

October 30, 2009

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

**Re: FDA-2009-D-0346; Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Tomatoes; Draft Guidance**

On behalf of companies in the fresh tomato supply chain, United Fresh Produce Association ("United Fresh") appreciates the opportunity to comment on FDA's draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Tomatoes ("Guidance").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 tomatoes. We note that many of the recommendations are directly or adapted from the industry's 2006 and 2008 Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain [FDA Ref. 9] and the more recent Tomato Metrics Initiative, and appreciate FDA's recognition of the tomato 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 While the industry representatives that are providing these comments generally agreed with the recommendations in the draft Guidance, we believe that the following suggestions would improve its utility and clarity, consistent with FDA's intentions.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 II. Background:**

*"Findings [from the Tomato Safety Initiative] will also be incorporated into future editions of this guidance, as appropriate."*

- o FDA's ongoing Tomato Safety Initiative has proven to be a successful opportunity for exchange of information between the tomato industry, FDA and state public health agencies. We urge FDA to include key, illustrative learnings from the Initiative in this version of the Guidance.

**Comments to III. Scope and Use**

*Figure 1. General Supply Chain Flow for Tomatoes*

- o The figure, reprinted from an early version of the Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain, 2<sup>nd</sup> Edition, was corrected in the July 2008 release of the document. A corrected version of the figure is attached with these comments, with permission granted.

**Comments to IV. Definitions**

*"Fresh-cut fruits and vegetables or fresh-cut produce..."*

- o While we recognize that the definition provided is generic to fresh-cut produce, we believe that application of this definition to fresh-cut tomatoes may create misunderstanding. For example, the definition refers to "the possible exception of washing" prior to consumption. We are unaware of any fresh-cut tomato product for which washing before consumption is recommended. Therefore, we suggest, in the second paragraph of the definition, the following sentence be added: "Unless specifically noted on the label by the manufacturer,

commercially prepared fresh-cut tomatoes have been washed, are ready-to-eat and do not require additional washing prior to consumption.”

- 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](http://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.

### **Comments to V. Open Field Production**

3. Near-by Land Use: *“Assessing near-by land for activities or conditions that may pose a food safety risk for tomatoes such as livestock, wildlife, landfills, sewage treatment facilities, and chemical plants”*

- We suggest adding “raw manure storage” as an activity that may pose a food safety risk.

4. Water Use in the Field: *“Ensuring that water used for application to edible portions of tomato crops, such as foliar applications, is of appropriate microbial quality for its intended use”*

- 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 tomatoes must have the microbiological quality of drinking water. We therefore suggest that the bullet be revised as follows: “Ensuring that water used for application to edible portions of tomato crops, such as foliar applications, meets the requirements of 40 CFR Part 141.63 regarding the microbiological quality of drinking water.” We suggest that FDA similarly revise recommendations for water used for crop protection sprays in this section and in Greenhouse.

5. Hygienic Practices in Tomato Fields: *“Implementing policies that encourage hand washing with soap and water at the appropriate time, such as before starting work, after breaks, using the toilet, sneezing, or coughing”*

- We believe that policies that merely encourage hand washing and other necessary hygienic practices are insufficient. We therefore suggest that FDA recommends “Implementing policies that require hand washing with soap and water at the appropriate time, such as...” We suggest that FDA similarly revise recommendations in the Greenhouse and Packinghouse sections of this Guidance.

7. Tomato Production Practices: *“Refraining from use of raw animal manure”*

- We believe there is ample evidence that use of uncontrolled raw animal manure presents too great a food safety risk, particularly when properly composted materials, with or without animal manure, are readily available. We further believe that FDA should

expressly recommend against the use of sewage sludge or biosolids as soil amendments. We suggest that this sentence be replaced with "Eliminating use of sewage sludge, biosolids, and raw or improperly composted animal manure as a soil amendment."

8. Equipment and Containers *"Cleaning and sanitizing containers, bins, food-contact equipment, and utensils at regularly scheduled intervals during use (e.g., daily), or more often as needed, to remove sand, grit, dirt, and other residue"*

- This bullet appears to be redundant to the first bullet in this subsection; i.e., *"Cleaning and sanitizing any containers and food contact surfaces of other equipment at a frequency sufficient to prevent the surfaces from becoming a source of contamination."* We suggest adding "utensils" to the first bullet, to avoid misunderstanding, and deleting this third bullet as unnecessarily repetitious. We suggest that FDA similarly revise recommendations in the Harvest Practices, Field Packing and Greenhouse sections of this Guidance.

### **Comments to VII. Field Packing**

6. Cleaning Procedures *"If materials, such as cloths, are used repeatedly for cleaning tomatoes, steps should be taken to ensure they do not become a source of direct or cross-contamination"*

- While this recommendation is consistent with guidance in the 2008 Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain, representatives of the tomato industry have since struggled with practical ways to use cleaning cloths on unwashed tomatoes that do not pose a significant risk of cross-contamination. Failing that, those tomato supply chain representative who participated in the 2009 Tomato Metrics Initiative decided that, until such time that a safe procedure can be developed, tomato field packing operations "shall have a policy that cloths, towels, or other cleaning materials shall not be used to wipe tomatoes. Employees are trained that wiping tomatoes with cloths or other multiple use materials may pose a risk of cross-contamination and are prohibited." Similar restrictions on cleaning cloths were implemented for Greenhouse and Repacking operations. We therefore suggest that FDA recommend against the use of cleaning cloths on unwashed tomatoes.

9. Washing or Otherwise Treating Tomatoes in the Field: *"Ensuring that the water used for washing or otherwise treating tomatoes is of sufficient microbial quality for this purpose"*

- As noted above, we believe that "sufficient microbial quality" does not provide adequate guidance in this context. We further believe that water that contacts the edible portion of tomatoes, post-harvest, must have the microbiological quality of drinking water. We therefore suggest that the bullet be revised as follows: "Ensuring that the water used for washing or otherwise treating tomatoes meets the requirements of 40 CFR Part 141.63 regarding the microbiological quality of drinking water."
- We suggest that FDA similarly revise recommendations which currently advise "sufficient microbial quality"; i.e.,
  - VIII. Greenhouse Production, 4. Pre-harvest Agricultural Water, Water Sources ("Ensuring that water is not contaminated and meets the requirements of 40 CFR Part 141.63 regarding the microbiological quality of drinking water for any foliar application to tomatoes...");
  - VIII. Greenhouse Production, 14. Cleaning and Washing Procedures, Washing Tomatoes ("Following CGMPs to ensure that all water meets the requirements of 40 CFR Part 141.63 regarding the microbiological quality of drinking water at start-up..." and "Ensuring that water used in postharvest processes meets the requirements of 40 CFR Part 141.63 regarding the microbiological quality of drinking water..."); and

- IX. Packinghouse, 3. Water Supply and Plumbing (“Ensuring that any water that contacts tomatoes or food-contact surfaces, whether intended or unintended, is not contaminated and meets the requirements of 40 CFR Part 141.63 regarding the microbiological quality of drinking water...”).

### **Comments to IX. Packinghouse**

7. Postharvest Water Use, Temperature and Disinfection of Water Supplies Used in Postharvest Applications: *“Maintaining water temperature at least 10°F warmer than the pulp temperature of the tomato.”*

- To avoid misunderstanding, we suggest that this bullet be modified by adding a sentence to recognize that spray wash or rinse systems are excluded from this temperature recommendation; i.e., “Such temperature differential is not required for safety for spray wash or rinse systems in which tomatoes are not submerged.”
- We suggest that FDA similarly revise recommendations in XI. Fresh-cut/Value-Added Processing, 7. Whole Tomato Wash; and XII. Foodservice and Retail, 8. Tomato Washing and Culling.

16. Labeling: *“Removing or correcting inaccurate labels from previously used containers.”*

- To prevent misunderstanding, clarifying that this refers to RPC or other reusable containers, and that FDA is not recommending reuse of corrugated or other containers intended to be single use, we suggest revising this bullet as follows: “Removing or correcting inaccurate labels from previously used containers which are acceptable for reuse.”

### **Comments to X. Repacking and Other Distribution Operations**

2. Product tracing, Lot Identification:

“Repacking tomatoes into their original boxes if tomato lots are not commingled...”

- To avoid misunderstanding that FDA expects each tomato to be repacked into its original box, we suggest revising this bullet as follows: “Repacking tomatoes into boxes that are clean and sanitary. When original containers of a grower or packinghouse supplier are reused (i.e. the tomatoes are removed, resorted, and returned to the original clean and sanitary containers), the repacker should label the container as being repacked, indicating the commodity, the repacker, and lot identification.”

“Repacking tomatoes into new boxes that are clean and sanitary if tomato lots are commingled...”

- We are not aware of research demonstrating a risk of cross-contamination from boxes that are reused, provided the boxes are clean and sanitary, as recommended in the first bullet. Nevertheless, we agree with FDA that commingling of production lots should be minimized where practical, to minimize the number of affected lots in the event of a traceback. Therefore, we suggest revising this bullet as follows: “It is preferred that incoming lots of tomatoes are not mixed/commingled during repacking. If tomato lots are commingled, the tomatoes should be clearly and accurately labeled indicating the lot information and repacker information ensuring that the original identification information on the box has been removed or otherwise made clear that it is no longer accurate. The lot information should maintain the integrity of tracing information for all tomatoes in the commingled lot, back to their sources. Such information about commingling should also be captured in the firm’s records and the documentation that moves with the tomatoes through the supply chain. In the event of a recall, all tomatoes in the commingled lot could be affected.”

## Comments to *XII. Foodservice and Retail*

### 6. Preparation within Foodservice/Retail Establishments, Employees Preparing Tomatoes

- We noted a misspelling in the second bullet: "Aree".

### 8. Tomato Washing and Culling

*"Soaking tomatoes or storing them in standing water is not recommended"*

- As written, we are concerned that the recommendations may not prevent tomato handlers from immersing tomatoes. Therefore, we suggest adding recommendations regarding maintaining a minimum 10°F temperature differential whenever tomatoes are submerged at greater than 1 ft depth, consistent with other sections in this Guidance.

### 9. Storing Cut/Sliced/Diced Tomatoes

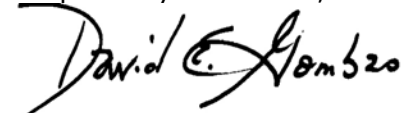
*"Chilling to and maintaining tomatoes at ≤41°F after cutting."*

- Putting tomatoes in ice water has been a common practice for firming tomatoes immediately prior to slicing. We believe that, like other immersion practices, this presents a potential for infiltration of pathogens, if present, and FDA should expressly note that the practice is not recommended.

Members of United Fresh and others in the tomato supply chain appreciate this opportunity to contribute to FDA's efforts to communicate safe production and handling practices for fresh tomatoes. 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,



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