

**Testimony of  
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Before the**

**Subcommittee on Oversight and Investigations  
Committee on Energy and Commerce  
United States House of Representatives**

**Hearing on  
"American Lives Still at Risk: When Will FDA's Food Protection Plan  
Be Fully Funded and Implemented?"**

**June 12, 2008**

Mr. Chairman, Mr. Shimkus, members of the subcommittee, I appreciate this opportunity to testify on the resource challenges facing the Food and Drug Administration in implementing its Food Protection Plan. I applaud the subcommittee for tackling this important topic.

Introduction

FDA has long been looked to as the focal point for food safety leadership in the United States and internationally. It oversees 80% of the U.S. food supply (including an even greater share of imported food) and is the steward of a long tradition of effective, science-based regulation to protect public health. Unfortunately, FDA's ability to provide food safety leadership, or even meet its basic food safety responsibilities, is now badly impaired, in large part because society simply has not given FDA the tools it needs to the job society expects it to do. These tools includes a modern statutory mandate, an

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adequate and stable resource base, and an institutional structure capable of national and international leadership on food safety.

The focus of this subcommittee, and the Committee on Energy and Commerce as a whole, on giving FDA the tools it needs to do food safety right is thus timely and important. Getting food safety right at FDA is essential to the public's health, to the confidence people want to have in the food they feed themselves and their families, and to the economic success of the food system. The subcommittee's leadership will be essential to achieving these outcomes.

I consider FDA's new Food Protection Plan an important step toward the food safety reform we need. It marks a shift in strategic direction for FDA, from primarily reacting to food safety problems after they occur to taking an integrated systems approach that focuses on prevention and on the risk-based targeting of initiatives and resources to reduce the risk of foodborne illness. The FDA plan embodies many of the elements of a more effective and efficient food safety program that have been recommended over the last decade in a series of reports by the Government Accountability Office (GAO) and expert committees of the National Academy of Sciences (NAS).

It is thus appropriate that Congress address FDA's implementation of its Food Protection Plan, including the resources FDA will need to put the plan into practice. In my testimony, I will identify some specific activities that I believe deserve priority

management attention and funding to begin the shift to a prevention paradigm, as well as address the scale of FDA's resource needs for food safety in the long term.

It is important, however, to consider the implementation of FDA's Food Protection Plan and resource needs in the context of the broader statutory and organizational problems that must be addressed for FDA's food safety program to succeed. I will thus note briefly how the obsolete food safety laws and fragmented organizational structure under which FDA operates stand in the way of full and effective implementation of the new plan and how these problems can be solved.

### FDA's Food Safety Funding Crisis

FDA's Food Protection Plan is based on four "cross-cutting principle," all of which are sound and all of which have significant resource implications. These are:

1. Focus on risk over a product's life cycle from production to consumption.
2. Target resources to achieve maximum risk reduction.
3. Address both unintentional and intentional contamination.
4. Use science and modern technology.

Building on these principles, the plan includes three core operational elements: (1) **Preventing** foodborne illness in the first place; (2) **Intervening** with risk-based FDA actions at critical points in the supply chain; and (3) **Responding** rapidly when contaminated food or feed is detected. Under these three core elements, FDA lays out

eight broad new initiatives and a total of 38 specific actions to strengthen its food safety program.

In every case, these initiatives and actions involve either an entirely new effort by FDA or a significant enhancement of something FDA is doing now. Under the critical first element of prevention, for example, the plan calls for FDA to, among other things, work with the food industry to promote corporate responsibility and best practices for food safety, increase FDA's presence overseas, generate new data and develop new models for prioritizing risks, and develop and implement a research plan on sources of contamination and methods to prevent it.

These activities are all worthy, as are the 34 other activities called for in the plan. All should be pursued. Moreover, the agency should be pursuing food safety initiatives that are not included in the plan, such as increasing the overall frequency of FDA inspection and establishing and enforcing mandatory on-farm standards to ensure the safety of fresh produce.

And legislation being developed by Chairman Dingell and other leaders in Congress would give FDA responsibility for implementing two major and needed new programs: the first involves mandatory adoption of preventive controls by all food facilities (domestic and foreign) that produce food for the U.S. market; the second makes importers accountable for assuring that foreign produced products meet U.S. standards.

These efforts to strengthen FDA's food safety program all require investment in such essential inputs to an effective program as increased scientific expertise and staffing levels, research and data collection to guide the new science- and risk-based preventive approach, new information management systems, and the operating funds needed to establish a leadership presence nationally and internationally. FDA has issued its Food Protection Plan and Congress is considering major new initiatives at a time, however, when the agency lacks the resources to meet even its base food safety responsibilities, much less fund the worthy new initiatives.

The seriousness of FDA's food safety funding crisis was made crystal clear by the December 2007 report of the FDA Science Board, which found, starkly, that "FDA does not have the capacity to ensure the safety of food for the nation" and that "[t]he nation's food supply is at risk." The Science Board report said further that FDA's food program lacks the resources "to develop the science base and infrastructure needed to efficiently support innovation in the food industry, provide effective routine surveillance, and conduct emergency outbreak investigation activities to protect the food supply." The Science Board also noted "an appallingly low inspection rate" for FDA-regulated food facilities.

The Science Board is not alone in its concern about the current state of FDA's resources for food safety. In its January 2008 testimony before this subcommittee, the GAO found that staffing levels and funding had "not kept pace with the agency's growing responsibilities." GAO pointed out the Science Board findings that the number of

domestic establishments and food import entries for which FDA is responsible has grown significantly, yet, from 2003 to 2006, staffing levels in FDA's Center for Food Safety and Applied Nutrition (CFSAN) and in the field force responsible for food safety inspection and enforcement, actually declined, by 14 percent and 11.5 percent, respectively. Some 200,000 overseas food facilities are registered with FDA, but the agency expects to conduct only 125 foreign food inspections this year.

FDA's funding constraints and downward trends provide a weak foundation on which to build a modern, science- and risk-based food safety program. Recognizing the need to re-build FDA's scientific base and both headquarters and field capacity, the Science Board recommended in February 2008 substantial increases in FDA's budget for overseeing the food supply, to be phased in over a five-year period. FDA's FY 2008 budget for overseeing the food supply (which includes resources for all of CFSAN, part of the Center for Veterinary Medicine, food-related field functions managed by the Office of Regulatory Affairs, and elements of the Office of the Commissioner and the National Center for Toxicological Research) is about \$620 million. The Board recommended this be increased by \$128 million in FY 2009, \$283 million in FY 2010, \$441 million in 2011, \$598 million in 2012, and \$755 million in 2013.

This would bring FDA's food-related budget in FY 2013 to \$1.375 billion, which is not much more than the approximately \$1.1 billion the President requested in his FY 2009 budget for USDA to oversee the safety of just 20 percent of the food supply. I agree that

FDA needs resources on this scale to transform its food safety program from the current paradigm of reacting to problems to a paradigm of risk-based prevention.

The President's original FY 2009 budget requests for FDA included an increase of less than \$43 million over the 2008 budget, which would just barely keep pace with FDA's core inflation rate of 5.8%. This would mean keeping FDA's actual operating capacity for food safety at essentially the same level that the Science Board found inadequate "to ensure the safety of food for the nation."

I was pleased that on June 9, 2008, HHS Secretary Leavitt announced that the President's FY 2009 budget request for FDA is being amended to add \$275 million, of which \$125 million would be available for food safety-related work, for a total FY 2009 increase for food safety of \$168 million, which exceeds the Science Board proposal. This is a good sign that the administration has recognized FDA's food safety funding crisis.

I am concerned, however, about when these additional funds, if agreed to by Congress, would become available. The earliest possibility, of course is October 1, 2008, the beginning of FY 2009, but that assumes Congress will pass FDA's FY 2009 budget on time, as opposed to a continuing resolution, which could extend FDA's 2008 funding level well into calendar year 2009. This would substantially delay implementation of the Food Protection Plan.

Regardless of the prospects for the FY 2009 budget, FDA needs immediate budget help to get started with its prevention-oriented food safety strategy, as today's on-going and widespread outbreak of illness associated with salmonella-contaminated tomatoes so graphically demonstrates. I thus hope Congress will providing FDA additional food safety funds in the pending 2008 supplemental appropriations bill and that Congress will commit itself to a long-term funding plan for food safety at FDA, in keeping with the recommendations of the FDA Science Board.

### Near-Term Priorities to Implement FDA's Food Protection Plan

The magnitude of the transformation that FDA's Food Protection Plan envisions, coupled with inevitably finite management capacity and budgets, means that FDA must set priorities for how it invests its time and money to implement the plan, regardless of what action Congress takes on the 2008 supplemental and FDA's FY 2009 appropriation.

To this end, the first thing FDA should do is determine the resources it needs to implement the Food Protection Plan and develop a detailed resource plan, including priorities, for their deployment. Clearly, based on the Science Board report, FDA needs to build its scientific base and information infrastructure for food safety, in addition to having the operating funds to take the many specific actions called for in the Food Protection Plan. The Plan was silent on resource needs but can be credible and effective only if accompanied by a realistic resource plan that Congress funds.

Beyond that, I'd like to suggest four specific actions that FDA can pursue now. I think these deserve high priority because they would both begin the shift to the prevention paradigm and address some of today's most pressing food safety problems. Though all can be pursued under current law, they would also help lay the foundation for implementing new legislative mandates, such as contained in the discussion draft circulated by Chairman Dingell and on which Chairman Pallone held a hearing on April 24, 2008.

### **Begin Risk-Based Priority Setting and Risk Management**

The essential starting point for a risk-based, preventive approach to food safety is knowing what the most important risks are and systematically devising affirmative strategies to reduce them. FDA has not taken this approach in the past, but the Food Protection Plan's initiatives 1.2 (Identify Food Vulnerabilities and Assess Risks) and 1.3 (Expand the Understanding and Use of Effective Mitigation Measures) signal FDA's intention to move in this direction.

This is not, however, a small undertaking. It involves: (1) identifying the most significant hazards in the food supply, meaning the specific combinations of foods and microbial or chemical contaminants that are likely to have the greatest adverse impact on public health, (2) prioritizing these hazards based on the magnitude of the potential risks they pose and the availability, likely effectiveness, and cost of measures to reduce the risks, and (3) developing risk reduction strategies for the highest priority hazards, including appropriate safety standards for each hazard, an inspection and enforcement

plan to ensure the standards are met, and a plan to monitor the effectiveness of the strategy in reducing risk to the public.

At the outset, FDA could, for example, identify the 20 most significant hazards within its jurisdiction and commit initially to devising prevention strategies for the top five. As this work progresses, FDA should regularly update its assessment of the hazards and, as appropriate, select additional hazards for priority risk management attention.

In addition to guiding FDA's priority setting and resource allocation, regular assessment and reporting by FDA on the most significant hazards in the food supply has the important advantage of informing the industry about risks companies should be addressing in their own food safety plans, whether or not those risks are being addressed immediately by FDA.

Sufficient information exists today to begin risk-based priority setting and risk management. It is also clear that more complete information and better tools for analyzing and managing information will improve the efficiency and quality of the effort. FDA should, therefore, draw on its current knowledge and early experience with risk-based priority setting to map out a plan for obtaining and managing the information it needs. The plan should address institutional roles and responsibilities and resources for meeting FDA's information needs.

## **Strengthen the Contribution of Food Safety Epidemiology to Prevention**

One of FDA's most critical information needs is better knowledge of the actual burden and root causes of human illness associated with foodborne pathogens and other hazards. Such information is essential to the risk-based prevention approach of the Food Protection Plan and to the individual efforts of food companies to prevent the risks arising in their operations. FDA should thus make it a high priority to improve the quantity, quality and timeliness of the food safety epidemiology data it receives.

FDA is dependent for this information, however, primarily on the efforts of state and local health departments and the Centers for Disease Control and Prevention (CDC). These agencies operate under their own budget constraints and have other priorities and limitations that have been obstacles to FDA getting the information it needs in a timely fashion. The Food Protection Plan implicitly recognized this reality in calling for FDA to work with CDC to better attribute pathogens and illnesses to particular foods and identify where in "the production life cycle" the foods became contaminated.

FDA should thus work through the Office of the Secretary of Health and Human Services to make the nation's food safety epidemiology enterprise as responsive as possible to FDA's information needs and the needs of other federal and state agencies and the food industry in their efforts to prevent foodborne illness. A focal point for leadership should be established within the Office of the Secretary to coordinate the efforts of FDA, USDA, CDC, and state and local health officials for this purpose, and FDA should have resources to finance specific enhancements in the way food safety epidemiological data are

collected, analyzed and made available to better support implementation of the risk-based prevention strategy embodied in the Food Protection Plan.

### **Conduct a Compliance and Effectiveness Audit of FDA's Seafood HACCP Program**

The seafood HACCP (Hazard Analysis and Critical Control Points) program that FDA established in 1996 foreshadowed the approaches to prevention and improved oversight of imports contained in the Food Protection Plan and pending food safety legislation. It requires all seafood processors, domestic and foreign, to prepare and implement a preventive control plan (specifically a HACCP plan), and it requires importers to take affirmative steps to ensure that the seafood they import was produced under conditions that meet the HACCP requirement. The HACCP rule's provision for imports is particularly important since a large majority of the seafood consumed in the United States is imported.

For resource reasons, FDA's oversight of importers and inspection of foreign processing facilities is very limited, and, as seafood imports have grown, state and federal laboratories have documented a growing problem with chemical contaminants and antibiotic residues in farm-raised fish products, especially those coming from Asia. This raises questions about the reliability of the "affirmative steps" being taken by importers and the overall effectiveness of FDA oversight of seafood. Last year, FDA banned certain seafood imports from China.

Because seafood safety is an important issue in its own right, and because preventive control plans and strengthened industry responsibility for prevention – through preventive control plans – are important elements of FDA’s new strategy, FDA should conduct a compliance and effectiveness study of the seafood HACCP program for both domestic and imported seafood. The purposes should be to: (1) assess compliance rates and the overall effectiveness of the seafood HACCP rule in preventing violations of U.S. food safety standards, (2) identify legal, resource and other constraints on the effectiveness of the seafood HACCP rule, and (3) draw lessons for FDA’s development of preventive control plans for other commodities and sectors of the food supply.

### **Begin Targeted Rulemaking on the Safety of Fresh Produce**

Over a year ago, the United Fresh Produce Association and the Produce Marketing Association called on FDA to establish produce safety standards that are “federally mandated, risk-based and allow for commodity-specific regulation.” I agree FDA should establish such standards, and I believe FDA should begin the rulemaking process as soon as possible.

It will be a challenge for FDA to develop workable, science-based standards that can evolve as the science of produce safety evolves. I also recognize that most of the pending food safety legislative proposals would mandate FDA establishment of produce safety standards. I support such legislation. Nevertheless, FDA should begin the process now with respect to one or more specific categories of produce – such as leafy greens and tomatoes – by gathering and analyzing the relevant scientific and technical information,

beginning serious dialogue with experts in the produce industry and academia, and proposing regulatory options.

In my view, the basic elements of the new standards should include a mandatory preventive control plan developed by each grower and tailored to local hazards and conditions, and, as appropriate and feasible, enforceable criteria or standards for key risk factors, such as microbial quality of irrigation, manure management, and control of livestock and other animal vectors for contamination. FDA should also evaluate the feasibility and reliability of utilizing state inspectors or private audit firms to review the sufficiency and implementation of these food safety plans and accompanying records on a regular basis and report their findings to FDA.

By beginning the rulemaking process now, FDA will be acting to protect public health and will begin making the shift from reaction to prevention a reality for this important sector of the food supply,.

### Modernizing FDA's Legislative Mandate and Authority

FDA's Food Protection Plan is a good start, and solving FDA's food safety funding crisis is essential, but it is equally essential that Congress modernize the food safety laws under which FDA operates. The basic provisions of the Federal Food, Drug, and Cosmetic Act under which FDA addresses the central public health problem of hazardous food contaminants and food imports were enacted in 1938, well before today's understanding

of the public health importance of microbial pathogens and the globalization of the food supply that continues to accelerate.

FDA's core statutory tools consist primarily of a few broad definitions of "adulteration," authority to inspect food facilities (but not, in general, food safety records), and a set of cumbersome-to-pursue judicial enforcement tools (seizure, injunction and criminal prosecution). FDA has made creative use of its authorities to set informal action levels and other de facto performance standards and adopt the seafood HACCP rule, but there is no mandate in the law, and thus no accountability for FDA to implement, a systematic science- and risk-based program to prevent foodborne illness.

FDA should have such a mandate and, assuming adequate funding, should have clear accountability for carrying it out successfully. Otherwise, I question whether the new strategic direction presented in the Food Protection Plan will be sustained.

### Organizationally Unifying and Elevating the FDA Food Safety Program

In addition to providing a modern statutory mandate and adequate resources, Congress should ensure that FDA has an organizational framework that enables the agency to provide national and international leadership on food safety and to run a coherent, well-planned program that makes the best use of available resources to improve food safety.

For several reasons, FDA lacks such a framework.

First, within FDA, the food program has historically taken a back seat to the drug and medical device programs in the competition for management attention and resources. This is due in part to the intense interest that drug and device companies, health professionals, and patients all have in FDA's "gatekeeper" role for therapeutic products and is reflected in the fact that most FDA commissioners come from a biomedical or health care background. This strong tilt toward drugs and devices was exacerbated by the drug and device user fee laws, which have further focused FDA management attention, accountability, and resources on the therapeutic side of the agency. History has taught that the job of providing effective national leadership simultaneously on both therapeutic products and food safety is too big a job for any one person.

Second, FDA's organizational structure for food safety is fragmented and lacks a clear focal point for leadership. CFSAN ostensibly has the lead on food safety at FDA, but CFSAN actually shares food safety jurisdiction with the Center for Veterinary Medicine, which regulates pet food and animal drug and feed additive residues in human food, and with the Office of Regulatory Affairs, which manages the majority of FDA's food safety resources through its field force of inspectors, compliance officers and laboratory personnel. The recent appointment in the Office of the Commissioner of an Associate Commissioner for Foods reflects the agency's awareness of the problem but does not solve it. I have great respect for Associate Commissioner David Acheson, but his position lacks budget or line authority for programs and thus in some ways further clouds responsibility and accountability for food safety within FDA.

Finally, food safety leadership at FDA rests at least two bureaucratic layers removed from the Secretary of Health and Human Services. As decisionmaking in the executive branch continues to be centralized at higher and higher levels, with OMB having enormous influence on regulatory policy, the full time leader of the nation's premier food safety program needs to have the greater clout in the system that comes from being presidentially appointed and reporting directly to the Secretary.

In my view, the solution to this structural weakness in FDA's food safety plan is to unify the food-related components of FDA into a single organization and elevate that organization within HHS under the leadership of a presidentially-appointed official reporting directly to the Secretary.

### Conclusion

Thank you again, Mr. Chairman, for the opportunity to testify on these important issues. I look forward to answering your questions and the questions of your colleagues on the committee.

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**on**  
**"American Lives Still at Risk: When Will FDA's Food Protection Plan**  
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**Major Points**

- I consider FDA's new Food Protection Plan, with its integrated and risk-based systems approach to preventing illness, to be moving in the right direction toward the food safety reform we need.
- FDA's ability to implement the Food Protection Plan is seriously constrained by FDA's food safety funding crisis.
- From 2003 to 2006, FDA's headquarters and field resources for food safety actually declined as the number of domestic establishments and food import entries grew significantly, leaving FDA with a weak foundation on which to build a modern, science- and risk-based food safety program, as envisioned by the Food Protection Plan.
- I support the FDA Science Board's call for a long-term commitment to re-build FDA's science base and food safety oversight capacity both at headquarters and in the field, as well as the Science Board's specific recommendation to more than double the FDA food safety budget over a five-year period from the current \$620 million to \$1.375 billion in 2013.
- FDA should move forward now, however, to begin implementing the Food Protection Plan by developing a detailed a resource plan and pursuing the following high priority actions:
  - Risk-based priority setting and risk management for the most significant hazards;
  - Strengthening the contribution of food safety epidemiology to prevention;
  - Conducting a compliance and effectiveness audit of FDA's seafood HACCP program; and
  - Targeted rulemaking on the safety of fresh produce.
- In addition to providing FDA needed resources, Congress should modernize FDA's food safety legislative mandate and direct that FDA's food safety program be unified and elevated organizationally with the Department of Health and Human Services.