tap water or scrub with a clean vegetable brush while rinsing with running tap water.

- Dry vegetables with a clean cloth towel or paper towel.
- Never use detergent or bleach to wash fresh vegetables. These products are not intended for consumption.

Separate

- When shopping, be sure fresh vegetables are separated from household chemicals and raw foods such as meat, poultry and seafood in your cart and in bags at checkout.
- Keep fresh vegetables separate from raw meat, poultry or seafood in your refrigerator.
- Separate fresh vegetables from raw meat, poultry and seafood. Do not use the same cutting board without cleaning with hot water and soap before and after preparing fresh vegetables.

Cook

- Cook or throw away vegetables that have touched raw meat, poultry, seafood or their juices.
- Refrigerate all cut, peeled or cooked fresh vegetables within two hours.

Throw Away

- Throw away fresh vegetables that have not been refrigerated within two hours of cutting, peeling or cooking.
- Remove and throw away bruised or damaged portions of vegetables when preparing to cook them or before eating them raw.
- Throw away any vegetable that will not be cooked if it has touched raw meat, poultry or seafood.

Detailed Background Guidance Information:

Required Reference Documents

9. *IFPA/PMA Fresh-cut Produce Handling Guidelines*
10. *FMI Total Food Safety Management Guide: A Model Program for Raw Ready-To-Eat Fresh-cut Produce*
11. *AFDO Guidance for Processing Fresh-cut Produce in Retail Operations*
12. *FMI SuperSafeMark: Retail Best Practices and Guide to Food Safety and Sanitation*
13. *National Restaurant Association Education Foundation ServSafe® Food Safety Program*

Information & Resources

The following references are listed to provide additional information about lettuce/leafy greens produce safety. This is not intended to be an all-inclusive list; rather it is representative of materials that are currently available.

Association of Food and Drug Officials (AFDO)

- Guidance for Processing Fresh-cut Produce in Retail Operations
  (www.afdo.org/afdo/upload/Fresh-cutProduce.pdf)

California Department of Health Services

- Safer Processing of Fresh-cut Produce
  (www.dhs.ca.gov/ps/fdb/PDF/FreshCutOrderform4.pdf)
- Handling of "Value Added" Produce in Retail Markets
  (www.dhs.ca.gov/ps/fdb/HTML/food/Fsn9903.htm)
- Reducing Risk of Foodborne Illness Associated With Green Onions and Other Produce – A Guide For The Retail Food Industry
  (www.dhs.ca.gov/ps/fdb/PDF/Produce%20Handling%2011%202503A.pdf)

Food and Drug Administration (FDA)

- Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables
  (www.foodsafety.gov/~dms/prodguid.html)
- 2005 U.S. FDA Model Food Code
  (www.cfsan.fda.gov/~dms/fc05-toc.html)
- 2005 Dietary Guidelines for Americans - Chapter 9 Food Safety
  (www.health.gov/dietaryguidelines/dga2005/report/PDF/D9_FoodSafety.pdf)
- FDA Advises Consumers on Fresh Produce Safety
  (www.cfsan.fda.gov/~lrd/tpproduc.html)

Food Marketing Institute (FMI)

- Total Food Safety Management Guide: A Model Program for Raw Ready-To-Eat Fresh-cut Produce
  (www.fmi.org/forms/store/ProductFormPublic/search?action=1&Product_productNumber=2014)
- SuperSafeMark: Retail Best Practices and Guide to Food Safety and Sanitation
  (www.fmi.org/supersafemark/)
- *www.fmi.org*

International Fresh-cut Produce Association (IFPA)

- Food Safety Guidelines for the Fresh-Cut Produce Industry 4th Edition
- Fresh-Cut Produce Handling Guidelines 3rd Edition
- *www.fresh-cuts.org*

National GAPs Program at Cornell University

- Food Safety Begins on the Farm - A Grower's Guide: Good Agricultural Practices for Fresh Fruits and Vegetables *(www.gaps.cornell.edu/PUBS/FSBF_Bk_Eng.pdf)*
- Food Safety Begins on the Farm: A Grower Self Assessment of Food Safety Risks *(www.gaps.cornell.edu/pubs_fsbf_ws.html)*
- Minimize Pathogen Contamination During Production and Harvest of Fresh Produce *(www.gaps.cornell.edu/pubs/risks.pdf)*
- *www.gaps.cornell.edu*

National Restaurant Association (NRA)

- National Restaurant Association Education Foundation ServSafe® Food Safety Program
- 3rd Edition *(www.nraef.org/servsafe)*
- NRA *(www.restaurant.org)*
- NRA Educational Foundation *(www.nraef.org)*

Partnership for Food Safety Information Fight BAC!

- Produce Handling Education Campaign *(http://portal.fightbac.org/pfse/toolsyoucanuse/phec/)*
- BAC Down! *(http://portal.fightbac.org/pfse/toolsyoucanuse/BACDown/)*

Produce Marketing Association (PMA)

- Fresh-Cut Produce Handling Guidelines
- *www.pma.com*

United Fresh Fruit and Vegetable Association (UFFVA)

- Food Safety Auditing Guidelines: Core Elements of Good Agricultural Practices for Fresh Fruits and Vegetables *(www.uffva.org/training/)*
- Food Safety Questionnaire for Fresh Fruits and Vegetables *(www.uffva.org/training/)*
- Field Cored Lettuce Best Practices *(www.uffva.org/news/fccbest8_3a.pdf)*
- *www.uffva.org*

Websites

Gateway to Government Food Safety Information
www.foodsafety.gov/

Partnership for Food Safety Information Fight BAC!
www.fightbac.org

Produce Education Handling Campaign
http://portal.fightbac.org/pfse/toolsyoucanuse/phec/

BAC Down!
http://portal.fightbac.org/pfse/toolsyoucanuse/BACDown/

U.S. Code of Federal Regulations (CFR) All
www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1

U.S. Code of Federal Regulations (CFR) 21CFR 100-169 cGMPs and other Food Regulations
www.access.gpo.gov/nara/cfr/waisidx_04/21cfrv2_04.html

U.S. Code of Federal Regulations (CFR) Food Labeling
www.access.gpo.gov/nara/cfr/waisidx_00/21cfr101_00.html

USDA, ARS Agriculture Handbook Number 66 The Commercial Storage of Fruits, Vegetables, and Florist and Nursery Stocks: Produce Food Safety
www.ba.ars.usda.gov/hb66/024foodsafety.pdf

U.S. Environmental Protection Agency (EPA) Drinking Water Standards:
www.epa.gov/safewater/standards.html

U.S. Food and Drug Administration
www.fda.gov

World Health Organization (WHO) Drinking Water Standards
www.wca-infonet.org/servlet/BinaryDownloaderServlet?filename=1063379476163_1.pdf&refID=110012

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Beuchat LR, Adler BB, Lang MM. 2004. Efficacy of Chlorine and a Peroxyacetic Acid Sanitizer in Killing *Listeria monocytogenes* on Iceberg and Romaine Lettuce Using Simulated Commercial Processing Conditions. J. Food Prot. 67(6):1238-1242.

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Glossary

This glossary of definitions have been obtained from Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, October 1998 (www.foodsafety.gov/~dms/prodguid.html) and the definitions describing risk are those adopted on an interim basis at the 22nd Session of the Codex Alimentarius Commission.

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

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

Clean: means that food or food-contact surfaces are washed and rinsed and are visually free of dust, dirt, food residues, and other debris.

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

Control Measure: any action or activity that can be used to prevent, reduce, or eliminate a microbiological hazard.

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

Field Packed: means that grading, sorting, sizing, packing, and palletizing are carried out in the field.

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, such as containers and conveyor belts, which contact fresh produce, whether used in harvesting, post-harvesting, or packaging operations. It would not include tractors, forklifts, handtrucks, pallets, etc., that are used for handling or storing large quantities of contained or packed fresh produce and that do not come into actual contact with the food.

Good Agricultural Practices: refer to the guidelines set forth in the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," which was published by the U.S. Food and Drug Administration in 1998 (www.foodsafety.gov/~dms/prodguid.html).

cGMPs (current Good Manufacturing Practices): Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food (21 CFR 110).

Hazard: any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Human Pathogen: means a microorganism capable of causing disease or injury to people. This is different from a plant pathogen which may cause disease to plants.

Microorganisms: include yeasts, molds, bacteria, protozoa, helminths (worms), and viruses. Occasionally, the term “microbe” or “microbial” is used instead of the term “microorganism.”

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

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

Packing Shed/Packinghouse:
means a facility where raw agricultural commodities are washed, trimmed or sorted and packed in commercial containers, e.g. cartons or totes.

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.

Raw Agricultural Commodity:
any fruit or vegetable in its raw or natural state, including all fruits and vegetable that are washed, colored, or otherwise treated in the unpeeled natural form prior to marketing.

Risk: is a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

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

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

Shed Packed:
means grading, sorting, sizing, packing, and palletizing are carried out in a packing shed/packinghouse.

Spring Mix: a blend of baby lettuces, mustards, chards, spinach and chicories that will vary based on availability of supply.

Value-Added or Fresh-cut Produce:
refers to fruits or vegetables that have been trimmed and/or peeled and/or cut into 100% usable product that is bagged or pre-packaged. These products are very often packed in protective plastic films and are typically "ready-to-eat" food products, if they are labeled as "washed," "triple washed" or "ready-to-eat" as they have gone through a vigorous washing process before being packaged and sold. Products that are not labeled as such are raw agricultural commodities and should be considered raw agricultural commodities even if they are packaged in a plastic overwrap or polyfilm.

FDA Jurisdiction Over Fresh Fruits and Vegetables

FDA's regulations regarding current good manufacturing practices (cGMPs) exclude from their purview the following:

> Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

21 C.F.R. § 110.19(a). Section 201(r) of the Food, Drug, and Cosmetic Act defines "raw agricultural commodities" as

> any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

21 U.S.C. § 321(r). It is this regulatory language that is usually regarded as the fresh fruit and vegetable "exemption" from FDA regulation. The same regulation, however, goes on to provide as follows:

> FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

21 C.F.R. § 110.19(b). The agricultural commodity exemption from cGMPs exists by regulation; it can be revoked by regulation.

It is important to note that despite the regulatory exclusion from the specific requirements of the cGMP regulations, FDA still has jurisdiction over raw agricultural commodities as food. Fresh fruits and vegetables are "food" within the meaning of the FD&C Act, and, as such, subject to adulteration and misbranding provisions of the Act.

> A food shall be deemed to be adulterated –
>
> Poisonous, insanitary, etc., ingredients
>
> (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health. (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 346 of this title; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a(a) of this title; or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 348 of this title; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 360b of this title; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

FD&C Act § 402(a), 21 U.S.C. § 342(a).

FDA has long used subsection (a)(4) of the adulteration provisions to take enforcement action against food facilities that have insanitary conditions. Importantly, it is not necessary for FDA to demonstrate that the food at issue is actually contaminated, only that the food was held under such conditions that it *may* have become contaminated.

Agriculture's regulatory "exemption" from the GMP regulations – which also address sanitation – do not alter the statutory provisions regarding adulteration. FDA could, at any time, take enforcement action against an agricultural producer. FDA has the statutory authority to institute court proceedings to restrain violations of the Act (FD&C Act § 302, 21 U.S.C. § 332), criminally prosecute responsible persons for violations of the Act (FD&C Act § 303, 21 U.S.C. § 333), and seize adulterated or misbranded product (FD&C Act § 304, 21 U.S.C. § 334). Under section 303 of the Bioterrorism Act, FDA now has the authority to administratively detain adulterated food that presents a threat of serious adverse health consequences or death. FD&C Act § 403(h), 21 U.S.C. § 334(h). Under section 304 of the Bioterrorism Act, FDA now also has the authority to debar persons from importing adulterated food into the United States. FD&C Act § 306, 21 U.S.C. § 335a.

These guidelines are recommendations only, and the International Fresh-cut Produce Association, the Produce Marketing Association, the United Fresh Fruit and Vegetable Association and Western Growers and all other contributors and reviewers, do not make any claims or warranties about any specific actions contained herein. It is the responsibility of any purveyor of food to maintain strict compliance with all local, state and federal laws, rules and regulations. These guidelines are designed to direct inquiries and develop information that must be independently evaluated by all parties with regard to compliance with legal and regulatory requirements. The providers of this document do not certify compliance with these guidelines and do not endorse companies or products based upon their use of these guidelines. Differences between products, production processes, distribution and consumption, and the ever-changing state of knowledge regarding food safety make it impossible for any single document to be comprehensive and absolutely authoritative. Users of these guidelines should be aware that scientific and regulatory authorities are periodically revising information regarding best practices in food handling, as well as information regarding potential food safety management issues. Users of this document must bear in mind that as knowledge regarding food safety changes, so will measures to address those changes, as will the emphasis on particular issues by regulators, as well as regulations themselves. Neither this document, nor how food producers and distributors should address food safety are set in stone. Users are strongly urged to maintain regular contact and utilize information available through their trade associations, the U.S. Food and Drug Administration, U.S. Department of Agriculture, U.S. Environmental Protection Agency, the Centers for Disease Control and Prevention, as well as state agricultural, environmental, academic, and public health authorities.

Acronyms

CCP: A point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.

CP: This stands for control point which is a step in a process where control my be applied to manage a food safety risk

FDA: This acronym stands for the U.S. Food and Drug Administration.

GAPs: This acronym stands for Good Agricultural Practices and synonymously refers to the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" published by the U.S. Food and Drug Administration. www.foodsafety.gov/~dms/prodguid.html

cGMPs: current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food (21 CFR 110) www.access.gpo.gov/nara/cfr/waisidx_04/21cfr110_04.html

Required Reference Documents

1.FDA Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (www.foodsafety.gov/~dms/prodguid.html)

2.UFFVA Food Safety Auditing Guidelines: Core Elements of Good Agricultural Practices for Fresh Fruits and Vegetables (www.uffva.org/training/)

3.UFFVA Food Safety Questionnaire for Fresh Fruits and Vegetables (www.uffva.org/training/)

4.National GAPs Program Cornell University: Food Safety Begins on the Farm: A Grower Self Assessment of Food Safety Risks (www.gaps.cornell.edu/pubs_fsbf_ws.html)

5.IFPA/NFPA/UFFVA Field Cored Lettuce Best Practices (www.uffva.org/news/fccbest8_3a.pdf)

6.IFPA Food Safety Guidelines for the Fresh-Cut Produce Industry (www.fresh-cuts.org/index.php?page=37)

7.Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food (21 CFR 110) (www.access.gpo.gov/nara/cfr/waisidx_04/21cfr110_04.html)

8.DRAFT Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables (www.cfsan.fda.gov/~dms/prodgui2.html)

9.IFPA/PMA Fresh-cut Produce Handling Guidelines (www.fresh-cuts.org/index.php?page=37)

10.FMI Total Food Safety Management Guide: A Model Program for Raw Ready-To-Eat Fresh-cut Produce (www.fmi.org/forms/store/ProductFormPublic/search?action=1&Product_productNumber=2014)

11.AFDO Guidance for Processing Fresh-cut Produce in Retail Operations (www.afdo.org/afdo/upload/Fresh-cutProduce.pdf)

12.FMI SuperSafeMark: Retail Best Practices and Guide to Food Safety and Sanitation (www.fmi.org/supersafemark/)

13.NRA Education Foundation ServSafe Coursebook (www.nraef.org/servsafe)