State of California—Health and Human Services Agency
Department of Health Services

California Department of Health Services

SANDRA SHEWRY
Director

ARNOLD SCHWARZENEGGER
Governor

January 25, 2006

Mr. Tom Nassif, President
Western Growers Association
17620 Fitch Street
Irvine, CA 92614

Dear Mr. Nassif:

As the State Public Health Officer for California, I have no responsibility more important than protecting the health of consumers and ensuring the safety of products produced in California. The outbreaks and illnesses associated with lettuce from the Salinas area are of concern to the California Department of Health Services (CDHS). Infection with E. coli *0157:H7* can result in significant adverse outcomes such as Hemolytic Uremic Syndrome, and occasionally death, in the very young. CDHS Director, Sandra Shewry, and I recently met with Dr. Robert Brackett of the U.S. Food and Drug Administration (FDA) on this issue. At this meeting, we discussed our mutual concerns on this topic and we relayed our strong support for the issues identified in the recent letter from FDA to the California lettuce industry (enclosed) and for the areas FDA identified for immediate actions.

Following this discussion between FDA and CDHS, the California lettuce industry convened a meeting in Salinas to which FDA and CDHS representatives were invited. I understand these meetings were productive, as were recent initial discussions with the Western Institute for Food Safety and Security Lettuce Steering Committee. However, we strongly urge you as an industry to take immediate steps in the four areas outlined in the FDA letter to ensure the safety of this product. In addition to the steps identified in the recent FDA letter, I am directing staff to work with appropriate state, federal, and local agencies to determine what additional regulatory actions may be necessary. These measures may include:

- A reassessment of current manure composting regulations to see if revisions are needed in light of recent scientific findings;
- An assessment of the adequacy and enforcement of local, regional, and state environmental statutes and regulations that address areas such as septic tank systems that may leak and/or flow into agricultural ditches or creeks bordering fields used to grow ready-to-eat produce;

1501 Capitol Avenue, Suite 6001, MS 0000 • P.O. Box 997413 • Sacramento, CA 95899-7413
(916) 440-7400 • (916) 440-7404 FAX • Internet address: www.dhs.ca.gov

- An assessment of enforcement of state and federal statutes regarding farm worker access to portable toilets and hand washing facilities;
- An assessment of the locations of fields known to flood frequently and whether these growers should be advised to plant non ready-to-eat crops in these locations; and
- An assessment of the need for additional statutes or regulations such as mandatory Good Agricultural Practices and/or mandatory Hazardous Analysis Critical Control Point for fresh cut produce processors.

Our efforts with other industries to address recurrent food safety problems, such as in the California raw almond industry, have resulted in a commitment by the industry to take ownership of the problem, identify both short term and long term research plans, commit funding for these research priorities, and develop and implement effective mitigation steps at the appropriate growing or processing level.

CDHS is available to work with your industry in addressing food safety issues in your product. If you have any questions or need additional information, please contact Dr. Larry Barrett, Chief, Division of Food, Drug, and Radiation Safety, at (916) 440-7880.

Sincerely,

Mark B. Horton, MD, MSPH
State Public Health Officer

Enclosure

cc: See Next Page

cc: Kevin Reilly, D.V.M., M.P.V.M.
Deputy Director
Prevention Services
California Department of Health Services
MS 7000
P.O. Box 997413
Sacramento, CA 95899-7413

Larry Barrett, D.V.M., M.S., DACVPM, Chief
Division of Food, Drug, and Radiation Safety
California Department of Health Services
MS 7600
P.O. Box 997413
Sacramento, CA 95899-7413

Jeff Farrar, D.V.M., M.P.H., Ph.D., Chief
Food Safety Section
Food and Drug Branch
California Department of Health Services
MS 7602
P.O. Box 997413
Sacramento, CA 95899-7413

Robert E. Brackett, Ph.D.
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
5600 Fishers Lane
Rockville, MD 20857

Ms. Barbara Cassens
District Director
U.S. Food and Drug Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070

Hugh F. Stallworth, M.D., M.P.H.
Monterey County Health Officer
1270 Natividad Road, #B304
Salinas, CA 93906

U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

CFSAN/Office of Plant and Dairy Foods
November 4, 2005

Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce

This letter is intended to make you aware of the Food and Drug Administration's (FDA's) serious concern with the continuing outbreaks of foodborne illness associated with the consumption of fresh and fresh-cut lettuce and other leafy greens. We also outline below what we plan to do and the actions that we expect your industry will take to enhance the safety of these products.

FDA is aware of 18 outbreaks of foodborne illness since 1995 caused by *Escherichia coli* O157:H7 for which fresh or fresh-cut lettuce was implicated as the outbreak vehicle. In one additional case, fresh-cut spinach was implicated. These 19 outbreaks account for approximately 409 reported cases of illness and two deaths. Although tracebacks to growers were not completed in all 19 outbreak investigations, completed traceback investigations of eight of the outbreaks associated with lettuce and spinach, including the most recent lettuce outbreak in Minnesota, were traced back to Salinas, California.

Because these products are commonly consumed in their raw state without processing to reduce or eliminate pathogens, the manner in which they are grown, harvested, packed, processed, and distributed is crucial to ensuring that microbial contamination is minimized, thereby reducing the risk of illness to consumers. In 1998, the FDA issued guidance to industry entitled "Guide to Minimize Microbial Food Safety Hazards for Fruits and Vegetables." This Guide recommends good agricultural practices (GAPs) and good manufacturing practices (GMPs) that growers, packers, and shippers may undertake to address common risk factors in their operations, and thereby minimize food safety hazards potentially associated with fresh produce.

On February 5, 2004, FDA issued a letter to the lettuce and tomato industries to make them aware of our concerns regarding continuing outbreaks associated with these two commodities and to encourage these industries to review their practices in light of FDA's GAPs/GMPs guidance and other available guidance.

In view of continuing outbreaks associated with fresh and fresh-cut lettuce and other leafy greens, particularly from California, we are issuing this second letter to reiterate our concerns and to strongly encourage firms in your industry to review their current operations in light of the agency's guidance for minimizing microbial food safety hazards in fresh fruits and vegetables, as well as other available information regarding the reduction or elimination of pathogens on fresh produce. We encourage firms to consider modifying their operations accordingly to ensure that they are taking the appropriate measures to provide a safe product to the consumer. We recommend that firms from the farm level through the distribution level undertake these steps.

Foodborne illness investigations rarely pinpoint the point of origin of the contamination. However, claims that "we cannot take action until we know the cause" are unacceptable. We believe that there are actions that can and should be undertaken immediately to address this issue. For example, at least some outbreaks may be related to contamination that may have occurred in the production environment. In June 2004, the California Department of Health Services, Food and Drug Branch (CDHS-FDB) initiated multi-agency, collaborative research aimed at identifying the environmental reservoirs for *E. coli* O157:H7, and understanding how lettuce may become contaminated. In a preliminary report presented at the August 2005 annual meeting of the International Association for Food Protection, *E. coli* O157:H7 was isolated from sediment in an irrigation canal bordering a ranch that had been identified in three separate outbreaks. The ranch is bowl-shaped; it sits upon a drained lake, and is highly susceptible to localized flooding. Expanded sampling in the Santa Rita Creek and the Salinas Valley area indicate that creeks and rivers in the Salinas watershed are contaminated periodically with *E. coli* O157:H7. The specific source of contamination that led to the outbreaks was not identified. However, several possible sources of contamination were identified, both on the ranch initially studied and upstream. Although it is unlikely that contamination in all 19 outbreaks was caused by flooding from agricultural water sources, we would like to take this opportunity to clarify that FDA considers ready to eat crops (such as lettuce) that have been in contact with flood waters to be adulterated due to potential exposure to sewage, animal waste, heavy metals, pathogenic microorganisms, or other contaminants. FDA is not aware of any method of reconditioning these crops that will provide a reasonable assurance of safety for human food use or otherwise bring them into compliance with the law. Therefore, FDA recommends that such crops be excluded from the human food supply and disposed of in a manner that ensures they do not contaminate unaffected crops during harvesting, storage, or distribution. Adulterated food may be subject to seizure under the Federal Food, Drug, and Cosmetic Act, and those responsible for its introduction or delivery for introduction into interstate commerce may be enjoined from continuing to do so or prosecuted for having done so.

We have worked in partnership with the fresh produce industry in the U.S. and abroad since the release of our GAPs/GMPs guidance in 1998 to promote our recommendations and to advance the scientific knowledge applicable to enhancing the safety of fresh fruits and vegetables. We recognize and appreciate the efforts that academia and some industry members have taken to date to provide fresh produce that is safe to consumers, and we are confident that you will continue to work proactively to pursue this goal. However, we are also aware that efforts by the CDHS over the last three years to engage the lettuce industry have not yet resulted in a comprehensive, collaborative plan to address the issue of *E. coli* O157:H7 in lettuce. In light of continuing outbreaks, it is clear that more needs to be done.

On October 18, 2004, FDA posted our 2004 Produce Safety Action Plan. FDA developed the 2004 Produce Safety Action Plan to minimize further foodborne illness associated with the consumption of fresh produce following comments from a public meeting and subsequent written comments. This Action Plan is designed to incorporate "lessons learned" in implementing the 1998 GAPs/GMPs guidance and expand on existing produce food safety programs.

There are four general objectives set out in the Action Plan: prevent contamination of fresh produce; minimize the public health impact when contamination occurs; improve communication between all parties; and facilitate research relevant to the contamination of fresh produce. For each objective, the plan identifies steps or actions by the industry as well as regulators that could contribute to the achievement of the objectives. We believe that many of the steps set out in the Action Plan are relevant to the goal of reducing foodborne illness caused

by *E. coli* O157:H7 associated with lettuce and leafy greens.

Consistent with the Action Plan, we strongly encourage your industry to begin or intensify immediately efforts such as, but not limited to, the following:

- Communication - actively participate in dialog with FDA, California Department of Health Services and the California Department of Food and Agriculture (CDFA), academia, and other industry partners to ensure widespread, active participation and support of activities to address the issue of *E. coli* O157:H7 contamination of lettuce and leafy greens; develop an industry action plan with tangible measures of progress;
- Guidance - expedite completion of the industry-led lettuce and leafy green-specific supply chain guidance. (We recommend that this guidance include what to do if crops are flooded.);
- Outreach - promote implementation of the lettuce and leafy green supply chain guidance and other best practice recommendations; and
- Research - establish a coalition to identify critical, risk based research, including research to address environmental reservoirs for *E. coli* O157:H7; provide adequate support for such research to ensure it is conducted; and facilitate technology transfer of research findings.

FDA stands ready to continue to engage and assist in these endeavors. FDA will soon publish a draft guidance for the fresh-cut industry, which guidance we believe may be helpful to your industry.

We intend to meet with the California Director of Health Services and Secretary of Food and Agriculture in the near future regarding this ongoing public health problem to explore ways we can work together to prevent future outbreaks. Together with CDHS and CDFA, we also intend to meet with the lettuce and leafy greens industry in the near future to engage the industry to prevent further outbreaks.

As you are aware, food produced under insanitary conditions whereby it may be rendered injurious to health is adulterated under § 402(a)(4) of the Federal Food, Drug, and Cosmetic Act ((21 U.S.C. 342(a)(4)). FDA is investigating regulatory options and will consider enforcement actions against firms and farms that grow, pack, or process fresh lettuce and leafy greens under such insanitary conditions.

Sincerely,

Robert E. Brackett, Ph.D.
Director
Center for Food Safety and Applied Nutrition

cc: A.G. Kawamura, Secretary, California Department of Food and Agriculture
Sandra Shewry, Director, California Department of Health Services