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Affecting FDA-Regulated Products*

## **CFSAN's Program Priorities: From Food Safety to Food Security**

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# CFSAN's Program Priorities: From Food Safety to Food Security

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## I. INTRODUCTION

The events of September 11, 2001, have had a major impact on the priorities of the Food and Drug Administration's (FDA's) foods program, as illustrated by the following description of some changes at the agency. Each year for the past four years, FDA's Center for Food Safety and Applied Nutrition (CFSAN) has published a Program Priorities document, which publicly outlines the goals the Center intends to meet in the coming year. At the start of fiscal year (FY) 2001, the theme of the work plan was program continuity. CFSAN intended to continue, complete, or begin the next logical round of projects that would provide the most benefit to American consumers. The greatest emphasis was placed on items related to food safety, food additives, dietary supplements, and biotechnology. The document also addressed the Center's pending move to a new building located in College Park, Maryland, and outlined the areas that CFSAN would be working on to achieve a successful move. Only one out of approximately 100 "A" list priority items addressed bioterrorism preparedness.

In early 2002, several months after the tragic events of September 11, CFSAN unveiled its Program Priorities document for FY 2002.<sup>1</sup> Ninety-two "A" list priorities were set. In assembling the priorities, CFSAN again asked the question, "Where do we do the most good for consumers?" Again, food safety, food additives, dietary supplements, and food biotechnology were items of high importance. The topics of food allergens; transmissible spongiform encephalopathies; and chemical contaminants, pesticides, and other hazards also were noted as important and worthy of special attention, as was CFSAN's move to its new College Park building. No goal, however, ranked higher than that of increasing the *security* of the U.S. food supply.

This article will provide an overview of FDA's role in food security and preventing the intentional introduction of pathogens or harmful chemicals into the food supply. Because many of the systems designed to improve food safety also address food security, this article will describe the major food safety systems currently in place and will outline new efforts meant to bolster security even further.

## II. FDA'S GROUNDWORK

Since September 11, 2001, we have had to face the possibility that the U.S. food supply could be the target of terrorist actions. What concerns FDA is the fact that food

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<sup>1</sup> CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN), FOOD AND DRUG ADMIN., CFSAN 2002 PROGRAM PRIORITIES (Jan. 29, 2002), available at <http://www.cfsan.fda.gov/~dms/cfsa102b.html> (last visited Mar. 18, 2003). See also CFSAN 2002 PROGRAM PRIORITIES, ACCOMPLISHMENTS THROUGH JUNE 15, 2002 (July 17, 2002) and CFSAN 2002 PROGRAM PRIORITIES REPORT CARD (Nov. 20, 2002), available at <http://www.cfsan.fda.gov/~dms/cfsan3.html> (last visited Mar. 18, 2003).

is a *possible* vehicle for harmful contaminants. Were the food supply successfully targeted, the result could be significant morbidity and mortality as well as significant economic loss. It is because of this potential threat that FDA and the food industry agree on the need to substantially increase our preparedness. We need to ensure that we are prepared for what is reasonably foreseeable, and that we have the flexibility to respond swiftly and effectively to the unexpected.

To accomplish this, FDA is increasing its vigilance, while continuing to rely on science-based approaches to solve public health and safety problems. Fortunately, FDA has a strong base from which to build, so we are by no means starting from zero. Indeed, over the past few years, the food safety system has been significantly strengthened across the entire food distribution chain—from farm to table. This includes newer surveillance systems, stronger prevention programs, and faster outbreak response. These are the same types of systems that will assist in preventing or responding to a terrorist attack.

### A. *Surveillance Systems*

One of the areas in which food safety has made great strides is in the creation of newer surveillance systems. The ability to “identify the risk” is a necessary first step for any food safety protection program. In the past decade, systems such as FoodNet, PulseNet, and the National Antimicrobial Resistance Monitoring System (NARMS) have come into use, and a new program called eLEXNET (electronic Laboratory Exchange Network) has been piloted. FoodNet, PulseNet, and NARMS are all operated through the Centers for Disease Control and Prevention (CDC)<sup>2</sup> and have been described extensively elsewhere.

eLEXNET, the most recent of the surveillance systems, is the nation’s first Internet-based data exchange system for federal, state, and local government food safety laboratories. It contains data on *E. coli* O157:H7, *Listeria monocytogenes*, *Campylobacter jejuni*, and all *Salmonella* species. As of November 2002, the system has been piloted successfully, and seventy-seven laboratories in forty-five states are either actively entering data into the eLEXNET system or are in the development queue. Current plans project the expansion of the surveillance system to laboratories in all fifty states, including data entry on additional microbiological and chemical agents.

### B. *Prevention Programs*

The ability to detect the presence of, and to correctly identify, foodborne pathogens is important, but the ultimate goal is the reduction or elimination of pathogens from the food chain prior to consumption. To accomplish this, proactive prevention measures must be taken. Toward such a goal, FDA has published regulations and guidance documents addressing many foodborne hazards, including seafood safety through Hazard Analysis and Critical Control Points (HACCP), juice HACCP, good agricultural practices (GAPs), sprout safety, egg safety, and others. Concurrently, the Food Safety and Inspection Service (FSIS) at the U.S. Department of Agriculture (USDA) has developed and implemented its HACCP/pathogen reduction program for meat and poultry. These programs were all designed with the purpose of improving food safety; however, the principles and procedures involved also decrease the chances that intentional tampering will go unnoticed.

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<sup>2</sup> For information on CDC, FoodNet, PulseNet, and NARMS see [www.cdc.gov](http://www.cdc.gov), [http://www.cdc.gov/foodnet/what\\_is.htm](http://www.cdc.gov/foodnet/what_is.htm), <http://www.cdc.gov/pulsenet/>, and <http://www.cdc.gov/narms/>, respectively.

On a level closer to consumers, proper food preparation in the retail setting further reduces the likelihood of contracting a foodborne illness. Geared toward retail food establishments such as restaurants and grocery stores, as well as food service institutions such as hospitals, day care centers, and nursing homes, FDA published the latest version of the Food Code in December 2001.<sup>3</sup> This document serves as a reference guide on how to prevent foodborne illness in the retail setting, and is being adopted by more and more state and local jurisdictions each year. FDA updates the Food Code periodically. With fifty cents of every food dollar spent on food prepared outside of the home, adherence to the food safety principles outlined in the Food Code is of ever increasing importance.

### C. *Outbreak Response*

Despite best efforts, we cannot expect to prevent every foodborne illness outbreak. We should expect, however, that when an outbreak does occur, federal, state, and local authorities work together to identify the problem, perform traceback investigations, and remove the product or products from the market as quickly as possible. With the use of new technology known as “DNA fingerprinting,”<sup>4</sup> outbreaks are identified much sooner than they were several years ago. That translates into lives being saved and the number of illnesses being reduced.

Indeed, faster outbreak response is one of the most substantial improvements in the food safety system over the past five years. In addition to the use of “DNA fingerprinting,” guidelines have been developed for responding to multistate foodborne illness outbreaks.<sup>5</sup> These guidelines address coordination among different federal agencies, as well as among federal, state, and local officials.

These new systems for surveillance, prevention, and outbreak response have resulted in substantial public health gains. Based on FoodNet data from 1996-2001, CDC has reported a nationwide reduction of twenty-one percent in foodborne illness from the four most common pathogens. Now, these systems of surveillance prevention and response must be viewed through a new lens—the security of our food supply.

## III. FOOD SECURITY—ANTICIPATION, DETERRENCE, AND RESPONSE

### A. *Anticipation*

Building on this strong foundation, the first step in meeting the challenge of food security is the ability to anticipate threats so that we can institute preventive measures wherever possible. This means applying the principles of risk identification to the food security process.

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<sup>3</sup> FOOD AND DRUG ADMIN., FDA FOOD CODE (2001), at <http://www.cfsan.fda.gov/~dms/foodcode.html> (last visited Mar. 18, 2003).

<sup>4</sup> *PulseNet “fingerprints” deadly foodborne bacteria*, CDC, PULSENET NEWS, at [http://www.cdc.gov/pulsenet/press\\_releases.htm](http://www.cdc.gov/pulsenet/press_releases.htm) (last visited Mar. 18, 2003); *Fingering Food Poisoning Faster*, CDC, PULSENET NEWS, at <http://www.cdc.gov/pulsenet/articles.htm> (last visited Mar. 18, 2003); *What is PulseNet?*, CDC, PULSENET NEWS, at [http://www.cdc.gov/pulsenet/what\\_is.htm](http://www.cdc.gov/pulsenet/what_is.htm) (last visited Mar. 18, 2003).

<sup>5</sup> NATIONAL FOOD SAFETY SYSTEM PROJECT, OUTBREAK COORDINATION AND INVESTIGATION WORKGROUP, MULTISTATE FOODBORNE OUTBREAK INVESTIGATIONS, GUIDELINES FOR IMPROVING COORDINATION AND COMMUNICATION (Feb. 2001), available at [http://www.fda.gov/ora/fed\\_state/NFSS/Outbreak\\_Coordination.pdf](http://www.fda.gov/ora/fed_state/NFSS/Outbreak_Coordination.pdf) (last visited Mar. 18, 2003).

Following September 11, FDA conducted its own extensive food supply threat assessments, taking into account the nature of the food category, the applicability of different select agents (e.g., biological and chemical), and different points in the food processing and distribution system. These assessments have been "classified" so as to not provide roadmaps to those seeking to do harm. FDA has contracted with the Institute of Food Technologists to validate the process used to conduct these assessments. FDA also has contracted with the Battelle Memorial Institute to provide its expertise through an independent assessment of the food and cosmetic products FDA regulates.

Finally, through FDA's Office of Criminal Investigations (OCI), the agency is enhancing its relationships with law enforcement and intelligence communities. OCI has extensive experience with product tampering, and its longstanding law enforcement ties are being increasingly utilized. FDA's ability to obtain timely intelligence information is paramount to its ability to target its activities effectively.

### B. *Deterrence*

In an effort to establish deterrent measures for protecting the food supply, FDA developed two draft food security guidance documents, which were published in January 2002.<sup>6</sup> One of the guidance documents is tailored toward food producers, processors, transporters, and retailers; the other is addressed to importers and filers. Both documents provide recommendations for potential preventive measures that firms can take to reduce the risk that food under their control will be subject to tampering or to intentional contamination. The guidance documents discuss a variety of production systems, types of products, and importing processes, thus allowing individual firms to apply what is most relevant to their particular business. FDA is in the process of finalizing the guidance based on comments it has received in recent months, and is developing a separate guidance document for the retail setting.

One method for helping industry conduct security assessments is called Operational Risk Management (ORM). ORM is a system-based concept that was developed to improve safety and reduce losses in aircraft, space vehicles, and nuclear power. It is a six-step process intended to increase operational effectiveness by anticipating hazards and reducing the potential for loss. If applied properly, ORM can help minimize safety and security risks to acceptable levels while organizations pursue their missions.

This is a start, but effective deterrence goes beyond issuing and applying guidance. Deterrence also calls for increased resources, inspections, and staffing. To address this, as part of the FY 2002 Supplemental Appropriation, Congress provided FDA with \$151 million intended for use in counterterrorism efforts. Of that amount, \$97.1 million is targeted for food safety activities. With this additional funding (together with funding in the regular FY 2002 food safety appropriation), FDA has hired over 800 new field employees, with a primary focus on strengthening the surveillance of imported foods. Indeed, a majority of these new field employees are serving in FDA's import inspection program, either at the borders or in laboratories, thus allowing FDA plans to double the number of import field exams performed (to 24,000 in FY 2002),<sup>7</sup> and double again (to 48,000) in FY 2003. To aid in this endeavor, FDA is working toward better targeting of its examinations,

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<sup>6</sup> CFSAN, FDA, Guidance for Industry, Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance (Jan. 9, 2002), available at <http://www.cfsan.fda.gov/~dms/secguid.html> (last visited Mar. 18, 2003); CFSAN, FDA, Guidance for Industry, Importers and Filers: Food Security Preventive Measures Guidance (Jan. 9, 2003), available at <http://www.cfsan.fda.gov/~dms/secguid2.html> (last visited Mar. 18, 2003).

<sup>7</sup> In fact, FDA far exceeded this goal and performed 34,000 import field exams in FY 2002.

and is developing new strategies to accomplish this. This is an area of critical importance because the number of imports has increased dramatically in recent years.

During the course of a field exam, samples may need to be collected and sent to a laboratory for analysis. To analyze the increased number of samples collected, new laboratory analysts have been added to the existing staff. These chemists, microbiologists, and other specialists perform rapid screening tests on the samples and, when appropriate, more precise confirmatory tests.

Imports are not the only area receiving increased attention. Over 100 new FDA employees are serving as compliance officers and domestic inspectors. These same employees will provide assistance should any domestic response be necessary in time of security breaches or crises.

### *C. Response*

By anticipating threats and taking preventive measures, FDA hopes that attacks on the food supply will be deterred. There is no guarantee, however, that such threats will be completely avoidable, and the agency must be ready to respond. In preparation for such a scenario, FDA led an emergency response exercise in January 2002 with representatives from CDC, USDA, the Federal Bureau of Investigation, the Department of Defense, state agencies, and others. The purpose of this exercise was to improve coordination of responses between various agencies, so that those responses are smooth and appropriate and so that all needed parties are involved. Other interagency exercises have followed, and more are being planned, as well as more limited exercises within FDA.

An essential part of any food safety response is taking steps to make sure that any contaminated food or cosmetic product is removed from the marketplace as rapidly as possible. While that agency may uncover information that reveals exactly which products might be contaminated, it is likely that testing will be required to determine the safety of certain suspect products. In the event that a large number of products need to be tested for contamination in a short period of time—so much that it would stretch the limits of FDA's resources, even with recent increases in its laboratory personnel—FDA has been working with CDC to augment its "surge capacity" by developing a nationwide Laboratory Response Network (LRN) for food testing, through agreements with state and other federal laboratories. By acting collectively, the government will have the ability to test a much higher than normal volume of samples.

Part and parcel of an effective laboratory network for foods is to have the right detection methods in place, including ones for biological and chemical agents not traditionally associated with foods. In anticipation of this scenario, the agency is hiring additional scientists in CFSAN, and is redirecting fifteen percent of its food safety research program to develop rapid analytical methods for a variety of contaminants and types of products. It is especially important that the agency have available reliable tests that are designed to identify specific agents in a food matrix. FDA will use a combination of intramural and extramural laboratories to develop these testing methods.

An important component of any response is conveying accurate and timely information to the public. In doing so, FDA hopes to keep consumers abreast of what is and is not known, and what FDA is doing in response to the threat. FDA also needs to advise consumers of any steps they might take to protect themselves. In times of uncertainty, it is even more important to keep the lines of communication open and maintain the public's trust.

#### D. *New Legislation*

Stronger legislative authority also is an important component of enhanced food security. Addressing this need, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,<sup>8</sup> which President Bush signed into law on June 12, 2002. Among many things, the law strengthens oversight of imported food and facilitates FDA's ability to quickly conduct traceback investigations when illnesses associated with food are identified. CFSAN is currently working to issue regulations addressing four provisions of the law: registration of food facilities; prior notification of imported food shipments; establishment and maintenance of records; and administrative detention.<sup>9</sup> FDA published for public comment the first two proposed rules—registration<sup>10</sup> and prior notification of imports<sup>11</sup>—on February 3, 2003, and plans to publish the remaining proposals later this spring. Final rules are scheduled to publish later this year, and will take effect, beginning in December 2003.

#### E. *Coordination and Communication*

Of course, effective and comprehensive food security calls for improved communication and coordination at all levels of government. Although existing communication structures for food safety have existed for some time, they must be fine-tuned to meet new challenges. Together, federal agencies have formed the Food Threat Preparedness Network (PrepNet) to enhance communication and collaboration. PrepNet also will include state representatives from the major food and public health associations. FDA has a long history of partnering with public health and food related agencies, while the degree of contact with law enforcement and intelligence communities needs to expand. By improving information sharing and collaboration among these groups, the nation will be better able anticipate, deter, and respond to current and future threats.

### IV. CONCLUSION

In the post-September 11 world, FDA faces many new challenges and is working hard to meet them. FDA is a strong science-based agency with capability, know-how, and a history of successfully responding to challenges. Food security issues are new, but they are closely related to food safety and much of the required infrastructure already is in place. Additionally, FDA enjoys positive relationships with industry, strong public trust, and an *esprit-de-corps* within its own ranks. Through proper planning, FDA hopes to meet foreseeable challenges and have the flexibility to respond to unexpected ones as well. Our nation's consumers expect—and deserve—no less.

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<sup>8</sup> Pub. L. No. 107-188, 116 Stat. 594 (2002). For additional information on the Bioterrorism Act of 2002, FDA's efforts to implement the Act, and other information on FDA actions addressing the security of the food supply see FDA, *The Bioterrorism Act of 2002* (Sept. 11, 2002, last updated Mar. 13, 2003), at <http://www.fda.gov/oc/bioterrorism/bioact.html> (last visited Mar. 18, 2003); CFSAN, FDA, *Food Safety and Terrorism* (last updated Mar. 13, 2003), at <http://www.cfsan.fda.gov/~dms/fsterr.html> (last visited Mar. 18, 2003); CFSAN, FDA, *Protecting the Food Supply: FDA Actions on New Bioterrorism Legislation* (Jan. 2003, last updated Mar. 12, 2003), at <http://www.cfsan.fda.gov/~dms/fsbtact.html> (last visited Mar. 18, 2003).

<sup>9</sup> See Letter from Joseph A. Levitt, Director, CFSAN, FDA, to FDA Foods Community and Stakeholders (July 17, 2002), available at <http://www.cfsan.fda.gov/~dms/sec-ltr.html> (last visited Feb. 24, 2003).

<sup>10</sup> 68 Fed. Reg. 5377 (Feb. 3, 2003).

<sup>11</sup> 68 Fed. Reg. 5427 (Feb. 3, 2003).