

**Comments of
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To
U.S. Food and Drug Administration
Public Meeting on Regulatory Options: Safety of Fresh Fruits and Vegetables
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Good morning. My name is Sally Greenberg. I am Senior Counsel in the Washington office of Consumers Union, the nonprofit publisher of *Consumer Reports* magazine, with 4 million subscribers, and *Consumer Reports Online*, with more than 2.5 million subscribers.

I appreciate today's opportunity to participate in this public conversation with the FDA about the safety of fresh produce. I hope to bring you an additional consumer perspective. In just the last five months alone more than 204 unlucky consumers across 26 states ate spinach contaminated by a particularly virulent form of E. coli (O157:H7) that killed as many as five, hospitalized more than 100 and sickened another 100. This spinach disaster was quickly followed by a Salmonella outbreak from contaminated tomatoes served at a restaurant, which sickened 183 people in 21 states. On the heels of this came another E. coli outbreak from shredded lettuce at Taco Bell and Taco John Restaurants that sickened 152 individuals.

A national survey released by Rutgers University's Food Policy Institute last month suggests that last September's spinach recall could have lasting effects on consumers' consumption of spinach and other vegetables. The survey showed that about 1 in 5 people who were aware of the recall also stopped eating other bagged produce. More than 75 percent of respondents with spinach in their home threw it out during the recall, and 7 percent threw out fresh produce other than spinach. More than half of the people who typically ate spinach prior to the recall had not returned to eating it when the survey was taken, months later.

At this moment all across America, the consumer perspective is one of deep concern that government agencies, both at federal and state levels, have failed to safeguard the food supply, deep distrust in the leafy green industry that is responsible for two dozen food-borne illness outbreaks in the last ten years, and confusion about whether fresh vegetables and fruits are the most healthful foods to eat or whether they're potentially deadly.

In 1997, President Clinton, as part of a produce safety initiative aimed at assuring Americans that fruits and vegetables meet the highest safety standards, directed FDA to issue voluntary industry guidelines outlining good agricultural and management practices for growers, processors, and distributors. Ironically, from almost the minute those voluntary guidelines were issued in 1998, the public has endured recall after recall of produce containing microbial contamination. According to the database maintained by the Center for Science in the Public

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Interest (CSPI), of over 5,000 foodborne illness outbreaks from 1990-2004, 13% or 639 were linked to produce; CSPI also reports that the annual number of produce-related outbreaks has doubled in US from 1998 – 2004. Clearly, the FDA’s voluntary approach to regulation of fresh produce has utterly failed to make it safer.

Fruits and vegetables are the cornerstone of a healthy diet and we want to encourage the public to purchase and consume these fresh foods.¹ With increased consumption, however, there is increased risk. There is only one way to ensure that the fruits and vegetables that reach the marketplace are safe and only one way to rebuild consumer confidence—FDA must assume the authority and be given the staff to effectively mandate Good Agricultural Practices (GAPs) for every farm and Hazard Analysis Critical Control Point (HACCP) programs for every processor, including thorough and regular inspection programs, effective trace-back systems, third-party audits, and rigorous enforcement of standards. The leafy green industry, in particular, has brought dangerous products to market too many times for consumers to believe that it will suddenly meet voluntary safety standards. For many consumers, it’s just safer to stop buying leafy green products, healthy diet notwithstanding.

In the absence of strong FDA regulation, some growers are taking things into their own hands. Florida is the nation's largest producer of tomatoes for the fresh market. Tomato growers also have faced 12 outbreaks of salmonella in the past decade. A bill in the Florida legislature and backed by growers would require food-safety inspections of all tomato fields, greenhouses and packinghouses.² The growers say they hope the bill becomes law and takes effect before the fall planting season, believing it is vital for their business. The program will require positive identification, new containers where the product will be easily traced, and includes totally unannounced government inspections.

As my colleague Elisa Odabasian noted several weeks ago at the FDA hearing in Oakland, the California Department of Food and Agriculture (CDFA) is going the other direction. In partnership with the leafy green industry, the agency is furiously pushing forward a marketing agreement to develop voluntary “Best Practices” standards. This is being done behind closed doors without any public input. Furthermore, the CDFA is allowing the oversight Board to be made up almost exclusively of the leafy green industry, some of which have been accused of marketing contaminated products. CDFA has admitted that they will accept whatever Best Practices the very industry that brought us spinach contaminated by E. coli comes up with. This is a serious abdication of government’s duty to safeguard the food supply and protect the public. Industry self-regulation seldom protects consumers and often provides industry with cover when contamination occurs. Simply put, if the leafy green industry ever hopes to regain consumer trust, it must be regulated by an authority other than itself.

By its very nature, a voluntary program of safety standards does not account for the bad actors and does not ensure that all products that come to market are safe. Nor do voluntary standards create an incentive for everyone to comply, particularly when meeting safety standards

¹ Americans are consuming more fruits and vegetables, with fresh tomato consumption increasing to 17.5 pounds per person in 2005 from 14.3 pounds in 1995, according to the U.S. Department of Agriculture. Lettuce consumption more than doubled during that period, to 11.2 pounds per person from 5.5 pounds.

² Tomato growers push for tougher food-safety rules, Palm Beach Post, April 2, 2006.

costs money. If all producers and processors are not subject to the same standards, the door remains open for contaminated produce to reach consumers, with all the attendant negative public health effects, publicity and economic impact that inevitably ensues.

We also noted in our comments in Oakland that California's industry-driven marketing agreement includes a certification mark to convey to consumers that leafy green products from participating farms and processors in California are subject to Best Practices. This approach turns safety into value-added in the marketplace. The safety of the food we buy is a fundamental expectation of consumers, and government must use its standards-setting, investigative and enforcement powers to see that this expectation is fulfilled. Safety should not be used as a marketing tool when it comes to food; safety should not be something that consumers must search out and possibly pay extra for, leaving poorer consumers at risk.

The fact that states are feeling the need to step in and take action simply underscores the vacuum the FDA's inaction has created. We need uniform federal action, not a patchwork of state laws, to keep our food safe. Now is the time for the FDA to do everything in its power (including seizing adulterated products as authorized by Section 402 of The Federal Food, Drug, and Cosmetics Act, and establishing HACCP programs on farms, as authorized by Section 361 of The Public Health Services Act) to ensure the safety of produce. Further, Congress must step forward and fully fund the FDA, giving the agency the resources and staff to effectively enforce mandatory authority over this industry. Again, the voluntary approach to regulating this industry simply has not worked and will continue to endanger consumers with contaminated produce.

A recent Associated Press analysis of federal records found that in 2006 FDA conducted half the inspections of U.S. food manufacturing facilities than it did three years earlier in 2003, and that it conducted 75 percent fewer safety tests of U.S.-produced food in 2006 than it did in 2003. Last May, former FDA official William Hubbard published an opinion piece in the *Washington Post* in which he explained that for some years now the FDA's budget has remained essentially flat while major new responsibilities have been piled on, resulting in a serious weakening of the agency. Mr. Hubbard wrote that FDA food inspections dropped from 50,000 in 1972 to about 5,000 in 2006 (a 90% reduction), that "U.S. food processors are inspected on average about every 10 years" and "the chance of a food product from overseas being inspected is infinitesimal." Clearly, FDA must be given considerably more resources for food safety inspectors and Congress must appropriate the necessary funds immediately to ensure the safety of the food supply.

The FDA's voluntary industry guideline, published last week, states that "prevention of microbial contamination at all steps in the farm-to-table continuum is preferable to treatment to eliminate contamination after it has occurred." Representing the table side of that continuum, Consumers Union could not agree more. But prevention of microbial contamination in fresh-cut fruits and vegetables requires mandatory regulation that is enforced by a government watchdog that does not have as part of its charge the promotion of the industry it regulates. Some essential components of the regulation should be:

- GAPs for all farms and HACCP programs for all processors;
- written food safety plans showing how producers will comply with GAPs;

- third-party audits;
- trace-back systems that include package identifiers so that each item can be traced all the way back to the field in which it originated;
- FDA inspections at least yearly, made possible by substantially increased funding by Congress;
- FDA enforcement with stiff penalties.

The FDA's guidelines fall well short of industry oversight. They state, "FDA's guidance documents...do not establish legally enforceable responsibilities. Instead, [they] describe the Agency's current thinking on a topic and should be viewed only as recommendations...The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required."

We leave you today with a couple of \$100 million questions from the consumer perspective:

- 1) Why is the FDA only "suggesting" and "recommending" safe practices for the fresh produce industry, and not requiring them, despite numerous incidences of contaminated fresh produce reaching the marketplace and harming, even killing, consumers?
- 2) How many more deadly outbreaks must there be before FDA's should becomes a must, and their "suggestions, recommendations and current thinking" become rigorous, mandatory oversight by a credible government watchdog that is well-funded and adamant about protecting the food supply and public health?

While we are waiting for credible answers to those questions, consumers' health hangs in the balance.