International Fresh-cut Produce Association

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

FROM: Jim Gorny, Ph.D., V.P. Technology & Regulatory Affairs, IFPA

RE: Comments Regarding The FDA's Proposed Produce Safety From Production to Consumption: An Action Plan to Minimize Foodborne Illness Associated With Fresh Produce; [Docket No. 2004N–0258]

The International Fresh-cut Produce Association's (IFPA) mission is to advance the industry by supporting its members with technical information, representation and knowledge to provide convenient, safe and wholesome food. Our membership is comprised of fresh-cut fruit and vegetable processors, produce grower/shippers, food service companies, retailers and those who provide goods and services to the fresh-cut produce industry.

Assuring consumer safety is an issue the IFPA and the fresh-cut produce industry take very seriously as it is of paramount importance. The IFPA and our member companies are steadfastly committed to providing fresh, safe and wholesome products to consumers.

The IFPA respectfully submits the following comments regarding the U.S. Food and Drug Administration's "Produce Safety From Production to Consumption: An Action Plan to Minimize Foodborne Illness Associated With Fresh Produce"; [Docket No. 2004N–0258].

Respectfully,

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2. What major practices contribute to the contamination of fresh produce by harmful pathogens? What intervention strategies will prevent, reduce, or control this contamination?

Comment: Specific areas within the produce supply chain that warrant review to identify risk and potential development of best practices to reduce risk are:

- Safe Water Use
- Environmental Contamination
- Sanitary Equipment and Facility Design
- Effective Employee Hygiene
- As of Yet Unidentified Sources of Contamination

It is important to not simply focus on the suspected primary causes of produce contamination in the supply chain, but have an open mind to allow for discovery of hitherto unidentified actual causes of produce contamination. This process should include a review of current scientific literature and identify areas where further research and understanding are needed.

Recommendations
The FDA and industry must collaborate, facilitate and support produce food safety research that provides a meaningful assessment of fresh produce handling practices during field production, processing and preparation by retailers and consumers. A better understanding of the interaction between produce and human pathogens will aid in the development of intervention strategies and increase the safety of the food supply.

A meaningful assessment of the safety of fresh produce involves understanding the microbiology of fresh produce, as well as field production, processing and handling practices. Produce handlers must definitively understand the food risks that they are facing because if we don't clearly understand the risk then we can't manage such risks. Speculative actions that attempt to reduce produce food safety risk, if incorrect, potentially take limited food safety resources away from actual risks which have not been addressed while adding to the perception that the issue has been addressed, and raising expectations. Enhanced research efforts and financial support are needed to clearly identify means of intervention and quantify how much risk is reduced by specific actions, so that limited food safety resources can most effectively be deployed.

There are a number of food safety issues related to fresh and fresh-cut produce production and handling that warrant further investigation to gain a better basic understanding of how human pathogens and produce interact. A better understanding of this interaction will aid in the development of intervention strategies and increase the safety of the food supply. Five areas of research that are of high priority for the fresh and fresh-cut produce industries are:

A. Microbial Ecology of Human Pathogens in the Agricultural Production Environment

Human pathogens in agricultural / farm environs may be present in low numbers and frequency. Preventing human pathogen contamination of produce is currently the most effective means of reducing foodborne illness risk. However, there is a significant lack of information regarding human pathogens on the farm and in postharvest produce environments. Understanding the microbial of ecology, persistence, niches, harborages, life cycle, and factors effecting survival and growth of human pathogens in an agricultural / farm environment, including water and soil amendments, are essential to developing and implementing intervention and control measures to reduce the risk of contaminating fresh produce.

B. Agricultural Water

GAPs rely on management practices that prevent contamination of produce on the farm and during postharvest handling operations. Water is a significant potential source of human pathogens in the farm environment. Assuring agricultural water is of sufficient microbial quality for its intended purpose is critical in assuring the safety of produce. Therefore, identification of better methods to determine the food safety risk associated with a particular irrigation water source for a particular use warrants further investigation. Potential lines of investigation include identification of indicator microorganisms that highly correlate with the presence/absence of viable human pathogens.

C. Soil Amendments

Identification of better methods to determine the food safety risk associated with a particular lot of composted manure to be used as a soil amendment is warranted. Identification of indicator microorganisms that correlate well with the presence/absence of viable human pathogens is needed as well as determination of time/temperature composting variables which are needed to significantly reduce the risk of human pathogens in composted manure.

D. Proximity To Potential Contaminant Sources

No produce operation is an island onto itself. Therefore it is important to assess risks posed by adjacent agricultural and non-agricultural operations that are known to be potential sources of human pathogens. Greater understanding and quantification of risk posed by such adjacent operations is needed to formulate strategies to reduce risk. Simply put, how close is too close?; what factors should be contemplated when assessing adjacent operations risk to produce operations? and what mitigation steps would be most effective to reduce risk?

E. Intervention Strategies to Reduce the Risk of Human Pathogens Contaminating Fresh Produce.

Aqueous based wash water disinfectants do not achieve significant reductions in microbial populations of human pathogens on fresh produce. Investigation of alternative non aqueous based disinfectants on produce, such as the use of vapor phase ozone and chlorine dioxide disinfection technologies, warrants further investigation.

4. What measurements should be used to measure progress toward the overarching goal (to minimize foodborne illness associated with fresh produce consumption)? What measures should be used to measure progress toward the individual objectives?

Comment: Standardized metrics and baseline data must be established. It is currently unclear if recent outbreaks associated with consumption of produce are due to lack of compliance with GAPs or if there are deficiencies in GAPs as they are currently formulated. It is imperative that the agency collaborate with industry to accurately establish baseline information regarding compliance to GAPs. Future surveys would then be able to determine the efficacy of the agency's produce action plan and industry outreach efforts.

Secondly, data detailing foodborne illnesses associated with produce consumption must be indexed and standardized to assure that the data that is being reported accurately reflects actual illness incidence data trends and are not simply reporting anomalies due to increased surveillance, improved detection techniques or increased per capita consumption of a specific commodity. Without the ability to accurately quantify foodborne illness and compare data over a prolonged period of time, it will be impossible to accurately measure progress and efficacy of any produce safety action plan tactics that are implemented.

Thirdly, the current draft produce safety action plan puts forth an objective of expanded surveillance of fresh produce for the presence of human pathogens. Human pathogens are found on fresh produce infrequently and in low numbers. Because of this fact increased surveillance or sampling will not best serve the public health goal of reducing foodborne illnesses associated with produce consumption because it is simply an ineffective strategy. One simply cannot sample your way to a safer food supply. The strategy of increased produce sampling or surveillance will also take valuable and limited resources away from research efforts that identify risk factors and mitigation strategies. Increased surveillance is also redundant with current ongoing programs such as the USDA Microbiological Data Program (MDP) that offer little insight as to the actual causes of contamination.

5. Does FDA's current GAPs/GMPs guidance (http://www.foodsafety.gov/~dms/prodguid.html) need to be expanded or otherwise revised? If yes, please describe generally the areas that need expansion or other revision.

Comments: The fresh-cut industry is a unique hybrid industry, half produce industry and half food processing industry that transforms raw agricultural commodities into fresh ready-to-eat food products. The fresh-cut produce industry has had the advantage of building on years of science based food safety expertise and programs such as GMPs and HACCP, which were developed by other food processing industries. This is not the case for raw agricultural commodities that do not have the advantage of building upon long standing food safety programs in agricultural production situations.

Raw agricultural commodity production and postharvest handling practices are not as clearly defined and commonly agreed upon as GMPs and HACCP in the food processing industry. Little scientifically based data exists regarding the risk associated with many of the production and postharvest handling practices commonly used in production agriculture and in postharvest handling situations or what the most effective risk management strategies may be.

It is also clear that food safety programs, which are well defined and function well within the control environs of a food processing plant, may not necessarily be appropriate in production agriculture situations. For example as one moves operations from a confined four walled food processing facility to a three walled packinghouse operation and/or back to an open agricultural growing operation, it is obvious that not all GMP's can be implemented. This is why 21CFR§110.19 specifically exempts raw agricultural commodities from compliance with GMPs. Good Agricultural Practices (GAPs) first formulated in 1998 have been widely implemented by the fresh fruit and vegetable industry to fill this void. GAPs as formulated provide the produce industry an excellent description of broad prescriptive actions that may be taken to enhance produce food safety. However, review and refinement of some specific aspects of GAPs may be warranted as new data regarding intervention strategies and the causes of foodborne illness outbreaks associated with produce consumption becomes available.

6. **In today's production and food preparation environments (farms, packing houses, retail establishments, and consumers), what conditions, practices, or other factors are the principal contributors to contamination of produce with a pathogen? What interventions would reduce, control, or eliminate this contamination?**

Comment: It is currently unclear if recent outbreaks associated with consumption of produce are due to lack of compliance with GAPs or if there are deficiencies in GAPs as they are currently formulated. Therefore, there must be more efficient and effective traceback investigations to more effectively identify and communicate where in the supply chain and what the most likely cause of contamination was. Traceback investigations have yielded no definitive information as to the causes of recent produce associated foodborne illness outbreaks. The inability to clearly identify where contamination occurred and the actual causes of recent foodborne illness outbreaks associated with produce consumption is frustrating to the industry and regulators alike and is a significant hurdle to developing a means of assuring that similar outbreaks do not occur. Without clear science based data which identifies the cause of recent foodborne illnesses associated with produce consumption only speculation and opinion can be used to hypothesize what may have gone wrong.

Recommendations

- It is recommended that the FDA review and revise the agency's "Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations" last revised in April 2001 to more effectively identify the actual causes of foodborne illness outbreaks associated with produce consumption.

- It is also recommended that the agency utilize produce industry experts to assist in trace back investigations to assist in identifying the causes of produce contamination.
- It is recommended that the agency collaborate with industry to harmonize terminology to facilitate communication. Examples include misuse of the terms "processing" when what is really meant is "postharvest handling" of fruits and vegetables. Another example is inaccurate categorization of a wide diversity of products under one category, such as identifying foodborne illness outbreaks associated with spinach and spring mix as "lettuce" associated outbreaks.

7. **There is broad variation within food operations including variations in size of establishments, the nature of the commodity produced, the practices used in production, and the vulnerability of a particular commodity to microbial hazards. How, if at all, should the produce action plan be structured to take into account such variation? For example, should there be different sets of interventions for identifiable segments of the fresh produce industry?**

Comment: In the 1998 "Analysis & Evaluation of Preventive Control Measures for the Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-Cut Produce FDA CFSAN the agency stated that "The diversity of cropping systems, scale of operation, use and design of equipment, regional and local practices, environmental influences, specifics of on-farm soil related factors, and many other production factors defy any attempt to develop an encompassing assignment of microbial risk to commodities or to crop management practices."

Also "Although the available scientific literature is adequate to identify sources of contamination and estimate microbial persistence on plants, the specific influence and interactions among the production environments and crop management practices are not sufficiently understood to provide detailed guidance to growers and shippers. Climate, weather, water quality, soil fertility, pest as well as irrigation, and other management practices are difficult to integrate towards the development and implementation of microbial risk prevention and reduction programs on the farm."

Since 1998, significant efforts have been made by industry and the research community to understand the complex influence and interactions of cropping systems, production practices and handling practices related to produce microbial risk. However, more research and understanding is needed to effectively reduce risk for the myriad of production and handling practices currently employed in the produce industry. Therefore, commodity specific guidance may not be the most effective means of enhancing produce food safety. A supply chain approach which includes everyone in the supply chain that handles fresh produce including growers, packers, processors, distributors, retailers, consumers and food service operators would be more effective as data regarding the risk reduction associated with commodity specific practices may not be available.

8. What roles can and should Federal, State, and local agencies and the food industry play in developing and implementing action items to help achieve the objectives in this action plan?

Comment: It is imperative that the FDA improve communications with industry and consumers to best serve public health goals. First and foremost the fresh produce industry is extraordinarily diverse and complex in the number of products that are handled and the geographic areas from which these products are sourced. It is imperative that the agency directly communicate and engage in dialog with all sectors of the produce industry community including regional produce associations, commodity boards and specialty produce trade associations. The more directly the agency communicates with persons actively involved in industry the more accurate the information that will flow back to the agency regarding current industry practices and procedures.

Agency development of communications protocols that inform consumers quickly of potential foodborne illness outbreaks associated with produce consumption must first and foremost must be done in a manner that accurately informs consumers. While informing the public of a potential health risk in a timely manner is important, it would be alarmist and irresponsible to release unsubstantiated information simply for the sake of expediency. Therefore, we urge the agency to allow for public review and comment regarding the agencies communications protocols to assure that public health is best served and to avoid potentially devastating miscommunications or misinformation.

Recommendations

A) Enhanced Educational Outreach The entire supply chain must enhance educational outreach to the entire produce continuum from field to fork, to facilitate the exchange of the most current and effective produce food safety information and best practices. Education outreach with the latest food safety information is essential to enhancing produce food safety. Specifically more training and educational outreach efforts are needed in the areas of sanitary equipment and facility design, as well as effective employee hygiene training.

B) Review of Statutes and Enforcement - Effective and efficient enforcement of existing laws related to produce food safety is an obvious first step in reducing foodborne illnesses. This should be the first step in lieu of development of new rules or regulations, as new rules that are based on speculation as to the cause of produce related foodborne illness incidence will most likely miss the mark and not achieve their intended purpose of solving the problem.

Secondly, a comprehensive review of conflicting regulations to identify discordant municipal, county, state and federal statutes that increase produce food safety risk and work for their amendment. Two examples of discordant food safety statues are the Endangered Species Act which may force growers to preserve habit for wild animals in close proximity to growing fields or water reclamation statues which require reuse of irrigation water.

9. Are there existing food safety systems or standards (such as international standards) that FDA should consider as part of the agency's development and implementation of a produce safety action plan? Please identify these systems or standards and explain what their consideration might contribute to this effort.

The IFPA and our members have worked diligently and deliberately to enhance the safety of fresh-cut products. Food safety and assuring consumer confidence in fresh-cut produce are top priorities for the fresh-cut produce industry. The IFPA, our associated members and allied produce trade associations wish to work with federal, state and local government agencies to enhance produce food safety and we encourage active collaboration to help assure the delivery of safe and wholesome fresh-cut produce. It is recommended that the agency review current information developed by industry groups, academia and other sources to incorporate the current state of knowledge regarding how to assure produce food safety.
Specifically for fresh-cut produce,

A. <u>Fresh-cut Industry Specific Guidance and Educational Outreach</u>

- "Food Safety Guidelines for the Fresh-cut Produce Industry" published in 2001is the core industry guidance document regarding food safety systems such as Good Agricultural Practices (GAPs), Good Manufacturing Practice (GMPs), Sanitary Standard Operating Procedures (SSOPs), Standard Operating Procedures (SOPs) and Hazard Analysis Critical Control Point (HACCP) plans for the fresh-cut industry. The first edition of this document was published in 1992.
- In 2003, a Spanish language version of the fourth edition of the IFPA "Food Safety Guidelines for the Fresh-cut Produce Industry" was published.
- "IFPA Model Food Allergen Management Plan for the Fresh-cut Produce Industry" was published in 2004 to provide the industry with practical allergen management practices.
- "Packaging Design for Fresh-cut Produce" published in 2003, this document contains an entire chapter addressing produce packaging and food safety interactions, as well as an appendix which provides an "Assessment of the Risk of Botulism Contributed by Modified Atmosphere Packaging of Fresh-cut Produce".
- "Safer Processing of Fresh-cut Produce" video published in 2003.
- University of Georgia/IFPA HACCP Workshop for the Fresh-cut Industry materials.
- University of California/IFPA "Maintaining the quality and safety of fresh-cut products" workshop materials.
- There are also consolidated auditing standards published in 1999 by AIB and numerous IFPA member fresh-cut processors have actively embraced and implemented the USDA QTV (Qualified Through Verification) program.

The fresh-cut produce industry has also not confined its food safety efforts to fresh-cut processing plants but we have actively engaged in outreach to our consumers and our raw agricultural commodity suppliers.

B. Retail and Food Service Guidance

- In 1999, the IFPA in collaboration with the Produce Marketing Association (PMA) published fresh-cut produce handling guidelines for retailers and food service customers.
- In 2004 the IFPA assisted in development of an Association of Food and Drug Officials (AFDO) "Guidance for Processing Fresh-cut Produce in Retail Operations".
- In 2004, the IFPA assisted in development of a retail total food safety management guidance document for fresh-cut produce developed by the Food Marketing Institute (FMI).

C. Raw Agricultural Commodity Guidance

- In 2001 IFPA collaborated with the National Food Processors Association and United Fresh Fruit and Vegetable Association to publish a best practices guidance document for field cored lettuce.
- In 2004 the IFPA is collaborating with the Tri State Consortium (University of California, University of Florida and Texas A&M University) and other leading regional produce trade associations including Western Growers, Florida Fruit and Vegetable and the Texas Produce Association to co-sponsor three Sanitation workshops in California, Florida and Texas. These workshops are focused on addressing sanitation issues related to produce packinghouse, value-added harvest and fresh-cut processing plant operations. The issues covered in these workshops: equipment and facility sanitary design, cleaning and sanitation basic principles, effective employee hygiene training tools and programs and assuring safe water use directly address food safety issues that FDA investigators have identified during traceback investigations as being the most likely cause of produce related foodborne illness outbreaks.

In summary, the IFPA would like to thank the FDA for the opportunity to offer comments. We look forward to working with the agency to develop effective approaches to enhance produce food safety.

Respectfully,

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