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Fact Sheet

Weaknesses in FDA's Food Safety System

As of October 6, 2006, 199 persons in 26 states have been infected with *E. coli* 0157:H7 in an outbreak traced back to fresh spinach. The infection has been severe in affected cases, with at least 102 persons hospitalized, 31 cases of hemolytic uremic syndrome, and three deaths.¹

This most recent outbreak is not an isolated occurrence. The outbreak is the 20th outbreak of *E. coli* in fresh produce since 1995, and the second outbreak specifically linked to spinach. Produce-related outbreaks have doubled from 44 outbreaks in 1998 to 86 in 2004.² Overall, an estimated 76 million cases of foodborne disease occur each year in the United States, causing about 325,000 hospitalizations and 5,000 deaths annually.³

As this fact sheet explains, the growing incidence of contamination in fresh produce is a symptom of weaknesses in the federal food safety system.

Declining FDA Food Safety Budgets

Food safety funding has not kept pace with rising costs and new responsibilities. Nominal funds for FDA food programs have risen from \$407 million in 2003 to \$439 million in 2006.⁴ This funding increase, however, has not been enough to keep up with rising personnel costs and new duties protecting the food supply from terrorism. According to an FDA budget official, the agency's food division operated under a shortfall of \$135 million in 2006 due to increased personnel costs and new terrorism responsibilities, which the official described as equivalent to a

¹ Centers for Disease Control and Prevention (CDC), *Update on Multi-State Outbreak of E. coli* 0157:H7: *Infections From Fresh Spinach* (Oct. 6, 2006).

² E-mail from Ken Kelly, Center for Science in the Public Interest, to Minority Staff, House Government Reform Committee (Sept. 25, 2006). See also Center for Science in the Public Interest, *Outbreak Alert! Closing the Gaps in our Federal Food-safety Net* (revised Nov. 2005).

³ CDC, *Foodborne Illness: Frequently Asked Questions* (Jan. 10, 2005).

⁴ Food and Drug Administration, *Justification of Estimates for Appropriations Committees, Fiscal Year 2005*, (online at <http://www.fda.gov/oc/oms/ofm/budget/2005/FOODS.htm>); Food and Drug Administration, *Justification of Estimates for Appropriations Committees, Fiscal Year 2007*, at 1 (online at <http://www.fda.gov/oc/oms/ofm/budget/2007/PDF/3ConsolidatedNarrative.pdf>).

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24% budget cut.⁵ The official stated: “as long as the resources available to FDA do not keep up with the realities of increasing costs, it is increasingly difficult for FDA to perform in a way that meets public expectations.”⁶

The most recent Bush Administration budget proposes additional core food safety cuts.

The Administration's most recent budget has proposed further reductions in funding for critical food safety functions. Under the Bush Administration's fiscal year 2007 budget proposal, produce safety and other base food programs would be cut by \$22.6 million from 2006 levels and staffing would be reduced by 105 full time employees in order to fund “priority initiatives such as food defense and pandemic influenza.”⁷

Declining FDA Food Safety Inspections

Decreased spending has resulted in fewer inspectors. FDA inspectors are responsible for overseeing approximately 210,000 domestic food establishments.⁸ Since 2003, however, the number of field staff, primarily inspectors and inspection support staff, has dropped by 12%, from 2,217 to 1,962.⁹

Decreased spending has resulted in fewer inspections. In 1972, FDA conducted approximately 50,000 food safety inspections.¹⁰ In fiscal year 2003, FDA conducted only 13,567 domestic food safety inspections. According to FDA budget documents, this number will drop even further to 9,255 inspections in fiscal year 2006.¹¹ This is a 32% drop in federal inspections since 2003 — and an 81% drop since 1972.

⁵ Frank Claunts, Office of Management, Food and Drug Administration, *FDA: Financial realities*, at 14. (Aug. 10, 2006, updated Aug. 17, 2006).

⁶ Frank Claunts, Office of Management, Food and Drug Administration, *FDA: Financial realities*, at 19. (Aug. 10, 2006, updated Aug. 17, 2006).

⁷ Food and Drug Administration, *Justification of Estimates for Appropriations Committees, Fiscal Year 2007*, at 7 (online at <http://www.fda.gov/oc/oms/ofm/budget/2007/PDF/3ConsolidatedNarrative.pdf>) (accessed Sept. 27, 2006).

⁸ FDA, *Justification of Estimates for Appropriations Committees, Fiscal Year 2007* at 3 (online at www.fda.gov/oc/oms/ofm/budget/2007/PDF/3ConsolidatedNarrative.pdf) (accessed Sept. 27, 2006). According to FDA's website, only about 122,000 domestic food establishments have registered with FDA as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. FDA, *Registration of Food Facilities, Compliance Information: Registration* (Apr. 12, 2006) (online at <http://www.cfsan.fda.gov/~furls/ffregsum.html>) (accessed Sept. 28, 2006).

⁹ FDA, *Justification of Estimates for Appropriations Committees, Fiscal Year 2005* (online at <http://www.fda.gov/oc/oms/ofm/budget/2005/FOODS.htm>) (accessed Sept. 27, 2006); FDA, *Justification of Estimates for Appropriations Committees, Fiscal Year 2007* at 1 (online at www.fda.gov/oc/oms/ofm/budget/2007/PDF/3ConsolidatedNarrative.pdf) (accessed Sept. 27, 2006).

¹⁰ William Hubbard, *Wrongly Blaming the FDA*, Washington Post (May 8, 2006).

¹¹ FDA, *Justification of Estimates for Appropriations Committees, Fiscal Year 2005* (online at <http://www.fda.gov/oc/oms/ofm/budget/2005/FOODS.htm>) (accessed Sept. 27, 2006); FDA, *Justification of Estimates for Appropriations Committees, Fiscal Year 2007* at 32 (online at www.fda.gov/oc/oms/ofm/budget/2007/PDF/3ConsolidatedNarrative.pdf) (accessed Sept. 27, 2006).

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Over time, FDA has shifted some inspection duties to the states.¹² But this has not compensated for the reduction in federal inspections. The combined number of state and federal FDA inspections has fallen by 10% from 21,957 in 2003 to 19,855 in 2006.¹³

Food plants are inspected by FDA on average about once every ten years. At the 2006 rate of 19,855 state and federal inspections, only 9% of the 210,000 food establishments can be inspected by FDA in any given year. FDA has asserted that high risk firms, including those producing fresh leafy greens, are inspected annually. But even an annual inspection rate for high-risk facilities means that plants processing fresh produce are inspected far less frequently than meat and poultry plants, which are inspected by Department of Agriculture officials on a daily basis.¹⁴

Inspections do not always include sampling and testing that are essential to ensuring safety. When FDA does inspect a food establishment, the inspection may not include testing or sampling, relying instead primarily on visual inspection.¹⁵ Visual inspection is insufficient to identify microorganisms such as *E. coli*. In the case of *E. coli* 0157:H7, as few as 10 microscopic single cell organisms can cause severe illness, including hemolytic uremic syndrome or even death.¹⁶

FDA does not inspect the field operations of fresh produce firms, except in response to specific outbreaks. Food safety inspections include an examination of field conditions only if the inspection is part of an investigation tracing an outbreak back to the farm.¹⁷ In August, FDA announced a lettuce safety initiative that expanded the scope of inspections of some fresh produce farms by state and federal officials.¹⁸ Spinach was added to this initiative only after the current outbreak began.¹⁹

¹² See, e.g., FDA, *Justification of Estimates for Appropriations Committees, Fiscal Year 2005* (online at <http://www.fda.gov/oc/oms/ofm/budget/2005/FOODS.htm>) (accessed Sept. 27, 2006); FDA, *Justification of Estimates for Appropriations Committees, Fiscal Year 2007* at 32 (online at www.fda.gov/oc/oms/ofm/budget/2007/PDF/3ConsolidatedNarrative.pdf) (accessed Sept. 27, 2006).

¹³ FDA, *Justification of Estimates for Appropriations Committees, Fiscal Year 2005* (online at <http://www.fda.gov/oc/oms/ofm/budget/2005/FOODS.htm>) (accessed Sept. 27, 2006); FDA, *Justification of Estimates for Appropriations Committees, Fiscal Year 2007* at 32 (online at www.fda.gov/oc/oms/ofm/budget/2007/PDF/3ConsolidatedNarrative.pdf) (accessed Sept. 27, 2006).

¹⁴ Briefing by staff of the CDC and FDA to House Government Reform Committee Staff (Sept. 21, 2006); 9 C.F.R. §§ 309, 310.

¹⁵ Briefing by staff of the CDC and FDA to House Government Reform Committee Staff (Sept. 21, 2006).

¹⁶ Food and Drug Administration, *Foodborne Pathogenic Microorganism and Natural Toxins Handbook: Escherichia coli 0157:H7* (online at <http://www.cfsan.fda.gov/~mow/chap15.html>) (accessed Sept. 26, 2006).

¹⁷ FDA, *Guide to Produce Farm Investigations* (Nov. 2005) (online at http://www.fda.gov/ora/inspect_ref/igs/farminvestigation.html) (accessed Sept. 27, 2006).

¹⁸ Briefing by staff of the CDC and FDA to House Government Reform Committee Staff (Sept. 21, 2006); FDA, *Lettuce Safety Initiative* (Aug. 23, 2006).

¹⁹ FDA, *FDA Statement on Foodborne E.Coli 0157:H7 Outbreak in Spinach, Update: Saturday, September 16, 2006* (Sept. 16, 2006) (online at <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01452.html>) (accessed Sept. 27, 2006).

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Inadequate Enforcement and Regulatory Action

FDA relies on vague and unenforceable standards to govern the production of fresh produce. FDA last updated the regulations that establish good manufacturing practices for food safety in 1986.²⁰ In their current form, these regulations do not specifically address processes used for fresh produce.²¹ The rules also do not describe specific practices for packaged fresh produce, which was not a significant market item in 1986.²² In 1998, FDA issued voluntary guidelines on good manufacturing practices and good agricultural practices for fresh produce, but as voluntary recommendations, these guidelines were unenforceable and explicitly nonbinding.²³ Since 1998, FDA has undertaken a number of “initiatives” on produce safety and issued a series of letters to industry. But all of these measures rely on voluntary cooperation.²⁴

Even where FDA has clear authority to act, the agency fails to enforce food safety requirements. FDA has authority to take enforcement actions when firms market fresh produce that is “adulterated.”²⁵ Enforcement options include notices of violation, warning letters, seizures, and injunctions.²⁶ Despite repeated outbreaks, however, FDA has failed to take serious enforcement action against the fresh produce industry. Warning letters from the FDA Center for Food Safety and Applied Nutrition have dropped by 45% under the Bush Administration, from 335 in 2000 to 183 in 2005.²⁷

The latest outbreak has not changed FDA's reliance on unenforceable voluntary guidelines. As part of its “next steps,” FDA has stated that the agency and California “now expect industry to develop a plan to minimize the risk of another outbreak.... Implementation of these plans will be voluntary, but FDA and the State of California are not excluding the possibility of regulatory requirements in the future.”²⁸

²⁰ FDA, *Food CGMP Modernization—A Focus on Food Safety* (Nov. 2, 2005) (online at <http://www.cfsan.fda.gov/~dms/cgmps3.html>)

²¹ 21 CFR § 110.

²² United States Department of Agriculture, *U.S. Fresh Produce Markets: Marketing Channels, Trade Practices, and Retail Pricing* at 8 (Sept. 2003). Fresh-cut produce and packaged salads rose from 1% of produce department sales in 1987 to 15% in 1997. *Id.*

²³ FDA, *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruit and Vegetables* (Oct. 1998).

²⁴ FDA, *Letter to Firms that Grow, Pack, or Ship Fresh Lettuce and Fresh Tomatoes* (Feb. 5, 2004); Food and Drug Administration, *Produce Safety from Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption* (Oct. 2004); FDA, *Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce* (Nov. 4, 2005); FDA, *Lettuce Safety Initiative* (Aug. 23, 2006).

²⁵ 21 U.S.C. §§ 331, 342.

²⁶ FDA, *FDA Enforcement Activities* (online at <http://www.fda.gov/oc/enforcement.html>) (accessed Sept. 27, 2006); 21 U.S.C. §§ 332, 333, 334.

²⁷ FDA, *The Enforcement Story, Fiscal Years 2000, 2005*.

²⁸ FDA, *FDA Announces Findings From Investigation of Foodborne E. Coli O157:H7 Outbreak in Spinach*, (Sept. 29, 2006) (online at <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01474.html>) (accessed Oct. 3, 2006).

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Pending Legislation to Preempt State Food Safety Authority

H.R. 4167 would undermine the authority of state and local food safety officials. State and local food authorities conduct 80% of the food safety work in the United States.²⁹ In the recent outbreak, these state and local officials have been working closely with FDA to investigate and address the possible sources of the *E. coli* contamination.³⁰ Yet despite their pivotal role in ensuring food safety, legislation passed by the House of Representatives and currently pending in the Senate would preempt key state and local authorities. According to Association of Food and Drug Officials (AFDO), passage of the National Uniformity for Food Act would jeopardize the ability of state and local agencies to respond to incidents of food contamination and adulteration.³¹

²⁹ Letter from Marion Aller, President of the Association of Food and Drug Officials, to Rep. Mike Rogers (Dec. 5, 2005).

³⁰ Letter from Charlene Bruce, President of the Association of Food and Drug Officials, and Joseph Corby, Director of Public Policy of the Association of Food and Drug Officials (Sept. 26, 2006).

³¹ *Id.*