



December 31, 2008

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 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. We are submitting these comments at this time in order to comply with FDA's December 31, 2008 published deadline. However, as noted in our November 25 request for extension, we believe that changes to the GAPs Guide should not be considered lightly, and we anticipate one or more meetings in the next few months to engage more segments of the fresh produce industry in active discussion. We hope that comments arising from those meetings also will be accepted and considered when they are submitted to FDA.

United Fresh Produce Association is an international trade association representing the interests of produce growers, shippers, fresh-cut processors, distributors and marketers throughout the total supply chain. Our members include small family-owned businesses as well as the largest national and international companies in the produce industry. The association was founded in 1904 and has worked consistently to provide a strong industry voice in government and regulatory policy, food safety and quality assurance, nutrition and health promotion, and helping member companies develop positive business growth through supply chain solutions, training and education.

Since early 2007, the United Fresh Produce Association has advocated, to protect public health and ensure consumer confidence, for produce safety standards that:

- Must allow for a commodity-specific approach, based on the best available science.
- Must be consistent and applicable to the identified commodity or commodity sector, no matter where grown or packaged in the U.S., or imported into the country.
- Must be federally mandated with sufficient federal oversight of compliance in order to be most credible to consumers.

In responding to FDA's request, United Fresh considered the impact of its comments on small and large operations, across all commodities intended to be encompassed by the 1998 GAPs Guide, and all growing regions in the U.S.

## **Comments to FDA's Specific Questions.**

- 1. Should any future GAPs/GMPs Guide rank or prioritize among potential issues according to relative risk or importance? If yes, please offer suggestions of how that information could most effectively be presented in a way that does not detract from the broad scope of the current guidance.*

The 1998 FDA GAPs Guide has proven successful over the past 10 years in describing those policies and procedures that fresh produce growers/packers/shippers should consider in developing their operation-specific food safety plans. This is demonstrated both by 1) the absence of food safety incidents linked to the vast majority of commodities commonly referred to as “fresh produce” and 2) that the 1998 GAPs are still inclusive of the food safety practices that are the basis of the dozens of food safety education programs, standards and audits that have evolved since then. While numerous qualitative risk assessments, speculations, and private sector food safety standards have attempted to prioritize those practices most critical to assuring produce food safety, reality is that neither research nor produce-related outbreak investigations have revealed any procedures or practices as more important than others. The primary targets of risk management generally recognized for fresh produce production can be grouped into workers (health and hygiene), animals (livestock and wildlife), water (irrigation and other produce contact uses), and waste (animal manure-containing soil amendments). The relative risk of these four will vary depending on the specific commodity, production location, and production practices. Therefore, it is recommended that, first, an operation conduct its own, operation-specific hazard assessment, to identify those food safety hazards reasonably likely to occur in the absence of control, and develop a food safety plan to minimize risks from those hazards. Because the relative importance of control of these hazards will vary among commodities, growing regions, and growing practices, the GAPs Guide should not try to prioritize the importance of these risks and practices.

- 2. How should the GAPs/GMPs Guide be organized to enhance its usefulness?*

First, we respectfully suggest that the GAPs Guide replace GMPs with another term that is more appropriate for growing operations. GMPs (Good Manufacturing Practices) have a connotation appropriately associated with facilities required to operate under 21 CFR part 110. While several of the requirements in that regulation may be applicable to produce (see answer to Question 6, below), this has been a distraction in communication and an ongoing opportunity for misunderstanding. FDA published in February 2008 a separate Guide for fresh-cut produce operations, which operate under 21 CFR part 110, and recommendations for those operations should not overlap here. If the GAPs Guide continues to include GMP-like recommendations, then they should be referred to as GAP recommendations to be clear on their intended application.

The GAPs Guide should be left as guidance for those commodities for which standard practices have proven effective. Commodities that have been linked repeatedly to foodborne illness events may require more intensive food safety management practices during production and harvest, and these would be described in commodity-specific guides. A fresh produce operator will want to concentrate on their section of the GAPs Guide, not the whole Guide and not flip between pages.

Therefore, we recommend that the GAPs Guide be reorganized into a chronological flow, divided into production stages from field preparation to packinghouse (e.g., field/greenhouse preparation, produce treatments during growing, harvesting/field packing, transportation, packinghouse), including all information relevant at that stage of production, recognizing there will be a degree of redundancy in content between stages.

We further recommend a clear description/definition of the stages of production to which the GAPs Guide pertains.

3. *While the GAPs/GMPs Guide has been generally accepted and widely adopted, we know that there are entities in the fresh produce industry that are not aware of it. What measures can be taken, and by whom, to expand awareness by the fresh produce industry of the GAPs/GMPs Guide?*

Over the past decade, numerous initiatives have been successful in promoting and educating the industry on the risks and recommendations described in the Guide, to those companies representing all but the smallest providers of commercially available fresh produce. These initiatives have been sponsored and undertaken by trade groups, trade press, land grant universities, regional trade associations and private sector as well as customers such as retailers and foodservice companies and associations. However, new companies and responsible individuals are continually entering the fresh produce supply chain, requiring continual opportunities and reinforcement of awareness and training. Further, as indicated in the question, we recognize that there are entities that continue to be uninformed, either unintentionally or otherwise, about the existence or need for implementation of the recommendations in the GAPs Guide. These entities, while individually a small part of the supply chain are, combined, reasonably likely to constitute a major source of produce available to consumers. While the above described initiatives will continue to drill down to this group, particularly in smaller, regional meetings, we recommend that FDA, with its inherent authority, develop and hold public education sessions specifically targeting those entities not normally attending GAP educational sessions. Such education sessions may be undertaken entirely by FDA, with or without assistance from industry organizations, or be contracted to educators competitively on the basis of proposals to reach these entities. FDA should also consider partnering with USDA and state agricultural agencies, which may be better able to account for regional differences in risks and recommendations during outreach. Some models of effective outreach efforts include the Partnership for Food Safety Education's FightBAC!, retailer requirements for produce requiring intensive food safety management practices, USDA's recognition of the American Meat Institute's *Listeria* Control Program, and outreach by FDA for bioterrorism preparedness. United Fresh and the produce industry stand ready to assist FDA in developing such outreach and educational programs.

4. *How should the GAPs/GMPs Guide be modified to motivate all operations to implement? Please include information on economic impact.*

We believe that reorganizing the GAPs Guide as described in our response to Question 2 will make it more user friendly for operations. Use of real-world illustrative examples of scenarios, forms and procedures can better inform specific operation plans and compliance efforts. Information developed by the National GAPs Program may be useful. Examples of FDA investigational findings that illustrate good and bad practices would also help provide useful information to enhance intended

compliance practices. United Fresh and the produce industry stand ready to work with FDA to identify appropriate examples.

As educational outreach by FDA is implemented and greater awareness by leading growers takes place, more producers will be motivated to meet the emerging new standards. Commodity groups, such as lettuce/leafy greens, tomatoes and melons, in their outreach and development efforts utilizing their commodity specific guidelines, will be good motivators for the entire industry to participate. Voluntary marketing agreements, being developed with the assistance and oversight of USDA AMS, are being successfully and widely implemented within commodities and could also serve as model examples, promoted as successful and existing industry efforts; for example, the California/Arizona Leafy Greens Marketing Agreements and the California Tomato Farmers Cooperative.

5. *Can the GAPs/GMPs Guide be applied equally to, and implemented by, domestic and foreign growers and packers? If not, should the GAPs/GMPs Guide be revised to incorporate additional options or special considerations (e.g., utilizing draft animals for agricultural tasks) for application and implementation? Please explain.*

As noted in our answer to Question 4, we believe that produce food safety standards must be consistent for an individual produce commodity group wherever sourced, domestic or imported. We recognize that there are regional and growing practice differences that will affect how facilities will achieve those standards – for example, regional differences must be recognized, such as differences in the potential risk presented by amphibians in production areas, or the use of untreated biosolids in agricultural operations in different growing regions. Further, while the food safety objectives for a specific commodity group should be consistent across all production regions, how those objectives are achieved may differ. For example, conventional farming practices may differ from organic, both of which may differ from practices that use animals intentionally during production (e.g., Amish, Mennonite). We further recognize that enforcement of these standards outside of the U.S. may be problematic, and production practices outside the U.S. may be significantly different than those used by operations in the U.S. FDA is aware that consistency of food safety standards between imports and domestic products is not unique to fresh produce, and we recommend that policies being considered by FDA for import safety assurances for other food products also be considered for fresh produce. For example, the premise used in the Seafood and Juice HACCP Regulations (21 CFR parts 120 and 123), to hold importers responsible to perform “affirmative steps to ensure that the products being offered for entry were processed under controls that meet the requirements”, may also be appropriate to fresh produce imports.

6. *Is there a need for additional guidance to assist an operator in determining which provisions of the Current Good Manufacturing Practice regulations in part 110 (21 CFR part 110) (e.g., post-harvest water quality, disease control, cleanliness, and supervision) could be implemented voluntarily for operations that currently are excluded under § 110.19? If so, which ones?*

As noted above, FDA’s referral to cGMPs for operations not currently required to comply with 21 CFR part 110 (i.e., operations intended to be covered by the GAPs Guide) has been a distraction and has created an opportunity for misunderstanding. FDA is aware that practices applicable to one sector of the food industry may also be applicable to other sectors. We see no need to label

recommended practices applicable to non-regulated operations with the same terminology used for regulated operations. If the Guide includes specific recommendations for grower/shipper/packing operations, they need be identified in the GAPs Guide only as Good Agricultural Practices.

In reviewing the requirements in 21 CFR part 110, we believe that many practices may be relevant and appropriate to some operations intended to be covered by the GAPs Guide, for example, in-field preparation and packaging operations, and packinghouse operations. FDA has noted, in several outbreak investigation reports, where lack of GMP-like controls may have contributed to contamination of produce, and the GAPs Guide would benefit from illustrative examples. However, we also believe that appropriate controls will vary with the risks and hazards reasonably likely to occur for specific commodities, regions, growing practices, stages of the supply chain and operations, and appropriate controls for a specific operation should default to operation-specific food safety plans.

7. *Should the GAPs/GMPs Guide recommend that growers and/or other relevant operations develop a written food safety plan, written SOPs, and/or written SSOPs? If so, please describe the types of information or recommendations that you believe would be helpful.*

We agree that the GAPs Guide should recommend that all growers and/or other relevant operations develop a food safety plan. However, any requirement for a written food safety plan should be limited to commodities that require more intensive food safety management practices. The need for and extent of documentation should depend on the commodity, the specific growing location and growing practices. As practiced in the industry, a food safety plan may be a high level assessment of the operation and its potential challenges. In other instances, it may be a detailed description of potential risks, control measures, responsibilities, monitoring activities and frequencies, corrections, record keeping activities and verifications. Generally, the former have been successful for the vast majority of commodities we refer to as fresh produce and intended to be covered by the GAPs Guide; i.e., commodities whose production and handling immediately post-harvest have been rarely, if ever, associated with a foodborne illness. The latter may be more appropriate for commodities that have been linked repeatedly to foodborne illness events (i.e., “high risk”) and appear to require more intensive food safety management practices during production and harvest.

A food safety plan for an operation covered by the GAPs Guide should not be confused with HACCP. While a process analogous to Hazard Analysis is strongly recommended for all operations that handle fresh produce, it must be remembered that the second Principle of HACCP, as described by Codex Alimentarius, the National Advisory Committee on Microbiological Criteria for Foods and two FDA regulations for food safety based on HACCP (21 CFR parts 120 and 123), define Critical Control Points (CCPs) as points in the process that can be controlled and are essential to assure the safety of the product. Almost universally, there are no “points” in the production process (i.e., in the field) at which food safety hazards can be controlled. In almost all cases, there are multiple points that must be managed for a specific hazard to be minimized. For example, at what “point in production” will a grower control animal incursions? What “critical limit” would apply to controlling animal incursions? What monitoring activity and frequency would be sufficient to ensure that the critical limits are never exceeded, or are detected when they are exceeded? What records would be kept to demonstrate compliance with such a CCP? The same inability to apply

HACCP Principles relates to the control of hazards in irrigation water. While control of these risks can be forced into the CCP definition, it's an uncomfortable fit that doesn't hold up in practice.

Rather, Good Agricultural Practices, and any resultant food safety plan, are better described as "prerequisite programs". Prerequisite programs are procedures and policies that set the foundation for HACCP to work. In processing facilities operating under functional HACCP programs, Good Manufacturing Practices like worker health and hygiene, pest control, water quality and supplier approval programs are all considered prerequisite programs. Facilities used to include these programs in their HACCP plan (pre-1993), but they overburdened the HACCP plan to the extent that the plan was too complicated to follow and, so, was often violated. In 1993, the Canadian Food Safety Enhancement Program introduced the concept of prerequisite programs to be those practices that would reduce the likelihood of certain risks. If properly designed and maintained, occasional slips in performance of a prerequisite program will not be likely to create a food safety issue. For example, if the irrigation system is well designed (well, well head, distribution lines and backflow prevention), then being a day late in testing the water will not mean the produce is potentially unsafe for a day. Likewise for worker hygiene: if workers and supervisors are well trained and hygienic facilities and supplies are well designed and maintained, then a missed inspection record for the field toilet facility doesn't mean that the produce can't be harvested. In other words, a well designed and implemented prerequisite program, like GAPs, is important but, if well designed and implemented, an occasional lapse in adherence does not mean that a hazardous condition is reasonably likely to occur.

Prerequisite programs must still have a structure that is adhered to consistently: they must have defined procedures and responsibilities, be monitored at a defined frequency, records of performance kept, and corrections made if the program is not managed correctly, but each of those activities operates differently in prerequisite programs than in HACCP.

8. *Records can be divided into the following two broad groups: (1) Records to facilitate traceback, and (2) non- traceback or operational records. Does the GAPs/GMPs Guide provide sufficient recommendations regarding record keeping? If not, please describe what would be most helpful and why, e.g., information about the record keeping regulation (21 CFR 1 subpart J), guidance on what makes a "good" record, guidance on periodic record review and verification, and required or recommended record retention times. What types of monitoring records or other documentation would be most useful to industry and regulators?*

The GAPs Guide would benefit from illustrative examples of both operational and traceback records, how they should be prepared and retained. Such examples may assist in more uniform record keeping practices and records in the industry. United Fresh and the produce industry stand ready to assist FDA in developing such examples.

Good record keeping is a critical part of any good 'process' and both types of records (traceback and non- traceback) are essential. The current Guide's recommendations for traceability and record keeping provide more of a general overview, and really should provide strong "how to" information to the operator. The current wording, which specifies labeling produce with "source of the product and mechanism for marking or identifying the product that can follow the product from the farm to the consumer", is far too general and not nearly specific enough to meet today's needs. We

recognize that farm operations were exempted from FDA’s record keeping requirements described in 21 CFR part 1 subpart J. However, packinghouses and other direct recipients of produce from farms are required to comply with the regulation, providing traceability back to the fields from which the produce came. Nevertheless, the produce industry has committed to industry-wide practices enabling whole chain traceability. This “Produce Traceability Initiative” (PTI) was sponsored by United Fresh Produce Association, the Produce Marketing Association and the Canadian Produce Marketing Association, and included over 40 companies in the fresh produce supply chain, as well as industry trade associations representing all stages in that supply chain. The PTI Steering Committee concluded its recommendations in 2008 as follows:

- Brand owners must obtain their own GS1-issued Company Prefixes and assign 14-digit GTINs (Global Trade Item Numbers) to all case configurations.
- Brand owners must provide their GTINs (and corresponding data) to their buyers.
- Those packing the product are responsible for encoding the GTIN and Lot# in a GS1-128 barcode, and providing the information in barcode and human-readable format on each case.
- Each subsequent handler of the case must have the systems and capability to read and store the GTIN and Lot # from each case of produce received and each case of produce shipped.

With implementation of these recommendations, cased whole produce will be traceable back to its source in the same manner that packaged produce is now, utilizing bar codes with human readable information as back-up, in a uniform language and with uniform standards across the produce industry.

We recognize that implementation of these standards will take time and commitment by the participants, as is true for any major change in any culture. At this time, already more than 30 companies in the fresh produce supply chain have committed to implementation of the PTI milestones. More information about the PTI and its specific objectives can be obtained from the United Fresh website at [www.unitedfresh.org](http://www.unitedfresh.org). We invite FDA to work with us to hold the industry to this commitment.

9. *The recent produce safety initiatives concerning leafy greens and tomatoes (Refs. 5 and 6) have highlighted the importance of performing environmental assessments (e.g., assessing water source quality, water distribution systems, animal presence, and other risk factors that may be associated with the production environment) before planting, throughout production, and prior to harvest. Would it be useful to enhance coverage of these concepts in the GAPs/GMPs Guide? If yes, please describe.*

As commented above, the complexity required in a food safety plan should be commensurate with the food safety risk inherent for that specific commodity, growing location, growing practices, etc. While the hazard assessment strategies may be useful in evaluating the growing environment for some production operations, their importance should be appropriately based on the commodity being grown. Each hazard assessment should identify factors that are relevant to the specific crop and location under consideration. FDA should avoid generalized recommendations that may be appropriate for some operations, but burdensome and economically punitive without enhancing food safety for other operations.

For those specific commodities, growing locations, growing practices, etc. that would benefit from performing hazard assessments, the GAPs Guide should provide coverage of these concepts. We would refer FDA to an example of procedures that have been used successfully for performing hazard assessments; i.e., the procedures described in the California Leafy Greens Handler Marketing Agreement Best Practices (<http://caleafygreens.ca.gov>).

*10. Several newer produce safety programs, such as the California Leafy Green Products Handler Marketing Agreement (Ref. 8), incorporate recommendations (or requirements) for microbial testing. Does the information on microbial testing in the GAPs/GMPs Guide provide sufficient information to assist operators in designing a meaningful and cost effective testing program? If not, please describe what types of additional information would be most useful, such as how and where microbial testing might best be used to achieve food safety objectives, e.g., building a history of agricultural water quality, making best management decisions, verifying food safety operations.*

The FDA GAPs Guide provides recommendations only for water testing, and then primarily to identify cautions in its use. The final advice regarding Microbial Testing of Agricultural Water, i.e., that “growers can consult local water quality experts, such as state or local Environmental Protection or Public Health agencies, extension agents or land grant universities, for advice appropriate for individual operations”, has not proven effective, as there is still considerable confusion and misinformation about effective use of microbiological testing. The fresh produce industry is working to identify microbiological testing practices that ultimately may be useful in food safety assurance, but those practices have not yet been developed. FDA knows that microbiological testing of finished product is not generally effective to guarantee the safety of a given lot of product, and is particularly problematic for short-shelf life, perishable products like fresh produce, but microbiological testing may be effective in verifying process, sanitation effectiveness or environmental controls. FDA also knows that ineffective uses of microbiological testing takes limited food safety resources away from more effective preventive control programs. However, guidance on the appropriate use of microbiological testing in the GAPs Guide can be helpful to operators and the industry. United Fresh and the produce industry stand ready to work with FDA to provide in the GAPs Guide specific examples of where microbiological testing may be, and is not, an effective process verification tool. Any recommendations for appropriate uses of microbiological testing should also include examples of appropriate practices, interpretation, considerations in setting action levels and actions, and documentation. Any recommendations added to the GAPs Guide should not be prescriptive but directional.

*11. Some comments submitted in connection with the 2007 public hearings expressed concerns that field management activities intended to minimize microbial hazards, such as removing vegetation to reduce animal harborage near the production field, could have a negative, albeit unintended, impact on the environment and water sheds, among other areas. What data support these concerns? Could/should the GAPs/GMPs Guide do more to identify, address, and possibly mitigate unintended environmental consequences of food safety measures?*

The objective and focus of the GAPs Guide appropriately is food safety programs for fresh produce production. It is important that this focus not become diluted with non-food safety objectives, such as environmental issues. However, growers are also faced with other, non-food safety regulations,

or interpretations of those regulations, which may appear to conflict with GAPs Guide recommendations. Some examples include Florida and California local water use rules requiring water re-use, the use of cleaning and sanitizing chemicals in the field which may conflict with stream run-off rules, watershed improvement plans, agricultural water waivers, and fence rules for specific animals such as deer. While the GAPs Guide should take these potential conflicts into consideration, we respectfully request FDA to develop, separately from the content of the GAPs Guide, a process for identification of legal or regulatory conflicts with GAPs Guide recommendations, and an open and transparent process for resolution of the conflicts by utilizing all available relevant expertise.

12. *Are there existing regulatory requirements at the Federal, State, or local level that act as a disincentive (or as an incentive) for growers or other operators to implement agricultural or manufacturing practices that should be taken into consideration when updating this guidance to reduce the risk of microbial contamination of fresh produce? If yes, please identify and explain.*

Please see response to Question 11.

### **Other Comments.**

In addition to these answers to FDA's specific requests for comments, we respectfully recommend the following revisions to Section II. Water, Section 2.2 Antimicrobial Chemicals of the GAPs Guide.

#### **Page 16, Header box**

"Prevention of contamination is preferred over application of antimicrobial chemicals after contamination occurs."

**Concern:** While we do not argue with this statement we believe that, for the section on antimicrobial treatments, it may be more important to emphasize that water can spread contamination if it isn't properly treated.

**Recommendation:** Replace the sentence in the box with the following. "Antimicrobial chemicals in water can minimize the spread of contamination but may not totally eliminate contamination from the field."

#### **Section 2.2 Antimicrobial Chemicals, first 3 paragraphs**

**Concern:** Much research has been done on antimicrobial chemicals since the document was first published and updates are needed to reflect findings. Additionally, the concerns for water for these products are very similar, if not identical to those for fresh-cut produce, and consistency, to the extent possible, between the documents would be beneficial.

**Recommendation:** Replace the first 3 paragraphs under GAP 2.2 Antimicrobial Chemicals with the following wording, adapted from FDA's *Guide to Minimize Microbial Food Safety Hazards for Fresh-Cut Fruits and Vegetables*, section VIII. Production and Process Controls, C. Specific Processing Steps, 2. Processing Water, a. Maintaining Water Quality:

"When used appropriately with adequate quality water, antimicrobial agents such as chlorine, hypochlorous acid, ozone, peroxyacetic acid, chlorine dioxide and others help to minimize the

potential for microbial contamination of processing water and subsequent cross-contamination of the product.

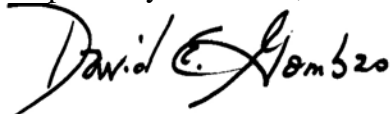
The effectiveness of an antimicrobial agent, as well as the amount that should be used, depends on the treatment conditions, such as water temperature, acidity [pH], water hardness, contact time, amount and rate of product throughput, type of product, water to product ratio, amount of organic material, and the resistance of pathogens to the particular antimicrobial agent.

If an operator uses an antimicrobial agent to prevent cross-contamination in processing water, the operator should monitor the water for antimicrobial agent concentration and other factors as recommended by the manufacturer or chemical supplier.

Operators should consider options for maintaining the quality of water most appropriate for their individual operations. Operators may wish to contact a local agricultural extension agent, their chemical supplier, or a food safety consultant for help in deciding what water treatment chemicals to use. In addition, operators may refer to 21 CFR 173.315, 'Chemicals used in washing or to assist in the peeling of fruits and vegetables,' for additional information about chemicals approved for use in wash water."

Again, the companies which comprise United Fresh Produce Association and its allied associations appreciate this opportunity to provide comments on the 1998 GAPs Guide and the specific questions listed in the Federal Register notice. These comments are provided in the spirit of minimizing food safety risks and maximizing the healthful benefits of fresh produce to all consumers. Please feel free to contact me if I can provide more information or clarification.

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'.

David E. Gombas, Ph.D.  
Senior Vice President Food Safety and Technology