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July 15, 2008

The Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Leavitt:

For over a month now, since June 3, 2008, the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have been communicating to the public and with the fresh produce industry about an extensive outbreak of *Salmonella* while conducting a trace-back investigation to determine the source of the outbreak. The growing outbreak - with 1,148 persons infected with *Salmonella* Saintpaul to date and with a growing list of suspected fresh produce items - points to the need for better coordination and communication among federal agencies and departments, and with states and industry. Most importantly, the outbreak once again underscores the need for a tracking and trace-back system that is modern, effective, and protects public health. This outbreak has shown that the systems in place at FDA and CDC to track down the source of a contamination event, regardless of whether the contamination is intentional or not, are woefully inadequate. The *Salmonella* outbreak also shows that substantive changes are needed in how FDA and CDC communicate with the public and with industry.

I don't doubt the difficulty of the task or the dedication and hard work of FDA and CDC personnel. There are, however, many questions that need to be answered about this particular investigation, particularly if the source of the contamination is determined to be a product other than tomatoes, the primary suspect in this particular *Salmonella* outbreak. Both the tomato industry and at least one prominent food safety expert have questioned the slow, cumbersome, and potentially erroneous manner in which FDA has been conducting its trace-back investigation. For example, FDA and CDC have not emphasized comparing the origin of food products consumed by individuals who became ill with *Salmonella* Saintpaul and the origin of the same type of food products consumed by individuals who have not become ill from *Salmonella*. This practice of conducting a trace-back investigation of food products consumed by patients who are not sick seems to be one tool commonly used to identify the source of contamination. Why haven't FDA and CDC employed this strategy during their own outbreak investigation? It seems that the scope of the search could have been narrowed down early by better investigation techniques and had a functional trace-back system been in place.

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The inability of FDA and CDC to trace food products from farm to fork has been called into question by the *Salmonella* outbreak. There should have been a better system in place before this outbreak. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires facilities that manufacture, process, pack, transport, distribute, receive, hold, or import food, except for farms and restaurants, to keep records on the immediate previous source and the immediate subsequent recipients of the food to establish a better trace-back process. The implementation of this Act's trace-back requirement, as well as the trace-back techniques used in outbreak investigations, needs to be re-evaluated and improved upon in order for the agencies to conduct efficient and adequate trace-back investigations in the future. It is essential FDA move quickly to establish a strong trace-back system using its authority under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and its other authorities. I believe there is adequate existing FDA authority to implement an effective trace-back system. If FDA lacks authority in any respect to achieve this critical objective, Congress must be advised immediately on what is needed.

The events surrounding the *Salmonella* outbreak demonstrates a startling unfamiliarity with an industry whose safe food production FDA is supposed to oversee. The tomato industry as well as the U.S. Department of Agriculture (USDA) have extensive knowledge and information on harvests, distribution patterns, and retailers that FDA and CDC can tap into in order to speed up trace-back investigations. USDA, the federal department that has the most contact with our nation's agriculture producers, has been woefully underutilized throughout the entire outbreak process. It has been disturbing to witness FDA and CDC choose not to access this readily-available information from USDA or the tomato industry. This was most apparent by FDA's compilation of a list of states and foreign countries that were not implicated in producing tomatoes suspected to be the source of the *Salmonella* outbreak.

If a good share of the tomato supply had been eliminated as a source early on, that would have helped to refocus the search and would have likely sped up solving the mystery, it would have allowed consumers to consume tomatoes and not worry, and would have avoided the enormous losses experienced by tomato growers and distributors. It would seem that FDA and CDC could have easily compiled a list of states and countries where tomatoes were not being harvested at the time of the outbreak. Instead, it was up to all 50 states as well as foreign countries to contact FDA and make a case why they should be on the list of cleared states and foreign countries. Consequently, the process used by FDA to determine which states were not the source of contaminated tomatoes seemed to be a subjective determination based on the ability of the state or country to contact FDA and make the case why that state or foreign country should be declared as a safe tomato producing region for purposes of the *Salmonella* outbreak. The manner in which this list was compiled is contrary to a logical investigation where decisions are based on objective information, and where FDA automatically could have ruled out all states that were not harvesting tomatoes during the outbreak.

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Another point that highlights the need for better communications from FDA and CDC is the continued warnings against tomato consumption. It seems highly unlikely that tomatoes harvested in April would still be consumed fresh by consumers in late June. It does not make sense why there remains a strong warning against eating certain fresh tomatoes when most states have been cleared by FDA as having produced tomatoes not implicated in the *Salmonella* outbreak. The warning could be stated in a clearer fashion to assure customers that most tomatoes are safe to eat and are not part of the *Salmonella* outbreak. FDA and CDC have also failed to clearly inform consumers and retailers that only a fraction of fresh tomatoes were suspect and that many varieties were safe to eat as were all tomatoes from some states. Large restaurant chains, such as McDonald's, discontinued all tomato purchases needlessly, since there were and still are plenty of tomatoes cleared of any implication of *Salmonella* contamination. The agencies should have provided clearer information to tomato retailers since some retailers' complete ban on tomatoes added immensely to consumer misinformation. FDA and CDC should have also provided stronger, publicly-available guidelines to tomato retailers about which tomatoes to sell in order for consumers to know that retailers were not serving tomatoes not approved by the FDA.

FDA and CDC need to take measures immediately to improve their ability to trace-back products and to improve communications with the public and industry. The federal government has been cautioned numerous times in recent years about the potential threats that exist for intentional and non-intentional contamination of the food supply. If we do not have adequate trace-back and communications, the damage to public health and to industry in a future outbreak event can be much more devastating than the current *Salmonella* outbreak. It is clear that stronger prevention measures of food-borne illness outbreaks are needed, but this particular outbreak shows that our response system is in sore need of improvements as well.

I appreciate your attention to these pressing questions and I look forward to your response.

Sincerely,



Tom Harkin
Chairman

cc: Dr. Andrew von Eschenbach, Commissioner, Food and Drug Administration
Dr. Julie Gerberding, Director, Centers for Disease control and Prevention
The Honorable Ed Schafer, Secretary, U.S. Department of Agriculture