

**CSPI** CENTER  
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PUBLIC INTEREST

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July 21, 2004

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

To Whom It May Concern:

Enclosed are comments submitted by the Center for Science in the Public Interest (CSPI) on the proposed Produce Safety Action Plan, Docket 2004N-0258. We appreciate the opportunity to submit these comments. Thank you.

Sincerely,



Stephen Watkins  
Research Associate  
Program on Food Safety

2004N-0258

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July 21, 2004

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

**Re: Comments on Proposed Produce Safety Action Plan,  
Docket No. 2004N-0258**

On behalf of the Center for Science in the Public Interest (CSPI), we appreciate the opportunity to submit written comments on FDA's proposed Produce Safety Action Plan. CSPI is a nonprofit health advocacy and education organization focused on food safety, nutrition and alcohol issues. CSPI is supported principally by the 890,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants. We accept no government or industry funding.

We support FDA's efforts to improve the safety of fresh produce. In the last month, the FDA has reported illness outbreaks related to *Salmonella* Bovismorbificans in raw alfalfa sprouts and *Cyclospora* in raw basil and mesculin/spring mix salad.<sup>1</sup> The alfalfa outbreak, which caused 12 cases in Oregon and Washington state, is particularly troubling since it is caused by a form of *Salmonella* rarely seen in the United States but capable of causing serious and sometimes fatal

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<sup>1</sup> FDA, FDA Statement, *Sprouters Northwest, Inc. Recalls Raw Alfalfa Sprouts Due to Possible Health Risk* (June 3, 2004), at <http://www.fda.gov/bbs/topics/news/2004/NEW01075.html>; FDA News, *FDA Issues Alert on Foodborne Illness Associated with Certain Basil and Mesculin/Spring Mix Salad Products* (May 21, 2004), at <http://www.fda.gov/bbs/topics/news/2004/NEW01071.html>.

infections in young children, the elderly and those with weakened immune systems.

Contamination of romaine lettuce with *E. coli* O157:H7 has been blamed for three foodborne illness outbreaks reported between July 2002 and October 2003.<sup>2</sup> According to CSPI's database of foodborne illness outbreaks, there have been 428 outbreaks with 23,857 cases linked to produce and produce dishes between 1990 and 2003. In fact, more cases are attributed to produce than any other type of food.<sup>3</sup>

This signals that FDA's current approach – based on a program of voluntary compliance with guidelines, education, and awareness – is not effective in preventing foodborne illness from fresh produce. While the proposed action plan represents a first step toward a comprehensive health-based produce safety program, the plan has major weaknesses. Below we answer some of the questions raised by FDA.

## **I. FDA Should Issue Regulations Requiring Process Control Systems Along the Entire Food Chain**

The FDA has asked whether the principles identified in the Proposed Action Plan are appropriate for achieving the overarching goal of minimizing foodborne illness associated with the consumption of fresh produce. We agree that the first objective – prevention of contamination of fresh produce with pathogens – must be the focal point for the Proposed Action Plan for several reasons: 1) FDA surveys show that samples of fresh produce, such as scallions

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<sup>2</sup> See Dania Akkad, "Local produce linked to *E. coli* outbreaks," *The Salinas Californian* (May 29, 2004), at <http://www.californianonline.com/news/storeis/20040529/localnews/532178.html>. See also FDA, FDA News, *FDA Issues Nationwide Alert to Consumers About Spokane Brand Romaine Lettuce Due to Possible Health Risk* (July 29, 2002).

<sup>3</sup> *Center for Science in the Public Interest, Outbreak Alert!* (Revised and updated – 2004).

and cantaloupes, regularly test positive for human pathogens;<sup>4</sup> 2) pathogens can be internalized in certain fruits and vegetables, particularly during post-harvest handling;<sup>5</sup> and 3) surface treatments, such as washing, have limited effectiveness in reducing microbial populations.

We do not agree, however, that FDA can achieve this objective merely by “promoting” the application of the voluntary Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) and other guidance to fresh produce production as the agency proposes.

Continuing illness outbreaks linked to contaminated produce demonstrate that FDA’s current approach – based on a program of voluntary compliance with guidelines, education, and awareness – is not effective in preventing foodborne illness from fresh produce. The best way to minimize or prevent contamination is through implementation of hazard identification and process control systems. FDA should begin to mandate these systems starting with the highest risk products first – those that have been repeatedly linked to illness outbreaks. To that end, FDA should develop regulations that require growers, processors and others in the fresh produce supply chain to have written plans that identify hazards associated with their product and the steps, interventions, and programs taken to address those hazards. Documentation of procedures is critical to assure that producers and others are doing everything possible to reduce microbial risks associated with their products. Hazard control measures should be based on the best management practices and other guidance developed for various sectors of the produce industry and should apply at all stages of fresh produce production, including growing, harvesting,

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<sup>4</sup> See, e.g., FDA, CFSAN, FDA Survey of Domestic Fresh Product, FY 2000/2001 Field Assignment (Jan. 2003), at <http://vm.cfsan.fda.gov/~dms/prodsu10.html>,” FDA Survey of Imported Fresh Produce, FY 1999 Field Assignment (Jan. 30, 2001), at <http://www.vm.cfsan.fda.gov/~dms/prodsur6.html>.

<sup>5</sup> FDA, CFSAN, *Potential for Infiltration, Survival and Growth of Human Pathogens within Fruits and Vegetables* (Nov. 1999), at <http://vm.cfsan.fda.gov/~comm/juicback.html>.

sorting, packaging, and storage.

The most important benefit of a mandatory regulatory program for the highest risk products is that it would help assure that all growers and processors implement good agricultural practices. While many of the best growers and processors use HACCP-like systems and adhere to good agricultural practices, compliance is far from universal. Indeed, despite the fact that FDA's guidance on minimizing microbial hazards in fresh produce was issued almost five years ago in 1998, many growers and producers still are either unaware of or are not complying with the guidance.<sup>6</sup> For example, in February 2004, FDA was forced to send a letter to firms that grow, pack, or ship fresh lettuce and/or fresh tomatoes reminding them to review their current operations in light of the agency's guidance.<sup>7</sup> Moreover, at the June 29, 2004 public meeting to discuss the proposed Product Action Plan, Dr. Robert Gravani of Cornell University's Food Science Department reported that a Good Agricultural Practices Survey of Farm Workers in New York State showed that approximately 30% of producers were unaware of GAPs for their particular crop.

Mandatory process control systems would force all producers and processors to focus on the hazards associated with their products and have written plans in place to identify where contamination is likely to occur and how to address it. It targets resources to critical areas and reduces risk based on prevention - the first goal of the proposed action plan.

## **II. The Current GAPs Guidance Should be Revised**

The FDA also has raised the question of whether the current GAPs/GMPs guidance

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<sup>6</sup> USDA, FDA, CDC, *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards For Fresh Fruits And Vegetables* (Oct. 26, 1998).

<sup>7</sup> FDA, CFSAN, *Letter to Firms that Grow, Pack, or Ship Fresh Lettuce and Fresh Tomatoes* (Feb. 5, 2004), at <http://www.cfsan.fda.gov/~dms/prodltr.html>.

should be expanded or otherwise revised.<sup>8</sup> As long as the existing voluntary system remains in effect, the fresh produce guidance must be strengthened and clarified. The current guidance frequently lacks specific recommendations on how to identify and address the risks inherent in produce production and is written in language that does little to assure compliance.

*A. The Guidance Should Be Commodity-Specific*

The survival and/or growth of pathogens on fresh produce is influenced by the organism, produce item, and environmental conditions in the field.<sup>9</sup> Because agricultural production practices are diverse, process controls and other practices recommended to minimize microbial contamination will be more effective when applied to a specific commodity. FDA, therefore, should develop a series of GAPs guidance that focus on specific hazards in specific produce and how to control those hazards. The agency should apply the most up-to-date knowledge and make specific recommendations for specific crops, or where they can be grouped into classes, to classes of crops. For example, all fruits grown on and harvested from trees potentially could be grouped into a single class.

FDA could also develop separate guidelines on sanitation, pest control, worker hygiene and training that would be applicable to specific production sectors, such as packers/growers, processors, and those engaged in shipping and handling.

There should be recommendations all along the fresh produce supply chain, from harvest to final distribution. In addition to good agricultural practices and sanitation, the guidance

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<sup>8</sup> 69 Fed. Reg. 33,393, 33,94 (June 15, 2004).

<sup>9</sup> FDA, CFSAN, *Analysis and Evaluation of Preventive Control Measures for the Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-Cut Produce*, Chapter IV, Outbreaks Associated with Fresh and Fresh-Cut Produce. Incidence, Growth, and Survival of Pathogens in Fresh and Fresh-Cut Product (Sept. 30, 2001), at p. 6

should indicate effective temperature controls for the product during storage and distribution as well as state the shelf-life expectancy with a use-by date that minimizes the likelihood that pathogens will grow to elevated levels.

The commodity-specific guidance should focus on the highest risk products first - those that have been linked to repeated outbreaks, such as tomatoes, lettuce, cantaloupes, green onions, herbs, and sprouts. As a starting point for commodity-specific GAPs, FDA could use best practices manuals developed by industry groups, such as that developed for field-cored lettuce.<sup>10</sup>

*B. The Language of the GMPs/GAPs Should be Less Passive and More Direct*

Growers and processors must be made aware that strict adherence to the recommendations is the key to minimizing health risks associated with the presence of pathogens. One of the greatest weaknesses of the current GAPs guidance is the passive language used. Growers should not be asked to “consider” irrigation water quality and use, or “consider” the temperature of wash water for certain produce. Rather, they should be told with specificity which interventions and measures will best control hazards relating to the safety of their particular product. If FDA does not have this specific information, then growers and processors should be advised that they must conduct a facility-specific review to identify the potential hazards in their operations and have written plans that identify hazard controls and interventions. Extension officers and grower association staff should also act as a resource to producers, traveling on-farm to describe risks and how to reduce them. In addition to the GAPs, an effective training program aimed at the level and language of employees should be provided since employees are the first line in prevention of pathogens.

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<sup>10</sup> See National Food Processors Association, International Fresh-cut Product Association, and United Fresh Fruit & Vegetable Association, “FC Lettuce” Best Practices (Apr. 23, 2001).

The FDA also should consider developing checklists that growers and others can use for each stage of evaluation. For instance, to assure that sanitation programs or waste water control programs are developed and followed, FDA should provide a list of necessary procedures and then a check list that can be used as documentation that the procedure has been completed or followed.

Another weakness of the current GAPs guidance is that it offers only minimal guidance in certain areas, such as transportation of fresh produce. A 2000 survey of 71 California fruit and vegetable shippers, who sell products to all regions of the country, demonstrates that transportation sanitation is a problem. Fourteen percent of the shippers reported that the physical condition of the trailer was not sufficiently clean.<sup>11</sup> The same survey reported concerns about maintaining appropriate temperatures in mixed loads.

This portion of the guidance should be revised to give specific advice on proper sanitation, including use of dedicated vehicles, ways to prevent potential cross-contamination and appropriate temperature control during transportation. A potential model are the guidelines for the transportation and distribution of meat, poultry and egg products developed by USDA's Food Safety and Inspection Service (FSIS).<sup>12</sup>

*C. In Addition to Commodity-specific Guidance, FDA Should Develop Industry-wide Guidance for Water and Manure Use*

Contaminated irrigation or washing/processing water is one of the most significant public health concerns. Surface water used to irrigate leaf lettuce was identified as the possible cause of

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<sup>11</sup> California Agricultural Technology Institute, College of Agricultural Sciences and Technology, California State University, Fresno, Center for Agricultural Business, Part VII: *Produce Trucking Perceptions* (2000), at <http://www.cati.csufresno.edu/CAB/rese/99/990301/perceptions.htm>.

<sup>12</sup> FSIS, *FSIS Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry and Egg Products*, 68 Fed. Reg. 45,7889 (Aug. 4, 2003).

a 1995 outbreak of *E. coli* O157:H7 in Montana that sickened at least 29 people.

Direct or indirect contamination from animal or human waste can occur at many points in the fresh produce chain. Pre-harvest contamination can come from irrigation water, improperly composted manure used as fertilizer, human workers, and domestic and wild animals. During processing, contamination may occur from wash water, poor worker hygiene, or improperly cleaned equipment.

The GAPs guidance should go beyond recommendations that growers “be aware of risk factors” and “consider practices that will protect irrigation water quality” and include lists of potential sources of contamination and identify ways to protect against those risks.

Testing irrigation water is one way growers can evaluate the safety of their water. However, because there are no federal irrigation water standards, the GAPs guidance should include appropriate indicators for fecal contamination, identify levels of microbial contamination that are acceptable, and specify testing frequencies, particularly if the water passes near livestock or sewage treatment. To the extent FDA does not have information on these issues, this is an area where FDA should focus its research efforts.

It is also critical that FDA specifically address manure and compost issues for growers. For instance, for composting, the guidance only states that the high temperature will kill most pathogens in a number of days. It does not identify either a minimum temperature or minimum time for composting the manure prior to field application. FDA should require that producers follow the manure compost standards set forth in the National Organic Program as a way to reduce animal pathogens in fresh produce.<sup>13</sup>

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<sup>13</sup> 7 C.F.R. § 205.203(c)(1) (Soil fertility and crop nutrient management practice standard).

### **III. FDA Must Implement A Mandatory Recordkeeping Program to Assure Adequate Tracebacks**

One of the goals of the Proposed Action Plan is to minimize the public health impact when contamination does occur. One way FDA hopes to achieve this is to increase the speed and accuracy of tracebacks.

Speedy and accurate tracebacks depend on adequate documentation and records at all stages of production from harvest through distribution. The problems associated with lack of adequate documentation were demonstrated during a 2002-2003 romaine lettuce outbreak. Since the lettuce was sold under different brand names, the FDA did not have a complete list and was unsure which states had received shipments.<sup>14</sup>

While parts of the produce industry will be required to keep certain records under FDA's recordkeeping rule under the Bioterrorism Act, farms are exempt from this requirement. The FDA should mandate that growers maintain certain records that are critical to the agency's ability to identify the source of potential contamination in the event of an illness outbreak. Such records should include all brand names under which the produce is marketed. For those already subject to FDA recordkeeping requirements, FDA should identify any additional records it needs in order to assure traceability, which could include distribution records, water quality and supply records, temperature control records, equipment maintenance records, and sanitation and pest control records.

Source labeling, maintained along the entire supply chain, could be particularly important where there is product co-mingling or where packers or handlers recycle shipping containers. It

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<sup>14</sup> The Associated Press, *FDA Warns of E. coli-Lettuce Link*, The Seattle Medium (July 31, 2002).

could assist FDA in more quickly identifying a link between a suspect food vehicle and a specific food facility in the event of an illness outbreak.

In addition to requiring certain records, FDA should require that producers, processors, and others have a written traceback program that outlines the procedures the company will implement in the event of a recall. Requiring companies to maintain written traceback plans assures that traceback investigations lead to a specific company or greenhouse rather than an entire commodity. As a result, the economic burden of a recall is not imposed on an entire industry, but only on those responsible for the problem.

Finally, FDA has stated that it will increase focused surveillance and sampling of produce with a history of an association with illness outbreaks. This surveillance should include not only produce with a history of outbreaks but particular facilities that have had problems.

#### **IV. FDA Should Increase Enforcement and Verification of Application of Guidance**

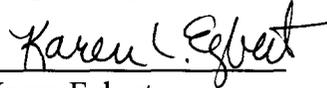
Adoption of mandatory, regulatory requirements is the best way to ensure that producers, processors and others in the fresh produce supply chain address the risks inherent in the production of fresh produce. However, if FDA determines to continue the current voluntary, self-policing system, the Proposed Action Plan should identify how FDA intends to assure produce safety. At a minimum, FDA should specify that it intends to increase inspections, particularly at facilities whose produce has been associated with illness outbreaks, and exercise more rigorous enforcement when adulterated products are sold.

#### **Conclusion**

Foodborne illness outbreaks related to fresh produce are not a minor public health problem. Risk prevention, detection and control measures must be in place at every step of fresh produce production to help ensure food safety risks are minimized. Voluntary guidelines are not

the public health response needed to address the food safety problems cropping up in fruits and vegetables. Ultimately, regulatory requirements for fresh produce would provide the maximum protection for the public. In the absence of regulatory requirements, FDA must strengthen the existing GAPs guidance and improve adherence to this guidance through increased inspections and enforcement.

Respectfully submitted,



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