



Department of Health and Human Services
U.S. Food and Drug Administration

Food Protection Plan

An integrated strategy for protecting the nation's food supply

NOVEMBER 2007

PREVENTION · INTERVENTION · RESPONSE

"Americans enjoy unprecedented choice and convenience in filling the cupboard today, but we also face new challenges to ensuring that our food is safe. This Food Protection Plan will implement a strategy of prevention, intervention and response to build safety into every step of the food supply chain."

Michael O. Leavitt

Secretary of Health and Human Services
U.S. Department of Health and Human Services

Cover Photos



An investigator from the FDA's San Francisco District (left) working with an investigator from the California Department of Health Services, collecting soil samples as part of an investigation into an *E. coli* outbreak in spinach.

Black Star/Steve Yeater for FDA



A senior import specialist in FDA's New York District, reconciling importers' invoices with shipping labels and collecting samples at a food warehouse.

Black Star/Michael Falco for FDA



Today's consumers have come to expect increased levels of convenience and choice, both of which contribute to the need for a global food supply.

Getty Images

As a physician and the Commissioner of Food and Drugs, protecting America's food supply is extremely important to me.

American consumers have one of the safest food supplies in the world, but the world is changing and we know it can be safer. New food sources, advances in production and distribution methods, and the growing volume of imports due to consumer demand call for a new approach to protecting our food from unintentional or deliberate contamination. The U.S. Food and Drug Administration (FDA) must keep pace with these changes so that the safety of the nation's food supply remains second to none.

In the past few years, FDA has introduced several initiatives that address microbial and other food safety hazards with domestic or imported produce and that guide industry practices in the safe production of fresh-cut fruits and vegetables. FDA has also worked hard to raise awareness about food defense issues and preparedness. These are just a few things we are doing to improve food safety and food defense.

Recent nationwide recalls remind us how devastating foodborne illness can be. In the past year, contaminated peanut butter led to illnesses in more than 300 people and at least 50 hospitalizations. Contaminated spinach resulted in 206 illnesses, three deaths, and more than 100 people hospitalized. Reports of kidney failure and deaths in cats and dogs prompted a recall of more than 100 brands of pet food.

For every one of these emergencies, the FDA responded immediately to minimize harm. FDA investigators traced each problem's source and worked without delay to remove the affected products from market shelves. FDA staff continue to work diligently to protect our food supply, by containing outbreaks and preventing further illnesses.

With this FDA Food Protection Plan we are going even further. It is a forward-oriented concept that uses science and modern information technology to identify potential hazards ahead of time. By *preventing* most harm before it can occur, enhancing our intervention methods at key points in the food production system, and strengthening our ability to respond immediately when problems are identified, FDA can provide a food protection framework that keeps the American food supply safe.

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

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FDA is implementing a Food Protection Plan (the Plan) that addresses both food safety and food defense for domestic and imported products. The Plan is integrated with the Administration's Import Safety Action Plan. The Food Protection Plan operates through a set of integrated strategies that:

- Focus on risks over a product's life cycle from production to consumption
- Target resources to achieve maximum risk reduction
- Address both unintentional and deliberate contamination
- Use science and modern technology systems

FDA's Integrated Strategy Provides Three Elements of Protection

PREVENT Foodborne Contamination

- Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses
- Identify Food Vulnerabilities and Assess Risks
- Expand the Understanding and Use of Effective Mitigation Measures

INTERVENE at Critical Points in the Food Supply Chain

- Focus Inspections and Sampling Based on Risk
- Enhance Risk-Based Surveillance
- Improve the Detection of Food System "Signals" that Indicate Contamination

RESPOND Rapidly to Minimize Harm

- Improve Immediate Response
- Improve Risk Communications to the Public, Industry and Other Stakeholders

FDA recognizes the need to partner with Congress to make the changes necessary to transform the safety of the nation's food supply. This Plan identifies the administrative actions we are proposing to take within the Agency. This Plan also recommends legislative changes to strengthen FDA's ability to continue to protect Americans from foodborne illnesses.

Additional Protections that Involve Legislative Changes to FDA's Authority

PREVENT Foodborne Contamination

- Allow FDA to Require Preventive Controls to Prevent Intentional Adulteration by Terrorists or Criminals at Points of High Vulnerability in the Food Chain
- Authorize FDA to Issue Additional Preventive Controls for High-Risk Foods
- Require Food Facilities to Renew Their FDA Registrations Every Two Years, and Allow FDA to Modify the Registration Categories

box continued on page 4 ...

INTERVENE at Critical Points in the Food Supply Chain

- Authorize FDA to Accredit Highly Qualified Third Parties for Voluntary Food Inspections
- Require New Reinspection Fee From Facilities That Fail to Meet current Good Manufacturing Practices (cGMPs)
- Authorize FDA to Require Electronic Import Certificates for Shipments of Designated High-Risk Products
- Require New Food and Animal Feed Export Certification Fee to Improve the Ability of U.S. Firms to Export Their Products
- Provide Parity Between Domestic and Imported Foods if FDA Inspection Access is Delayed, Limited, or Denied

RESPOND Rapidly to Minimize Harm

- Empower FDA to Issue a Mandatory Recall of Food Products When Voluntary Recalls Are Not Effective
- Give FDA Enhanced Access to Food Records During Emergencies

FDA plans to enhance its information technology (IT) capabilities to fully support the implementation of the FDA Food Protection Plan.

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To download a copy of this report, go to <http://www.fda.gov/oc/initiatives/advance/food/plan.html> or for the PDF version go to <http://www.fda.gov/oc/initiatives/advance/food/plan.pdf>

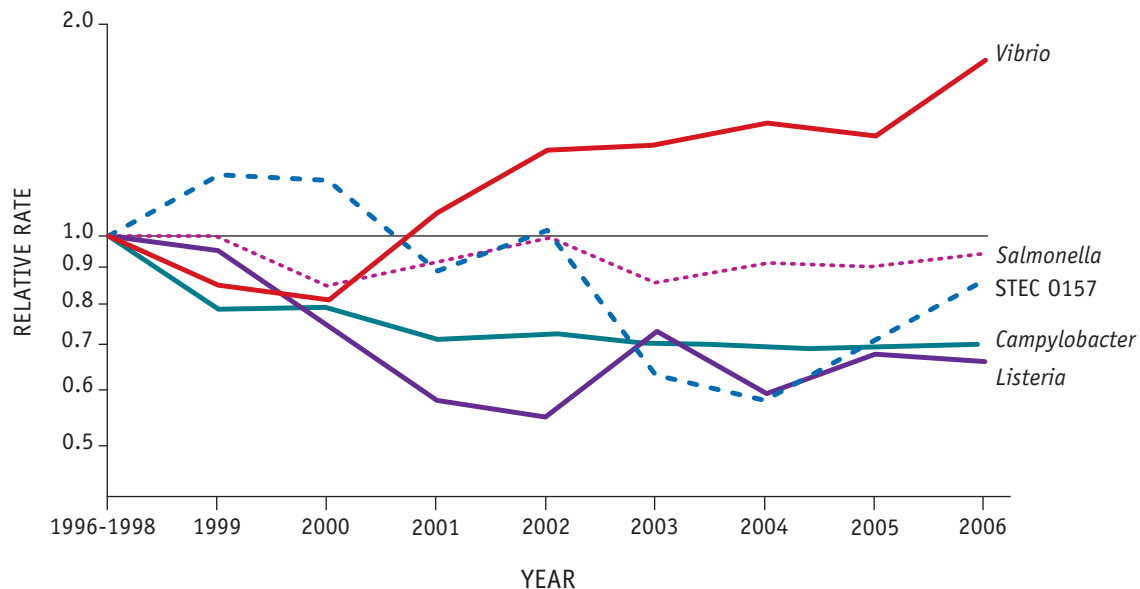
For more in-depth information on the many programs FDA has underway to protect the nation's food supply, go to the Food Protection main page at <http://www.fda.gov/oc/initiatives/advance/food.html>

II. INTRODUCTION

Every day across the country, people eat out, buy groceries, and cook meals for their families. Americans expect that all their food will be safe, and FDA plays a critical role in making sure this is true. FDA is responsible for the safety of the vast range of food Americans eat; about 80 percent of all food sold in the United States. This includes everything except for meat, poultry, and processed egg products, which are regulated by the U.S. Department of Agriculture (USDA).

In May 2007, Secretary of Health and Human Services Michael O. Leavitt and Commissioner of Food and Drugs Andrew C. von Eschenbach, M.D., charged FDA with developing a compre-

Relative rates compared with 1996-1998 baseline period of laboratory-diagnosed cases of infection with *Campylobacter*, STEC 0157, *Listeria*, *Salmonella* and *Vibrio*, by year.



Under its FoodNet program (www.cdc.gov/foodnet), the Centers for Disease Control and Prevention (CDC) monitors foodborne microorganisms that cause illness and tracks trends. This graph shows the progress that has been made in reducing foodborne infections. Other than recent increases in *Vibrio*- and Shiga toxin-producing *Escherichia coli* (STEC) 0157-related illness, the incidence of illnesses associated with these foodborne microorganisms has mostly remained steady or gone down since the late 1990s, although further progress is needed. Note that the graph represents all illnesses associated with the five types of bacteria, not just that from contaminated food. The graph also represents illnesses from foods not regulated by FDA.

Source: Centers for Disease Control and Prevention

hensive and integrated FDA Food Protection Plan to keep the nation's food supply safe from both unintentional and deliberate contamination. Driven by science and modern information technology, the Plan aims to identify potential hazards and counter them before they can do harm. A cornerstone of this forward-thinking effort is an increased focus on prevention.

The Plan builds in safety measures to address risks throughout a product's life cycle, from the time a food is produced to the time it is distributed and consumed. The Plan focuses FDA's efforts on preventing problems first, and then uses risk-based interventions to ensure preventive approaches are effective. The Plan also calls for a rapid response as soon as contaminated food or feed is detected or when there is harm to people or animals.

FDA's integrated approach, within the Food Protection Plan, encompasses three core elements: prevention, intervention and response.

- The *prevention* element means promoting increased corporate responsibility so that food problems do not occur in the first place. By comprehensively reviewing food supply vulnerabilities and developing and implementing risk reduction measures with industry and other stakeholders, FDA can best address critical weaknesses.
- The *intervention* element focuses on risk-based inspections, sampling, and surveillance at high risk points in the food supply chain. These interventions must verify that the preventive measures are in fact being implemented, and done so correctly.
- The *response* element bolsters FDA's emergency response efforts by allowing for increased speed and efficiency. It also includes the idea of better communication with other federal,

FDA's integrated approach, within the Food Protection Plan, encompasses three core elements: prevention, intervention and response.

state, and local government agencies and industry during and after emergencies. Whether contamination is unintentional or deliberate, there is a need to respond quickly and to communicate clearly with consumers and other stakeholders. The communication should emphasize identifying products of concern as well as assuring the public of what is safe to consume.

FDA is committed to strengthening the nation's food protection system through implementation of the FDA Food Protection Plan. The Plan's strategic and partnered activities are driven by science and incorporate the use of 21st-century technologies.

Scope of the Food Protection Plan

1. Applies to food for people and animals
2. Addresses domestic and imported products
3. Encompasses food safety (unintentional contamination) and food defense (deliberate contamination)

FDA Regulates Roughly 80 Percent of the U.S. Food Supply

- FDA regulates \$417 billion worth of domestic food and \$49 billion in imported food¹ annually.
- FDA has oversight of more than 136,000 registered domestic food facilities (including more than 44,000 U.S. food manufacturers and processors and approximately 113,000 U.S. food warehouses, including storage tanks and grain elevators).²
- FDA or state and local authorities regulate more than 2 million farms, roughly 935,000 restaurants and institutional food service establishments, and 114,000 supermarkets, grocery stores, and other food outlets.³ FDA provides guidance, model codes, and other technical assistance to state and local partners.
- Approximately 189,000 registered foreign facilities manufacture, process, pack, or hold food consumed by Americans.

¹ Based on FDA value-of-shipment information, 2003.

² Facilities that are engaged in more than one type of activity (e.g., manufacturing and warehousing) are counted in both categories; thus, the sum of the individual numbers of type of facilities exceeds the number of total registered facilities.

³ Data from U.S. Department of Agriculture, National Restaurant Association, and U.S. Census Bureau.

III. CHANGES AND CHALLENGES

Current trends in the food industry promise better nutrition and wider choices for consumers. At the same time, multiple factors pose challenges. These include changing food production technology, patterns of human demographics and behavior, business practices, new threats, and communication issues.

Trends in Demographics and Consumption

Changes in demographics and consumption have increased consumers' susceptibility to foodborne illness. For example, by 2015, it is estimated that 20 percent of the population will be 60 or older. Older Americans are among those at highest risk for foodborne illness.

Also, the practice of a family buying a head of lettuce and preparing a salad at home is not as common. Increasingly, consumers want the convenience of opening up a bag of salad that's already prepared, and immediately serving it.

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It used to be that when a single head of lettuce was contaminated, the resulting illness affected one family. Now, contaminated heads of lettuce may be processed with thousands of other heads of lettuce and placed into bags of convenience salad that many consumers can buy. These bags of salad end up in thousands of homes, potentially resulting in hundreds of illnesses.

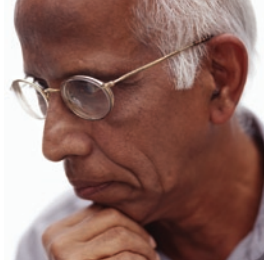
The shifting demographics have increased the numbers of susceptible consumers, and the convenience factors have meant that small problems can lead to large outbreaks—both indications of the need to make changes to ensure a continued high level of food protection.

Shifting Demographics

Our population demographics are changing. Shifting demographics means that more of the U.S. population is, and increasingly will be, susceptible to foodborne illness.

- In 2007, 20-25 percent of the population is in a high-risk category (young, older, pregnant, immune-compromised). These Americans face a risk of serious illness or death from foodborne illness*.
- In 1980, 15 percent of the population was 60 or older. By 2025, the number will be 25 percent.
- Four percent of the population is immune-compromised (transplant patients, people who are HIV positive, people receiving chemotherapy or other immunosuppressive treatments, people with chronic diseases).

** For example in a joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) report on *Listeria monocytogenes* (LM) microbiological risk assessment, it was estimated that transplant patients had a 2,584 increased probability of becoming ill from LM, compared with a healthy adult less than 65 years old. The same report indicated that AIDS patients had an 865-fold increase and an otherwise healthy adult over the age of 65 had a 7.5-fold increase [<http://ftp.fao.org/docrep/fao/007/y5394e/y5394e00.pdf>].*



Convenience Trends

Americans are consuming more convenience foods. Foods prepared outside the home may be subject to cross-contamination from other foods, as well as contamination from food workers.

- Ready-to-eat foods (bagged salad, cut fruit) and prepared foods (including hot bars with main and side dishes, as well as salad bars) and frozen dishes that can be cooked quickly are increasing in popularity.
- Cooking in the home is decreasing—people are eating out and bringing prepared foods home.
- Spending on foodservice items, such as supermarket deli foods, accounts for about half of all U.S. food spending.



Consumption Patterns

A greater variety of foods are eaten year round. Also, foods that are consumed raw or with minimal processing are often associated with foodborne illness.

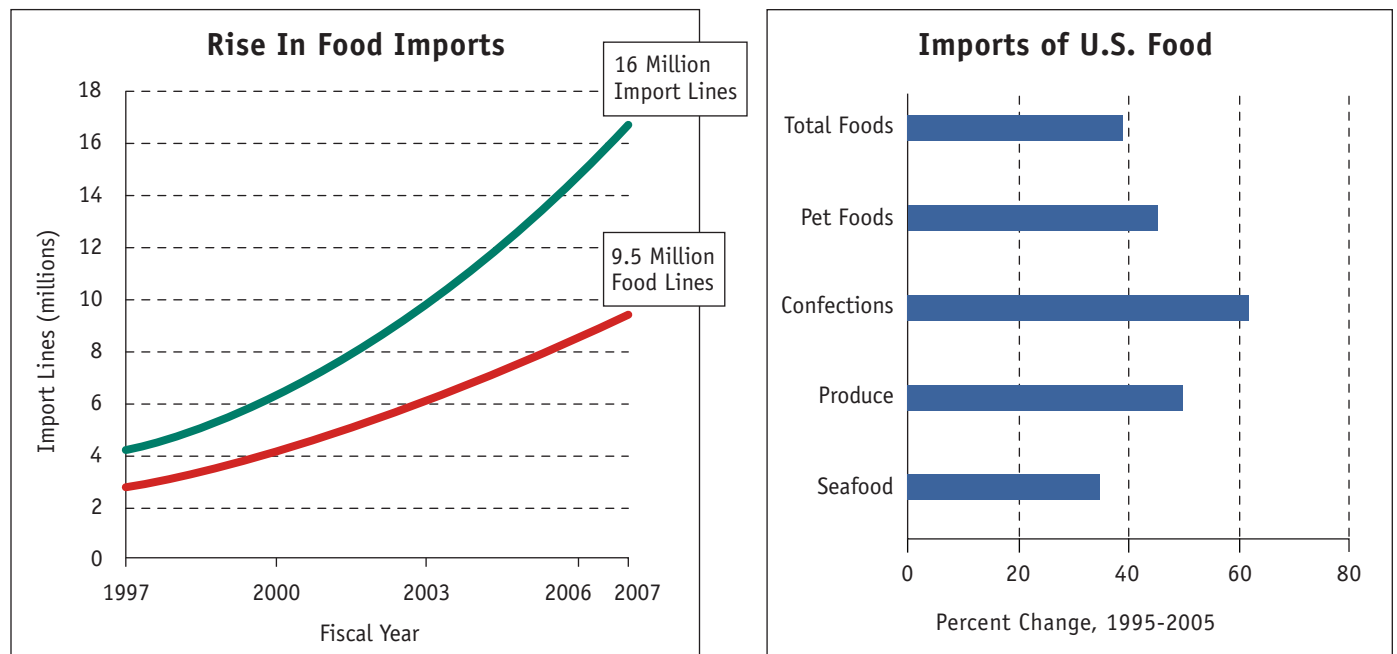
- Consumers are encouraged to make healthier food choices and increase consumption of fruits and vegetables (5-9 servings/day), including fresh produce.
- U.S. per capita consumption of fresh fruit and vegetables increased 36 percent from 1981 to 2000.
- A typical grocery store carried 173 produce items in 1987 and now carries 558 produce items.
- Produce items that were once considered seasonal are available on a year-round basis.
- Increased consumption of exotic foods whose safety hazards are not well understood.



Sources: U.S. Census Bureau and USDA Economic Research Service

Global Food Supply

There have been dramatic changes in the volume, variety, and complexity of FDA-regulated products arriving at U.S. ports. The United States trades with over 150 countries/territories with products coming into over 300 U.S. ports. In the last decade, the number of food entry lines¹ has tripled. According to the USDA Economic Research Service, approximately 15 percent of the overall U.S. food supply by volume is imported. However, in certain food categories a much higher percentage is imported. For example, approximately 60 percent of fresh fruits and vegetables consumed in the U.S. are imported, which fills the gap when U.S. domestic production is inadequate or out of season (e.g., bananas, tropical fruits, etc.). Imports of seafood rose from less than 50 percent of U.S. seafood consumption in 1980 to more than 75 percent today.



The type of imported foods is changing. In the past, the bulk of FDA-regulated imports consisted of unprocessed food ingredients with subsequent processing of those ingredients covered by FDA domestic regulatory oversight. Today, foods that are inherently more likely to pose risks, such as ready-to-eat food products, fresh produce and seafood, account for an increasing proportion of imported foods.

This is not to suggest that food imported into the United States, as a whole, poses a greater food safety risk than domestically produced food. But increases in the volume and complexity of imported foods have taxed the limits of FDA's approach to handling imports. Currently, data on 100 percent of the shipments are submitted through the electronic systems of the U.S. Customs and Border Protection (CBP) and FDA. The data are screened electronically to determine whether the food appears to present a significant risk to public health. Some foods are then inspected physically based on perceived risk. Food products of greater concern are physically inspected more frequently.

Currently, FDA often has very limited information regarding conditions under which most food is produced in foreign countries. While many foreign countries have well-developed regulatory systems to ensure food safety, other countries have systems that are less well-developed and that may not be able to ensure food safety to the same degree.

¹ An entry line means each portion of an import shipment that is listed as a separate item on an entry document. Items in an import entry having different tariff descriptions must be listed separately.

Growth in Foreign Manufacturers Exporting Low-Acid Canned Foods		
	1973	2004
Domestic LACF/AF Firms	742	1,300
Foreign LACF/AF Firms	34	6,700

One example of how the source of food has changed is in the import of canned or sealed fruits, vegetables, fish, and other products (collectively known as low-acid canned food/acidified food or LACF/AF). As the table shows, the number of domestic firms nearly doubled between 1973 and 2004. By contrast, there was close to a 200-fold increase in the number of foreign firms manufacturing these products for importation into the United States during the same period.

New Threats

New Foodborne Pathogens

Symptoms of foodborne illness range from mild stomach discomfort to life-threatening neurologic, liver, and kidney syndromes. In 1999, the CDC estimated that there were around 76 million cases per year of illness from foodborne agents, with 325,000 hospitalizations and 5,000 deaths in the United States each year. These data do not identify exactly how many are spread via foods (as opposed to person-to person contact or by some other means) nor do they indicate how the food became contaminated. However, we know that the most severe cases tend to occur in people who are very young, very old, or who have compromised immune systems.

Foodborne illnesses are caused by more than 200 different foodborne pathogens (agents that can cause illness) of which we are currently aware. These include viruses, bacteria, parasites, and toxins, plus a vast number of potential chemical contaminants and metals. The variety of agents associated with foodborne illness has steadily grown over the last few decades, and there is every probability that this list will continue to increase.

One example of a newer foodborne pathogen is *Enterobacter sakazakii*, which can cause serious illness such as sepsis (blood infection) and meningitis (inflammation of the membrane surrounding the brain and spinal cord). In 2002, FDA, working with CDC, discovered and subsequently alerted health care professionals to clusters of *E. sakazakii* infections reported in a variety of locations among hospitalized newborns, particularly premature or other immuno-compromised infants who were fed powdered infant formulas.

The emergence of new foodborne pathogens requires updated technologies that can detect the presence of new agents in a variety of foods. Addressing these emerging hazards requires cooperation among industry, academia, and government to share information and establish testing protocols.

Pathogens Newly Associated with Foodborne Illness Since the Mid-1970's	
<ul style="list-style-type: none"> • <i>Campylobacter jejuni</i> • <i>Cryptosporidium parvum</i> • Shiga toxin-producing <i>E. coli</i> • Noroviruses • <i>Salmonella</i> Typhimurium DT104 • <i>Vibrio cholerae</i> O139 • <i>Vibrio parahaemolyticus</i> 	<ul style="list-style-type: none"> • <i>Campylobacter fetus</i> • <i>Cyclospora cayetanesis</i> • <i>Listeria monocytogenes</i> • <i>Salmonella</i> Enteritidis • <i>Vibrio vulnificus</i> • <i>Yersinia enterocolitica</i> • <i>Enterobacter sakazakii</i>

Intentional Contamination

We must also consider food as a potential vehicle for intentional contamination. Such intentional contamination of food could result in human or animal illnesses and deaths, as well as economic losses.

The stark possibilities are suggested by the recent incident in which vegetable protein products, which were represented as wheat gluten and rice protein concentrate, were contaminated with melamine and melamine analogues. Though not considered an act of terrorism, the incident appeared to be a deliberate act for economic gain. It resulted in the sickness and deaths of cats and dogs, the recall of hundreds of brands of pet food products, state quarantine or voluntary holds on livestock that consumed suspect animal feed, and concern regarding the possible associated human health risks.

FDA has no reason to believe any physical harm was intended, but the melamine event indicates the danger of attempts to deliberately compromise the U.S. food system.

Communication

Effective communication requires active collection and use of incoming information and timely communication to external groups. FDA uses the information it receives to make appropriate decisions about food safety. FDA also shares information and advice with consumers, news media, industry, and state, local, and foreign agencies. Providing information that is timely, useful, and easy to understand is critical.

FDA, states, and industry receive food safety information in various ways. Signals of potential problems come in the form of consumer complaints, inspection data, positive test results, adverse event reports, and other reports of illness. FDA is committed to improving information flow to improve detection and response to signs of trouble.

FDA collects data from several sources. Data from the testing of food, inspections, and reports of illnesses are collected in federal and state systems. Data from foodborne illness and pathogen identification are entered into systems maintained by the CDC, the lead federal agency for conducting disease surveillance and outbreak investigations. Data from imports are entered into specific import systems. Currently, states conduct 10,000 inspections under contract to FDA and another 40,000 inspections under state law. These inspections include the collection of 300,000 food samples each year.

Enabling FDA's information systems to communicate more effectively with internal and external data sources is essential. This will increase productivity of FDA staff and streamline response times during food emergencies. The overall success of the Plan depends on improving the integration and analysis of the vast amount of information collected.

Just as consumers and businesses have important roles to play in providing information to FDA, the FDA plans to improve communication with stakeholders during food emergencies. In the 2007 outbreak involving chili sauce contaminated with *Clostridium botulinum*, the recalled product remained on the shelves of small retailers weeks after the recall announcement. Improving outreach to all segments of the food industry will ensure that harmful products are removed from the market quickly.



Black Star/Chris Cone for FDA

A scientist at FDA's Forensic Chemistry Center examines wheat gluten for possible melamine contamination.

IV. AN OVERVIEW OF THE APPROACH

Core Elements

While American consumers enjoy one of the safest food supplies in the world, growing challenges require a new approach to food protection at FDA—an increased emphasis on prevention.

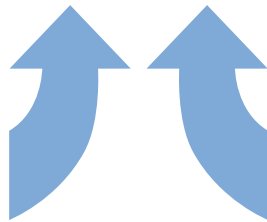
The Food Protection Plan

PREVENTION: *Build safety in from the start*

INTERVENTION: *Risk-based inspections and testing*

RESPONSE: *Rapid reaction, effective communication*

**FOOD
SAFETY**



**FOOD
DEFENSE**

Greater attention to prevention requires closer interaction with growers, manufacturers, distributors, retailers, food service providers, and importers.

Recent outbreaks linked to fresh produce, peanut butter, and pet foods show how FDA responds quickly to contain food safety problems. While this level of response needs to be maintained and even enhanced, there is also a need to focus more on building safety into products right from the start to meet the challenges of today. The FDA will work with the private sector to build on the actions of the food industry to ensure product safety. Building safety into products is described in one word: *prevention*.

This shift to an increased emphasis on prevention is at the core of FDA's Food Protection Plan, and will be evident immediately as the FDA begins an industry-wide effort to focus attention on prevention, from general best practices for all foods to the possibility of additional measures for high-risk foods. *Prevention* needs to be augmented by targeted *intervention* that focuses inspection and testing on the areas of greatest risk. This will reduce the likelihood that contaminated products will reach consumers. However, even the best system in the world cannot prevent all incidents of foodborne illness. Along with prevention and intervention, faster and more focused *response* is needed once a problem is detected.

Prevention – *Build safety in from the start.*

FDA must strategically place greater emphasis on preventive measures for food safety and food defense. These measures will promote improved food protection capabilities throughout the food supply chain. This will require close interaction with growers, manufacturers, distributors, retailers and food service providers, and importers. These partners have the ability to implement preventive approaches and to require them of their suppliers. FDA will continue to work with industry, state, local, and foreign governments to further develop the tools and science needed to identify vulnerabilities and determine the most effective approaches. With regard to imports, FDA will also work with foreign governments, which have a greater ability to oversee manufacturers within their borders to ensure compliance with safety standards.

Intervention – *Verify prevention and intervene when risks are identified.*

FDA, along with other federal agencies and state, local, and foreign governments, must undertake interventions in a coordinated and risk-based manner. Interventions, in the form of targeted inspections and testing, verify that preventive controls are working and that resources are being applied to the areas of greatest concern—either when the product is at the manufacturing facility, on its way to stores, or at a port of entry. Successful intervention will also require enhanced risk analysis, along with new detection technology to allow for faster analysis of samples. A successful and fully integrated food protection system will identify signals that indicate the need for intervention. Such signals may be a positive test for a harmful contaminant following an inspection, an industry report, a consumer complaint, or a full blown outbreak.

Response – Respond rapidly and appropriately.

Working with its food safety partners, FDA will improve its response system to more rapidly react when signals indicate either potential or actual harm to consumers. As part of an improved response system, the FDA will develop faster and more comprehensive ways to communicate with consumers and others during a food-related emergency.

Cross-Cutting Principles

Four important cross-cutting principles will allow a comprehensive food protection approach along the entire production chain.

Principles of the Food Protection Plan
<ol style="list-style-type: none">1. Focus on risks over a product’s life cycle from production to consumption.2. Target resources to achieve maximum risk reduction.3. Address both unintentional and deliberate contamination.4. Use science and modern technology systems.

1. Focus on risks over a product’s life cycle from production to consumption.

Comprehensive food protection requires considering the safety and defense risks associated with foods through their whole life cycle whether domestically produced or imported. Consideration must be given to areas that are potentially vulnerable to both unintentional and intentional contamination such as the point at which food is grown or produced, every processing or manufacturing step, points involved in distribution, transport, and warehousing, as well as all the points at the retail level through distribution to consumers. It is also important to consider the role that consumers play in safeguarding food once it is in their homes.

Consideration of the risks throughout a product’s life cycle is a significant shift in the Agency’s approach not only for domestic products but for imported foods too. A focus on prevention at the point of manufacture based on risk will provide data to strengthen risk-based inspections domestically, at the border, and overseas. In particular, FDA plans to work with foreign governments and federal partners to ensure that foods produced in foreign facilities meet U.S. safety requirements. Risk-based targeted inspections at the border will serve as a second layer of protection, rather than the principal one.

2. Target resources to achieve maximum risk reduction.

A comprehensive risk-based approach must consider the many variables that define risk. Such variables include:

- the possibility that consuming a particular food will result in a foodborne illness due to contamination of the product, which depends on such factors as the number of microbes present or the level of a chemical or toxin present, the susceptibility of the person to the contaminating agent, and whether the food was properly handled and cooked;
- the severity of that illness, should it occur;
- the point in the production cycle where contamination is most likely to occur; and
- the likelihood of contamination and steps taken during the production cycle to reduce the possibility of contamination

Foodborne illnesses range from distressing, but tolerable, symptoms to critical and life-threatening health problems. Illness due to *E. coli* O157:H7 can lead to kidney failure. Exposure to botulinum toxin can cause paralysis. Other, less severe illnesses may cause diarrhea and vomiting.

Some foods, such as those grown in the ground, may have little or no processing before they arrive in consumers' homes. Other foods are cooked to high temperatures (e.g., canned goods). Examining all aspects of the product life cycle helps define the areas of greatest risk. Implementation of the Plan will involve acquiring the data to best address risk, or, where the data is unavailable, working with appropriate partners to determine those risks.

3. Address both unintentional and deliberate contamination.

Food safety, which traditionally refers to unintentional contamination, has been a cornerstone of public health for many years. The idea that someone may use food as a vehicle to deliberately cause harm is a risk that must be addressed. There is a heightened awareness of terrorism as a real possibility that could cause a major public health crisis. To this end, FDA has devoted significant efforts over the last six years to address food defense—defending the food supply against deliberate attack.

Whether dealing with intentional or unintentional contamination, the same regulatory experts, resources, and industry partners are involved. The best way to handle food safety and food defense is to develop approaches that appropriately address both. Although there are differences in how these events are addressed, there are also many overlaps and parallels between the two. For example, the concepts of prevention, intervention, and response apply equally to both.

4. Use science and modern technology systems.

A successful plan for food protection is based on science. FDA's Food Protection Plan emphasizes the need to know the science underpinning how and where food becomes contaminated and the associated risks. The Plan also highlights the use of science to determine optimal interventions to reduce the likelihood of contamination. If contamination does occur, then the priority is to minimize the likelihood that it will cause significant harm. For example, successful intervention relies in large part on the science of epidemiology to understand which foods pose risks and the science of modern detection methods to identify harmful agents quickly.

The Food Protection Plan also highlights the need to further integrate information systems. Too often, sophisticated data systems lack the ability to share information. A priority in the Plan involves creating interoperable data systems, along with making current systems more interoperable, to allow for the exchange of product information along the whole life cycle. The goal is to make the most of important data from all relevant systems, and to obtain easier access to critical information.

Those at highest risk for serious foodborne illness include young children, older adults, pregnant women, and people with weakened immune systems.

V. THE INTEGRATED PLAN

The Food Protection Plan is based on three integrated elements of protection:

1. **Preventing** foodborne illnesses in the first place;
2. **Intervening** with risk-based FDA actions at critical points in the food supply chain; and
3. **Responding** rapidly when contaminated food or feed is detected.

Implementation of the elements will begin immediately, be phased in over time, and be integrated with the Administration's Import Safety Action Plan. All of the elements build on existing partnerships and direct resources to the areas of greatest risk.

But the FDA cannot take some key actions without new legislative authority. We summarize below in each element the new authorities needed to fully implement the Plan and strengthen

our ability to protect Americans. We look forward to working productively with Congress to ensure understanding of the design of and need for these authorities.

CORE ELEMENT #1: PREVENTION

Prevention is the first essential step for an effective, proactive food safety and defense plan. FDA's Plan implements three key prevention steps, which will move forward concurrently. The prevention steps are risk-based and will be implemented as appropriate to particular segments of the industry, taking into account that some foods are inherently safer than others.

The Plan's Key Prevention Steps

1. Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses
2. Identify Food Vulnerabilities and Assess Risks
3. Expand the Understanding and Use of Effective Mitigation Measures

FDA designed its Plan for the full life cycle of food—from production to consumption whether it be domestic or imported. The prevention elements of the Plan emphasize the importance for FDA and corporations to work collaboratively to prevent food problems from occurring.

This will be accomplished through a comprehensive review of food supply vulnerabilities. FDA will work with industry and other stakeholders to develop effective tools and science to head off outbreaks of foodborne illness caused by unintentional and intentional factors.

Some examples of enhanced corporate responsibility might include:

- evaluating safety and security vulnerabilities and possible impacts
- when appropriate, implementing preventive measures—both required and voluntary—to ensure that food is produced safely and securely
- developing a contingency plan to aid in a response in the event of contamination

1.1 Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses

Strengthen FDA Actions

- Meet with states and consumer groups to solicit their input on implementing preventive approaches to protect the food supply.
- Meet with food industry representatives to strengthen science-based voluntary prevention efforts, including developing best business practices and food safety guidelines.
- Develop written food protection guidelines for industry to a) develop food protection plans for produce and other food products, and b) implement other measures to promote corporate responsibility.
- Issue in Spring 2008, a final regulation requiring measures to prevent *salmonella* in shell eggs and resulting illnesses.
- Meet with foreign governments to share results of domestic prevention efforts and develop approaches for improving food safety at the source.
- Provide foreign countries with technical assistance so that they can enhance their regulatory systems.
- Analyze food import trend data and integrate it into a risk-based approach that focuses inspection resources on those imports that pose the greatest risk.
- Focus foreign inspections on high-risk firms and products.
- Improve FDA's presence overseas.



USDA

The Food Protection Plan builds on partnerships and directs resources to the areas of greatest risk.

Additional Legislative Authority Needed

Allow FDA to Require Preventive Controls Against Intentional Adulteration by Terrorists or Criminals at Points of High Vulnerability in the Food Chain

The FDA requests authority to require entities in the food supply chain to implement measures solely intended to protect against the intentional adulteration of food by terrorists or criminals. This authority would allow FDA to issue regulations requiring companies to implement practical food defense measures at specific points in the food supply chain where intentional contamination has the greatest potential to cause serious harm, such as requiring locks on tanker trucks transporting food. The specific points would be determined using vulnerability assessments such as CARVER+Shock¹, and the authority would only apply to food in bulk or batch form, prior to being packaged, which have clearly demonstrated vulnerabilities (e.g., short shelf life), and where it would affect multiple servings and there is a high likelihood of serious adverse health consequences or death from intentional adulteration. These regulations will be developed, taking into account the best available understanding of the uncertainties, risks, costs, and benefits associated with alternative options. The requirement would utilize industry best practices and would not apply to raw produce or food on farms, except for milk. FDA also proposes that firms be extended an affirmative defense in civil litigation if they comply with these controls.

Authorize FDA to Issue Additional Preventive Controls for High-Risk Foods

The FDA requests explicit authority to issue regulations requiring specific types of foods (those that have been associated with repeated instances of serious health problems or death to humans or animals from unintentional contamination) be prepared, packed, and held under a system of preventive food safety controls. Such authority would strengthen the FDA's ability to require manufacturers to implement risk-based Hazard Analysis and Critical Control Point (HACCP) or equivalent processes to reduce foodborne illnesses from high-risk foods.

Require Food Facilities to Renew Their FDA Registrations Every Two Years, and Allow FDA to Modify the Registration Categories

FDA requests statutory changes that would require facilities to register every two years and authorize the FDA to establish food categories within the registration system. These categories would allow FDA to tailor registration categories based on up-to-date food safety information. Under current law, FDA must use preexisting food categories that were not designed for registration purposes and therefore are of limited usefulness for evaluating potential threats to food protection. This change would ensure accurate, up-to-date registration data from facilities. Facilities whose registration remains unchanged would be able to file a simplified renewal registration or affirmation to that effect.

¹The CARVER+Shock model, explained in detail at <http://www.cfsan.fda.gov/~dms/vltcarv.html>, stands for Criticality, Accessibility, Recuperability, Vulnerability, Effect, and Recognizability, plus Shock. It is available as a software tool to evaluate the potential vulnerabilities of farm-to-table supply chains of various food commodities, as well as individual facilities or processes.

Why These Actions Are Important and What They Will Accomplish

Those with the biggest stake in food safety, after the consumers who eat the food, are the people and companies who grow, process, and sell food. Their livelihood depends entirely on the confidence of their customers. A poor reputation for proper food handling can drive a company to bankruptcy. Promoting increased corporate responsibility is key in shifting FDA's food protection effort to a proactive rather than a reactive one. The FDA will seek partnerships with industry to enhance consumer confidence. FDA will continue to work with industry in a) developing food protection plans that address safety and defense vulnerabilities, b) implementing prevention steps, and c) developing contingency plans to improve response to an outbreak of foodborne illness.

The FDA will primarily focus on promoting the use of risk-based, preventive systems that companies can apply at all levels of food production and processing, when appropriate. Voluntary approaches may be as basic as good manufacturing practices to ensure proper equipment sanitation and employee safety training. Potentially high-hazard food categories may require additional control measures. FDA will work with industry, consumer, and federal, state, local, and international partners to help model and promote preventive controls based on best industry practices.

FDA plans to acquire additional data to develop a better understanding of foreign country practices for food and feed. This may include the examination of best practices around the food safety control systems of other countries as well as increased understanding of the difficulties faced in implementing food protection measures. FDA will also seek to share U.S. food safety and defense best practices with foreign governments and provide technical assistance, when possible, to those countries exporting food products to the U.S. so they can enhance their regulatory systems. As part of its review of foreign systems and products, the Agency will analyze food import trend data and integrate it into a risk-based approach that focuses inspection resources on those imports that pose the greatest risk. This approach will also focus foreign inspections on high-risk firms. In the near term, a special emphasis will be placed on firms located in countries where imports into the United States have been refused repeatedly and import violations have threatened the health of U.S. consumers.

FDA's current and planned actions, along with the proposed legislative changes, would:

- Build safety and defense into the full food product life cycle—from production to consumption.
- Support work with industry, and state, local, and foreign governments to understand industry best practices and identify how and where preventive controls would work best.
- Promote the adoption of voluntary preventive controls throughout the food supply chain.
- Enhance relationships with trading partners and improve FDA's presence abroad.

1.2 Identify Food Vulnerabilities and Assess Risks

Strengthen FDA Actions

- Work with the food industry, consumer groups, and federal, state, local and international partners to generate the additional data needed to strengthen our understanding of food safety and food defense risks and vulnerabilities.
- Use enhanced modeling capability, scientific data, and technical expertise to evaluate and prioritize the relative risks of specific food and animal feed agents that may be harmful.
- Establish a risk-based process to continuously evaluate which FDA-regulated products cause the greatest burden of foodborne disease.
- Work with CDC to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated.

No additional legislative authority needed.

Why These Actions Are Important and What They Will Accomplish

These FDA actions provide important tools to facilitate increased corporate responsibility to prevent food contamination. These actions also address the need for additional information to better understand food safety and defense vulnerabilities and possible impacts. FDA will continue its work in this area and further engage industry and other outside groups to identify and target the greatest risks.

FDA actions will include gathering data for risk assessments and to conduct risk evaluations of commodity-agent combinations and relative risk ranking of commodities. A comprehensive, risk-based approach allows the FDA to maximize the effectiveness of its available resources by focusing on food products that have the potential to pose the greatest risk to human and animal health.

By analyzing data collected throughout the food product life cycle, we are better able to detect risks posed by food products. We are also better able to recognize key junctures where timely intervention can reduce or avoid those risks. Working with CDC, FDA will also build the capacity to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated.

Once established and emerging risks have been identified, assessed, and ranked, we can more effectively allocate our available resources to manage these risks as addressed below.

FDA's current and planned actions would:

- Strengthen the FDA's risk assessment capabilities and capacity to provide risk evaluations efficiently and rapidly.
- Advance collaborative work with CDC, USDA, and other federal, state and local agencies to understand attribution data on the food commodities that cause foodborne illnesses.

1.3 Expand the Understanding and Use of Effective Mitigation Measures

Strengthen FDA Actions

- Focusing on higher-risk foods, develop and implement a basic research plan on sources of contamination, modes of spreading and best methods to prevent contamination.
- Research, evaluate, and develop new methods to detect food contaminants.
- Encourage outside development of new contamination detection and prevention technologies.
- Develop Web sites and other platforms for disseminating research results and new steps industry can use to address vulnerabilities.

No additional legislative authority needed.

Why These Actions Are Important and What They Will Accomplish

Building on risk assessments, FDA will initiate basic research to enhance our understanding of sources of contamination, modes of spreading, and how best to prevent contamination. This information in turn will inform FDA's efforts above to promote increased corporate responsibility to implement effective preventive steps.

Focusing on higher-risk foods, FDA—working with other agencies—will undertake basic research and leverage relationships with outside organizations. The FDA will also research, evaluate, and develop new methods to detect contaminants in foods, and seek to facilitate new technologies that enhance food safety.

FDA's current and planned actions would:

- Initiate risk-driven research about sources, spread and prevention of contamination.
- Develop new mitigation tools and implement appropriate risk management strategies.

CORE ELEMENT #2: INTERVENTION

Because no plan will prevent 100 percent of food contamination, we must have targeted, risk-based interventions to provide a second layer of protection. These interventions must ensure that the preventive measures called for are implemented correctly. These interventions must also identify contaminated food that either unintentionally or intentionally circumvent our prevention plan. The Plan includes three key intervention steps.

The Plan's Key Intervention Steps
<ol style="list-style-type: none">1. Focus Inspections and Sampling Based on Risk2. Enhance Risk-Based Surveillance3. Improve the Detection of Food System "Signals" that Indicate Contamination

These steps emphasize targeted interventions at the point of manufacture and during distribution. They allow FDA to safeguard domestic products while increasing protection against importation of unsafe food.

Using robust risk-based analysis, FDA will conduct high-priority inspections that rely on statistical sampling and advanced risk detection tools. The FDA will verify industry busi-

ness practices across the food chain to ensure that effective preventive measures are in place. Gathering and analyzing test results, adverse event reports, consumer complaints, and other information will help the FDA track emerging food protection problems.

2.1 Focus Inspections and Sampling Based on Risk

Strengthen FDA Actions

- Focus food and feed safety inspections and sampling based on risk.
- Identify, evaluate and, if appropriate, validate and implement innovative foodborne pathogen detection methods and tools capable of quickly and accurately detecting contaminants in foods, such as real-time diagnostic instruments and methods that allow for rapid, on-site analysis of a particular sample.
- Train FDA and state investigators on new, technically complex, and specialized food manufacturing processes, as determined by a risk-based needs assessment, and modern inspection strategies.
- Collaborate with foreign authorities to reduce potential risk of imported food.

Additional Legislative Authority Needed

Authorize FDA to Accredite Highly Qualified Third Parties for Food Inspections

The universe of domestic and foreign food establishments subject to FDA inspection is immense and continuing to grow faster than the FDA's inspection resources. Even with the most sophisticated detection tools and laboratory capabilities, the FDA's inspection resources are finite. Therefore, legislation to authorize the FDA to accredit independent third parties, or to recognize entities that accredit, to evaluate compliance with FDA requirements would allow FDA to allocate inspection resources more effectively.

To establish such an accreditation program for voluntary food inspections, FDA would undertake a public process to determine best practices and solicit industry input in the design of the program. An FDA accreditation program would require FDA to accredit third-party organizations, or recognize an entity that accredits third parties. Third-party organizations could be, as appropriate, federal departments and agencies, state and local government agencies, foreign government agencies, or private entities without financial conflicts of interest. FDA would also:

- *Audit the work of these organizations to ensure that FDA requirements were consistently assessed;*
- *Review their inspection reports; and*
- *Provide ongoing training criteria to ensure they maintain their skills and knowledge, especially as technology and requirements change over time.*

FDA would use information from these accredited third-party organizations in its decision making but not be bound by such information in determining compliance with FDA requirements. Use of accredited third parties would be voluntary and might offer more in-depth review and possibly faster review times and expedited entry for imported goods manufactured in facilities inspected by accredited third parties. Use of accredited third parties may also be taken into consideration by the FDA when setting inspection and surveillance priorities.

Require New Reinspection Fee From Facilities That Fail to Meet Current Good Manufacturing Practices (cGMPs)

As part of the 2008 budget process, the Administration proposed a new user fee requiring manufacturers and laboratories to pay the full costs of reinspections and associated follow-up work when FDA reinspects facilities due to failure to meet cGMPs or other FDA requirements. Where FDA identifies violations during an inspection or issues a warning letter, FDA conducts follow-up inspections to verify a firm's corrective action. The proposed reinspection fee ensures that facilities not complying with health and safety standards bear the cost of reinspection.

Why These Actions Are Important and What They Will Accomplish

Effective FDA intervention means getting product risk information quickly to FDA investigators who oversee the regulated products, including a high volume of import entries. This information will allow the FDA to make better-informed decisions about what products

should be examined more closely and tested. It also signals when to initiate further action such as additional surveillance or an enforcement action.

FDA will look to leverage the resources of outside parties to accomplish more in-depth review of food products. By improving product knowledge and communication with all of our partners, including foreign authorities and the import community, we also can identify lower-risk products requiring less FDA scrutiny at U.S. facilities and at the border. This would enable the FDA to shift more resources to evaluating more closely products that are more risky, less well known, or from unknown manufacturers.

Modern detection tools and methods are critical for effective inspections and sampling. Better detection tools will allow FDA and other partners involved in food testing to more quickly and accurately detect contaminants. Because of its relevant expertise and experience, the FDA has unique capabilities to develop these tools.

Such tools could include real-time diagnostic instruments and methods that allow for rapid, on-site analysis of a particular sample or entry, especially those that are considered high-risk. For example, rapid contamination detection technology could be expanded to cover new agents and new food types, such as produce and dairy products. This type of technology could reduce analysis time from days to minutes. Increasing the speed at which the FDA can detect problems will allow FDA to expedite import entry review decisions or provide critical health information to the public when a problem is identified.

In addition to modernizing detection tools using information technology, the FDA must modernize inspectional strategies. This means increasing the probability that investigators will observe and identify potential problems.

FDA's current and planned actions, along with the proposed legislative changes, would result in:

- Focused risk-based inspections and sampling across the food chain.
- Development of rapid detection and testing tools.
- Increased involvement of federal, state, local, and foreign governments, in coordination with other food safety partners.
- Greater product knowledge and oversight through the accreditation of independent third parties.
- Modernized inspectional strategies.

2.2 Enhance Risk-based Surveillance

Strengthen FDA Actions

- Further enhance FDA's ability to target imported foods for inspection based on risk and publish the *Prior Notice of Imported Foods* Final Rule in 2008 as part of Bioterrorism Act implementation.
- Conduct foreign food and animal feed inspections more efficiently using the tools designed to target high-risk firms.
- Use advanced screening technology at the border.
- Improve data quality and handling capacity for food imports.
- Enhance information sharing agreements with key foreign countries.

Additional Legislative Authority Needed

Authorize FDA to Require Electronic Import Certificates for Shipments of Designated High-Risk Products

For food imports, the burden falls primarily on FDA to inspect and detect contamination at the U.S. border. With the explosion in import volume, this burden has become a serious challenge. The FDA should have

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the option of moving the inspection of high-risk products of concern “upstream” by entering into agreements with the exporting country’s regulatory authority for that authority (or an FDA-recognized third-party inspector) to certify each shipment or class of shipments for compliance with FDA’s standards prior to shipment. FDA would apply this requirement for imported products that have been shown to pose a threat to public health for U.S. consumers and thus would be unlike other imports where there is no such showing of risk. Such import certificate programs would be used for designated products imported from countries with whom FDA has concluded an agreement on a certification program that provides a level of safety sufficient to meet HHS/FDA standards. FDA would implement the government-to-government agreement by requiring importers to provide certificates from either relevant government agencies or accredited third parties.

While FDA would retain the authority to verify the safety of imported products, this approach shares the burden of ensuring the safety of food products with the exporting country. Shipments that fail to meet requirements would be refused entry.

For such a system to be effective, FDA will have to establish an in-depth collaboration with the relevant foreign government authority to ensure that the standards, processes, and criteria the foreign authority or third party uses in certifying products are sufficient to ensure compliance with FDA food safety standards. The FDA will also have to take several steps to ensure a secure system that prevents counterfeiting of the certificates and takes into consideration transshipment of products as a way to avoid certification.

FDA would use non-discriminatory science and risk-based criteria to determine the focus of this proposed authority and would use the authority only to the extent necessary to protect human or animal life or health.

Require New Food and Animal Feed Export Certification Fee to Improve the Ability of U.S. Firms to Export Their Products

As part of the 2008 budget process, the Administration proposed a new export certification fee for the issuance of export certificates for foods and feeds to those situations where exportation is restricted without this type of certificate. Private sector exporters would bear the cost of the program, but would reap its benefits through the FDA’s enhanced ability to facilitate product exports. Importantly, collection of these user fees will enable the FDA to issue certificates without redirecting resources from other critical food and animal feed safety programs devoted to protecting the public health. Such fees are currently collected by the FDA for export certificates for drugs and devices.

Provide Parity Between Domestic and Imported Foods if FDA Inspection Access is Delayed, Limited, or Denied

While FDA currently has the authority to obtain a warrant or initiate criminal proceedings if it is denied access to inspect facilities here in the U.S., its ability, under the Federal Food, Drug & Cosmetic Act, to enforce the inspection provisions for overseas sites is very limited. In particular, the FDA cannot refuse admission of food, even if its efforts to conduct a foreign inspection were unduly delayed, limited or denied at a facility where the product was manufactured, processed, packed or held. Having the authority to prevent entry of food from firms that fail to provide FDA access will enable the FDA to keep possibly unsafe food from entering U.S. markets. This authority provides strong motivation for firms to allow FDA to perform inspections, motivation similar to that provided to domestic firms. The authority would include several procedural safeguards, including an informal hearing if food is refused admission into the United States, such as is available for food that may be refused entry for other reasons.

Sampling the highest priority imports, especially those posing a significant public health threat, is critical ...

Why These Actions Are Important and What They Will Accomplish

FDA must prevent products that pose food safety and food defense threats from entering the United States. A targeted, risk-based approach to foreign product regulation is essential. Sampling the highest priority imports, especially those posing a significant public health threat, is critical and dependent on data related to the practices in the foreign facility. The activity will enhance FDA’s import programs and focus these programs on the life cycle of the imported product, through such means as enhanced use of information-sharing agreements with key foreign countries.

In addition, FDA will continue to look for enhanced ways to use risk-based screening technology to identify products that pose health risks at the border. For example, a screening technology prototype is currently being tested on imported seafood products in Los Angeles. If demonstrated successful, this technology could be extended to other imported products

and ports, thus enhancing the FDA's ability to quickly screen products at the border.

FDA's current and planned actions, along with the proposed legislative changes, would:

- Better focus on the imported products' total life cycle.
- Improve data systems to monitor foreign-produced food products.

2.3 Improve the Detection of Food System "Signals" that Indicate Contamination

Strengthen FDA Actions

- Deploy new rapid screening tools and methods to identify pathogens and other contaminants.
- Improve FDA's adverse event and consumer complaint reporting systems, including capturing complaints made to food manufacturers and distributors.
- Work to create a *Reportable Food Registry* for reports of a determination that there is a reasonable probability that the use of or exposure to an article of food will cause serious harm or death to humans or animals [as defined in the 2007 Food and Drug Administration Amendments Act (FDAAA)]. Under FDAAA, industry is expected to report such situations to the FDA within 24 hours.
- Work to create an *Early Warning Surveillance and Notification System* to identify adulterated pet food products, outbreaks of pet illness and to provide notice to veterinarians and other stakeholders during pet food recalls (as defined in the 2007 Food and Drug Administration Amendments Act or FDAAA).

No additional legislative authority needed.

Why These Actions Are Important and What They Will Accomplish

FDA can better detect and more quickly identify risk "signals" in the food supply chain via two key approaches: 1) deploying new rapid screening tools and methods to identify pathogens and other contaminants; and 2) enhancing its ability to "map" or trace adverse events back to their causes (whether reported to FDA or the food manufacturer or distributor) by improving its adverse event and consumer complaint reporting systems. This additional information will serve as a supplemental warning indicator for trending emerging food protection problems.

To provide the information necessary to allow for early detection of, and intervention with, contaminated animal feed, FDA will develop a centralized database for veterinarians that captures data on food safety incidents and the causes of food-related illness. The FDA will populate the database with key information from the veterinary community, veterinary hospitals, and other private U.S. sources.

FDA's current and planned actions would identify:

- signals that may indicate a problem with food from routine testing, consumer complaints, industry reporting and documented illnesses.

CORE ELEMENT #3: RESPONSE

During the past year, FDA responded to food safety problems with contaminated spinach, lettuce, vegetable proteins, and peanut butter, among other foods. Whether contamination is unintentional or deliberate, there is a need to respond faster and communicate more effectively with consumers and other partners.

The following key response steps will increase FDA's ability to quickly identify food safety problems, better coordinate a rapid emergency response among FDA, state and local government response teams as appropriate, and improve communications to the public, industry and other partners. This will better protect public health, help reduce the economic hardship affected industries face, and most importantly, maintain consumer confidence in the U.S. food supply following an incident.

The Plan's Key Response Steps

1. Improve Immediate Response
2. Improve Risk Communications to the Public, Industry and Other Stakeholders

CORE ELEMENT #3:
RESPONSE
continued

3.1 Improve Immediate Response

Strengthen FDA Actions

- Enhance the data collection, incident reporting and emergency response mapping capabilities of FDA's Emergency Operations Network Incident Management System.
- Work with stakeholders to develop an action plan for implementing more effective trace-back process improvements and technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients.
- Increase collaboration with foreign, federal, state, and local FDA partners to identify a contamination source, remove contaminated products, and implement corrective actions.
- Work with CDC and other selected federal, state, and local testing labs to communicate real-time testing results among FDA and lab members.

Additional Legislative Authority Needed

Empower FDA to Issue a Mandatory Recall of Food Products When Voluntary Recalls Are Not Effective

Although FDA has the authority to seize adulterated or misbranded food, this is not a practical option when contaminated product has already been distributed to hundreds or thousands of locations. And while the FDA has been able to accomplish most recalls through voluntary actions by product manufacturers or distributors, there are situations in which firms are unwilling to conduct a recall. In such situations FDA needs the ability to require a firm to conduct a recall to ensure the prompt and complete removal of food from distribution channels. This authority would be limited to foods that the Secretary has reason to believe are adulterated and present a threat of serious adverse health consequences or death. It would be imposed only if a firm refuses or unduly delays conducting a voluntary recall. An order to recall food could only be issued by the HHS Secretary, Deputy Secretary, or Commissioner of Food and Drugs, and would be accompanied by appropriate due process rights.

Provide FDA Enhanced Access to Food Records During Emergencies

During food-related emergencies, the FDA needs more complete and streamlined access to records necessary to identify the source of foodborne illness and take needed action. Improved access to information, including records related to an article of food or related articles of food that may present a threat, will enhance FDA's ability to identify problems, respond quickly and appropriately, and protect public health.

Currently, emergency access to records is limited to instances where, for an article of food, FDA has a reasonable belief that the food is adulterated and presents a threat of serious adverse health consequences or death. FDA proposes to expand access to records of related articles of food, such as food produced on the same manufacturing line. FDA also proposes, in food-related emergencies, to remove the adulteration requirement to allow its inspectors access to records in emergency situations where FDA has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death. The recent melamine situation in which FDA had early clinical evidence that a specific food was causing illness in pets but did not have clear evidence of a specific adulteration is an example of such a scenario.

The records access would relate only to safety or security of the food and would not apply to records pertaining to recipes, financial data, pricing data, personnel data, research data, and sales data. The requirement would not impose any new recordkeeping burdens, and would maintain the current statutory exclusions for the records of farms and restaurants.

Why These Actions Are Important and What They Will Accomplish

Recent food safety threats have demonstrated the importance of FDA's emergency response system. Contaminant tracing—or identifying where the contaminant has traveled within the food or feed supply—is critical in rapidly containing potential risks. Working with partners, FDA will pursue improvements to the current trace-back process and develop an action plan for implementing process improvements to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients.

As part of that effort, FDA will work with selected federal, state, and local testing labs to communicate real-time testing results among FDA and lab members.

FDA will also increase collaboration with foreign, state, and local regulators to identify the source of contamination, remove contaminated products as quickly as possible, and implement measures needed to prevent future contamination.

These improvements will allow FDA to quickly isolate problems, prevent contaminated products from reaching consumers, and ensure targeted recalls of products. Such steps aim to minimize the public health and economic impact from an outbreak.

FDA's current and planned actions, along with the proposed legislative changes, would:

- Enhance the nation's food emergency response system.
- Expand the FDA's trace-back process.
- Improve multi-partner collaborations, including with foreign regulators.

3.2 Improve Risk Communications to the Public, Industry, and Other Stakeholders

Strengthen FDA Actions

- Work with communications and media experts, including FDA's Risk Communication Advisory Committee, to design and conduct consumer communications and behavior response studies.
- Update the Food Protection Risk Communications Plan using the most effective strategies for sharing information with consumers.
- Build a consumer Web site to communicate relevant food protection information.
- In a food-related emergency, implement this communications plan, including utilizing all relevant media and technologies to reach consumers, retailers, industry, public health officials, and other stakeholders resulting in a better informed and thus more resilient population.

No additional legislative authority needed.

Why These Actions Are Important and What They Will Accomplish

Consumers protect themselves and their families from foodborne illness by responding promptly to FDA alerts. Important messages must be communicated clearly and through multiple forms of media to be effective, because different segments of the population use different technologies, ranging from television and newspapers to text messages and podcasts. In addition, major segments of the population do not use English as their primary language and rely on still other sources of information. This increases the challenge of implementing effective communication strategies.

Retailers, public health officials, industry and other key stakeholders likewise use an array of communications vehicles and sources. FDA's communication strategy during emergencies must use all such media to reach these different audiences and ensure that potentially harmful products are removed promptly.

FDA will enhance its risk communication program through aggressive, targeted food safety campaigns that disseminate clear and effective messages and regular updates through multiple venues to all targeted audiences. This program's designers will solicit input from the

new FDA Risk Communications Advisory Committee, which is tasked with obtaining expert advice in the field of risk communications.

FDA's current and planned actions will enable the FDA to:

- Communicate more effectively with consumers.
- Provide more rapid alerts to all stakeholders, including retailers, industry, public health officials, and the consumers.

CORE ELEMENT #3:
RESPONSE
continued

VI. ENHANCE INFORMATION TECHNOLOGY

In support of all three components of the Food Protection Plan, FDA plans to enhance its IT systems related to both domestic and imported foods. The focus will be to help the FDA more rapidly identify food importers, and maintain, update, and search records on food facilities and shipments more efficiently.

In particular, FDA will enhance collaboration with CBP on IT systems to more accurately identify firms involved in the food import supply chain during the import screening and review processes. These systems will allow for analysis of historical risk data about firms when making entry decisions for the firms' products.

A new systems approach can eliminate many problems with our current data. For example, assigning a unique identifier will eliminate duplicate records and make risk data about a firm easier to access. Policies for requiring the use of the new single national identifier will need to be established and agreed upon, recognizing the impact on industry worldwide.

Nearly all FDA business processes will benefit from more reliable and accurate information. Implementation of a new system will require a coordinated multi-agency effort that will benefit all federal agencies that process imported foods. CBP's existing data and ongoing activity will play a key role.

Finally, FDA will ensure that its infrastructure and disaster recovery system for IT systems and data are ready to deal with planned (maintenance and upgrades) and unplanned outages. This will provide the necessary support for import operations, which require the availability of multiple FDA systems around the clock. As an example, shipments arrive at U.S. ports day and night, and Prior Notice data are submitted at all hours. IT systems provide screening of the data as they are submitted, and Prior Notice Center (PNC) staff work around the clock to review the risk presented by shipments before their arrival. The PNC needs to review shipment data in as little as two hours from submission. Any interruption in the availability of the computer systems prevents the filing and timely review of information. This affects the flow of goods into the United States, and poses a safety risk to consumers.

An integrated, IT infrastructure—with data gathering, sorting, mining, and trending capability built into the systems—is critical to the success of FDA's food protection efforts.

VII. CONCLUSION

Ensuring that FDA-regulated products are safe and secure is a vital part of FDA's mission—to protect and promote public health. The FDA remains committed to working closely with its partners to protect the nation's food supply.

In the United States, market forces give companies a strong motivation to be vigilant and even innovative in ensuring food safety. The laws of regulation must encourage, not disrupt, these motivations. Rather than taking over responsibility from food companies, FDA wants to protect their flexibility to pursue it vigorously.

Although we have made progress, much remains to be done. Recent incidents of contaminated food and animal feed have highlighted the importance of a strong food protection system. Americans rightly expect to purchase food without having to worry about safety.

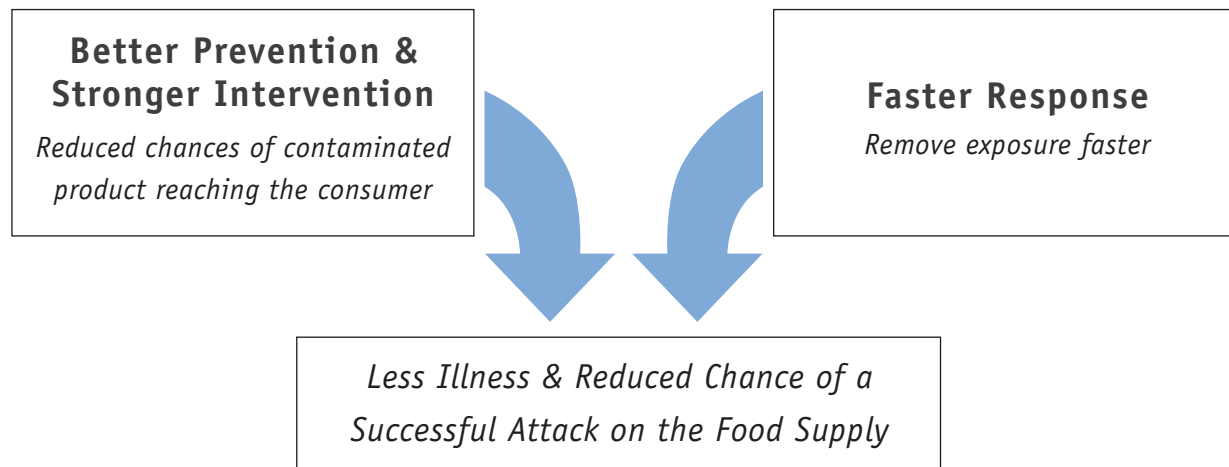
Rising food imports, increasing consumption of convenience foods, and new foodborne pathogens are among the challenges we face. To address these challenges, we must move toward a food safety and defense system that is more proactive and strategic.

FDA's Food Protection Plan contains three core elements—prevention, intervention, and response—with greater emphasis on preventive measures that keep contaminated food from ever reaching consumers. The Plan operates through a set of integrated strategies that address the product life cycle, a risk-based allocation of resources, the integration of food safety and food defense, and builds on a foundation of science and modern information systems.

FDA's Food Protection Plan complements the nation's strategic framework for import safety, which was released by the U.S. Department of Health and Human Services in September 2007. Both plans focus efforts on working smarter and better with importers, manufacturers, and other government agencies.

FDA will aggressively pursue the Food Protection Plan so that U.S. consumers can be assured that their food remains among the safest in the world.

The Public Health Impact of the Food Protection Plan





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