



Safe Food for a Healthy Life

An Initiative of The Pew Charitable Trusts at Georgetown University

FDA Actions Regarding Produce Safety

For more than a decade, the U.S. Food and Drug Administration (FDA) has recognized the challenge of making fresh produce safer. However, it has relied on voluntary guidelines. This document summarizes a decade of government initiatives that fall short of the mandatory and enforceable federal safety standards needed for domestic and imported fresh fruits and vegetables:

February 2008

FDA issues *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*.¹

Guidance document addresses food safety hazards and good agricultural and management practices for “fresh-cut produce” -- fresh fruits and vegetables have been minimally processed and altered in form by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing, prior to being packaged.

Because it is a guidance document and not a regulation, the guide does not have the force and effect of law and thus is not subject to enforcement.

October 2007

FDA and the California Department of Public Health Leafy Greens Initiative.²

FDA and the California Department of Public Health expand their efforts in the Lettuce Initiative and focus more broadly on a range of leafy greens, including spinach. FDA investigators will visit farms in California to assess the prevalence of factors in and near the field environment, which may contribute to potential contamination of leafy greens.

June 2007

FDA releases Tomato Safety Initiative.³

Initiative is in response to recurring *Salmonella* outbreaks associated with fresh and fresh-cut tomatoes. FDA will visit tomato farms and packing facilities in Virginia and Florida to assess their food safety practices.

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August 2006

FDA introduces *Lettuce Initiative*.⁴

Initiative is in response to recurring outbreaks of *E. coli* O157:H7 associated with fresh and fresh-cut lettuce. Using a risk-based approach, resources will be directed toward the areas that are most likely to be the source of contamination. FDA indicates that it will consider regulatory action, as appropriate.

November 2005

FDA sends letter to Firms that Grow, Pack, or Ship Fresh Lettuce and Fresh-Cut Lettuce.⁵

After continued outbreaks relating to lettuce and other leafy greens, FDA writes to producers of fresh and fresh-cut lettuce and other leafy greens, particularly from California, reiterating its safety concerns. It “strongly encourages” firms to review their current operations and modify them accordingly to ensure that they are taking the appropriate measures to provide a safe product to consumers.

June 2004

FDA issues *Produce Safety Action Plan*.⁶

The Action Plan has four general objectives: to 1) prevent pathogenic contamination of fresh produce; 2) minimize the public health impact when contamination of fresh produce occurs; 3) improve communication with producers, preparers, and consumers about fresh produce; and 4) facilitate and support research relevant to fresh produce.

FDA indicates that it will measure achievement of these objectives by considering the issuance of guidance, regulations and other tools, as well as by the incidence of contaminated produce identified during sampling surveys.

February 2004

FDA sends letter to Firms that Grow, Pack, or Ship Fresh Lettuce and Fresh Tomatoes.⁷

FDA “strongly encourages” firms that deal with fresh lettuce or tomatoes to review their current operations to ensure that they are taking the appropriate measures to provide a safe product to consumers.

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September 2001

FDA releases report *Analysis and Evaluation of Preventive Control Measures for the Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-Cut Produce*.⁸

Report summarizes the current scientific research relating to the various methods of eliminating or reducing pathogens on whole and fresh-cut produce.

January 2001

FDA releases results of its survey of imported fresh produce⁹

The initial survey of imported produce found that 4% of the samples were positive for pathogenic contamination, and the two produce items with the greatest incidence of pathogen contamination were cilantro and cantaloupe.

October 1999

FDA issues *Reducing Microbial Food Safety Hazards for Sprouted Seeds and Microbial Testing of Spent Irrigation Water During Sprout Production*.¹⁰

These are two guidance documents, one that advises sprout producers and seed suppliers of steps they should take to reduce microbial hazards common to sprout production, and a second that provides the latest information about testing spent irrigation water.

Because these are “guidance documents” and not regulations, they do not have the force and effect of law and thus are not subject to enforcement.

March 1999

FDA initiates a sample survey focused on high-volume imported fresh produce.

This is the first of a series of surveys of domestically produced and imported fresh fruits and vegetables, the goal of which are to obtain more data on the incidence and extent of pathogen contamination.

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April 1998

FDA issues the *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*.¹¹

Guidance document addresses microbial food safety hazards and good agricultural and management practices common to the growing, harvesting, washing, sorting, packing, and transporting of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (raw) form.

Because it is a “guidance document” and not a regulation, the guide does not have the force and effect of law and thus is not subject to enforcement.

October 1997

FDA introduces *Produce Safety Initiative*¹²

The goal of this initiative is to enhance FDA oversight for imported foods by pushing for enactment of new legislative authority; developing guidances on Good Agricultural and Manufacturing Practices; and improving monitoring and inspection activities abroad.

May 1997

Clinton Administration issues, *From Farm to Table: A National Food Safety Initiative*¹³

FDA indicates that it will immediately identify preventive measures to address public-health problems associated with fruits and vegetables; undertake a comprehensive review of current production and food-safety programs including inspection, sampling, and analytical methods; and will work with USDA to evaluate the feasibility of the Hazard Analysis and Critical Control Point (HACCP) approach for fresh produce.

¹HHS, *Guidance for Industry, Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, 1997.

²HHS, FDA, CFSAN, *Leafy Greens Safety Initiative- 2nd year* (2007), <http://www.cfsan.fda.gov/~dms/lettsaf2.html> .

³ HHS, FDA, CFSAN, *Tomato Safety Initiative* (2007), <http://www.cfsan.fda.gov/~dms/tomsafe.html>.

⁴ HHS, FDA, CFSAN, *Lettuce Safety Initiative* (2006), <http://www.cfsan.fda.gov/~dms/lettsafe.html>.

⁵HHS, FDA, CFSAN, Office of Plant and Dairy Foods, *Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce*,(2005), <http://www.cfsan.fda.gov/~dms/prodltr2.html>.

⁶ HHS, FDA, CFSAN, Office of Plant and Dairy Foods, *Produce Safety From Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption* (2004),<http://www.cfsan.fda.gov/~dms/prodpla2.html>.

⁷HHS, FDA, CFSAN , Office of Plant and Dairy Foods, *Letter To Firms that Grow, Pack, or Ship Fresh Lettuce and Fresh Tomatoes*, (2004), <http://www.cfsan.fda.gov/~dms/prodltr.html>.



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⁸ HHS, FDA, CFSAN , *Analysis and Evaluation of Preventive Control Measures for the Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-Cut Produce* (2001), <http://www.cfsan.fda.gov/~comm/ift3-toc.html>.

⁹ HHS, FDA, CFSAN, Office of Plant and Dairy Foods and Beverages, *FDA Survey of Imported Fresh Produce, FY 1999 Field Assignment*, <http://www.cfsan.fda.gov/~dms/prodsur6.html> and <http://www.cfsan.fda.gov/~dms/prodsur9.html>.

¹⁰ HHS, FDA, CFSAN, *Reducing Microbial Food Safety Hazards For Sprouted Seeds and Sampling And Microbial Testing Of Spent Irrigation Water During Sprout Production* ,<http://www.cfsan.fda.gov/~dms/sprougd1.html> and <http://www.cfsan.fda.gov/~dms/sprougd2.html>.

¹¹ HHS, FDA, CFSAN, *Guidance for Industry, Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetable (1997)*,<http://www.cfsan.fda.gov/~dms/prodguid.html>.

¹² The White House, Office of the Press Secretary, *Memorandum for the Secretary of Health and Human Service and the Secretary of Agriculture, Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables(1997)*, <http://www.foodsafety.gov/~dms/fs-wh2.html>.

¹³ HHS, FDA, USDA, EPA, CDC , *Food Safety From Farm to Table: A National Food Safety Initiative Report to the President (1997)*, <http://www.foodsafety.gov/~dms/fsreport.html>.

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