Re: Comments on Handling Regulations for Leafy Greens Under the Agricultural Marketing Agreement Act of 1937 (Docket No. AMS-FV-07-0090; FV07-962-1 AN)

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the Agricultural Marketing Service (AMS) proposed rulemaking regarding the establishment of a marketing program to address the handling of fresh and fresh-cut leafy green vegetables. CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by the 900,000 subscribers to its Nutrition Action Healthletter and by foundation grants.

I. Background

Foodborne illness outbreaks related to fresh produce are a major public health problem. According to CSPI’s database of 5,000 foodborne illness outbreaks, fruits and vegetables caused 13 percent (639) of outbreaks with an identified food and pathogen and nearly 21 percent (31,496) of the associated illnesses between 1990 and 2004. Norovirus, Salmonella and E. coli 0157:H7 illnesses have been traced to a wide variety of produce, including lettuce, salads,
melons, sprouts, tomatoes, and many fruit- and vegetable-containing dishes. In fact, foodborne illnesses from these produce outbreaks surpassed those from all other foods, including beef, chicken and seafood. The average size of these outbreaks is larger than outbreaks from other foods, thus affecting more people.

A series of produce outbreaks in the fall of 2006 was a wake up call for the public about the critical state of produce safety. Beginning in August, a nationwide outbreak of *E. coli* 0157:H7 from bagged fresh spinach sickened 205 and killed at least three. Then in late September, *Salmonella* found in tomatoes sickened 183 restaurant patrons in 21 states throughout the nation. *E. coli* O157:H7 appeared in produce once more before the year’s end when two separate incidents of contaminated shredded iceberg lettuce sickened a total of 152 individuals at chain restaurants Taco Bell and Taco John.

While many produce outbreaks occurred prior to 2006, the spinach outbreak provided the smoking gun that sourced the cause all the way to the farm. The Food and Drug Administration (FDA) traced the exact strain of the *E. coli* bacteria to a California spinach farm, finding it in nearby manure piles, in a creek and even in a wild pig. These findings definitively proved that the *E. coli* contamination that sickened so many people started right on the farm.

While the produce outbreaks of fall 2006 have triggered a wake-up call for produce safety, large-scale produce outbreaks are not a new phenomenon in this country. Outbreaks from produce, both imported and domestic, have resulted in deaths, illnesses, both mild and severe,

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1 Center for Science in the Public Interest, *Outbreak Alert!* (Revised and updated – 2006). This database of foodborne illness outbreaks is maintained by CSPI. It contains 15 years of data, from 1990–2004. Outbreaks are classified by both food vehicle and disease-causing agent. Food is classified by which agency regulates the product. During the years 1990 – 2004, there were 3,323 foodborne illness outbreaks from FDA-regulated foods (e.g. seafood, produce, eggs, milk); USDA regulated-foods (e.g. beef, poultry, pork) caused 1,344 outbreaks.


and great market disruptions. Domestic produce is largely unregulated, and regulatory agencies have done little more than coax, request, and warn producers to improve produce safety.

- In February 2004, following fourteen outbreaks linked to lettuce and tomatoes, FDA sent a letter to firms that grow, pack, or ship fresh lettuce and/or fresh tomatoes asking them to review their current operations in light of the agency’s guidance.\(^4\)

- After seeing 18 outbreaks since 1995 involving *E. coli* 0157:H7 in lettuce, FDA sent another letter in November 2005 specifically to California lettuce firms outlining actions the industry should take in order to ensure lettuce safety.\(^5\)

- At a June 2004 public meeting to discuss the proposed Produce Action Plan, Dr. Robert Gravani of Cornell University’s Food Science Department reported that a Good Agricultural Practices Survey of Farm Workers in New York State showed that approximately 30 percent of producers were unaware of Good Agricultural Practices (GAPs) for their particular crop. The numbers show the need for a mandatory regulatory program for fresh produce and the same should go for fresh-cut produce.

- A qualitative study examining food safety practices used by Iowa produce growers was conducted by researchers from Iowa State University. Observational and in-depth interview techniques were used to assess current food safety practices at each operation. Producers were conscious of product safety, but levels of awareness about risk varied. Areas that needed improvement included improved hand washing facilities and practices; provision of employee training; and the development of cleaning and sanitizing protocols for both products and food contact surfaces.\(^6\)

II. AMS is not the correct regulatory agency to address this critical public health concern.

The best way to minimize or prevent contamination is through implementation of hazard identification and process control systems. These systems should be mandated, starting with the

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highest risk products first – those that have been repeatedly linked to illness outbreaks. To that end, regulations should be developed that require processors and others in the fresh-cut produce supply chain to have written plans that identify hazards associated with their product 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 they can to reduce microbial risks associated with their products. Hazard control measures should be based on the best management practices and other guidance developed for various sectors of the produce industry and should apply at all stages of fresh-cut produce production, including growing, harvesting, sorting, packaging, and storage. However, it is critical that these mandatory programs be developed and implemented by FDA, the agency responsible for produce safety.

The most important benefit of a mandatory regulatory program is that it would help 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 far from universal. Voluntary guidance and marketing agreements are permissive, opaque, and ineffective. Although it would be beneficial for FDA to develop guidelines to minimize microbial food safety hazards in fresh-cut fruits and vegetables, the experience with the fresh produce guidance amply demonstrates that these guidelines will not be effective unless they are made mandatory and enforceable for both domestic and imported processors.

Adoption of mandatory regulatory requirements is the best way to ensure that producers, processors and others in both the domestic and import produce supply chain address the risks inherent in the production of their commodity. 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-cut produce production to help ensure food safety risks are
minimized. Voluntary marketing agreements are not an effective or appropriate public health response to address the food safety problems cropping up in fruits and vegetables. Ultimately, strong regulatory requirements for fresh-cut produce—promulgated and enforced by the responsible regulatory authority—would provide appropriate protection for the public.

Respectively submitted,

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