October 30, 2009

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: FDA-2009-D-0348; Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; Draft Guidance

On behalf of companies in the leafy greens supply chain, United Fresh Produce Association ("United Fresh") appreciates the opportunity to comment on FDA's draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens ("Guidance"). We applaud FDA's publishing of this Guidance, which establishes FDA's expectations for safe production, harvesting and post-harvest handling of fresh and fresh-cut leafy greens. We note that many of the recommendations are directly or adapted from the industry's Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens [FDA Ref. 8], and appreciate FDA's recognition of the leafy greens industry's food safety efforts. While the industry representatives that are providing these comments generally agreed with the recommendations in the draft Guidance, we believe that the following suggestions would improve its utility and clarity, consistent with FDA's intentions.

Comments to *Table of Contents:*

The draft Guidance is lengthy, over 30 pages. The Table of Contents, however, only lists the ten major sections of the document. We believe the Guidance would be more user-friendly if subsections were also listed in the Table of Contents. The electronic linking of the Table of Contents to the subsections would greatly facilitate users finding important information quickly.

Comments to *II. Background:*

"28 [produce-related outbreaks] were linked to the consumption of leafy greens…"

- While any foodborne illness related to fresh produce is unacceptable to the men and women who strive daily to bring only the safest fresh produce to the consumer, we believe there are valuable lessons to be learned from outbreak investigations. We also recognize that many outbreak investigations do not reveal a root cause of the contamination event that resulted in the outbreak. Indeed, some food items identified in outbreak investigations are only suspect, without definitive evidence of their being a vehicle for the pathogen. However, we believe that it would be instructive for FDA to include, in the Guidance, examples of findings from outbreak investigations related to leafy greens, even if the findings were "no cause found".

Comments to *III. Scope and Use*

"Leafy greens do not include herbs such as cilantro and parsley."

- While the 2006 and 2008 industry guidelines did not expressly include leafy herbs such as cilantro and parsley, current industry efforts (i.e., the proposed National Leafy Greens Marketing Agreement) consider food safety practices for such herbs to be similar enough

to other leafy greens that they can be included. We therefore recommend that FDA extend the applicability of this Guidance to include leafy herbs.

Comments to *IV. Definitions*

- To avoid misunderstanding and for ease of use, we suggest repeating the definition of Leafy Greens here.

- The term Control Measure is used only once in the Guidance (V. Production and Harvest, J. Greenhouse Production), and then not in a manner requiring definition for understanding. Further, the definition provided here is not consistent with the definition for Control Measure used in FDA's juice HACCP regulation, 21 CFR part 120.3. Therefore, to avoid confusion that FDA is recommending HACCP for field operations, we request deleting a definition for Control Measure.

- We suggest adding the following definition for water disinfectant: "antimicrobial agents approved for such use in 21 CFR part 173.315, Chemicals used for washing or to assist in the peeling of fruits and vegetables. These include materials such as sodium hypochlorite (and the other related sources of the active agent hypochlorous acid), chlorine dioxide, various peroxides and ozone."

  We note that the U.S. EPA defines a disinfectant as "A chemical that destroys vegetative forms of harmful microorganisms, but does not ordinarily kill bacterial spores." (www.epa.gov/pesticide/glossary/index.html). EPA guidance suggests that disinfectants "destroy or irreversibly inactivate infectious fungi and bacteria but not necessarily their spores, in contrast to "sanitizers" which are "used to reduce, but not necessarily eliminate, microorganisms from the inanimate environments to levels considered safe as determined by public health codes or regulations." Published literature on antimicrobial treatments for produce processing water demonstrates that treatments *reduce numbers but do not totally eliminate pathogens*. Therefore, the use of the term "disinfectant" would seem excessive if interpreted in EPA parlance. We suggest that clarity to the reader should be provided to avoid confusion.

"Fresh-cut fruits and vegetables or fresh-cut produce…"

- We agree with the definition of fresh-cut in that fresh-cut leafy greens may or may not require washing prior to consumption. We suggest that FDA emphasize this in the second paragraph by adding the sentences "Packaged fresh-cut leafy greens that are labeled ready-to-eat or washed or triple washed do not require further washing prior to consumption. If not expressly labeled as such, packaged fresh-cut leafy greens should be washed prior to consumption."

Comments to *V. Production and Harvest*

E. Hand Harvest - Contact with Soil During Harvest

- We are unaware of harvest practices in which contact of leafy greens cut surfaces with the soil would be acceptable. Indeed, current hand harvest practices endeavor to prevent contact of harvested product with the soil. Therefore we recommend revising the first bullet as follows: "…not placing ~~cut surfaces of~~ harvested product on the soil…"

H. Flooding

"Sampling previously flooded soil for the presence of microorganisms of significant public health concern or appropriate indicator microorganisms."

- o While we recognize that this guidance is consistent with the 2006 industry guidelines, thus far science has been unable to inform what microorganisms to sample for, how to sample or what acceptance criteria to use. Therefore, to prevent misunderstanding, we suggest deleting this bullet until research provides a usable answer.

I. Water Usage to Prevent Product Dehydration

"Testing this water periodically to ensure that it is of appropriate microbial quality for its intended use."

- o We believe that "appropriate microbial quality" does not provide sufficient guidance in this context. We further believe that water that contacts the edible portion of leafy greens post-harvest must have the microbiological quality of drinking water. We therefore suggest that the bullet be revised as follows: "Ensuring that water that contacts the edible portion of leafy greens, post-harvest, meets the requirements of 40 CFR part 141.63 regarding the microbiological quality of drinking water."

J. Greenhouse Production, Crop Protection Sprays

- o We note that this section is written differently from similar guidance for field operations (i.e., in section B. Water). For example, guidance in field operations is "Ensuring that loading, diluting, and mixing of crop protection sprays is done in a manner that will not contaminate the water source or leafy greens" while guidance for greenhouse operations is "Ensuring that loading, diluting, and mixing of pesticides is done in a manner that will not contaminate the water source". To avoid misunderstanding, we suggest that the language used in section B. Water be repeated here.

Comments to *VI. Postharvest*

A. Cooling

"Ensuring that water used to hydrovac cool leafy greens is of appropriate microbial quality for its intended use"

- o As noted above, we believe that water that contacts the edible portion of leafy greens post-harvest must have the microbiological quality of drinking water. We therefore suggest that the bullet be revised as follows: "Ensuring that water used to hydrovac cool leafy greens meets the requirements of 40 CFR part 141.63 regarding the microbiological quality of drinking water."

"D. Bulk Bin Modified Atmosphere Process (MAP)"

- o In the fresh produce industry, the acronym MAP means Modified Atmosphere Package or Packaging, not Process, so we suggest revising this subsection title to "Bulk Bin Modified Atmosphere Packaging (MAP)".

"Developing appropriate equipment and handling procedures so that packing of leafy greens bulk bins in a modified atmosphere is conducted in an environment that is protected from potential food safety hazards"

- o This recommendation is awkwardly worded, to the extent that we are uncertain of what FDA is recommending.

E. Condition and Cleaning and Sanitation of Transportation Vehicles

- o We believe FDA's recommendation for "establishing restrictions on previous cargoes to avoid the possibility of cross contamination", in the similarly titled section A in VIII. Distribution, is also appropriate for inclusion here.
- o Alternatively, we suggest using language from the Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain, 2nd Edition (2008), page 41, as follows: "If non-dedicated vehicles are used for transportation, verify records of prior loads.

Should there be any doubt as to previous loads transported or a potential risk from microbial contamination, such as from raw animal proteins, garbage or other refuse, then the vehicle [should] be cleaned and sanitized by a documented procedure prior to use."

Comments to *VII. Fresh-Cut/Value-Added Processing*

B. Wash Water

"Wash water disinfectants can be 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 sanitize produce surfaces. Washing RTE leafy greens during fresh-cut processing is necessary but does not ensure that fresh-cut produce is free of microbes."

- Antimicrobial agents used in wash systems inactivate/kill microorganisms rather than eliminate them. In addition, antimicrobial agents can reduce the levels of microorganisms on produce surfaces to some degree (which may provide a benefit). Therefore we recommend revising this sentence as follows: "Antimicrobial agents can be added to wash water to control microorganisms in the wash water. Antimicrobial agents may also reduce microbial contamination on RTE leafy greens; however, the use of antimicrobial agents in wash water does not ensure that fresh cut produce is free of microbes."

"Microbial reduction on leafy greens surfaces is a disinfectant concentration-by-time relationship. Human pathogens, if present on the surfaces of 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."

- The efficacy of antimicrobial agents in inactivating pathogens on leafy greens surfaces can be impacted by a number of process variables besides agent concentration and time. Therefore we recommend revising this sentence as follows: "The inactivation of microorganisms on leafy greens surfaces can be affected by a number of process variables including growing/soil conditions, cut vs. uncut leafy green surface, antimicrobial agent concentration in the wash water, washing time, wash water temperature, mechanical action during washing, and water pH/soil load. Microorganisms may be protected from contact with the antimicrobial agent because of the presence of soil or because of their physical location on the leafy green surface. Therefore, human pathogens, if present on the surfaces of leafy greens, may not be completely eliminated by washing."

"Water use in the washing of fresh-cut…"

- The information in this paragraph is addressed in the previous paragraph (revised – see above). Therefore we recommend eliminating this text.

Comments to *IX. Retail and Foodservice*

C. Leafy Greens Re-Crisping

"Changing the water at a frequency sufficient to ensure that it is of appropriate microbial quality for its intended use.

- It may be desirable to add a water disinfectant (i.e., as permitted by FDA in 21 CFR part 173.315) to the water to minimize the potential for cross-contamination. Depending on the type and level of antimicrobial added it may be necessary to rinse the produce with fresh water before serving or sale.

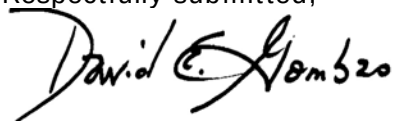
"Evaluating use of running water to re-crisp leafy greens as needed, in lieu of re-crisping by water soaking, to reduce the potential for cross contamination"

- We believe that re-crisping leafy greens under running water may be functionally impractical in a retail environment. Therefore, we suggest either deleting the bullet or revising it as follows: "Alternatively, evaluating the use of running water to re-crisp leafy greens as needed, in lieu of or in combination with re-crisping by water soaking.

Members of United Fresh and others in the leafy greens supply chain appreciate this opportunity to contribute to FDA's efforts to communicate safe production and handling practices for leafy greens. Please contact us to clarify or support any of the comments herein.

United Fresh Produce Association is the pre-eminent trade association for the produce industry in managing critical public policy issues; shaping legislative and regulatory action; providing scientific and technical leadership in food safety, quality assurance, nutrition and health; and developing educational programs and business opportunities for members to better meet consumer needs for increased consumption of fresh produce. Founded in 1904, United Fresh represents the interests of member companies from small family businesses to the largest international corporations throughout the global fresh produce supply chain, including growers, shippers, fresh-cut processors, wholesalers, distributors, retailers, foodservice operators, industry suppliers and allied associations.

Respectfully submitted,



David E. Gombas, Ph.D.
Senior Vice President, Food Safety and Technology