October 25, 2006

Governor Arnold Schwarzenegger
State Capitol Building
Sacramento, CA 95814

Sandra Shewry, Director
California Department of Health Services
1501 Capitol Avenue, Suite 6001
MS 0000
Sacramento, CA 95814

RE: PETITION FOR REGULATIONS TO ADDRESS PRODUCE SAFETY

Dear Governor Schwarzenegger and Director Shewry:

On behalf of the Center for Science in the Public Interest (CSPI) and our 900,000 subscribers to Nutrition Action HealthLetter, including 98,000 from California, I urge you to take immediate action to issue standards and regulations to govern the production of fresh fruits and vegetables in California. These regulations are clearly needed in the wake of the E. coli O157:H7 outbreak in spinach that sickened over 200 people in 26 states and resulted in at least three deaths. Many other similar outbreaks have been traced to California produce, so delaying the development and implementation of enforceable standards would only risk more unnecessary illnesses and deaths. Specifically, CSPI urges the State of California to develop mandatory regulations and auditing programs for produce growers and processors to reduce the likelihood of microbial contamination.

1. Produce outbreaks are increasing in frequency

The Center for Disease Control and Prevention (CDC) estimates that 76 million Americans get sick and 5,000 die from foodborne hazards each year in the United States. Many health-conscious Americans consume fresh produce as part of a balanced diet. But in the last decade the number of foodborne illnesses associated with fresh fruits and vegetables has doubled in the United States. According to CSPI’s database of foodborne illness outbreaks, there have been 639 outbreaks with nearly 31,500 cases linked to produce and produce dishes between 1990 and 2004. In fact, produce is responsible for more cases linked to outbreaks than any other specific food type and the size of each outbreak is larger, thus affecting more people.¹

In recent years, a variety of pathogens have been implicated in produce outbreaks. Salmonella illnesses have been traced back to lettuce, salads, melons, sprouts, tomatoes, and other fruit- and vegetable-containing dishes.² ³ ⁴ Numerous outbreaks have also been traced to E. coli 0157:H7. In addition to the recent spinach outbreak, this devastating pathogen has also been linked to at least 35 other produce outbreaks between 1990 and 2004, traced to lettuce, salads,
melons, sprouts, and spinach. Between the years 1998 and 2003, California consumers endured six *E. coli* 0157:H7 produce outbreaks, with 96 illnesses.

Emergency action is especially warranted to address problems with lettuce and spinach grown in California as these products have been implicated in 19 foodborne illness outbreaks since 1995, eight of which were linked directly to products grown in from Salinas, California.\(^5,6\)

![Graph showing number of produce outbreaks from 1990 to 2004.](image)

*Source: Center for Science in the Public Interest, *Outbreak Alert!* (Revised and updated – 2006)*.

2. **California’s Department of Health Services has not sufficiently addressed on-farm sources of produce contamination**

The surfaces of fresh fruits and vegetables can become contaminated with pathogenic microorganisms that are present in fields and orchards. One major source of contamination is manure. In fact, 30 percent of the produce outbreaks identified by CSPI were caused by pathogens commonly found in food animals and poultry. This clearly played a role in the 2006 spinach outbreak, as samples of cattle feces found near one of the fields that produced contaminated spinach matched the genetic pattern of the strain of *E. coli* found in the people who became ill.

On the farm, other potential contamination avenues include contact with contaminated water, lack of sanitation and handwashing facilities for field workers, and unclean containers and tools used in harvesting and packing. Over the past decade, the federal government has focused on reducing foodborne illness from all sources. Despite these efforts, foodborne outbreaks associated with fresh produce persist at a high rate. Given the importance of produce consumption and its central role in a healthy diet, it is imperative that California take concrete steps to reduce the incidence of foodborne illness cases associated with fresh produce.

California’s reliance on voluntary compliance with guidelines, education, and awareness has not been effective in preventing foodborne illness from fresh produce. The best way to minimize or prevent contamination is through implementation of hazard identification and process control systems. California should mandate these systems starting with the highest risk products first – like leafy green vegetables that have been repeatedly linked to illness outbreaks.

Regulations should require growers and processors in the produce supply chain to have written plans that identify hazards associated with their products and the steps, interventions, and programs taken to address those hazards. Documentation of procedures is critical to assure that
producers and processors are doing everything possible to reduce microbial risks associated with fresh and fresh-cut fruits and vegetables. Third-party auditing based on consistent standards can play an important role in helping California to monitor that the regulations are being fully enforced. Auditors should be subject to state oversight and approval to ensure that they provide consistently high services.

Hazard control programs should be based on the best management practices developed for various sectors of the produce industry together with other guidance codes, adopted by the federal FDA, and the World Health Organization. These programs should address all stages of fresh produce production, including growing, harvesting, sorting, processing, packaging, and storage.

The most important benefit of a mandatory regulatory program is that it would assure that all growers and processors implement good agricultural practices. While many of the best growers and processors use HACCP-like systems and adhere to good agricultural practices, compliance is clearly not universal.7

3. **On-farm regulations are needed to address sources of produce contamination**

The State of California should not wait for the federal government to take action. Mandatory hazard control programs for farms and fruit and vegetable processors should address the following areas:

**Manure:**
The grower must manage the application of manure to ensure that it does not contribute to the contamination of crops, including limitations on the times when and the crops where it may be applied. The use of raw manure on produce during the growing season should be prohibited. See 5 CFR Part 205.203(c) for manure application requirements under the National Organic Program.8 Composting should be monitored to ensure effective controls are used to destroy pathogens. Domestic animals should be excluded from fields and orchards during the growing and harvesting season and growing areas should have wildlife deterrents. Farmers and producers should ensure animal waste from adjacent fields, pastures, or waste storage facilities do not contaminate growing areas. Manure treatment and storage sites close to fresh produce fields increase the risk of contamination and the state should require livestock producers to move or otherwise control these sites.

**Water:**
Growers should ensure that the water supply used for irrigation and in food processing plants is suitable for its intended use. The internationally agreed-upon Codex Code of Hygienic Practice for Fresh Fruits and Vegetables Processors says that growers should assess the microbial and chemical quality of the water used in primary production.9 Vegetable processors should use only potable water in the processing facility for cleaning or sanitizing the facility and equipment, and for processing. Facilities should have an environmental monitoring program that includes sampling for pathogens to detect areas of harborage and to verify the effectiveness of cleaning and sanitizing programs in preventing cross-contamination. Sanitizers used for washing vegetables should be
approved by FDA and continuously monitored by the facility to ensure they remain at effective levels in the wash water. If effective sampling programs can be developed, water used for washing produce should be monitored for the presence of pathogens at a rate adequate to ensure highly contaminated batches are identified and either destroyed or sent for further processing.

**Hygiene:**
Growers and processors should ensure that employees have close access to bathrooms and that handwashing facilities are visible to supervisors. Employees with direct and indirect access to the production areas should be trained in preventive controls that will help to eliminate or minimize contamination of produce.

**Sanitation:**
Processors should establish mandatory sanitation standard operating procedures, including cleaning procedures for equipment, storage areas, air systems, and water storage areas. Facilities should be designed to facilitate maintenance and good sanitation practices so that contamination may be controlled throughout receiving, cooling, processing, packing, and storage operations. There should be limited access to the facility and to its processing areas; adequate space for operations; adequate drainage of processing and wash water; food contact surfaces that are easy to clean and maintain; and areas and structures designed to protect the product and equipment from contamination.

**Traceback:**
Processors should mark packaging to ensure easy traceback when fruits and vegetables are implicated in an outbreak. Package markings should be specific enough to extend all the way back to the farm/farms of origin. The ability to identify the source of a product is a critical component of food safety programs intended to prevent the occurrence of microbial contamination. Information gained from a traceback investigation can help limit the impact of an outbreak of foodborne illness and help to identify and eliminate conditions that may have contributed to product contamination.

**Conclusion**

Fresh fruits and vegetables are at the center of a healthy diet, so it is critical that steps are taken to improve their safety. California should consider emergency regulations requiring all fruit and vegetable producers and processors to focus on the hazards associated with their products and have written plans in place to identify where contamination is likely to occur and how to address it. This approach is appropriate for both large and small growers and processors. It targets resources to critical areas and reduces risk by using prevention. Adoption of mandatory, regulatory requirements is the best way to ensure that growers and in the produce supply chain address the risks inherent in the production of fresh produce.

California should also regularly conduct inspections of farm fields and facilities that process fresh-cut produce, oversee audits, and exercise more rigorous enforcement including product seizure and criminal sanctions whenever adulterated products are sold.
Foodborne illness outbreaks related to fresh produce are a major public health problem. Risk prevention, detection and control measures must be in place at every step of fresh produce production to help minimize food safety risks. Voluntary guidelines are not an effective public health response to address the food safety problems cropping up in fruits and vegetables.

As governor and as the chief public health officer in California, it is incumbent upon you to act now both to protect consumers and the California produce industry. These illnesses and deaths are entirely preventable. CSPI urges you to develop and implement mandatory regulations for the California produce industry that address the issues we have outlined to ensure a safer food supply.

Sincerely,

Caroline Smith DeWaal
Director, Food Safety
Center for Science in the Public Interest

1 Center for Science in the Public Interest, Outbreak Alert! (Revised and updated – 2006).
2 In 2004, there were three separate outbreaks involving 561 Salmonella infections that were linked to contaminated Roma tomatoes. CDC, Outbreaks of Salmonella Infections Associated with Eating Roma Tomatoes — United States and Canada, 2004, (May 2, 2006), at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5413a1.htm.
6 In October 2005, at least 17 people became sick from E. coli 0157:H7 after consuming Dole bagged salads. In 2003, an outbreak related to pre-washed spinach caused illness in 13 residents of a retirement home in California, resulting in the deaths of two people.