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## Produce Marketing Association

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July 21, 2004

Division of Dockets Management  
HFA-305  
U.S. Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

RE: Docket No. 2004N-0258, Produce Safety From Production to  
Consumption, 69 Fed. Reg. 33,393 (June 15, 2004)

Dear Sir or Madam:

The Produce Marketing Association (PMA) is pleased to submit these comments to the Food and Drug Administration (FDA) regarding the proposed produce safety action plan titled: "Produce Safety From Production to Consumption: An Action Plan to Minimize Foodborne Illness Associated with Fresh Produce" (Action Plan). Our comments refer to the Action Plan, <http://www.foodsafety.gov/~dms/fs-toc.html>, and to the questions referenced in 69 Fed. Reg. 33393 (June 15, 2004).

PMA is the largest global not-for-profit trade association representing companies that market fresh fruits and vegetables. Our more than 2,400 members range from grower-shippers and supermarket retailers, to hotel and restaurant chains and overseas importers. Within the United States, PMA members handle more than 90% of fresh produce sold at the consumer level.

PMA's purpose is to sustain and enhance an environment that advances the marketing of produce and related products and services. We also offer consumer outreach through our consumer website, [www.aboutproduce.com](http://www.aboutproduce.com). The association is funded primarily by members' dues, revenues from exhibits, product sales, and meeting registrations. In offering these comments, we want to stress that we are speaking on behalf of the entire fresh produce supply chain, including whole and fresh-cut produce.

PMA and its members are committed to minimizing foodborne illness associated with fresh produce, and we appreciate the opportunity to

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assist FDA in this endeavor. We are responding specifically to the questions raised in the Federal Register notice.

**I. What concepts or underlying principles should guide the 2004 Produce Safety Action Plan? Are the seven objectives in the working draft appropriate for achieving the overarching goal to minimize foodborne illness associated with the consumption of fresh produce?**

We believe that the Action Plan must identify and prioritize the areas of greatest risk in order to achieve the goal of minimizing foodborne illness associated with the consumption of fresh produce. The concepts must be science-based, effective and ensure that any information disseminated to the public does not result in unwarranted food scares. In the Action Plan, FDA recognizes that produce is an "important component of a healthy diet because it is a source of vitamins, minerals, fiber and antioxidants, and it plays an important role in weight management as well." Thus, materials used to educate consumers about safe handling practices should also emphasize the nutritional and health benefits derived from fresh produce to balance the message and encourage produce consumption. We stress that zero risk is not possible with agricultural products that may be handled by all segments of the supply chain, including consumers, and are often prepared and consumed without cooking. Despite that challenge, we are committed to decreasing foodborne illness attributed to produce, and view food safety as a paramount responsibility of the industry.

One important principle that should guide the Action Plan is that outbreaks associated with fresh produce may occur as a result of contamination introduced at any step in the chain, including improper handling in the final preparation. Therefore, we support step four of the first objective that calls for retail sector guidance. Clear worker/consumer safe handling guidance is essential to prevent the contamination of fresh produce. For example, the National Restaurant Association has already developed guidance (the National Restaurant Association's Education Foundation's ServSafe program) which is used extensively in foodservice and by many retailers but can still be further circulated. In addition, FDA may want to further expand the Partnership for Food Safety Education (the Partnership), of which FDA is a government partner. This program seeks to educate consumers on safe food handling, including safe produce handling messages that are due out this fall. We believe that funds should be committed to promote this type of guidance. We also agree with step three of the third objective, which is to raise and maintain consumer awareness about handling fresh produce safely through periodic distribution of information through the media. Industry, government and consumer groups are currently attempting to implement this step through the Partnership, as discussed above.

PMA recommends that FDA and industry review, develop and promote guidance pertaining to fresh produce production. Industry is in the process of developing commodity-specific guidance to address issues of concern and should be allowed to complete this work, utilizing its considerable expertise. In this regard, FDA and industry should discuss which commodities would most benefit from specific guidance, and then have industry develop the guidance.

We understand that FDA has only issued commodity-specific food safety guidance with respect to the production of sprouts. Sprout guidance is unique to that commodity and should not be applied to other commodities. We are unaware of other commodity-specific guidance, but any such existing guidance should be publicized.

We also agree with step four of the third objective that commodity-specific handling advice should be developed and shared with state and local agencies, and communicated to fresh produce preparers in the most effective way possible.

We recommend that the focus of the second objective, which seeks to minimize the public health impact when contamination occurs, be shifted towards trace-backs conducted by FDA rather than on routine testing for pathogens. Testing for pathogens in fresh products is not an effective approach to achieving food safety because pathogens, if present, may be distributed unevenly in products. We believe that FDA resources would be better spent on prevention rather than on surveillance.

We support increasing the speed and accuracy of trace-backs but believe that FDA is in the best position to accomplish this task, particularly in light of its expanded authority under the Bioterrorism Act and implementing regulations.

The second objective also calls for increasing the routine monitoring of all segments of the fresh produce chain. We understand monitoring to mean both testing and inspection. If this is correct, we are unclear what inspection criteria will be applied. FDA should clarify this point. In general, we believe that inspections are an inefficient use of resources because contamination is unlikely to be discovered through an inspection. Particularly given the uncertainty concerning causes of contamination, we advocate an education focus rather than an enforcement mode.

The third objective involves improving communication with consumers regarding foodborne illness outbreaks. We agree with this objective only if and when FDA has accurate information. We support informing consumers promptly when specific, actionable information is available. However, if the information is inaccurate, or not timely, public health may be compromised either because consumers will be deterred from consuming produce, or because they may mistakenly consume contaminated produce. For example, in the case of an alleged strawberry illness outbreak, many consumers purchased raspberries instead, and it was later discovered that raspberries were implicated rather than strawberries. Accordingly, consumers should only be informed that produce is contaminated if based on specific, current, and accurate information.

In addition, the provision to notify the public as "quickly as possible" is an insufficient standard in the event of preliminary information that may be inaccurate. If an outbreak is attributable to a particular batch of a commodity, a wider alert would be counterproductive. Alerts have been issued for "salad items" when only one commodity is associated with an outbreak. Accordingly, we agree that it is beneficial to have a

protocol covering alerts to the public, but believe that the protocol should be instituted through Level 3 Guidance so that industry will have the opportunity to comment.

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

We believe this question is unrealistic because the practices that contribute to contamination of fresh produce by harmful pathogens are often not known. Inconclusive trace-back investigations, due in part to inadequate analytical methods, have hindered efforts to prevent, reduce, or control contamination by implementing corrective measures. A better understanding of pathogen contamination and growth mechanisms is necessary in order to determine the major practices contributing to the contamination of fresh produce, which will in turn enable FDA and industry to develop effective intervention strategies.

We strongly endorse the steps outlined to achieve the fourth objective: the facilitation and support of research. In this regard, we urge that resources be focused on research that addresses the highest risks and the most effective interventions throughout the supply chain, including final preparation. Importantly, research data should be communicated among government, academia and industry, in a timely manner, to maximize the usefulness of key findings and help direct future studies. We intend to keep our members throughout the supply chain informed of relevant studies so that industry can take advantage of new scientific developments. Accordingly, greater knowledge of the causes of contamination must precede the issuance of detailed intervention strategies.

**III. The produce action plan covers fresh fruits and vegetables that have not been heat treated to reduce, control, or eliminate pathogens, or otherwise significantly processed. The draft action plan is not intended to cover frozen fruits and vegetables, fruit and vegetable juices, or other commodities such as tree nuts that are neither fruits nor vegetables and not typically regarded as produce. Should the produce action plan cover additional foods? If so, which foods?**

We believe that FDA should determine whether the Action Plan should cover additional foods.

**IV. 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?**

The Action Plan must cover fresh produce from farm to fork, and progress should be assessed both quantitatively and qualitatively. However, the statistics must be evaluated carefully before reaching conclusions. At this point, it is difficult to determine the extent to which reported cases may be attributable merely to a heightened

awareness of foodborne illness. As the surveillance of foodborne illness increases and analytical methodologies become more sensitive, there may appear to be a greater number of outbreaks which may in fact only reflect enhanced detection. The number of cases, the severity of symptoms, and the identity of the specific produce item should be tracked. After establishing a baseline, such data will provide a valuable means of measuring progress toward the overarching goal of minimizing foodborne illness associated with fresh produce.

Another measure of progress would be to contact virtually all members of industry regarding the adoption of applicable good practices, from farm to retail. While many businesses currently conform to all recommended guidance documents from government agencies and industry associations, some may remain unaware of the importance of implementing comprehensive food safety plans based on established guidance. FDA, state agencies, and industry associations can intensify their efforts to reach all businesses in the supply chain. Wide-spread industry knowledge of guidelines is an important measurement of progress toward the goal of minimizing foodborne illness. Conversely, we do not believe that routine sampling by regulators is a productive use of resources. Research, collaboration on good practices, and outreach should be the primary measures of progress.

**V. Does FDA's current good agricultural practices and good manufacturing practices (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.**

We believe that the current GAPs and GMPs should be reviewed periodically to assess whether any revisions are warranted based on scientific or operational considerations. However, the commodity-specific guidance that industry is drafting will supplement the general guidance to address special concerns, and thus expansion or other revision of the current GAPs/GMPs may not be necessary at this time.

PMA believes that the consistent use of GAPs and GMPs in fresh produce production is extremely effective in preventing, reducing or controlling the contamination of fresh produce with pathogens. Thus, we reiterate that further outreach concerning the current GAPs/GMPs is of critical importance, rather than expansion or other revision. PMA is committed to supporting the Action Plan's efforts to promote GAPs/GMPs in step one of the first objectives. Although we already actively promote the use of GAPs/GMPs, we intend to increase our efforts to heighten awareness of these systems, including enlisting commodity group members to facilitate this goal.

In addition, PMA recommends that buyers require their suppliers to implement GAPs/GMPs or comparable food safety programs, including verification that a particular practice or program is being used. This trend is becoming very prevalent in the industry, which is another means of educating even small businesses about the need for such systems. We do not endorse a specific food safety system because the use of other international standards may be preferable for export purposes.

**VI. 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?**

As stated in response to question II, this question is unrealistic because the conditions, practices and other factors that contribute to contamination are frequently not known. Again, we believe that this question cannot be adequately answered in the absence of research data to be generated pursuant to the fourth objective of the Action Plan.

**VII. 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?**

We urge that variation be taken into account so that the Action Plan is readily applicable regardless of the commodity, the size of the operation, and the type of business. Business must be given the flexibility to apply the principals in a way that will have the most effective impact for that company. The Action Plan should establish outcomes, but provide options for achieving the outcome, as with HACCP plans.

We do not agree with step two of the second objective. Increasing surveillance and sampling of commodities with a history of illness outbreaks will not necessarily minimize the public health impact given the problems inherent in locating pathogens in produce. This step would only be beneficial if trace-backs identified a particular operation as a continuing source of contamination. Thus, we disagree with the proposition that foods associated with problems in the past should necessarily be considered as high risk products. Any actions should only be undertaken when FDA believes that risk will be reduced.

**VIII. 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?**

We recommend that industry, government, and academia collaborate, based on their areas of expertise, to help achieve the objectives of the Action Plan. We agree with the fifth step of the third objective and the second step of the third objective. To prevent, reduce or control contamination of produce, it is essential that all agencies (federal, state and local) with responsibility for public health improve communications among themselves, disseminate accurate and timely information to the public, and deliver consistent messages.

We agree with step four of the second objective to prepare training or guidance for on-farm investigations because there is a need for greater standardization in this area. We also believe that industry should continue to take the lead in developing commodity-specific guidance on issues of concern because of their relevant experience.

**IX. 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.**

We recommend that FDA create guidance and education programs that are consistent with international standards, to the extent possible, in order to facilitate international trade. We also recommend that FDA compile such materials from industry groups to avoid duplicative efforts and to efficiently utilize resources. PMA has an entire web page devoted to food safety, [http://www.pma.com/Template.cfm?Section=Food\\_Safety3&Template=/TaggedPage/TaggedPageDisplay.cfm&TPLID=27&ContentID=3601](http://www.pma.com/Template.cfm?Section=Food_Safety3&Template=/TaggedPage/TaggedPageDisplay.cfm&TPLID=27&ContentID=3601), where members and the public can obtain information including the following: "Temperature Guidelines for Fresh Produce Poster," "Food Industry ISAC Alerts," "Temperature Guidelines Pocket Guide," "Issue Action Center," "Food Safety Education Efforts," "Issue Alerts," "PMA Statement on Pesticide Residues and Produce Safety," as well as links to fact sheets, articles, presentations/handouts, and the latest news. We support the fifth step in the third objective that calls for utilizing the internet to promote ready access to educational materials and would be happy to provide a link to the educational materials on our website.

We agree that FDA should collaborate with international organizations as outlined in step seven of the second objective, but believe that collaboration should extend beyond those countries that export to the United States.

\* \* \*

Thank you for the opportunity to present these comments. We are eager to assist FDA in any way that will facilitate development of the Action Plan. Please do not hesitate to call on us.

Sincerely,

A handwritten signature in black ink, appearing to read "Bryan Silbermann", with a long horizontal line extending to the right.

Bryan Silbermann, CAE  
PMA President