



NFPA
The Food Safety People

July 23, 2004

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

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

Re: Docket No. 2004N-0258; Produce Safety From Production to Consumption: An Action Plan to Minimize Foodborne Illness Associated With Fresh Produce; 69 Federal Register 33393; June 15, 2004

Dear Sir/Madam:

The National Food Processors Association (NFPA) is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers and international office (Bangkok, Thailand), its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical assistance, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

John R. Cady
President and
Chief Executive Officer

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We thank you for providing the opportunity to comment on the important issue of produce safety. Our comments will focus on the questions posed in your Notice in the June 15, 2004 *Federal Register* (69 FR 33393), as well as, the four objectives outlined in your proposed produce safety action plan.

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

For the action plan to be effective in reducing foodborne illness associated with the consumption of fresh produce, it must be based on the accurate determination of underlying risks and the identification of appropriate science-based control measures. Without a clear understanding of what the risks are, any efforts geared toward managing them would likely miss the mark. Furthermore, effective risk management must provide for the prioritization of the identified risks, as well as the associated remedies designed to mitigate them.

In order to further enhance fresh produce safety, the action plan must deal with all aspects of the supply chain, including growing, harvesting, cooling, packing,

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processing, distribution, and point-of-use issues. The objectives outlined in the proposed action plan can be improved upon. They seem to suggest the need for tighter controls of growers/processors, increased surveillance by regulatory agencies, and greater government oversight. Little emphasis is placed on distributors, retailers, food service operators, and consumers and how they potentially contribute to foodborne illness or what role they might play in preventing such illness. By using such an approach, entire segments of the supply chain are ignored and corresponding risks overlooked.

In our opinion, the proposed expanded government surveillance of fresh produce must be focused on the collection of data that are needed for conducting risk assessments. We also recommend that FDA review currently available data on produce safety when determining the need for such surveillance. For example, past surveys conducted by FDA on domestic and imported produce, as well as current sampling programs by USDA, have shown that the prevalence of pathogens on produce is low.

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

Knowledge about the actual modes by which fresh produce becomes contaminated with pathogenic organisms is limited and what is known is often extrapolated from research conducted in the laboratory or under conditions that are not representative of current industry practices. Traceback investigations are often inconclusive as to the cause of a foodborne illness outbreak. Epidemiological data sometimes can shed some light on where product contamination might have taken place. For example, an outbreak that is confined to one location suggests that the point of contamination is located in proximity to the point of use, whereas a multi-state outbreak tends to suggest a source closer to the geographic origin of the produce. However, these data generally will not allow one to pinpoint the exact location of the problem or let one ascertain what practices contributed to the contamination.

Clearly, more research is needed to determine what causes the contamination of produce with pathogens, and what can be done to prevent such contamination. Industry and regulators need to work together to develop research projects that provide answers that are applicable to the reality of how fresh fruits and vegetables are produced and consumed. The steps outlined in the proposed action plan under objective #4 seem to be an appropriate point of embarkation for such a process.

3. *Should the produce action plan cover additional foods? If so, which foods?*

NFPA supports the Agency's intent to limit the scope of the proposed action plan to fresh produce. We certainly agree that further processed commodities, e.g., thermally processed fruits and vegetables, frozen foods, and fruit and vegetable juices, should be excluded.

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?*

Many of the variables pertinent to measuring the goal, e.g., outbreak surveillance, detection methods, per capita consumption of produce, have changed dramatically over the years. These changes have made it exceedingly difficult to accurately and consistently track how the relative incidence of foodborne illness associated with fresh produce has changed. We believe that for the foreseeable future these difficulties will remain a formidable obstacle to the Agency's ability to accurately measure progress toward the stated overarching goal. We also believe the total number of foodborne illnesses attributable to fresh produce, even if this could be accurately determined, should not be the only measure of progress.

As to the issue of how to measure progress toward the individual objectives, each objective will pose different challenges. According to the proposed action plan, Objective #1, *Prevent Contamination of Fresh Produce with Pathogens*, would be mainly achieved by the issuance of and adherence to guidance documents. How such guidance would translate into the prevention of contamination is very difficult, if not impossible, to verify.

As to Objective #2, *Minimize the Public Health Impact when Contamination of Fresh Produce Occurs*, the short shelf life of fresh produce severely hampers the government's ability to take action against violative product after an outbreak. By the time an outbreak is detected and the causative food identified, the remaining product usually will have been consumed or discarded. It is not clear how increased surveillance, sampling and monitoring of produce would change this basic fact. Only significant improvements in the speed of outbreak investigations might enable the Agency to minimize any further public health impact. Such progress could be objectively measured.

As to Objectives #3 and #4, *Improve Communication with Producers, Preparers, and Consumers; Facilitate and Support Research Relevant to Fresh Produce*; progress could be simply measured by comparing the Agency's future actions with the steps outlined under those two objectives. An even better benchmark for the government's outreach efforts would be an assessment of its ability to communicate risks and issues related to fresh produce to the media and the consuming public in a manner that is informative yet does not create unnecessary fears. This will be especially important when it comes to informing consumers of ongoing foodborne illness outbreak investigations.

5. *Do FDA's current GAPs need to be expanded or otherwise revised? If yes, what areas need expanding or revising?*

We do not believe that a revision of the good agricultural practices guidance document is warranted at this time. Judging from some of the testimony presented at the recent FDA public meeting on the proposed action plan, potential problems on the agricultural side of the supply chain may be more the result of the fact that some growers are unaware of the GAPs rather than some intrinsic weakness in the GAPs document itself. We therefore think that the

Agency's resources are better spent on outreach efforts to improve the adoption of the GAPs by the industry than on a lengthy revision process. We also believe it is important to expand outreach programs overseas to ensure that imported fruits and vegetables are produced under GAPs. This may require collaborative efforts with groups such as the U.S. Agency for International Development.

NFPA does not believe that the issuance of commodity-specific guidance will significantly improve produce safety. The GAPs are comprehensive enough to be adaptable to the vast majority of operations in the fresh fruits and vegetables industry. We do acknowledge, however, that FDA was justified in issuing guidelines for the production of sprouts since sprouters are quite different from other types of produce operations, and the food safety problems appear to be linked to a process unique to sprout production.

6. *In today's production and food preparation environments, 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?*

See our comments under question #2.

7. *How, if at all, should the produce action plan be structured to take into account the broad variation within food operations? For example, should there be different sets of interventions for identifiable segments of the fresh produce industry?*

We agree with the Agency in their assessment that the fresh produce industry is exceedingly diverse and complex. As to the question of how specific foods should be covered by the action plan, we urge the Agency to take a risk-based approach. A review of available information on past food safety problems associated with specific produce commodities and an estimate of the public health impact of different types of products should guide the Agency in deciding what foods to focus on in the action plan. For example, the cut and packaged (fresh-cut) produce industry has had a very good food safety record over the last 20 years. Products in this category undergo considerable transformation from their raw state and are considered processed foods.

We do not think that the Agency should focus its limited resources on product categories that have had a proven food safety track record. Instead, FDA should provide guidance and assistance to those segments of the produce industry that could benefit most from such collaboration. In our opinion, the targeted allocation of funds based on risk would help the Agency to better achieve its objectives and provide the greatest public health benefit.

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 of this action plan?*

We believe that government agencies have a definite role to play in assuring the safety of our food supply. We recommend the Agency work closely with the Association of Food and Drug Officials (AFDO) to increase GAPs awareness with growers and instill proper food handling practices throughout the food chain. Producer awareness could also be improved through the various university extension programs if facilitated by FDA. The Agency should also step up its efforts to promote GAPs overseas.

The process of developing guidance documents associated with the action plan should be handled by the Agency in a transparent manner. Industry should be afforded the opportunity to provide input early in the development stages. Such a critical review by industry would make such guidance more meaningful and facilitate the process of achieving the objectives outlined in the action plan.

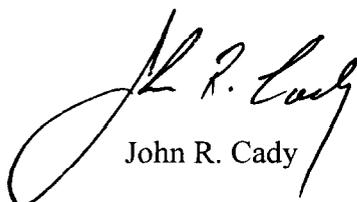
Improvements in the Agency's communications with industry and consumers would be helpful. Informing the consuming public, FDA's public health mandate, and the industry's concerns for due process each must be given appropriate consideration when developing any future protocols for foodborne illness outbreak communications. Public review and comment should be solicited by the Agency during the early development stages of the protocols.

9. *Are there existing food safety systems or standards that FDA should consider as part of the agency's development and implementation of a produce action plan?*

Existing food safety systems or standards cannot be easily applied to produce operations because agricultural enterprises are quite different from most other food industry operations. Therefore, we recommend that the Agency build on the GAPs guidelines when developing future plans to improve produce safety. The GAPs spell out Agency expectations and provide general guidance on how to meet them. The absence of prescriptive requirements affords the industry the flexibility it needs to devise the most appropriate control procedures to comply with the intent of the guidelines. This flexibility, not static standards, will promote the development and use of new technologies and operational controls to further improve the safety of produce.

We would like to thank you again for providing the opportunity to comment on FDA's action plan on produce safety. We look forward to working with the Agency on this important issue.

Regards



John R. Cady