July 3, 2008

Dr. Andrew C. von Eschenbach
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Emergency Regulation Needed in Wake of Ongoing *Salmonella* Investigation

Dear Dr. von Eschenbach:

The weeks-long investigation to uncover the source of the *Salmonella* Saintpaul bacteria that has sickened over 800 consumers in 36 states demonstrates the urgent need for changes in FDA's food safety programs. This massive outbreak might have been prevented if FDA had responded to the numerous produce outbreaks that preceded it. Since 1990, the Center for Science in the Public Interest (CSPI) has tracked over 700 outbreaks of foodborne illness linked to produce items, including two dozen outbreaks linked to tomatoes that caused more than 3,000 illnesses. Today, CSPI and the Consumer Federation of America are resubmitting CSPI's 2006 petition to FDA and urging the FDA to implement emergency regulations requiring source traceability for produce, written food safety plans for farmers, processors, and packinghouses, and tighter controls on repacking.

Traceability

Growers and processors should be required to mark fruits and vegetables to enable easy traceback when produce is implicated in an outbreak. Those marks should be specific enough to extend all the way back to the farm of origin. The ability to identify and quickly remove a contaminated product is vital to protecting public health and the credibility of FDA's food safety program. Information gained from a traceback investigation can help limit an outbreak and help to identify and eliminate conditions that may have contributed to product contamination.

The technology exists to implement effective traceability programs that go beyond the basics of country-of-origin labeling (COOL). While COOL provides a starting point for traceability—and is a program consumers both desire and deserve—it is simply not sufficient to address the gaps in the current traceability system. Effective traceability labeling must encompass the multiple steps along the path from farm to table, including farm-of-origin, packer, distributor, and retailer. Such a system should use a standardized code for all FDA-regulated items to streamline investigations and ensure effective record-keeping by all entities along the production chain.

Written Plans

Fresh fruits and vegetables are at the center of a healthy diet, so it is critical that immediate steps be taken to improve their safety, such as could be provided by an emergency regulation. FDA should require all fruit and vegetable producers, packers, and processors to develop written plans covering their specific operations to identify where contamination is likely to occur and how to prevent it. This approach is appropriate for both large and small growers and

processors. It would allow the agency to target critical areas and reduce risks. Adoption of mandatory requirements is the best way to ensure that growers and others in the produce supply chain address the risks inherent in the production of fresh produce.

Requiring food processors and producers to identify possible hazards and outline a control plan would put clear responsibility on the industry to know the food safety profiles of their products and to have management plans to address those hazards. Such written plans would be the responsibility of the processor or food producer, the entity that knows their processes best. Farmers, for example, know the environmental conditions and weather in the area better than any regulator and therefore should be in the driver's seat when it comes to food safety. But the written plans also would enable the FDA to understand the thinking of those in charge of food production at every factory or farm. Instead of starting from zero with every inspection, FDA could begin with an understanding of the process controls that are in use. If there were gaps in the hazard analysis, those could be pointed out and addressed. If there were failures in the system, they could be understood as being either a failure to execute the written plan, or a failure to fully understand the hazards. Most importantly, more failures could be caught before food gets to the market.

Repacking

The current *Salmonella* investigation has spotlighted the oft-used but rarely discussed industry practice of repacking produce. It is essential that repacking—which may entail the mixing of produce from various farms, states, and even countries before distribution to retailers—maintain the origin information that would be required under a traceability regime. Source data must be maintained on the individual product or, if bound for processing, preserved by the processor, in order to ensure the efficacy and integrity of the system.

Repeated outbreaks linked to fresh produce have drained public confidence in the safety of this important food group. CSPI and CFA have outlined above three areas where FDA must take action to correct deficiencies in the current system for preventing contamination of produce. We call on FDA to implement emergency regulations to prevent future outbreaks requiring source traceability, written food safety plans, and tighter controls on repacking.

Sincerely,

Michael F. Jacobson, Ph.D.
CSPI Executive Director

Caroline Smith DeWaal
CSPI Director, Food Safety

Chris Waldrop
Consumer Federation of America