<u>Food and Drug Administration: Safety of Fresh Produce Public Hearing</u>
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Written Testimony

The dual mission of FDA is to protect and promote the public health. FDA must place an equal emphasis on both aspects of its mission. FDA has a strong record in protecting the public health. While FDA has focused on this component of its mission, more could be done to promote the public health. Part of promoting the public health is increasing the consumption of fresh produce, which FDA supports.

In March 2004 FDA proposed an action plan to confront the nation's obesity problem. Increasing consumption of fresh fruits and vegetables is a critical element of any plan to reduce the obesity epidemic. In the May-June 2005 publication of FDA's consumer magazine, the article "Healthier Eating" notes the following: "Currently, the typical American diet is low in fruits, vegetables, and whole grains, and high in saturated fat, salt, and sugar. As a result, more Americans than ever are overweight, obese, and at increased risk for chronic diseases such as heart disease, high blood pressure, diabetes, and certain cancers." As part of its recommendations, the article suggests eating a variety of fruits and vegetables. Specifically, the article urges consumers to "get a variety of dark green vegetables such as broccoli, spinach, and greens." The article even points out that "you can buy salad in a bag" to make eating vegetables more convenient.

However, the net effect of the FDA consumer alert in the spinach E. coli outbreak has been to promote the non-consumption of fresh produce. In addition to spinach, many related commodity groups were also affected by the FDA warning. The loss of confidence in these products works against public health by discouraging consumers from increasing their consumption of lettuce and leafy greens, which public health advocates have urged for years as a means of reducing key diet-related illnesses such as heart disease and diabetes.

FDA must take into consideration the impact of public health warnings on the industry being implicated. FDA acted appropriately in its efforts to minimize the public health impact of the spinach E. coli outbreak. However, FDA failed to communicate the actual limited scope of the outbreak to the public. The result was, and continues to be, a widespread lack of consumer confidence in the safety of spinach and related leafy greens.

In its initial alert to the public on September 14, 2006, FDA implicated bagged fresh spinach as a possible cause of the E. coli outbreak associated with the consumption of produce. Based on the available information, FDA issued an advisory that consumers not eat bagged spinach until further notice. Given the uncertainty of the situation, it is understandable why FDA issued such a broadly worded and strongly stated warning to consumers.

However, the follow-up communication with the public had a devastating effect on the spinach industry, and related industries, and has left domestic and international consumers with a lasting uncertainty of whether these products and others can be safely consumed. Even though FDA issued daily updates during the first few weeks of the outbreak advising consumers to avoid spinach, it still has not provided clear, definitive follow-up to ensure consumers that the outbreak is over. This has prevented the industry from communicating to the public that the product in the marketplace can be safely consumed.

In less than one month, FDA had narrowed the scope of the investigation to a four fields associated with spinach that was produced on one day from a single processor. Rather than clearly communicating that the scope of the outbreak was limited, and that the source of the outbreak had been pinpointed, FDA left it to the marketplace to convince consumers of the safety of the product. Recent consumer surveys indicate the high degree of influence that FDA and other government agencies have on public behavior. Consumers look to FDA as the leading authority on the safety of the food supply. Complicating matters was the fact that all of the media attention had created an overarching fear that there was a fundamental breakdown in the safe production and handling of all leafy greens.

The FDA announced its finalized report on the spinach E. coli outbreak over six months after the outbreak began. On March 23, 2007, FDA concluded that "No definitive determination could be made regarding how E. coli O157:H7 pathogens contaminated spinach in this outbreak." At no point during the outbreak or since has FDA communicated closure to the spinach E. coli crisis. As result, many consumers still believe that spinach and other leafy greens are unsafe to eat. Estimates have reached over $100 million in lost revenue for growers and shippers as a result of the spinach E. coli outbreak – and the impact was not just felt in the spinach industry but in related leafy greens industries. Furthermore, there has been a ripple effect felt throughout the economy in farm equipment, inputs, packaging, processing, transportation, marketing, lending, and insurance. The $100 million figure is much higher when related industries are taken into account.

The FDA must acknowledge its role in restoring consumer confidence in the safety of spinach and leafy greens, thereby aiding in the revitalization of the industry. Western Growers and industry partners responded to the spinach E. coli outbreak with the enactment of the California Leafy Greens Handler Marketing Agreement on April 1, 2007. The Marketing Agreement was the quickest regulatory scheme that could be developed in light of the need for tough, uniform leafy greens safety standards in California. As part of the Marketing Agreement, the California leafy greens industry has accepted good agricultural practices that reflect the latest science and technology. Western Growers also supports the development of a federal approach to fresh produce safety regulation.

Clearly, the industry has responded to the call for enhanced food safety measures, and spinach and leafy greens are now safer than ever before. Why is this message not being communicated by FDA and its key representatives? Bob Krauter reported the following in the March 20, 2007, edition of the Capital Press: "Dr. Acheson said given the history of past food borne illness outbreaks, there are no guarantees that food safety efforts on farms and in processing facilities will prevent contamination of fresh produce in 2007. 'Is the food supply any safer today than it was in September? No, I don't believe it is. We are looking at a distinct probability of an outbreak linked to leafy greens in 2007,' he said. 'I hope not, but I am a pragmatist. I would be fooling consumers if I said problems solved, don't worry. Problem is not solved. Understand the relative risk." While we agree that there is no guarantee against another outbreak, even if the California metrics are adhered to by the entire industry, but our actions have clearly reduced the possibility.

Whether intentional (bioterrorism) or unintentional, contamination of a product generates widespread fear in consumers. The result of an outbreak is an erosion of consumer confidence in the safety of the food supply. Following an outbreak, FDA has the responsibility to assist in restoring consumer confidence in the safety of the food supply. FDA has acknowledged this role in relation to its food defense protocols. In its homeland security initiative, FDA recognizes that an attack on the food system could have catastrophic health and economic effects, and identifies its role in restoring confidence in the food supply. FDA's role in instilling consumer confidence in the food supply logically extends to unintentional contamination of products.

FDA has both an opportunity and a responsibility to assist the fresh produce industry in developing and promoting best practices that will minimize the risk of future illnesses associated with fruits and vegetables. FDA should facilitate the development of information and outreach to affected parties on key issues facing the industry so that informed policy decisions can be made.

FDA and the industry must collaborate to minimize the potential for future outbreaks and additional illnesses associated with fresh produce. This is in line with the charge for clear/enhanced communication as embodied in the Produce Safety Action Plan. Examples of these issues include the establishment of microbial standards for foods, the approval of potential kill steps, and the pros and cons of adapting other systems to provide national oversight, such as regulations and model codes.

FDA must extend beyond its efforts to reduce risk in the production and harvest unit operations by calling on other parts of the supply chain, including transportation companies, food service operations, and retailers, to develop their own robust best practices to ensure the safety and integrity of the product they receive, handle, and sell. Also, FDA should strongly discourage buyers from going around producers employing good agricultural practices in favor of a lower cost product.