

October 30, 2009

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

Re: FDA-2009-D-0347; Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons; Draft Guidance

On behalf of companies in the fresh melon supply chain, United Fresh Produce Association (“United Fresh”) appreciates the opportunity to comment on FDA’s draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons (“Guidance”).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 melons. We note that many of the recommendations are directly or adapted from the industry’s 2005 Commodity Specific Food Safety Guidelines for the Melon Supply Chain [FDA Ref. [1](#)], and appreciate FDA’s recognition of the melon 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 While the industry representatives that are providing these comments generally agreed with the recommendations in the draft Guidance, we believe that the following suggestions would improve its utility and clarity, consistent with FDA’s intentions.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:

“Cantaloupe was involved in 10 of the 13 outbreaks associated with melon consumption...”

- o 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, findings from outbreak investigations related to melons, even if the findings were “no cause found”.
- o As noted above, the industry recognizes that netted skin melons, like cantaloupe, have a different contamination risk profile from waxy skin melons, and this is reflected in the relative frequency that each has been associated with illness outbreaks. For example, we are unaware of any illness outbreaks linked to pathogen contamination of watermelon during production, harvest or packinghouse handling, and we suggest that this be so noted in the Guidance.

Comments to III. Scope and Use

"The use of the term "melons" in this document refers to cantaloupe (also known as muskmelons), honeydew, watermelon, and variety melons..."

- o To avoid possible confusion, we suggest that Tuscan be added as a variety of cantaloupe.
- o While production practices may be generally similar, the industry recognizes that netted skin melons, like cantaloupe, have a different contamination risk profile from waxy skin melons, like honeydew and watermelon. This difference is consistent for unpeeled melons throughout the supply chain. Therefore, we suggest that FDA note this distinction early in the Guidance, by moving here the first two sentences from the subsection Melon Rind Surface Characteristics and deleting the rest of that subsection.

Figure 2. General Supply Chain Flow for Melons

- o The figure does not capture melons which reach consumers by direct sales through farmers' markets, and we therefore suggest adding another red arrow from Harvest to a new box, "Farmers Markets".
- o The figure does not capture Repacking operations, which may occur directly from the Packinghouse or from Cold Storage.
- o Some Retail/Foodservice operations obtain melons directly from Terminal Markets. Therefore, we suggest amending the Retail or Foodservice Distribution Center box to include Terminal Markets.

Comments to IV. Definitions

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

- o The term Control Measure is not used in the body of the Guidance. Since a definition for a term not used is unnecessary, and to avoid confusion that FDA is recommending HACCP for field operations, we request deleting a definition for Control Measure.

"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 melons may create misunderstanding. For example, the definition refers to "the possible exception of washing" prior to consumption. We are unaware of any fresh-cut melon 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 melons have been washed, are ready-to-eat and do not require additional washing prior to consumption."

"Packinghouse or "packing shed" means a facility where..."

- o The activities listed for a packinghouse seem to offer an opportunity for misunderstanding. We suggest that the definition be revised to "Packinghouse or "packing shed" means a facility where raw agricultural commodities are handled prior to packing in commercial containers, e.g., cartons, totes or bins. Handling may include one or more operations such as sorting, sizing, labeling, wrapping, trimming or washing.

Comments to V. Production and Harvest

"Monitoring and reducing, to the extent possible, domestic animal, wildlife, and insect activity..."

- o The risk from insect activity appears to be overly emphasized in this Guidance, relative to the draft guidances for leafy greens and tomatoes. While we recognize that

insects, like virtually any other animal that can be found in a field, are capable of harboring and transferring *Salmonella* and other human pathogens to melons, we are unaware of a scientific justification for this emphasis. Therefore, we suggest deleting “insects” in this opening paragraph and in the 2nd bullet.

- o Further, we are concerned that “*reducing, to the extent possible*” may create a false impression of the ability to control certain wildlife in field operations. However, we recognize that animal intrusion, when it occurs, must be addressed. Therefore, we suggest deleting “*and reducing*” and modifying the sentence to read “Monitoring domestic animal and wildlife activity in melon production environments that may contaminate water and soil with human pathogens and directly or indirectly contact melons, thereby increasing the risk of product contamination, and having a corrective action plan to implement when necessary.”

“Delaying harvest and performing extra washing when heavy rains have recently occurred.”

Extra washing of melons will cause quality issues, damaging the melons due to excessive water uptake and potentially making them more vulnerable to contamination. Instead, we suggest replacing the guidance for “performing extra washing” with “performing steps as needed to reduce soil contamination”. Alternatively, the guidance could be “Harvesting melons in a manner that minimizes the potential for soil-to-melon contamination”

“Stem Scar and Melon Maturity”

- o This subsection deals with potential infiltration of pathogens into the stem scar. However, the guidance refers to “*Implementing postharvest handling practices to minimize stem scar and rind infiltration.*” Since the risk of infiltration and its control occur post-harvest, not during the field operations described in this section, and appropriate controls for this risk are well described in section VI, subsection *Melon Cooling Medium*, we suggest deleting this subsection.

“Evaluating soil amendments where melons directly contact soil.”

- o We believe that this provides insufficient guidance relative to the risk of pathogen contamination from improperly used soil amendments. 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; verifying composting procedures are adequate to eliminate potential pathogens of public health concern; and implementing management plans that assure soil amendment usage, e.g., timing of applications and storage of amendments, does not pose significant human health risks.”

“Using deceleration padding (when part of harvest and postharvest handling equipment) that is constructed of materials that can be cleaned and sanitized.”

- o While we agree with this FDA recommendation, we believe the sentence structure may cause misunderstanding that FDA recommends using deceleration padding in all cases. Therefore, we suggest rewording the sentence as follows: “If deceleration padding is used as part of harvest or postharvest handling equipment, that it is constructed of materials that can be cleaned and sanitized.”

“Multiple Harvests”

This section has multiple referrals to contamination risks from insects. As noted above, we are unaware of a scientific justification for this emphasis. Further, the guidance “Evaluating ways to reduce flying insect access, to the extent possible, to animal feces and other likely sources of human pathogens...” may create a false impression of the

ability to control insects in field operations. Also, the guidance *“Evaluating ways to dispose of culled melons...”* is impractical for field operations, which are the topic of this section. In the field, “culled” melons are simply left unharvested. Guidance to control animals that may be attracted to culls is redundant to earlier guidance for wildlife pest recognition and control. Finally, and most pertinent, we are unaware of research that demonstrates an increased wildlife pressure due to prior harvest operations, and anecdotal observations do not support this conclusion. Therefore, we suggest deleting this subsection, and adding the following sentence as a bullet to “FDA recommends” in the prior subsection Climatic Production Conditions and Environment: “Training harvest employees to recognize and not harvest melons that have mechanical damage or possible contamination from previous harvest operations or from wildlife activities.”

Comments to VI. Postharvest

“Field packing equipment and packinghouse operations may be used seasonally and thus be dormant for many months...”

- While this statement is true, it may create a false sense that shorter storage periods do not present a risk. Therefore, we suggest rewording this sentence to *“...may be used seasonally and thus be dormant between uses...”* or *“...may be used seasonally and thus not be continuously in use...”*
- We also suggest deleting “for many months” from the first bullet in this subsection and rewording the sentence to “Appropriately protecting from pest infestations field packing equipment and packing house operations that may be dormant between uses.”

“Where dry dump stations are used, using melon food-contact surfaces (including padding materials) constructed of materials that can be cleaned and sanitized.”

- While we agree with this FDA recommendation, we believe the sentence structure may cause misunderstanding that FDA recommends using padding in all cases. Therefore, we suggest rewording the sentence as follows: “Where dry dump stations are used, using melon food-contact surfaces (including padding materials, if used) constructed of materials that can be cleaned and sanitized.”

“Where dry dump stations are used, instructing employees not to walk or stand on dry food-contact surfaces during operations as this may increase the likelihood of food-contact surface contamination.”

- While we agree with the intent of this recommendation, we believe it may be overly prescriptive. Some melon operations may require employees to stand on dry food-contact surfaces. However, contamination of such surfaces can still be prevented by procedures such as sanitizing between each bin dump and wearing fresh shoe covers or dipped boots. Therefore, we suggest revising this sentence to “Where dry dump stations are used, either instructing employees not to walk or stand on dry food-contact surfaces during operations, or ensuring that procedures are in place to minimize the risk of contamination if employees must walk or stand on dry food contact surfaces.”

“Removing melons from harvest vehicles and containers by means other than immersion of the gondolas, trailers, or wagons...”

- While immersion may increase the potential for contamination of melons from the outside, non-sanitary surfaces of gondolas, trailers, or wagons, the increase is negligible if the immersion water is controlled properly. Therefore, to provide for acceptable use of this practice, we suggest rewording this bullet to “If removing melons from harvest vehicles and containers by immersion of the gondolas, trailers, or wagons, addressing the potential for product cross-contamination with field or road

debris in the facility's food safety plan, e.g., by proper control of immersion water antimicrobials." Further, in the next (4th) bullet, we suggest specifically recommending recording water antimicrobial levels: "...and monitoring and recording the levels to reduce the potential risk of cross-contamination."

"Delays in melon cooling when melon rinds are wet from washing operations or from dew may allow for multiplication of human pathogens on the rind surface of melons [Ref. 13]."

- o As noted in its Abstract, Reference 13 (Behrsing, J., et al., 2002) reported that cantaloupe and honeydew melons "did not support growth [of *Salmonella salford*, *Escherichia coli* and *Listeria innocua*] under the conditions employed...The exception was the growth of *L. innocua* on the skin of cantaloupe". Therefore, it appears that the stated risks from delays in melon cooling are not supported by this reference.
- o The vast majority of watermelons, for example, are not cooled at all. We suggest noting that, and adding a new bullet, "Utilizing a cooling method appropriate to the variety of melon."

"Flying Insect Control"

- o As noted above, the Guidance appears to overemphasize the risk of insects as a vehicle of pathogen contamination of melons, with little scientific support. Further, the Guidance creates a false impression of the ability to control insects in post-harvest operations. Meanwhile, the Guidance is silent on potential risks from other pests. Therefore, we suggest that this section be modified by removing specific mention of insects and adding monitoring and control, to the extent practical, of pests that may contaminate melons.

"Top Icing of Melons"

- o The opening sentence in this subsection, "Melons are typically top iced after cooling as a means of temperature control" is no longer accurate as an industry practice. Rather, the industry has recognized the potential food safety risks from top icing and has generally discontinued the process. Therefore, we suggest that this subsection be modified to discourage top icing, retaining the first bullet recommendation "Employing alternative means of keeping melons cool...", and deleting the other four bullets of how to top ice properly.

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

"Human pathogens may proliferate rapidly on fresh-cut melon products held under temperature abuse conditions"

- o To avoid misunderstanding, we suggest that the sentence be modified to recognize that whole melons do not require time/temperature control for safety: "While whole melons do not require temperature control, human pathogens may proliferate rapidly on fresh-cut melon products held under temperature abuse conditions."

Comments to IX. User Handling

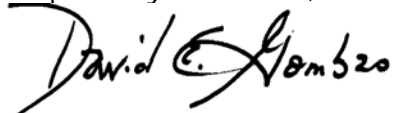
"Implementing a pest management program."

- o The Guidance correctly notes that "Specific procedures for storing and displaying food ... can be found in the FDA Food Code", thereby avoiding repetition of numerous safe handling practices common to many foods and not specific to handling of melons. Therefore, specific mention of implementing a pest management program seems out of place and we suggest deleting this bullet.

Members of United Fresh and others in the melon supply chain appreciate this opportunity to contribute to FDA's efforts to communicate safe production and handling practices for fresh melons, and we stand ready to clarify and 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,

A handwritten signature in black ink that reads "David E. Gombas". The signature is written in a cursive style with a large, stylized initial "D".

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Senior Vice President, Food Safety and Technology