



Consumer Federation of America

June 8, 2007

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2007N-0051

To Whom It May Concern:

The Consumer Federation of America (CFA) appreciates the opportunity to respond to the Food and Drug Administration's (FDA) request for public comments on the safety of fresh produce (**Docket No. 2007N-0051**). CFA is a nonprofit association of 300 consumer groups, representing more than 50 million Americans, that was established in 1968 to advance the consumer interest through research, education and advocacy.

Introduction

Fruits and vegetables are an important part of a healthy diet and federal nutrition guidelines encourage consumers to eat a variety of fruits and vegetables every day. It is important, however, that produce is free from contamination from foodborne pathogens if consumers are to fully gain the benefits of increased fruit and vegetable consumption. According to the Centers for Disease Control and Prevention, foodborne illness is a serious public health problem. Each year 76 million Americans are sickened by foodborne illness, 325,000 are hospitalized and 5,000 die¹. Increasingly, foodborne illness outbreaks are being linked to fresh produce. According to foodborne illness data compiled from 1990 to 2004 by the Center for Science in the Public Interest, produce has been responsible for 639 outbreaks involving 31,496 cases of illness² during that time period. Over the past several years, foodborne illness outbreaks have been increasingly linked to both domestic and imported produce including green onions, sprouts, melons, berries, tomatoes and leafy greens. Most recently in late 2006 and early 2007, the U.S. experienced several high-profile foodborne illness outbreaks linked to produce.

- In September 2006, a nationwide outbreak of *E. coli* O157:H7 was linked to bagged fresh spinach. The outbreak spread over 26 states and caused 199 cases of illness, including 31 cases of Hemolytic Uremic Syndrome (HUS), 102 hospitalizations and three deaths.

¹ Mead, P.S., et al. 1999. Food Related Death and Illness in the United States. *Emerging Infectious Diseases*, 5(5): 607-625.

² DeWaal, CS, Johnson, K, Bhuiya, F, *Outbreak Alert! Closing the Gaps in Our Federal Food Safety Net*. Center for Science in the Public Interest, updated and revised, December 2006.

- Also in September 2006, a Salmonella outbreak was linked to tomatoes consumed in restaurants across the country. The outbreak reached 21 states and caused 183 cases of illness.
- In November and December 2006, an outbreak of *E. coli* O157:H7 was linked to shredded lettuce served at Taco Bell and Taco John restaurants in eight states, causing 152 illnesses.
- In February 2007, peanut butter was linked to an outbreak of Salmonella, which caused 628 illnesses in 47 states.

These recent outbreaks linked to contaminated produce highlight an ongoing problem in our food safety system that must be addressed. Consumers expect and deserve that the produce they buy and eat is free from foodborne pathogens. These recent outbreaks indicate that not enough is being done by either government or industry to ensure the safety of fresh produce and protect consumers from foodborne illness.

Consumer Confidence Declines

As a result of the recent produce-related outbreaks, consumer confidence in the safety of the food supply has declined. In November 2006, the Food Policy Institute at Rutgers University conducted a telephone survey of 1,200 adults to determine awareness of FDA advisories and recall notices regarding the spinach outbreak and to determine what could be learned for future incidents³. The survey found that most Americans were aware of the spinach recall (87%) but were unclear about some of the details. Some consumers who were aware of the recall even continued to eat fresh spinach (13%) during the recall. Almost one-fifth (18%) of those who were aware of the recall said they stopped buying other bagged produce because of the recall.

The survey also found that consumers were confused about when the recall ended. While most respondents were either eating spinach again (44%) or planning to do so in the future (20%), five percent of those surveyed reported that they were unlikely to eat spinach in the future and an equal percentage would definitely not eat spinach. Additionally, 15 percent said that they would avoid specific brands of spinach and 19 percent said they would avoid spinach grown in particular parts of the country. In January 2007, four months after the *E. coli* O157:H7 outbreak linked to spinach was first announced, spinach sales were still down⁴.

Another survey, conducted by the Food Marketing Institute, a trade association representing food retailers and wholesalers, found consumer confidence in the safety of supermarket food had declined to its lowest point since 1989⁵. The FMI survey of 2,307 adult shoppers reported that the number of consumers “completely” or “somewhat confident” in the safety of supermarket

³Cuite, CL, Condry, SC, Nucci, ML, Hallman, WK, *Public Response to the Contaminated Spinach Recall of 2006*. Food Policy Institute, Rutgers University, February 2007.

⁴ Schmit, J, “E. coli’s long gone, but spinach sales are still hurting,” USA Today, January 29, 2007, at http://www.usatoday.com/money/industries/food/2007-01-29-spinach-usat_x.htm.

⁵ Food Marketing Institute, *U.S. Grocery Shopper Trends 2007*, 2007.

food declined from 82 percent in 2006 to 66 percent in 2007. These safety concerns resulted in consumers not purchasing certain foods, including spinach (71%), lettuce (16%) and bagged salad (9%).

Furthermore, consumer confidence in the ability of the FDA to protect consumers has dropped considerably. The Coalition for a Stronger FDA notes that a recent Harris Poll showed consumer confidence in FDA declined from 61 percent who felt that FDA was doing an excellent or good job in 2000 to only 36 percent in 2006. Moreover, nearly 60 percent thought FDA was doing a fair or poor job. If the FDA is to restore the level of consumer confidence in the Agency, it must respond efficiently and effectively to the problem of produce safety.

FDA Efforts to Address Produce Safety are Insufficient

Historical FDA efforts to address produce safety have consisted mainly of voluntary guidance to the industry. In 1998, the Agency published a set of Good Agricultural Practices (GAPs) for produce growers. In 2004, FDA released a Produce Safety Action Plan to reduce the risk of foodborne illness associated with consuming fresh produce. The plan relied on voluntary guidance to the produce industry for reducing microbial contamination and suggestions for improving communication along the food chain and areas of potential research. In March 2007, the Agency published draft final guidance to Minimize Microbial Food Safety Hazards of Fresh Cut Fruits and Vegetables, again consisting of voluntary guidance.

While many of the suggestions in the Agency's guidance to industry could be useful in reducing microbial contamination of fresh produce, the Agency is very clear that these documents are non-binding, do not have the force of law and are not subject to enforcement. In the FDA's 2007 draft final guidance, the Agency stated:

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations⁶.

The series of outbreaks linked to produce during late 2006 and early 2007 have made it painfully clear that this voluntary approach to ensuring the safety of fresh produce has failed consumers. Indeed, this approach has even failed the produce industry. Both the Produce Marketing Association and United Fresh Produce Association, the main trade associations for the produce industry, came out with statements supporting mandatory federal food safety regulations for produce⁷. As leaders in both the consumer community and the produce industry have noted, voluntary guidance is insufficient to protect consumers from foodborne illness associated with

⁶ Center for Food Safety and Applied Nutrition, "Guide to Minimize Microbial Food Safety Hazards of Fresh Cut Fruits and Vegetables," Food and Drug Administration, March 2007.

⁷ United Fresh Produce Association press release, "United Fresh Produce Association, Produce Marketing Association Endorse Common Principles for Federal Produce Safety Regulatory Oversight", May 23, 2007 at http://www.unitedfresh.org/news/327/United_Fresh_Produce_Association_Produce_Marketing_Association_Endorse_Common_Principles_for_Federal_Produce_Safety_Regulatory_Oversight

fresh produce. Instead, the FDA needs to develop strong mandatory, enforceable food safety regulations to adequately protect consumers and ensure the safety of fresh produce.

Recommendations

FDA has a model it could use to improve produce safety. In 1995, FDA promulgated a final rule requiring firms that produce seafood to develop and maintain HACCP plans to prevent and control microbial contamination. In 2001, FDA published a final HACCP rule for juice producers. These experiences should provide FDA a way forward in developing appropriate regulation to ensure the safety of fresh produce. Produce regulations should be mandatory and enforceable. Uniform standards should be developed by FDA for use of manure, water, hygiene, and sanitation. A uniform system for efficient traceback of products, including identifying information on any packaging, should be developed. Producers and processors should be required to keep a written HACCP plan of how they are monitoring and controlling possible points of contamination in their processes. Finally, on-site audits of each farm and firm should be undertaken at least once per growing season.

It became evident in the wake of the late 2006 outbreaks linked to fresh produce that not enough was really known about how produce can become contaminated with pathogenic bacteria. Little coordinated research was being done on the most effective interventions for controlling pathogens in fresh produce. As a result, definitive answers and solutions to the 2006 outbreaks were difficult to produce. As the federal agency responsible for the regulation of fresh produce, the FDA relies on data-driven research upon which to base their regulatory decisions.

In April 2007, the Produce Marketing Association pledged \$2 million to fund The Center for Produce Safety at the University of California, Davis. The Center will distribute research grants to foster study on how to best reduce pathogenic contamination in fresh fruits and vegetables. This is a highly commendable effort, but significantly more resources need to be focused on produce safety to achieve the desired results and regain consumer confidence. The FDA, especially, needs to be fully involved in these efforts and provide researchers with precise information about where the knowledge gaps lie from their perspective. The FDA should work closely with the produce industry and the research community to support a well-planned and coordinated program of applied research aimed at determining science-based criteria and standards for implementing good agricultural practices in produce.

The current system for ensuring the safety of fresh produce is seriously deficient. The FDA needs to develop strong mandatory, enforceable food safety regulations in order to adequately protect consumers, ensure the safety of fresh produce, and regain consumer confidence in both the Agency and the safety of the food supply.

Sincerely,

Chris Waldrop
Director, Food Policy Institute