



Building a Prevention-Oriented Food Safety System: FDA's Challenge and Opportunity

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What is the Food Safety Problem?

- Annual toll of foodborne illness
 - 5,000 deaths
 - 325,000 hospitalizations
 - 76 million cases
- Erosion of public confidence
 - Affecting well-being
 - Affecting food choices
- Big economic and trade impacts



Why Is Food Safety Hard?

- Vastness and diversity of the food system -- a trillion dollar share of the economy
- Complexity of causation and prevention
 - Multiple causative factors for most illnesses
 - Multiple opportunities for prevention
- Rapid change in the food supply
 - Technology
 - Consumer demand and behavior
 - Imports

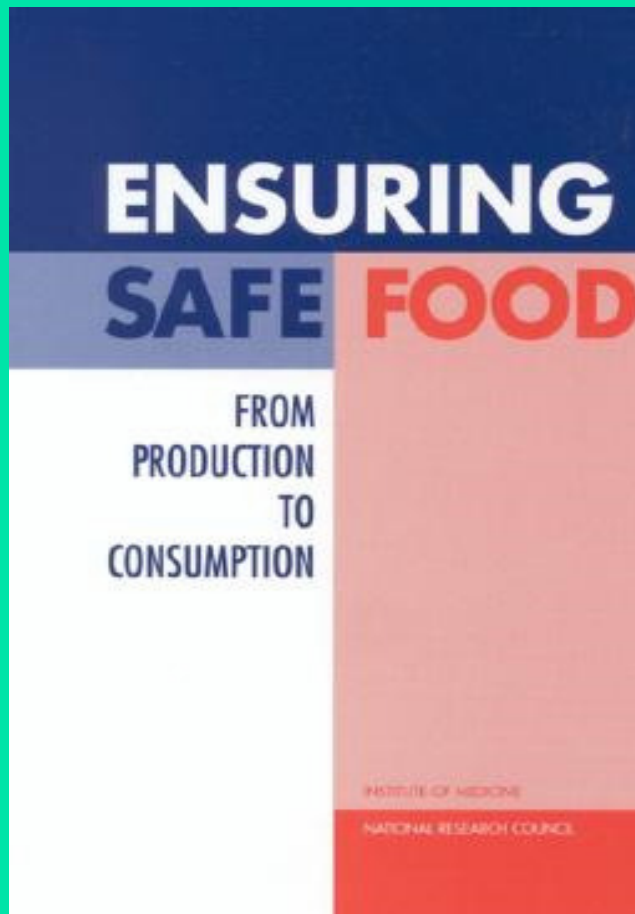


What is the Food Safety System?

- Private sector
 - Producers
 - Processors
 - Retailers/Food Service
- Public sector
 - Multiple federal agencies – FDA, USDA, EPA, CDC
 - State health and agriculture departments
 - Local health departments and sanitarians
- Complex web of interactions
 - Among federal, state, and local agencies
 - Between public and private sectors



1998 IOM Report





What's Wrong With the System?

- **Obsolete statutes**
 - Basic tools originated in 1906 and 1938
 - Focus on reaction rather than prevention
- **Fragmented structure**
 - FDA, USDA, and EPA share regulatory jurisdiction
 - FDA fragmented internally
 - No focal point for research
- **Poor use of inadequate resources**
 - Wasteful USDA inspection system
 - Broad inefficiency in inducing prevention



What's Good About FDA's Food Safety Program?

- Longstanding science and public health tradition
- Continued credibility, especially internationally
- Food safety expertise
- Well-trained field force



What's Wrong With FDA's Food Safety Program?

- No mandate for prevention
- Internally fragmented
 - Center for Food Safety and Applied Nutrition
 - Center for Veterinary Medicine
 - Office of Regulatory Affairs
- Poorly resourced
 - Declining staff – CFSAN down 14% since 2003
 - Tiny operating budget -- \$25 million for CFSAN
 - A third of federal food safety resource for 80% of food supply
- FDA food program takes back seat to drugs
- Result: FDA has limited capacity to provide prevention-oriented leadership on food safety



Core Government Role in Prevention of Foodborne Illness

- Define standard of care for industry adoption of preventive measures
- Set food safety performance standards as measure of accountability
- Inspect and enforce to ensure standards are met
- Drive generation and dissemination of knowledge



Reforms Needed to Make the System Preventive

- Clear mandate and legal tools for prevention
- Unified and prevention-oriented organizational structure(s)
- Increased resources for research, standard setting, inspection and enforcement
- Risk-based resource allocation



Legislative Options

- Comprehensive reform of the federal system – as in Durbin-DeLauro Bill (H.R 1148)
 - Modernize legislative mandate
 - Unify federal food safety agencies
- FDA-focused modernization
 - Restore FDA to food safety leadership
 - Modernize FDA's mandate
 - Unify and elevate food safety functions
- Targeted or problem-specific legislative change
 - Enforcement tools, such as recall authority
 - Produce
 - Imports



Solution: Focus First on Restoring FDA to Food Safety Leadership

- FDA oversees 80% of the food supply and faces more unsolved problems than USDA
- FDA is more eroded in its resource and leadership capacity than USDA
- Politically, FDA is more ripe for reform
- Long-term, food safety leadership belongs in HHS



Key FDA Reforms

- Mandate for prevention
- Modern legal tools for prevention
 - Mandatory preventive process control
 - Performance standards
 - Improved enforcement, especially for imports
- Organizational reform to unify and elevate food safety leadership
- Enlarged and stable resource base



Likely Reform Scenario

- Continued congressional hearings
- More bills introduced in 2007-2008
- Expanded dialogue among industry, consumers and policymakers to define common ground
- Refinement of legislative proposals in 2008
- Legislation in 2009 or beyond



The Import Challenge

- Growing volume and diversity of imports
- Weak controls in some exporting countries
- FDA's "pre-globalization" oversight system and thin resources
- Resulting loss of public confidence



Standard FDA Oversight Model

- Based primarily on port of entry inspection to detect problems
- About 1% of shipments visually inspected but only a fraction of those sampled and tested
- POE inspections partially targeted on “problem” countries and products
- But very limited foreign plant inspection and no defined responsibility for prevention by exporters or importers
- It’s a reactive system



USDA/FSIS Oversight Model

- Grounded in comprehensive (albeit outmoded) domestic inspection mandate
- Requires
 - Equivalent inspection system and standards in exporting countries
 - Approval of exporting plants based on FSIS audit and periodic inspection
 - POE inspection by FSIS of selected shipments
- It's preventive with respect to violations of U.S. standards



The Seafood HACCP Model

- HACCP requirement applies to imports
- Burden on importer to ensure HACCP compliance by –
 - Importing from countries that have equivalence agreement with FDA, or
 - Taking other “affirmative steps”
- Based on principal of prevention, but implementation constrained by resource and legal limitations



Elements of the Solution

- Private sector management of the supply chain
- Improved standards and oversight in the exporting country
- Improved international standard setting
- Improved U.S. oversight and enforcement based on principle of prevention



GMA's "Four Pillars" Are On the Right Track

- Based on importer accountability for prevention
- Harness industry expertise and capacity for supply chain management
- Provide incentives for industry adoption of "best practices"
- Recognize need to strengthen FDA authorities and resources



Interagency Working Group on Import Safety

- Initial framework report to the President on September 10
- Three organizing principles –
 - Build prevention in upstream
 - Intervene to address identified hazards
 - Respond rapidly to contain problems
- Good concepts but many details to fill in



Questions

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