

SAFE FOOD COALITION

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September 25, 2006

Andrew C. von Eschenbach, M.D.
Acting Commissioner (HF-1)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach,

The undersigned members of the Safe Food Coalition are deeply concerned about the recent outbreak of *E. coli* O157:H7 that has been associated with bagged spinach. To date, 173 people have been sickened, 92 people hospitalized and one person has died as a result of this outbreak, which has spread across 25 states.

We support the Food and Drug Administration's decision to immediately issue a consumer advisory warning consumers not to eat fresh spinach. With such a large outbreak and with little information regarding the source of the outbreak available in the early stages, FDA acted responsibly by erring on the side of public health protection in its communication to consumers. We also appreciate the diligent work of FDA investigators to determine the source of the outbreak over the past week.

We have concerns, however, with how FDA will go forward following this situation. Last year, Dr. Robert Brackett, Director of FDA's Center for Food Safety and Applied Nutrition issued a letter to California firms expressing concern about *E. coli* O157:H7 outbreaks that had been traced to fresh lettuce and urging firms to take appropriate steps to ensure the safety of their products. However, this letter was written after 19 other outbreaks had been linked to lettuce since 1995. Clearly, the lettuce industry had not been conforming to appropriate standards since well before this past year. The most recent outbreak traced to spinach emphasizes the need for more stringent regulations instead of a sternly-worded letter.

The Lettuce Safety Initiative that FDA has been touting is a useful first step but lacks any real force behind its recommendations. It is unclear whether FDA will do anything more than collect data and make assessments on current industry approaches to improving lettuce safety. In addition, FDA has recognized that fresh cut produce, including bagged spinach, is one of the fastest growing sectors of the produce industry. However, FDA's guidance documents for these products do not establish legally enforceable responsibilities. Rather, the Agency provides suggestions and recommendations to producers, yet refuses to take responsibility for protecting the public health. Voluntary

measures may be a useful way to encourage industry participation, but they do little to reassure the public that the food supply is being protected. Instead, mandatory regulations requiring firms that produce fresh produce to maintain strict sanitation levels and appropriate processing standards would go much further in ensuring the safety of the food supply and protecting the public health.

In addition, we support efforts to increase FDA's food safety and field staff to ensure that its regulations can be fully enforced. We urge you to strongly express to the Administration the need for a food safety budget from Congress that addresses this serious public health risk, instead of simply moving staff from one area to another, as the Agency has been doing for some time.

Second, consumers and the FDA would be well-served by the establishment of a comprehensive traceability system able to trace food products from the farm to the table. Individual firms and even industries have established tracking systems for their own products and business concerns, yet this does not create an interlocking web that would allow government regulators to quickly and easily trace the origin of a particular food. In the event of an outbreak, investigators need to respond rapidly to be able to trace an implicated food to its source. Without requiring a comprehensive system for traceability, the FDA is only hindering its own progress and putting the public at risk.

As a coalition of groups who are committed to reducing microbial contamination in the food supply and consequently, the burden of foodborne illness, we urge you to implement stronger regulations in the produce industry and a comprehensive traceability system to ensure that the public is truly protected from the risks of foodborne illness. If the agency does not believe that it has adequate authority to implement the recommended regulations, then we are ready to work with you to urge Congress to provide FDA with the necessary authority.

Sincerely,

Caroline Smith DeWaal
Center for Science in the Public Interest

Chris Waldrop
Consumer Federation of America

Jean Halloran
Consumers Union

Wenonah Hauter
Food & Water Watch

Jacqueline Ostfeld
Government Accountability Project

Alison Rein
National Consumers League

Barb Kowalczyk
Safe Tables Our Priority

Michael J. Wilson
United Food and Commercial Workers International Union

CC: Dr. Robert Brackett, CFSAN