Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Tomatoes
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 Tomatoes.” The industry has expended a great deal of effort in preparing food safety guidance for tomatoes over the last several years with the development of Tomato industry’s 2006 and 2008 Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain and the more recent Tomato Metrics Initiative. We recognize and applaud FDA for using these industry-developed documents (specifically the 2008 guidance) as the templates for the current FDA draft guide.

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 tomatoes. 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 two items about which PMA is hereby requesting more information.

In the first paragraph, FDA provides background information indicating that from 1996 to 2008, “14 produce-related outbreaks were linked to the consumption of tomatoes”. 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 tomatoes 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?

In the fourth paragraph, FDA describes the 2007 Tomato Safety Initiative and states: “Findings [from the Tomato Safety Initiative] will also be incorporated into future editions of this guidance, as appropriate”. From PMA’s perspective, 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.

IV. Definitions

- “Fresh-cut fruits and vegetables or fresh-cut produce”: This definition is appropriate as a generic definition appropriate for many fruits and vegetables, but its application 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 recommend that FDA add the following sentence to the second paragraph of the definition: “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.”

- Water disinfectant: The term “Water Disinfectant” 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. Open Field Production

• **Section 1. Environmental Assessments and Risk Reduction Practices:** FDA makes 
several recommendations regarding conducting risk assessment. PMA applauds this approach 
and commends FDA for basing this guidance on risk evaluation and management. Far too 
often, food safety programs have been based off audit checklists in a “one size fits all” 
fashion. True improvement in food safety performance can only be achieved when individual 
operators take responsibility for conducting operation specific risk assessments and 
developing management plans to mitigate or control identified risks.

• **Section 3. Near-by Land Use:** FDA recommends “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.

• **Section 4. Water Use in the Field:** FDA recommends “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 and leaves too much to interpretation. 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.”

• **Greenhouse section:** We suggest that FDA similarly revise recommendations for water 
used for crop protection sprays in this section.

• **Section 5. Hygienic Practices in Tomato Fields:** This section references “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”. In light of the fact 
that humans are effective vectors for human pathogens and tomato harvest inherently 
requires hand contact with fresh fruits, 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 before starting work, after breaks, using the toilet, sneezing or 
coughing.”
PMA Comments – FDA Draft Guidance for Tomatoes
Nov. 2, 2009
Page 4

- **“Greenhouse” and “Packinghouse” sections**: We suggest that FDA similarly revise recommendations in these sections of this draft guidance.

- **Section 7. Tomato Production Practices**: This section deals with the use of soil amendments. The first bulleted FDA recommendation states: “…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.

  PMA recognizes that even the term “properly composted” is ambiguous and that both the industry and FDA lack sufficient proven data to more fully define the parameters for treating various types of composts to ensure they are pathogen free. 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.

  The produce industry would benefit greatly from research that defines validated processes for reducing and/or eliminating pathogens from manure-containing composts. As FDA indicates in the opening paragraph of this section, the use of compost is a necessary element in maintaining soil fertility, composition, texture and productivity. Yet, raw manure that is composted 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.

  The Center for Produce Safety (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.

  In lieu of this type of data, we suggest that this recommendation read: “eliminating use of sewage sludge, biosolids, and raw or improperly composted animal manure as a soil amendment.”

- **Section 8. Equipment and Containers**: FDA’s third recommendation states: “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 recommendation appears to be redundant to the first recommendation in this section, “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.” Therefore, FDA should add “utensils” to the first bullet, to avoid misunderstanding, and delete this third bullet as unnecessarily repetitious.

- **Harvest Practices, Field Packing and Greenhouse sections:** We suggest that FDA similarly revise recommendations in these sections of the draft guidance.

- **Section 9. Documentation and Records, Product Tracing** subsection: This details FDA recommendations for producers to develop and 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 clearly expressed the difficulties it has faced in conducting efficient tracebacks from the point of consumer purchase or consumption back through the supply chain to the original producer during recent produce-related outbreaks of illness. 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 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 received (and growers paid) and it is how products are shipped (and buyers invoiced). 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 employ, 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. Harvest Practices

- **Section 1. Preharvest Environmental Assessment:** The opening paragraph and subsequent FDA recommendations deal with the performance of a preharvest risk assessment. PMA strongly supports this practice, which is currently employed by a wide segment of the tomato industry. As stated earlier, risk assessment is the heart of any comprehensive food safety program. Performing a secondary risk assessment prior to harvest permits growers to account for any changes in risk profile that might have occurred in the intervening time from pre-plant to preharvest.

VII. Field Packing

- **Section 6. Cleaning Procedures:** The opening paragraph states: “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 representatives 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.
• **Section 9. Washing or Otherwise Treating Tomatoes in the Field:** The first recommendation in this section reads: “Ensuring that the water used for washing or otherwise treating tomatoes is of sufficient microbial quality for this purpose”.

As noted earlier, we believe that “sufficient microbial quality” does not provide adequate guidance and leaves too much room for interpretation. In postharvest operations, water that contacts the edible portion of tomatoes should have the microbiological quality of drinking water.

We therefore suggest that FDA amends the first bulleted recommendation 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.”

Similarly, FDA should revise additional recommendations in this draft guidance that employ similar terminology regarding the use of water with “sufficient microbial quality”. The following sections should be amended to gain consistency:

• **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…”);

• **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…”); and

• **IX. Packinghouse, 7. Postharvest Water Use** (“FDA recommends that packinghouses follow cGMPs as appropriate to the operation to ensure that all water is of sufficient microbial quality…”).

**IX. Packinghouse**

• **Section 7. Postharvest Water Use, Temperature and Disinfection of Water Supplies Used in Postharvest Applications:** the third bulleted FDA recommendation specifies “maintaining water temperature at least 10°F warmer than the pulp temperature of the tomato”. This recommendation is appropriate for tank washing systems, but does not recognize spray wash systems.
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.

It is also important that FDA work with industry as the experimental data on maintaining a 10°F temperature differential between the wash water and pulp is further studied. CPS has recently funded a research program to examine this requirement. The original research that led to the standard practice of maintaining a 10°F differential was performed looking at plant pathogens and decay organisms and not human pathogens. As these studies are expanded, FDA and industry will need to communicate clearly so that future recommendations reflect the best science available.

- **Section 16. Labeling:** The second FDA recommendation, “removing or correcting inaccurate labels from previously used containers,” may lead to confusion as it could be misconstrued to mean single-use corrugated or other containers, where FDA actually intends to address plastic or appropriately reusable containers such as returnable plastic containers (RPCs).

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.”

**X. Repacking and Other Distribution Operations**

- **Section 2. Product Tracing, Lot Identification:** FDA recommends in bullet two: “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.”

Similarly, the third recommendation in this section states: “Repacking tomatoes into new boxes that are clean and sanitary if tomato lots are commingled…” 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.”

This should not be difficult for tomato repackers to implement, as it can be easily accomplished using a blending log that records lots used in specific repack operations, and ties them to any new lot assignments for trace purposes. A similar approach has been used in salad packing operations to track individual components in these mixtures.

- **Section 4. Cross-Docking and Terminal Markets:** Here FDA contends that these types of operations should “follow the recommendations in this guidance as appropriate to their specific operation”. PMA supports this supply chain approach from FDA and fully concurs that all participants in the supply chain, even if they only redistribute product, need to follow risk-based food safety practices.

**XII. Foodservice and Retail**

- **Section 8. Tomato Washing and Culling:** In the recommendations’ third bullet FDA states “Soaking tomatoes or storing them in standing water is not recommended”. We agree with the recommendation, but 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 one foot depth, consistent with other sections in this guidance.

- **Section 9. Storing Cut/Sliced/Diced Tomatoes:** FDA recommends “Chilling to and maintaining tomatoes at ≤41°F after cutting.”

Placing tomatoes in ice water has been a common practice for firming tomatoes immediately prior to slicing. We believe that, like other immersion practices, this may offer an opportunity for pathogen infiltration (if they are present) and FDA should expressly note that the practice is not recommended.
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.

Submitted by:

Robert J. Whitaker, Ph.D.
Chief Science Officer
Produce Marketing Association
1500 Casho Mill Road
Newark, DE 19711
Tel: 831-970-4350
E-mail: bwhitaker@pma.com