Division of Dockets Management [Docket No. FDA-2009-D-0347]
Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons
Submitted November 2, 2009

Produce Marketing Association (PMA) represents 3,000 member companies and organizations across the entire produce supply chain, from field production through the end users at retail and foodservice. For our members in the global produce industry, food safety is the most important and compelling issue facing the industry today. PMA is playing a catalytic role in working with our membership, related trade associations, Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), and state and local agencies to develop and implement improvements in our industry’s food safety practices. PMA is also providing technical expertise, input on industry practices and logistics, and constructive feedback to FDA on food safety issues ranging from product traceback to technical developments and agency guidance documents.

PMA has long advocated for produce-specific food safety legislation that is risk-based, commodity-specific, based on sound science, and applies to domestic production as well as imports, with the goal of creating a level playing field for our industry. Our work includes industry food safety education, such as educational workshops at PMA events and symposia designed to promote an industry-wide food safety culture. Our commitment to food safety extends to donating more than $2.5 million to fund creation of the Center for Produce Safety at the University of California at Davis; CPS’ mission is to fund and disseminate research to answer the produce industry’s food safety questions.

We are pleased for the opportunity to provide commentary on the FDA’s draft “Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons.” The industry has expended a great deal of effort in preparing food safety guidance for melons over the last several years, including developing “Commodity Specific Food Safety Guidelines for the Melon Supply Chain” in 2005.

PMA supports risk- and science-based federal regulation for produce safety that applies to fresh fruits and vegetables grown in the United States and imported into the United States. Beyond general rules for all produce, we support the development of commodity-specific regulations for those commodities that FDA has identified as most likely to be associated with foodborne illness outbreaks. We applaud FDA for moving forward with this guidance.

In preparing these comments, PMA enlisted input from growers, processors, retailers, and foodservice operators to gather perspective on specific issues. We also participated with allied associations in an exchange of ideas and perspective from a broad cross section of the industry. Our comments here reflect those discussions and PMA’s commitment to improving food safety
practices for leafy greens. We have used the headings of the FDA draft guidance to organize our comments as appropriate.

II. Background

The Background section of the draft guidance references an item about which PMA is hereby requesting more information.

In the first paragraph in this section FDA asserts melons have been associated with 13 outbreaks of illness during the period 1996 to 2006 and further that “cantaloupe was involved in 10 of the 13 outbreaks associated with melon consumption”. It would be beneficial for the industry and the research community to know more detail concerning these outbreaks, i.e.:

- how strong was the link back to melons or cantaloupes from an epidemiological perspective;
- was the original cause of the contamination determined;
- were there any seasonal, geographic, product format or demographic trends identified within or between outbreaks that might be useful in formulating risk management strategies; and
- what did FDA learn from these outbreaks and the subsequent epidemiological and traceback activities that might help the industry better manage food safety risks and assist FDA (and CDC) identify causative products or conditions in future outbreaks.

III. Scope and Use

- In the first paragraph, FDA notes “The use of the term ‘melons’ in this document refers to cantaloupe (also known as muskmelons), honeydew, watermelon, and variety melons”. To avoid possible confusion, we suggest that Tuscan be added as a variety.

As indicated above, 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, FDA should reinforce this distinction by moving the first two sentences of the Melon Rind Surface Characteristics section included under V. Production and Harvest (“Melons may have smooth or netted rind surfaces. Significantly more foodborne illness outbreaks have been associated with melons that have netted rinds”) to this Scope and Use section, and deleting the remainder of the Melon Rind Surface section.

- Note that in Figure 2. General Supply Chain Flow for Melons, the current figure is missing three distinct channels:
  - Melons can be sold directly from producers to consumers via farmer’s markets. We suggest that an arrow be drawn from “Harvest” to a new box titled “Farmers Markets”.
  - The current figure should be amended to capture “Repacking” operations, which may occur directly from the “Packinghouse” or from “Cold Storage”.
  - Some “Retail” and “Foodservice” operations obtain melons directly from “Terminal Markets”. Therefore, we suggest amending the “Retail or Foodservice Distribution Center” box to include “Terminal Markets”.

IV. Definitions

- **Fresh-cut fruits and vegetables or fresh-cut produce:** FDA should consider amending this definition. The current generic definition for fresh-cut produce listed in the guidance includes the statement, “the possible exception of washing prior to consumption”. We are unaware of any fresh-cut melon product for which washing before consumption is recommended owing to the protective barrier provided by the rind and the textural and surface characteristics of the flesh. To eliminate any potential for confusion, FDA should add the following sentence to the second paragraph of the definition: “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:** The provided definition may cause some confusion as currently listed because of the activities used to define packinghouse or packing shed activities or operations. FDA should consider this verbage: “‘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”.

- **Water disinfectant:** This term is used throughout the document. 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.”

V. Production and Harvest

- **Climatic Production Conditions and the Environment section:**
  - **Risk assessment:** In the first bullet, FDA correctly focuses on the importance of risk assessment, listing a number of potential sources of risk that producers should consider when conducting these assessments and building their food safety programs.

  PMA strongly supports the emphasis on risk assessment. Indeed, risk assessment should be the cornerstone of any food safety program. Performing a true risk assessment prior to planting, again immediately before harvest (“pre-harvest”) and at harvest essentially “forces” involvement and focused attention to food safety by those who know their operations best: the growers, harvesters and processors. This unique, individual action is favorably contrasted to the all too common one size fits all approach some operators have adopted to gain a favorable score on a mandated food safety audit. It is not uncommon for producers to use standards or audit checklists provided by customers, third parties or government sources as an outline to provide the required paperwork necessary to meet the audit criteria while not performing a real risk evaluation for their specific operation. PMA believes improvements in food safety performance can only be achieved when
individual operators all along the supply chain take responsibility for the safety of their products, conduct an operation-specific risk assessment and develop the follow-on risk management practices.

While this section of the draft guidance clearly speaks to risk assessment, PMA urges FDA to add a section (perhaps under III. Scope and Use) on the critical role of risk assessment throughout the supply chain (not just production and harvest), the basics of conducting a risk assessment, resources operators can use if they need assistance and the responsibilities each operator shares in evaluating risk and developing effective risk management practices.

**Wildlife:**

- In both the opening paragraph and the second bullet of this section, FDA lists wildlife species that may pose a contamination risk to melons. By comparison, the risk from insect activity appears to be overly emphasized in this draft guidance relative to those for leafy greens and tomatoes. While some preliminary research evidence points to insects as being capable of harboring E. coli, the data demonstrating successful transference to vegetables and the perspective on the impact of this vehicle are limited. Given this lack of true understanding and to gain consistency with the other draft guidance, FDA should delete “insects” in this opening paragraph and in the second bullet.

- In that second bullet, FDA uses the phrase “reducing, to the extent possible” in reference to wildlife and domestic animal intrusion. In discussions regarding this point, industry is concerned that this may be misconstrued to create an impression that growers can completely control certain wildlife in field operations. While we are concerned about issues of “control” or “reducing”, we recognize that animal intrusion, when it occurs, must be addressed. Therefore, we suggest FDA delete “and reducing” and modify 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.” This modification actually feeds nicely into the third bullet point recommendation in this section.

- The fifth bullet point in this section, “Delaying harvest and performing extra washing when heavy rains have recently occurred” is problematic from a melon quality perspective. In conference call discussions with growers, they clearly felt based on their experience that extra washing of melons will reduce quality, 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 section: FDA recommends “implementing postharvest handling practices to minimize stem scar and rind infiltration of human pathogens into the edible portions of melon flesh”. 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. Postharvest - Melon Cooling Medium, we recommend deleting this section.

Direct Melon to Ground Contact section: FDA recommends “Evaluating soil amendments where melons directly contact soil” in the first bullet point.

We recognize that both the industry and FDA lack sufficient research data to more fully define composting and handling of soil amendments. We are not aware of any documented, validated process for treating composts and handling processes for both raw and finished materials to diminish the chances for cross contamination. Subsequently, the industry and FDA are left with recommending that producers ask their compost suppliers for time and temperature records in lieu of requiring documentation that a scientifically validated process has been followed. In essence we are asking for verification of an unvalidated process.

The produce industry would benefit greatly from research that defines validated processes for reducing and/or eliminating pathogens from manure-containing composts. The use of compost is a necessary element in maintaining soil fertility, composition, texture and productivity. Yet, compost is also the only agricultural input where we know pathogens are reasonably likely to be present prior to the compost process. Therefore it is imperative that we develop validated processes to manage this potential risk.

CPS has funded a research program to specifically look at this area but much more is needed to bring real understanding and measurable criteria to this critical need. Since sufficient experimentally developed data and validation processes do not currently exist, FDA could be in a pivotal position to partner with CPS, industry, universities and other government agencies to fund research to define validated composting processes for the array of materials currently in use by growers around the country.

Absent more advanced knowledge, we believe that FDA should expressly recommend against the use of sewage sludge or biosolids as soil amendments and that growers implement procedures to verify the composts they use have been adequately treated. More specifically, FDA should replace the first bullet in this section with this language: “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.”

Mechanical Damage section: The first bullet states: “Using deceleration padding (when part of harvest and postharvest handling equipment) that is 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 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 section:** FDA asserts that the presence in the fields of damaged melons left over from previous harvests act as an attractant to pests and wildlife and thereby create an increased risk of contamination. FDA should consider these points:
  - While we acknowledge some damage can occur during harvest, “culled” melons are simply left un-harvested, i.e. whole materials. Further, we are not aware of any scientific data that supports FDA’s assertion of increased risk associated with multiple harvests and in conference call discussions with producers, their observations also failed to support the assertion.
  - Secondly, this section has multiple references to contamination risks from insects. As stated earlier, we are unaware of a scientific justification for this emphasis. The second bullet recommendation states: “Evaluating ways to reduce flying insect access, to the extent possible, to animal feces and other likely sources of human pathogens”. As previously discussed, we believe this may create a false impression of the grower’s ability to control insects in field operations.
  - Thirdly, the last bullet point: “Evaluating ways to dispose of culled melons…” is impractical for field operations. In the field, “culled” melons are simply left un-harvested. Guidance to control animals that may be attracted to culls is redundant to earlier guidance for wildlife pest recognition and control.
  - Therefore, we suggest deleting this subsection, and adding the following sentence as a bullet to “FDA recommends” in the prior section on **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.”

- **Documentation and Records, Product Tracing section:** FDA details recommendations for producers to develop “product tracing systems applicable to the melon supply chain” and further to “maintain standardized, clear records that can be used to enhance the ability to follow the movement of the product”.

During recent produce-related outbreaks of illness, FDA has expressed the difficulties it has faced in conducting efficient and effective tracebacks from the point of consumer purchase or consumption back through the supply chain to the original producer. As the industry and FDA well know, the issue of traceability really isn’t about the producer maintaining clear records, it’s about linking the various components of the traceback – i.e. the various stops the product may make in the supply chain, and the venues where it may be handled along with the associated paperwork that verifies its identity that often proves difficult.

For example, buyers often require growers, shippers or processors to place stickers or print traceback codes on their products at either the case or unit level, if not both. These stickers can be as simple as a small half-inch square adhesive-backed paper sticker that has only a use
by date and/or a supplier number to a larger sticker or jet print format that holds a proprietary
code in both human readable and barcode forms. No matter the complexity or format of
coding, they are generally tied to the grower’s lot number, harvest company, receipt
information and the harvest date (and perhaps the best if used by date). These codes are also
tied in with the original production documentation; i.e. production records, harvest records,
bills of lading, quality assurance records, food safety documentation, shipping invoices, etc.

In essence, products can be traced at the grower/shipper level because that is how products
are shipped (and buyers are invoiced) and received (and growers get paid). So inherently, the
production segment of the industry can trace product one step back to the original source and
one step forward to the initial customer as required by the Bioterrorism Act.

The real issue in traceability emerges as product moves up the supply chain and as the chain
branches out to reflect the multiple sources of single products retailers and foodservice
procure and sell, individual company practices for shipping and receiving, re-packing or raw
product blending to meet quality performance standards, the lack of uniformity or format for
product codes and the current inability to capture trace information along the supply chain.
The key to linking each step of the supply chain to enable rapid trace in the event of an
outbreak or product safety issue is to create a common format for the product coding
information.

That is why the industry formed the Produce Traceability Initiative (PTI), consisting of
growers, processors, retailers and foodservice companies, and coordinated via the industry
trade associations, including PMA, United Fresh Produce Association and Canadian Produce
Marketing Association. These trade associations have previously shared with FDA the
features of the PTI. The initiative calls for chain-wide, electronic product traceability by
prescribing a standard format based on globally-recognized GS1 coding standards for both
human readable and machine readable (scan-able bar code) labeling at the case or carton
level.

The PTI is not a trivial solution, and not without issue. PMA concurs with FDA that the
industry needs to have an effective mechanism for product traceback; we have far too many
recent instances where the market for entire categories or commodities was devastated when
the issue really involved only a single producer. Therefore, PMA is committed to working
with FDA to find a solution to produce traceback outside this current guidance. We urge you
to consider the PTI model as the standard to follow to promote traceability.

VI. Postharvest

- In the opening paragraph of this section FDA states: “Field packing equipment and packing-
  house operations may be used seasonally and thus be dormant for many months leaving them
susceptible to pest infestations”.

Indeed, packinghouses and equipment are used seasonally, and they often lay dormant
between seasons or crops. In the industry phone conferences we participated in there was a
concern that while this statement is true, it may create a false sense that shorter dormancy periods do not present a risk. Therefore, we suggest rewording this sentence to “Field packing equipment and packinghouses may be used seasonally and thus be dormant between uses” or “Field packing equipment and packinghouses may be used seasonally and thus not be continuously in use”.

We also suggest deleting “for many months” from the first bullet in this section and rewording the sentence to “ Appropriately protecting from pest infestations field packing equipment and packinghouse operations that may be dormant between uses.”

- **Packinghouse and Field Packing Cleaning and Sanitation section:** In bullets four and five, FDA employs the terminology “Validating and verifying…”. PMA supports the approach of validating a process works properly (in this case, sanitation), and then verifying that it is performed according to the validated process. Often these terms get used interchangeably when they are really quite different. FDA might consider adding these terms to the Definitions section to make it clear to the users of this guidance that they are indeed two separate activities.

- **Packinghouse Melon Dump Operations section:** The first bulleted FDA recommendation says: “Where dry dump stations are used, using melon food-contact surfaces (including padding materials) constructed of materials that can be cleaned and sanitized.” The sentence is awkwardly constructed and may be construed to mean that FDA recommends that padding be used in all cases. Therefore, we suggest rewording the sentence as follows: “Where dry dump stations are used, melon food-contact surfaces (including padding materials, if used) should be constructed of materials that can be cleaned and sanitized.”

- **Packinghouse Melon Dump Operations section:** The second bullet states: “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, the risk of contamination of such surfaces can still be managed by implementing 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.”

- **Packinghouse Melon Dump Operations section:** The third bullet reads: “Removing melons from harvest vehicles and containers by means other than immersion of the gondolas, trailers, or wagons to reduce potential product cross-contamination with field or road debris”.
PMA supports this recommendation. We understand that this practice of immersion is limited and not widely practiced in the industry. For those with investment in these immersion systems, FDA should also recommend that if immersion is used to off-load melons, the water be treated with disinfectant and appropriately monitored for active antimicrobial levels, pH and organic load. FDA should also recommend that verification records for disinfectant levels and other water quality management measurements be maintained. Indeed, The FDA recommendations for the next section on Melon Cooling Medium are germane to the water quality issues raised here.

- **Cooling Delays section:** FDA’s opening sentence reads: “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].” 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. 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.”

- **Fungicide section:** Here FDA’s first bulleted recommendation states: “Evaluating water in water-based fungicide solutions used for post-harvest melon treatments to ensure that the water is of sufficient microbial quality for its intended purpose”. We certainly agree with this recommendation. The only additional comment might be to better define “sufficient microbial quality”.

Perhaps FDA should define this water quality as drinking water quality as this is for postharvest application. This should pose no hardship for growers or packinghouse operators as they are likely to have access to water sources that are drinking water quality for their crews.

- **Flying Insect Control section:** This section is another example of the overemphasis on insects in this melon guidance that has been suggested earlier. Further, the draft guidance may create a false impression of the operator’s ability to control insects in postharvest 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 section:** The guidance reads, “Melons are typically top iced after cooling as a means of temperature control”. Our information indicates this is no longer an industry practice. FDA should consider modifying the opening sentence to say, “Historically,
melons may have been top iced after cooling...”, then amend the first bulleted recommendation to read: “Employing alternative means of keeping melons cool…”, and deleting the other four bullets of how to top ice properly.

VII. Fresh-Cut/Value-Added Processing

- **Pre-Processing Treatments section:** The third FDA recommendation uses the phrase “Using water of sufficient microbial quality for its intended purpose”. As discussed earlier, this is vague and perhaps open to interpretation by processors. We suggest FDA consider defining this more narrowly as drinking quality water.

- **Potential for Growth of Human Pathogens on Edible Melon Flesh section:** The opening sentence reads: “Human pathogens may proliferate rapidly on fresh-cut melon products held under temperature abuse conditions”. To avoid misunderstanding, we recommend that the sentence be modified to recognize that whole melons do not require time/temperature control for safety, as follows: “While whole melons do not require temperature control, human pathogens may proliferate rapidly on fresh-cut melon products held under temperature abuse conditions.”

PMA appreciates the opportunity to comment on this draft guidance and looks forward to working with FDA to clarify any comments made here and to help finalize this guidance document.

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