

April 27, 2009

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

Re: Docket No. FDA-2008-N-0455

Dear Sir or Madam:

The United Fresh Produce Association appreciates the opportunity again to respond to FDA's request for comments that may assist the agency to improve the *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, hereafter referred to as the GAPs Guide. As noted in our comments submitted December 31 2008, we anticipated meetings to engage more segments of the fresh produce industry in active discussion. The comments in this current submission are compiled from one such public meeting, held February 24-25, 2009 in Herndon, Virginia and attended by over 80 stakeholders. Although these comments are submitted past the December 31 2008 closing date indicated in the original Federal Register notice, we hope that they will be accepted and considered in FDA's deliberations on ways to improve the GAPs Guide.

Executive Summary

The following fourteen points, A-N, in no priority order, were generally agreed upon by the meeting attendees:

- A. The GAPs Guide should apply to all growers of fresh produce, whether domestic or intended for import to the U.S., but the Guide should be sensitive to capabilities and practices that may vary on the basis of an operation's size, scale and complexity.
- B. Regarding application to imports, it was recognized that there are limits to FDA's legal authority to enforce U.S. requirements in sovereign countries and even more so for just guidance. Alternate ideas to ensure consistency in application to imports included a) making importers responsible to ensure compliance, or b) benchmarking foreign programs, accrediting certification bodies, and similar programs to ensure equivalence in compliance.
- C. The GAPs Guide should remain broadly applicable to fresh produce, but focused on microbial food safety. GAPs guidance that is likely to apply to specific commodities should be relegated to separate, commodity-specific guides.
- D. The GAPs Guide should be arranged chronologically, from field preparation to production to harvest to post-harvest handling, transportation and traceability.
- E. The Guide should be arranged in modules, each in a stand alone format to make it easy to use by the target audience – the entities involved at that stage of production or handling.

- F. All operations should have a food safety plan, based on a risk assessment. The plan may be generic or specific to the operation, but the complexity of the plan should be reflective of the complexity of the operation.
- G. All recommendations in the Guide should be based on relative risk and supported by science. Recommendations should clearly define the risk so that growers can identify high risk behaviors from low risk behaviors.
- H. FDA should examine its field investigations associated with contamination events for root causes of contamination and incorporate lessons learned in the Guide.
- I. FDA must define “risk” and how it is measured in the context of the GAPs Guide. For example, are risks attributable to specific commodities or to the practices typically used with those commodities?
- J. While it is important for growers to know which commodities have been involved in foodborne illness outbreaks, FDA should consider a term other than “high risk” for produce commodities that are linked to foodborne illnesses. Foodborne illnesses are rarely linked to any fresh produce commodity relative to the billions of perfectly safe servings sold each year.
- K. Recommendations in the Guide should be as specific as possible and clearly communicate “what’s acceptable”. Working with the industry and other resources, FDA should establish acceptable food safety practices and standards for all produce, but remain sensitive to commodity and regional differences in practices and risks.
- L. The Guide should provide reasons and rationale for all recommendations, so that operations can comply with the intent, rather than the letter, of the recommendation. For example, provide a greater discussion when using the phrase “adequate for its intended use”.
- M. If the Guide recommends testing as a food safety tool, it should also provide guidance on situations when testing is and is not applicable, time and frequency to test, what to test for, how to test and what to do when results do not meet the standard.
- N. Training remains critical for cultural acceptance of the GAPs Guide recommendations. Where possible, the Guide should provide tools, examples, templates, decision trees and other resources to enable consistency and completeness in training. However, the Guide must remain sensitive to alternate but equally effective approaches.

Additional Comments

The meeting yielded a robust discussion of the GAPs Guide and a wealth of recommendations to enhance its usefulness and use. There may not have been general consensus expressed for all of the following points, however they are provided for FDA’s consideration, again in no priority order.

1. Meeting attendees were split whether GAPs guidance should remain recommendations or be promulgated as regulation (i.e., mandatory). Some were strongly in favour of a mandatory approach, but others were deeply concerned about what this would mean to small producers. However, there was general agreement that there are a minimum set of food safety practices that all should follow.
2. Some issues identified relative to imports included:
 - How do importers demonstrate compliance after they have been put on import alert or taken off a certification list?

- How does one achieve and retain confidence in foreign certification bodies? The same question was raised for domestic certification bodies.
 - Contamination events can arise both out of bad practices and “things happening” despite best intentions. FDA responses must take this into consideration.
 - If imports must meet the same standards as domestic production, domestic production must meet the same standards as imports.
3. 90% of GAPs elements are likely common to all fresh produce, but 10% are likely commodity specific. There was no clear resolution about how to develop or include the 10%, but attendees felt a need for small producers to be involved and that such guidance development should be industry led. Some felt a need for more than just guidance; recommendations should be piloted and the results reviewed.
 4. Some specific items were suggested for inclusion in the updated Guide:
 - Definitions for terms; e.g., GMPs, GHPs, HACCP.
 - Recommendations for greenhouse operations.
 - Guidance on records; e.g., their value, which should be kept, how to create and maintain good records.
 - Recommendations relative to the use and remediation of flooded land.
 - Protocols, methods, verification for harvest equipment cleaning & disinfection.
 - List of resources for growers to know where they can go for assistance; e.g., cooperative extension, commodity groups, National GAPs Program, USDA.
 5. The Guide should use examples in key areas.
 6. Recommendations should be designed to be auditable or enforceable.
 7. Recommendations must be science-based & agronomically appropriate.
 8. The GAPs Guide revision process should set a clear timetable, include a balance of stakeholders, clarify how commodity-specific guides or annexes are to be developed and used. Audit and implementation tools (e.g., extra guidance or training materials) should be developed concurrent with the GAPs Guide revision.
 9. When implementing the revised Guide, ensure that sufficient infrastructure is ready, including considerations of audits and certification, and qualifications, competency, and training of those who will measure compliance. FDA should plan for transition time, and be realistic. FDA should explore alternate approaches to audits and certification, particularly approaches that reduce costs. FDA should build on domestic and foreign examples that work.
 10. Asked “If you could know one thing, what would it be?”, attendees identified the following items they would like to see in the revised Guide:
 - Which point in the system is the riskiest
 - Which practices or combination of practices that reduce the greatest amount of risks
 - Pathogen survival in the field in soil and produce
 - Pathogen survival in compost
 - Commodity-specific chlorine/disinfectant levels
 - Acceptable temperature ranges in dump tanks
 - Water standards; e.g., what level of water contamination is acceptable for overhead use.
 - One food safety standard that is internationally recognized and endorsed by FDA
 - High risk versus low risk in growing and packing based on commodity and postharvest practices
 - Variable postharvest practices that can change risks

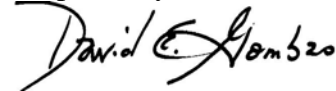
11. Asked “What do you want out of the next guidance document?”, attendees identified the following:
- Commodity-specific guidelines published and endorsed by the FDA
 - Specificity
 - Data and reasoning included with recommendations (this is an adult learning need)
 - Outline how to develop a food safety plan
 - The training section should be improved and enlarged
 - Recommendations based on the size/scale of the operation
 - Risk- and science-based information
 - Specific production practices
 - Education initiatives, not punitive actions
 - Recommendations should be benchmarked against other standards in the industry
 - Comprehensive review of other guidance documents, and address how the Guide will harmonize with other existing GAPs programs; e.g., CGP, AFDO, TGAPs, LGMA, NOP.
 - Commodities grouped by characteristics and required practices
 - Prioritization of practices based on outbreak data
 - Standards and test methods
 - More on traceability; e.g. discussion on what constitutes a lot, how to address commingling of product. The Guide should include recommendations of how to balance the methods, granularity and benefits of lot identification against the consequences of a lack or loss of lot identification.
 - More on transportation
12. Asked to identify “6 things that any farm could do to improve produce safety”, attendees agreed that all produce growers should be able to implement the following:
- Irrigation water evaluation
 - Employee training
 - Provide toilets and hand washing facilities
 - Traceability
 - Grower training in basic GAPs
 - General sanitation practices
13. Asked “How can FDA enhance adoption?”, attendees identified the following:
- Look at other models, for example: a) LGMA, which is industry driven, has voluntary participation coupled with mandatory requirements for participants, and government oversight; b) Canada's HACCP-based approach to GAPs and GHPs for growers, packers, storage intermediaries, repackers and wholesalers; c) organics’ use of a “mark”/”symbol” of adoption; d) development of a “Model Farm Code” (with science based variances) analogous to the Food Code.
 - Provide tools to help identify/assess risks
 - Provide a discussion of why GAPs are important to me and my industry; provide a better discussion of benefits.
 - Provide or support training for all, but different training for workers, managers, auditors and buyers
 - Increase the use of Extension Service to encourage adoption.
 - Outreach to the “sustainable agriculture” communities – smaller networks of smaller growers.

- If the revised FDA guidance could meet both government and market expectations, it could help achieve the industry goal of reducing multiple audits.
 - Consumers can help drive the process, especially with smaller growers who sell direct.
14. Asked “What are the barriers to adoption?”, attendees identified the following:
- Lack of clarity on what is an “acceptable” level of risk
 - Concern about use of testing, which is perceived as increasing exposure to lawsuits.
 - Growers feel left “on your own” if something goes wrong, leaving them vulnerable to lawsuits and regulatory response despite implementation.
 - “Misuse” of science; for example, perception that frog equals salmonella, so frog in field means salmonella in field, which means contaminated field.

The attendees also provided significant discussion on research needs that would help inform practices and standards. However, as those needs were not intended as enhancements to the writing or use of the Guide, they are not included here. Those research needs are included among the additional detailed information about the public meeting available on the United Fresh Produce Association website at www.unitedfresh.org.

On behalf of the 80+ stakeholders of the fresh produce supply chain who invested in their industry by attending this meeting and participating in the dialogue, United Fresh Produce Association appreciates this opportunity to provide information we hope FDA will find useful in the updating of the *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*. Please feel free to contact me for any clarifications or additional information.

Respectfully,



David E. Gombas, Ph.D.
Senior Vice President, Food Safety and Technology
United Fresh Produce Association
1901 Pennsylvania Avenue NW, Suite 1100
Washington D.C. 2006
(202) 303-3400
dgombas@unitedfresh.org