Chapter 8 – Outreach and Leveraging

Contents

Introduction

The events of Fiscal Year 2007 presented enormous challenges to FDA, especially those involving outbreaks of foodborne illness which resulted in numerous recalls.

FDA was able to achieve its mission because of the strong commitment of its hundreds of employees. Additional factors which enabled FDA to meet its mission included the strong relationships that FDA has forged throughout the years with its counterpart health agencies. These agencies include foreign health agencies, such as the World Health Organization, numerous federal government agencies, such as the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture (USDA), and state and local health agencies. These entities all assisted in the numerous investigations, recalls, and traceback efforts involved in responding to the continuous outbreaks of foodborne illnesses in FY 2007.

In addition to government health agencies, FDA forged positive relationships with industry and the private sector by initiating outreach programs, educational seminars, public meetings, and issuing a number of guidance documents.

Equally significant were FDA's efforts in creating new initiatives to further protect the public health such as the 2007 Tomato Safety Initiative, which was preceded earlier by the Lettuce Safety Initiative and the Leafy Greens Initiative.

Other examples of the combined efforts of federal, state, industry and academia working together were the Human Tissue Task Force, and the Joint Diabetes Initiative.

FDA is proud of the work it has accomplished in FY 2007. The Agency is also proud of those whom have assisted the Agency in the past year. Together, all those committed to protecting the public health have enabled FDA to meet its public health mission more effectively and efficiently.

In addition to describing the contributions outlined above, this chapter also provides a summary of the new FDA Amendments Act of 2007, and an overview of the Food Protection Plan and the Action Plan for Import Safety.

I. Managing Crises
"Headquarters, We Have a Problem!"

A. Public Health Emergencies-Responding to Foodborne Illness

Access to Records

For the first time in FY 2007, FDA invoked the authority granted to the Agency pursuant to Section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 to compel FDA's access to food manufacturing records after it had been determined that certain foods were adulterated and presented a threat of serious adverse health consequences or death in humans or animals. FDA subsequently exercised this authority on five additional occasions.

Overview: In 2007, FDA responded to public health crises caused by multiple outbreaks of foodborne illnesses as a result of contaminated foods. FDA's response to these outbreaks was swift and effective. On numerous occasions FDA worked around the clock with foreign, Federal, state and local counterpart agencies to rapidly remove the contaminated product from the marketplace and conducted traceback investigations to determine the cause of the contamination. The following are descriptions of some of the outbreaks of foodborne illnesses that occurred in Fiscal Year 2007.

1. December 2006 – E. Coli at Taco Bell

In December 2006, FDA investigated an outbreak of E. coli O157: H7 (*E. coli*) infection in consumers associated with eating food from several Taco Bell restaurants in Northeastern states. FDA actively worked with state and local health officials, and CDC, to determine the cause of these illnesses and prevent additional infections.

FDA also worked with Taco Bell Corp. and its suppliers and distributors to obtain information on sources and distribution of products and to aid in tracing back any products identified as contaminated with the *E. coli* pathogen. Based on a number of factors, iceberg lettuce was eventually considered overall to be the single most likely source of the outbreak.

2. December 2006 - E. coli at Taco John

Also in December 2006, another *E. coli* outbreak occurred in Taco John restaurants in Iowa and Minnesota. On January 12, 2007, FDA announced that the Agency had moved closer to identifying the source of illness for the Taco John *E. coli* outbreak. FDA and the State of California, working in conjunction with state health officials in Minnesota, Iowa, and Wisconsin, DNA-matched the strain of *E. coli* bacteria associated with the outbreak with two environmental samples gathered from dairy farms near a lettuce growing area in California's Central Valley.

This outbreak was not connected to the previous outbreak at Taco Bell restaurants.

3. *February 2007 - Salmonella in Peanut Butter*

Beginning in February 2007, more than 600 people from 39 states were sickened by *Salmonella*-tainted peanut butter manufactured at a ConAgra plant in Sylvester, Georgia. FDA, together with public health officials in multiple states and the CDC investigated this large multi-state outbreak. The outbreak of foodborne illnesses resulted in the recall of approximately 326 million pounds of peanut butter, including product produced under Peter Pan and Great Value brands. FDA inspectors conducted an inspection at the ConAgra plant in Georgia, and collected samples which were analyzed and found to be positive for *Salmonella*. Through its investigative efforts, FDA discovered that product from another ConAgra plant located in Tennessee was also implicated in the outbreak.

FDA continued to work closely with the CDC, states and local officials to identify how the contamination occurred in order to prevent similar foodborne illness outbreaks.

4. March 2007 – Melamine in Pet Food Results in Massive Recall

Following reports of illnesses and deaths of both cats and dogs, FDA coordinated a widespread investigation and massive recall involving over 5,300 pet food products. Every one of ORA's 20 District Offices and 170 Resident Posts were involved in responding to some aspect of this contamination. FDA's Florida District alone recorded 1,700 consumer complaints; and it is estimated that FDA received more than 12,000 consumer complaints associated with this emergency.

FDA's intensive, investigative efforts eventually found the cause of the pet food contamination. In March 2007, FDA found contaminants in wheat gluten imported to the United States from China and used as ingredients in pet food. FDA's Forensic Chemistry Center conducted its own analysis which identified melamine and melamine analogues in the pet foods and in the wheat products used as an ingredient in pet foods. FDA's investigative efforts eventually traced the suspect product to a single supplier in China.

FDA Worked Closely With a Broad Partnership of Scientists in Government, Industry, Academia, State and Local Health Authorities in the Pet Food Recall

In response to the contamination of pet food and animal feed, FDA worked closely with a broad partnership that included scientists in government, industry, and academia and with 50 state departments of agriculture, health authorities, veterinarians, and the Association of American Feed Control Officials. FDA utilized data from Banfield Pet Hospital (a nationwide network of veterinary hospitals), the Veterinary Information Network, Poison Control Centers, universities, and other organizations to assess the extent of the outbreak of cat and dog illnesses and deaths.

FDA scientists also worked with the Food Safety and Inspection Service (FSIS) of the USDA, the CDC, the Environmental Protection Agency, (EPA) and the Department of Homeland Security (DHS) to develop a risk assessment to evaluate the risk to human health from consuming pork, chicken, fish, and eggs from animals inadvertently fed animal feed containing pet food that contained melamine and melamine-related compounds. The assessment found that this consumption was unlikely to pose a human health risk.

5. *July, August, September 2007 – Deadly Clostridium botulinum Toxin in Variety of Products including Hot Dog Chili Sauce*

Beginning in July 2007, FDA oversaw yet another massive recall of foods potentially contaminated with the deadly *Clostridium botulinum* toxin. The botulism toxin can cause muscle paralysis which, in some cases, may lead to death. FDA worked aggressively with the manufacturer to expedite the recall in response to several reports of botulism illnesses. The deadly bacterium was subsequently confirmed through FDA analytical testing.

The implicated products were mainly a variety of brands of canned hot dog chili sauce, but also included four brands of dog food.

FDA announced in September 2007, that although the products had been recalled by "Castleberry's", the manufacturer, FDA investigators were continuing to find potentially contaminated product still being sold in stores. In response to this finding, FDA coordinated an audit "blitz" in which investigators visited over 12,000 stores. Contaminated product was found in over 1,000 stores.

FDA's food safety partners at FSIS and state agencies also visited thousands of retail stores. State agency inspectors identified an additional 1,192 stores that were still selling potentially contaminated product out of 10,073 stores visited.

This collaborative approach among the USDA, state agencies, and the FDA was implemented due to the size of the recall and the severity of the hazard, and was initiated very early in the recall process to augment the efforts of the recalling firm, which bears responsibility for conducting an effective recall. This unique, effective method resulted in the removal of harmful products from the marketplace, prevention of further injuries, and public health protection. This massive effort by FDA and its counterpart agencies and FDA's unprecedented communication efforts during the recall undoubtedly saved hundreds of lives.

6. *April 2007 – Olives with Clostridium botulinum*

In April of 2007, FDA alerted consumers of possible serious health risks from eating olives that may be contaminated with the deadly bacterium, *Clostridium botulinum*. The olives, made in Italy, were recalled by the manufacturer. The potential for contamination was noted after routine testing found that the product had a higher than required pH.

7. May 2007 -- Toothpaste with DEG

In response to reports in May 2007 of contaminated toothpaste imported from China that was tainted with a poisonous chemical called diethylene glycol (DEG), FDA undertook an extensive sampling effort to collect samples of Chinese dental products. This sampling effort took place both at the border and at discount retail stores around the country, effectively halting the likelihood that the product would end up in the possession of

U.S. consumers.

FDA issued a warning to consumers. On May 31, 2007, the Agency also published an Import Alert, "Detention without Physical Examination of Dentifrice Products Containing Diethylene Glycol (DEG)" to prevent Chinese toothpaste containing DEG from being sold in the United States. To view the full text of the Import Alert, go to: http://www.fda.gov/ora/fiars/ora_import_ia6674.html.

B. Resources for Crises Management

1. FDA's Emergency Operations Center

EOC Enables FDA to Initiate Investigations Quickly, Often the Same Day FDA Receives Information

Foodborne illnesses presented numerous challenges to FDA in FY 2007. These public health crises have demonstrated FDA's ability to respond quickly to effectively protect consumers. Upon becoming aware of a foodborne illness outbreak associated with FDA-regulated products, FDA's Emergency Operations Center (EOC) coordinates the Agency's response, providing a central point in the Agency for managing the early phases of an emergency so that crucial information can be shared and acted upon immediately by appropriate FDA offices. This enables FDA to initiate investigations quickly, often the same day as the developing information is obtained.

EOC coordination enables FDA to provide the public, in real time, accurate up-to-date information. EOC also provides technical experts within FDA with access to both investigational and analytical data to facilitate their ongoing evaluations with the goal of making appropriate recommendations to prevent further illnesses or other adverse impacts to human and animal health. EOC staff are available on an around-the-clock basis. FDA works closely with public health agencies such as the CDC, USDA, Customs and Border Protection, (CBP) the states, and other agencies, in any emergency response.

2. FDA/USDA Food Emergency Response Network (FERN)

FDA, with USDA's Help, Found the Source of *E. coli* O157:H7, that Caused Outbreak of Foodborne Illness from Fresh Spinach

The FDA/USDA Food Emergency Response Network (FERN) has continued to grow and enhance the nation's food testing capacity. FERN is a network of Federal, state, and local laboratories capable of testing food samples for microbiological, chemical, and radiological threat agents. This partnership provides essential analytical expertise and surge capacity during emergencies. The FERN network proved to be a critical asset in the *E. coli* O157:H7 outbreak associated with fresh spinach. FERN analysts worked closely with personnel from the CDC's Laboratory Response Network to harmonize and approve a modified FERN method for detecting *E. coli* O157:H7 in spinach. This method allowed for substantially improved testing of spinach samples as it allowed for the detection of *E. coli* O157:H7 at lower levels.

II. Imported Foods

A. Collaboration with Counterpart Agencies

Overview: Approximately $2 trillion worth of products are expected to be imported into the United States from around the world this year. FDA is working closely with counterpart agencies in many other countries to help ensure that FDA-regulated products coming into the United States meet the standards of safety and quality that Americans expect. While this section focuses on foods, other imported products include animal feed, human and animal drugs, cosmetics, medical devices, vaccines and other biological products, and radiation-emitting goods.

FDA analyzes about 30,000 import product samples annually. The Agency also performed over 80,000 examinations of imported goods in the field and conducted over 800 foreign inspections during the past fiscal year—from October 1, 2006, through September 30, 2007.

1. *International*

a. Increasing Cooperation with China

On December 11, 2007, FDA and its Chinese counterparts signed two agreements to increase cooperation and information sharing between the U.S. and Chinese governments. For additional information see Section B(1) of this chapter, *New FDA/Chinese Agreements.*

b. Other Foreign Counterpart Agencies

FDA Has Confidentiality Agreements with 31 Counterpart Agencies in 17 Countries

FDA also works with and provides training to our regulatory counterparts in foreign countries that focus on U.S. public health requirements and methods to improve product safety in the foreign country in order to assure that exporters meet our requirements. In addition, FDA works with foreign counterparts to share information regarding each country's respective laws, requirements and regulatory systems, and which also allow for notification to each other when significant violations or recalls are found in products that are exported.

FDA has confidentiality arrangements with 31 foreign counterpart agencies in 17 countries that permit the Agency to share and receive non-public information about imported products. For example, if the European Union (EU) has a problem with an imported commodity, the EU will send FDA notices. This allows the Agency to enter that data into Agency automated systems to learn whether or not FDA has received any of those products and to make sure that the Agency sets up the appropriate controls to ensure that those products don't come into the United States.

2. *Federal Agencies*

FDA's collaborative work with other Federal agencies is long-standing. These relationships better enable FDA to conduct much of its day-to-day enforcement activities more efficiently. More importantly, these collaborative relationships enable FDA to respond immediately in emergency situation resulting in increased protection of the public health.

a. Interagency Working Group on Import Safety

On July 18, 2007, President Bush issued Executive Order 13439 to promote and enhance the safety of all imported products. This Executive Order established the Interagency Working Group on Import Safety. The Working Group, which included representatives from 12 Federal departments and agencies, is tasked with reviewing the procedures, regulations, and practices for ensuring that imported food, drugs, and other consumer products are safe. Secretary of Health and Human Services, Michael O. Leavitt, chaired the working group and FDA played a key role. Secretary Leavitt and FDA Commissioner von Eschenbach traveled extensively throughout the country during FY 2007 visiting ports of entry and reviewing FDA field operations. The insights gained helped to shape the conclusions and recommendations of the Working Group.

On September 10, 2007, the working group provided the President with an initial report that laid out steps to improve import safety. The report, "Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety," outlines an approach that can build upon existing efforts to improve the safety of imported products, while facilitating trade. It recommends that the government work with the importing community in developing methods to address safety risks over the life-cycle of imported products and focus actions and resources to minimize the likelihood of unsafe products reaching our borders. In November, the working group issued an implementation plan with 50 specific recommendations in 14 different categories. A risk-based, prevention-focused model will help ensure that safety is built into products before they reach consumers. To read the complete "Action Plan for Import safety" go to: http://www.importsafety.gov/report/actionplan.pdf.

To read the full text of the Executive Order, go to: http://www.whitehouse.gov/news/releases/2007/07/20070718-4.html.

b. Centers for Disease Control and Prevention

FDA has a strong, long-standing, collaborative working relationship with its sister agency within the Department of Health and Human Services (HHS), the CDC. FDA has the lead responsibility within HHS for ensuring the safety of food products, while CDC has an equally important complementary and non-regulatory public health role. CDC is the lead Federal agency for conducting disease surveillance and outbreak investigations and routinely monitors the occurrence of specific illnesses in the United States attributable to contaminated foods within the food supply.

The disease surveillance systems coordinated by CDC, in collaboration with the states, provide an essential early-information network to detect and minimize the impact of foodborne illness outbreaks. FDA has hundreds of interactions with CDC throughout the year. Information from CDC results in a swift response time by FDA to outbreaks of foodborne illnesses. In addition, CDC's assistance with traceback investigations frequently results in resolution of the causes of outbreaks of foodborne illnesses.

As an example, when CDC informed FDA of a multi-state outbreak of *Salmonella tennessee* associated with Peter Pan peanut butter, FDA sent investigators into the ConAgra peanut butter plant within 24 hours. FDA issued a warning to consumers the day after CDC notified FDA of these outbreaks.

c. U.S. Customs and Border Protection

FDA Works Cooperatively with CBP to Identify Shipments Containing Potentially Dangerous Foods and Prevent their Entry Into the U.S.

Because of the tremendous volume of imports—about $2 trillion worth of products each year from more than 230 countries—FDA cannot physically inspect or examine every product entering the United States. FDA uses a targeted, risk-based approach, which means that the Agency works to inspect the right imports—those that may pose a significant public health threat.

FDA works cooperatively with CBP to help identify shipments containing potentially dangerous foods and prevent them from entering the country. By law, certain information must be submitted to FDA about food products before they are allowed to enter the U.S.

Advance notice of imported food shipments, called "Prior Notice," allows FDA, with the support of CBP, to electronically screen shipments for potential serious threats to health, (intentional, alleged or otherwise) before the food arrives and to target those products flagged by the electronic system as presenting the most significant risk. This allows FDA to conduct more intensive import security reviews on potentially high risk entries and to allocate resources for inspections more effectively.

Upon submission, all prior notice data is validated against FDA's Operational and Administrative System for Import Support (OASIS) for completeness to ensure that it meets minimal data submission requirements. Once the data is validated, it is then screened against specific food security criteria established in OASIS to identify and flag "high risk" shipments. Prior Notice high-risk screening criteria are based upon a number of different factors.

Shipments of imported food that are determined to pose a significant security risk are held upon arrival in the U.S. for joint examination by FDA and CBP personnel. FDA's efforts to oversee the Prior Notice provisions of the Bioterrorism Act are significantly enhanced by FDA's Prior Notice Center, a 24/7 operation, and CBP's National Targeting Center-Cargo facility.

d. U.S. Department of Agriculture

FDA, with USDA Help, Finds Source of *E. coli* O157:H7, that Caused Outbreak of FoodBorne Illness

FDA works closely with USDA's Agricultural Research Service (ARS) and Cooperative State Research, Education, and Extension Service (CSREES) to coordinate and mutually support our respective efforts related to food safety. This relationship allows FDA to augment its research resources and gain access to facilities and expertise we do not have. In this spirit, FDA

collaborated with ARS and CSREES to look for sources of *E. coli* O157:H7 in California's Salinas Valley, to analyze water samples from the Salinas watershed for *E. coli* O157:H7, and to relate the location of bacteria to geographical, seasonal, or rainfall variation. FDA used the information obtained from this study to inform produce growers about strategies to prevent pre-harvest microbial contamination.

Pet Food Recall: In addition, FDA worked hand-in-hand with USDA in the massive pet food recall that occurred in 2007. FDA and USDA conducted a comprehensive investigation of pet food contaminated with melamine and melamine-related compounds, and the feeding of contaminated pet food scraps to hogs and chickens.

When FDA learned that certain contaminated feed had been fed to animals, FDA and USDA took precautionary actions. Because the animal feed in question was contaminated, USDA did not allow this potentially contaminated meat to enter distribution channels.

Castleberry's Recall: FDA collaborated with USDA in another massive recall, this time involving certain canned food products and certain dog food produced by Castleberry's Food Company ("Castleberry's") of Augusta, Georgia. FDA, in collaboration with USDA's FSIS and numerous state agencies, visited thousands of retail establishments to ensure that canned food and pet food products manufactured and distributed by "Castleberry's" that could contain botulism were removed from store shelves and properly disposed.

Illegal Drug Residues in Cows: FDA has a long history of collaboration with USDA's FSIS in efforts to stop farmers from selling milk for human consumption and cows for slaughter for human consumption that have illegal drug residues in their tissues. USDA's analysis of drug residues in the tissues of cows assists FDA in taking enforcement action against farmers who illegally sell these cows for human food. Because of these collaborative efforts with USDA, in the last five years alone, FDA has enjoined 11 farmers from selling cows with illegal drug residues and has issued Warning Letters to numerous others. These actions were most often

based on the USDA's findings of illegal drug residues in the edible tissues of cows.

3. Academia: Scientific and Technical Affiliates

FDA strengthens the scientific basis for the Agency's outreach efforts by collaborating and learning with others, such as participating in many scientific and technical meetings on food safety. FDA participated in a forum sponsored by the *Western Institute for Food Safety and Security* to share information on assessing industry approaches to address the safety of lettuce and leafy greens on the farm and at packing, cooling, and processing facilities. In February 2007, the FDA-affiliated *Joint Institute for Food Safety and Applied Nutrition* and the *University of Florida* sponsored a workshop to improve understanding of how tomatoes become contaminated with *Salmonella* and other pathogens. In May 2007, FDA, the *National Center for Food Safety and Technology*, and the *University of Georgia's Center for Food Safety* co-sponsored a workshop on microbial testing to reach a consensus on the role of microbial testing to ensure the safety of produce.

To seek additional input from the public, FDA held two public hearings (March 20 in California and April 13 of 2007 in Maryland) concerning the safety of fresh produce.

4. Stakeholders: Industry and the Private Sector

To succeed in science-based efforts to promote food safety, FDA needs to enhance collaborations with stakeholders interested in food safety, particularly with respect to fresh produce. Fresh produce is grown on tens of thousands of farms, and contamination at one step in the growing and processing chain can be amplified at the next step. FDA has worked with the public and private sector to encourage industry to follow the recommendations and standards contained in FDA guidances. After enlisting the help of the scientific community and the industry, on March 12, 2007, FDA published a draft final guidance advising processors of fresh-cut produce how to minimize microbial food safety hazards common to the processing of most fresh-cut fruits and vegetables, which are often sold to consumers in a ready-to-eat form.

The document "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" (Guide) suggests that fresh-cut produce

processors consider a state-of-the-art food safety program such as the Hazard Analysis and Critical Control Point (HACCP) system, which is designed to prevent, eliminate, or reduce to acceptable levels the microbial, chemical, and physical hazards associated with food production. The Guide also recommends that processors encourage the adoption of safe practices by their partners throughout the supply chain, including produce growers, packers, distributors, transporters, importers, exporters, retailers, food service operators, and consumers.

An Outreach Success Story:

The following example involving fresh sprouts illustrates how successful the publication of guidance documents can be. In 1999, there were 390 reported illnesses associated with eating contaminated fresh sprouts. FDA published two guidance documents for sprouts that year. FDA believes that the subsequent decline in sprout-associated illnesses was in large part due to industry adhering to recommendations in those guidances through FDA's outreach and inspection efforts. In 2004, only 33 illnesses were reported associated with fresh sprouts, and in 2005 and 2006 there were none.

B. Imported Food from China

Overview: Over time FDA has maintained a concern about exports of food from China. Although FDA has witnessed some improvement in product quality, some Chinese companies continue to export substandard food products to the United States.

1. FDA/China Sign Two New Agreements

> New Agreements Will Enhance the Safety of Drugs and Medical Devices Imported From the People's Republic of China

In September 2007, a delegation of senior Health and Human Services (HHS) and FDA officials visited China. In October 2007, FDA leadership returned to China to begin negotiating agreements with FDA's Chinese regulatory counterparts. These formal agreements encourage a greater exchange of information and provide opportunities for FDA to collaborate with regulators and industry in China on the science and standards to ensure product quality and safety.

On December 11, 2007, HHS and the State Food and Drug Administration (SFDA) of the People's Republic of China signed Memoranda of Agreement (MOA) to enhance the safety of drugs, excipients and medical devices exported to the U.S. from China. These agreements were signed in Beijing by HHS Secretary Michael Leavitt and SFDA Commissioner Shao Mingli.

Specifically, the two countries established a bilateral mechanism to help ensure these imported products meet standards for safety and effectiveness by building quality into the process from the start. The two documents apply a three-pronged strategy of registration, certification and verification.

First, all Chinese producers of items covered under the agreement must register with Chinese authorities, who will share that data with HHS. Second, Chinese regulators will certify that food and feed covered by the agreement meet U.S. government standards. They will pursue a method to certify medical products as well. Third, to verify compliance, the Chinese are adopting quality-assurance methods. For example, Chinese authorities will develop a comprehensive electronic tracking system to follow products from production to exportation. This will help ensure that growers and manufacturers are building quality into their processes and that we can take action if they do not.

Another critical aspect of these agreements is information sharing. Chinese authorities have pledged to provide timely notification to U.S. regulators under a wide range of circumstances, including the failure of a facility to meet inspection requirements and the suspension or revocation of a manufacturer's certification status. The Agreements also allow inspectors from FDA to gain broader expedited access to Chinese production facilities.

The full text of the agreements is available online as follows:

Drugs and Medical Devices Agreement>>
http://www.globalheath.gov/news/agreements/ia/121107a.html.

Food and Feed Agreement>>
http://www.globalheath.gov/news/agreements/ia/121107b.html.

2. FDA Issues Import Alert for Aquaculture Imports from China

FDA Responded to the Presence of Illegal Residues in Seafood by Issuing a Broad Import Alert on All Farm-Raised Catfish, Basa, Shrimp, dace, and Eel from China

China is the largest exporter of aquaculture products to the United States, and FDA maintains an active program to test imports of Chinese aquaculture products for illegal residues. Beginning in November 2001, FDA issued a series of Import Alerts because shipments of Chinese aquaculture products tested positive for antibiotic residues or other contaminants.

Between October 2006 and April 2007, FDA repeatedly identified residues of unapproved drugs and food additives in seafood imported from China. The residues included malachite green, fluoroquinolones, nitofurans, and gentian violet. These compounds are often used to inhibit the growth of bacteria and fungus on seafood or to prevent parasites. However, FDA has not approved these products for use as drugs or food additives for use in farm-raised seafood in the United States.

Nitrofurans, malachite green, and gentian violet have been shown to be carcinogenic in animal studies. Fluoroquinolones in food animals may increase antibiotic resistance in human pathogens. FDA responded to the continued presence of residues by announcing on August 3, 2007, a broad Import Alert #16-131 "Detention Without Physical Examination of Aquacultured Catfish, Basa (Pangasius sp), Shrimp, Dace and Eel Products from the People's Republic of China Due to the Presence of New Animal Drugs and/or Unsafe Food Additives." Under this alert, FDA can detain all of these aquaculture products at the border until the shipments are proven to be free of residues that prompted the Import Alert. Although the levels of the drug residues in these food products are very low, FDA is concerned about long-term exposure and the possibility of antibiotic resistance.

To view the full text of the Import Alert, go to:
http://www.fda.gov/ora/fiars/ora_import_ia16131.html

3. FDA Issues Import Alert for Vegetable Protein from China

On March 15, 2007, FDA learned that certain pet foods were sickening and killing cats and dogs. Analysis by the Agency's Forensic Chemistry Center

revealed melamine and melamine analogues in pet foods and in wheat gluten used as ingredients in these pet foods. After FDA traced the suspect wheat gluten to a single supplier in China, the Agency issued an Import Alert focused on this firm and began sampling 100 percent of all wheat gluten from China. In April, FDA launched an investigation into imported rice protein concentrate that also was used as an ingredient in some pet foods and it, too, was found to contain melamine and its analogues. The Agency traced the suspect product to another Chinese supplier. FDA issued an Import Alert focused on this supplier and began sampling 100 percent of all rice protein concentrate from China.

Ultimately, FDA issued Import Alert No. 99-29 on April 27, 2007, which expanded on previous Import Alerts and covered all vegetable protein products from China. Under the Import Alert, FDA can detain these products unless third party analysis or other evidence demonstrates they are not contaminated with melamine or its analogues. FDA believes that all of the contaminated wheat gluten and rice protein from China used in the manufacture of pet food have been removed from commerce.

To view the full text of the Import Alert, go to: http://www.fda.gov/ora/fiars/ora_import_ia9929.html.

C. New State-of-the-Art Inspection Tools

FDA is continuing to explore existing technologies to adapt them for use in the field—not only for investigators, but also for use in FDA's mobile laboratories. Investigators collect samples of products in hundreds of locations, so it's not possible to have a laboratory established in close proximity to every collection site. However, the Agency does have two mobile labs that can be sent to the borders when needed. Most recently, FDA's microbiology mobile lab was sent to the southern border to detect bacteria and other pathogens on leafy greens. And at the northern border, the Agency's chemistry mobile lab has looked for pesticides, poisons, and toxins in a variety of food commodities. No contaminated product was found during either deployment.

III. The Food Protection Plan

On November 6, 2007, Health and Human Services Secretary Michael Leavitt announced a comprehensive initiative by FDA designed to bolster efforts to better protect the nation's food supply. The Food Protection Plan proposes the use of science and a risk-based approach to ensure the safety of domestic and

imported foods eaten by American consumers.

The Food Protection Plan, which focuses on both domestic and imported food, complements the Action Plan for Import Safety delivered by Secretary Leavitt to President Bush that recommends how the United States can improve the safety of all imported products. This year, $2 trillion worth of goods will be imported into the United States, and experts predict that amount will triple by 2015. The Action Plan for Import Safety lays out a road map with short- and long-term recommendations to enhance product safety at every step of the import life cycle. Taken together, the two plans will improve efforts by the public and private sector to enhance the safety of a wide array of products used by American consumers.

The Food Protection Plan is premised on preventing harm before it can occur, intervening at key points in the food production system, and responding immediately when problems are identified. Within these three overarching areas of protection, the plan contains a number of action steps as well as a set of legislative proposals. Taken together, these efforts will provide a food protection framework that ensures that the United States food supply remains safe.

To strengthen its efforts to prevent contamination, FDA plans to strengthen its support of the food industry's efforts to build safety into products manufactured either domestically or abroad. The FDA will work with industry, state, local, and foreign governments to identify vulnerabilities and will look to industry to mitigate those vulnerabilities, using effective methods such as preventive controls.

The plan's intervention element emphasizes bolstering inspections and sampling efforts based on risk at the manufacturer and processor level, for both domestic and imported products. This approach is complemented by targeted, risk-based inspections at the points where foreign food products enter the United States, including ports.

The plan calls for enhancing FDA's information systems related to both domestic and imported foods to better respond to food safety threats and communicate during an emergency.

To read the full text of The Food Protection Plan, go to:
http://www.fda.gov/oc/initiatives/advance/food/plan.html.

IV. Fresh Produce – "Ensuring the Safety of Fresh Produce"

Overview: As the 2006 outbreaks of *Escherichia coli* 0157:H7 (*E. coli*) proved, continued efforts to protect the public health from foodborne illness associated with fresh produce must continue. By identifying practices and conditions that can lead to product contamination, FDA and our food safety partners can improve guidance and policies intended to minimize chances of future disease outbreaks, as well as ascertain future produce-safety research, education and outreach needs.

A. Lettuce Safety Initiative

In 2004, the Food and Drug Administration (FDA) launched the 2004 FDA Produce Safety Action Plan which is intended to minimize the incidence of foodborne illness associated with consumption of fresh produce. In 2006, in furtherance of the Produce Safety Action Plan, and in collaboration with the State of California's Departments of Public Health and Food and Agriculture, FDA began a multi-year Initiative as part of a risk-based strategy intended to reduce public health risks by heightening the focus on preventive food safety efforts (e.g., in advance of an outbreak) on specific products, practices, agents, and growing areas of greatest concern. The first year of the Initiative focused on lettuce (Lettuce Safety Initiative) as a response to recurring outbreaks of *E. coli* O157:H7 associated with fresh and fresh-cut lettuce.

FDA's Produce Safety Action Plan is available online at:
http://www.cfsan.fda.gov/~dms/prodpla2.html.

The full text of the Lettuce Safety Initiative is available online at:
http://www.cfsan.fda.gov/~dms/lettsafe.html.

B. Leafy Greens Initiative

FDA and the California Departments of Public Health and Food and Agriculture continued efforts to ensure the safety of fresh produce in 2007 with a focus on a broader range of leafy greens, including spinach (Leafy Greens Safety Initiative). As a result, beginning in October 2007, FDA investigators, in coordination with their respective state counterparts, and with the cooperation of the industry, visited farms in California to assess the prevalence of factors in and near the field environment which may contribute to potential contamination of leafy greens with *E. coli* O157:H7 and the extent to which Good Agricultural Practices (GAPs) and other preventive controls are being implemented.

Other components of the initiative included:

- Continuing outreach with the industry at all points in the supply chain;
- Communicating early and often in the event of an outbreak or recall; and
- Continuing to build and strengthen collaborative relationships with federal, state and local public health officials in disease prevention, detection, and outbreak response.

To read the full text of the Leafy Greens Initiative, go to:
http://www.cfsan.fda.gov/~dms/lettsaf2.html.

C. Tomato Safety Initiative

FDA also began a multi-year Tomato Safety Initiative in 2007 to reduce the incidence of tomato-related foodborne illness in the United States. This initiative, which is also in furtherance of FDA's Produce Safety Action Plan, is a collaborative effort between FDA and state health and agriculture departments in Florida and Virginia. Several universities and members of the produce industry also are part of the effort.

Information about the Tomato safety Initiative can be found at:
http://www.cfsan.fda.gov/~dms/tomsafe.html.

The full text of the Tomato Safety Initiative is available online at:
http://www.cfsan.fda.gov/~dms/tomsafe.html.

V. Grassroots Initiatives on Food Safety

FDA has funded 25 Grassroots Education Projects for Foods

FDA, through the Center for Food Safety and Applied Nutrition (CFSAN), has funded 25 grassroots food safety, food defense and nutrition education projects. These outreach and education efforts are conducted around the country by FDA Public Affairs Specialists (PASs). A large number of the projects target underserved populations, while others are aimed at susceptible populations including pregnant women and seniors. A majority of the projects target culturally diverse populations. Many projects focus on nutrition education.

The CFSAN/PAS Education Project Award Program has used a variety of innovative and effective means to deliver vital food safety information and

training to consumers and key local multipliers such as WIC personnel, community organizations and local agencies serving multicultural populations.

Many of the funded projects are multicultural and multilingual, including:

- Raw produce and refrigeration safety training for low-income Hispanic consumers in Portland, Oregon;
- Food safety and nutrition campaign for Polish-speaking consumers in Chicago, Illinois and Milwaukee, Wisconsin;
- Food safety and nutrition training for low-income Hispanic consumers in the East End of Houston, Texas;
- Translation and dissemination of nutrition information for Asian communities in the Los Angeles and San Francisco, California areas, and
- Train the Trainer Programs in Oklahoma City, Oklahoma, to provide outreach to Hispanic consumers on prevention of food-related health problems such as obesity and diabetes.

To read the full text of the Grass Roots Initiative, go to: http://www.cfsan.fda.gov/~dms/cfsup144.html.

VI. FDA and State Inspection Programs

Overview: FDA partners with the states to protect the public health in many areas. FDA relies on the states to conduct inspections in four major areas: mmammography, retail food, milk, and shellfish. As part of this process, FDA provides training, regulatory guidance and scientific expertise to the states. The Public Health Service Act directs FDA to "assist states ... in the prevention of communicable diseases" and to advise states "on matters relating to preservation and improvement of the public health."

Inspection programs which are conducted by the states enable FDA to better utilize its resources in other areas.

A. Mammography Inspections: The Mammography Quality Standards Act (MQSA) requires that every Mammography facility meets quality standards. Mammography facilities include breast clinics, radiology departments in hospitals, mobile vans, private radiology practices, and other doctors' offices. FDA ensures that facilities all around the country meet MQSA Standards and that consumers receive uniform, high-quality services from Mammography facilities throughout the U.S. FDA conducts annual inspections of

mammography facilities and has also trained state inspectors for this purpose.

B. Retail Food Protection: FDA's regional food specialists provide training, oversight, and technical assistance to more than 3,000 state and local government agencies that regulate the Nation's retail food industry. They are responsible for over 1 million food establishments including restaurants and grocery stores, as well as vending machines, cafeterias, and other establishments such as health-care facilities, schools, and correctional facilities. FDA assists its state and local counterparts in these efforts through its publication of a model Food code which among other things, establishes standards for the management, operation, and inspection of retail facilities.

C. National Shellfish Sanitation Program: Molluscan shellfish has been identified as the source of a majority of seafood-borne illnesses and is often the subject of congressional, industry, and public concern. FDA has, therefore, given high priority to promoting and improving the sanitation of shellfish moving in interstate commerce through Federal/State cooperation and uniformity of state shellfish programs. One mechanism to achieve this has been through the incorporation of FDA's Seafood Hazard Analysis and Critical Control Point (HACCP) Regulation into the National Shellfish Sanitation Program (NSSP) Model Ordinance.

The NSSP and the NSSP Model Ordinance, serve as guidance for state shellfish sanitation programs in their promulgation of state regulations and laws concerning shellfish safety. FDA's Shellfish Sanitation Program has a regional staff that interacts with state officials to help bolster enforcement programs. These FDA shellfish specialists audit state programs to ensure compliance with laws, regulations and requirements of the NSSP and other criteria agreed on by the Interstate Shellfish Sanitation Conference. Their goal is to ensure that state officials comply with the NSSP in classifying harvesting waters, controlling illegal harvesting, as well as overseeing processing plant conditions and product labeling.

D. Milk Safety: FDA assists states in preventing disease transmitted through milk and helps enforce state milk regulations. FDA promotes and helps ensure compliance with the model Grade A Pasteurized Milk Ordinance, a document similar to the Food Code. FDA's regional milk specialists offer seminars to state officials to promote uniformity in interpreting the Pasteurized Milk Ordinance, as well as on other issues such as laboratory analytical methods.

VII. FDA Human Tissue Task Force Report

Collaborative Efforts among Federal, State, Industry, and Academic

Overview: The FDA Human Tissue Task Force (HTTF) is a collaborative effort among those FDA components involved in tissue safety, including the Center for Biologics Evaluation and Research (CBER), the Office of Regulatory Affairs (ORA), and the Office of the Commissioner (OC), and was established in August 2006, as part of the Agency's efforts to evaluate and, where needed, strengthen its risk-based system for regulating human cells, tissues, and cellular and tissue-based products (HCT/Ps) which went into effect in 2005. The primary goal of the HTTF was to assess challenges that had occurred in implementation of the new system and to identify any additional steps needed to further protect the public health by preventing the transmission of communicable disease while assuring the availability of safe products.

FDA is only one of many entities with an interest in tissue safety. Federal and state partners, industry associations, and the industry itself have important roles and responsibilities in protecting and advancing public health by having a safe supply of tissue available. Recognizing this, the HTTF sought to identify and pursue additional partnering and leveraging opportunities with federal, state, and/or industry stakeholders. Opportunities were explored to enhance tissue safety through education and outreach that would clarify our requirements and improve practices, as well as opportunities to improve our tissue safety program by obtaining and evaluating information from our stakeholders.

FDA's outreach and education efforts in the area of tissue safety have included collaboration with the following agencies and organizations:

1. *Federal*: Our two major federal partners in the Department of Health and Human Services are the CDC and the Human Resources Services Administration (HRSA). Communication with the FTC is also important because of the oversight it provides to aspects of the health care industry.

    a. CDC: The FDA has been in regular communication with CDC on tissue safety issues. Both agencies have a long history of working closely in public health investigations of adverse reactions related to tissue as well as with respect to emerging infectious diseases. CDC has played a major role in working with state public health

departments and in working with FDA to provide scientific and public health assessments and advice. To further explore opportunities for enhancing tissue safety and to enhance our ongoing interactions, we have initiated strategic discussions with CDC concerning current activities, tissue regulations, and potential future initiatives.

b. HRSA**:** Our connection with HRSA is principally in the area of organ donation, where HRSA is the lead federal agency with oversight, and with whom we share information concerning approaches to issues such as donor eligibility and testing, safe tissue processing, and emerging infectious disease threats. We presented information at a recent Advisory Committee on Organ Transplantation (ACOT) meeting. FDA has an ex officio representative on this committee.

c. FTC**:** CBER initiated discussion of opportunities to communicate FDA's tissue safety messages through FTC training programs and industry connections.

2. *States*: ORA continues to survey several key states to determine their interest in partnership opportunities. A model partnership agreement to be used with the states is being developed. At this preliminary stage, we see the most likely opportunities for, and benefit from partnerships with those states that have the most highly developed regulatory programs. Upon identification of appropriate partnership opportunities, ORA will fund or seek funding support for the agreements.

The benefits FDA expects to receive from an effective partnership agreement include: improvements to our communication network with state regulatory partners, expanded overall inspectional coverage of the industry through sharing of information and leveraging each other's work, and greater knowledge of industry operations and practices through review of information received.

a**.** In October 2006, FDA held a 50-state conference call to discuss tissue safety and regulatory oversight of tissue related activities. In advance of the call, we obtained background information from state health agencies regarding their systems of regulation and oversight. Many states provided information that we are

continuing to assess; our preliminary review reveals a varying degree of oversight. At least three states appear to have relatively comprehensive regulatory systems for tissue safety. All states appear to have a registration/licensure program for funeral homes, with varying degrees of inspectional oversight.

b. North Carolina Legislature - At its request, FDA presented an overview of FDA's tissue regulations to support the legislature's consideration of possible legislation to reinforce tissue safety in the state of North Carolina.

3. *Industry - Eye Banking and Tissue Industry***:** Industry associations that have active accreditation programs present another leveraging opportunity. FDA will continue to communicate and work with these industry associations in activities of mutual interest that support and enhance tissue safety.

   a. American Association of Tissue Banks (AATB) is a scientific, not-for-profit, peer group industry supported organization. Its mission is to facilitate the provision of high quality transplantable human tissue in quantities sufficient to meet national needs. AATB has an active accreditation program. AATB has several initiatives to enhance tissue safety.

   b. Eye Bank Association of America (EBAA) is a scientific, not-for-profit, peer group industry supported organization of eye banks dedicated to the restoration of sight through the promotion and advancement of eye banking. EBAA represents the ocular tissue industry and has an active accreditation program with nearly all eye banks in the U.S. being accredited.

4. *Academic/Professional Organizations*: The Joint Commission (formerly known as the Joint Commission for the Accreditation of Healthcare Organizations [JCAHO]) has standards for tissue tracking in healthcare organizations. FDA has contacted this organization to provide information on tissue regulation.

   a. American Academy of Orthopedic Surgeons (AAOS): Orthopedic surgeons are major users of musculoskeletal tissue. FDA has contacted AAOS to provide information on tissue regulation and has reviewed additional information provided by the organization

b. American Academy of Periodontology (AAP): Periodontists are also users of musculoskeletal tissue. We have contacted this organization to provide information on tissue regulation.

To view the full text of the Human Tissue Task Force Report, go to: http://www.fda.gov/cber/tissue/httf07report.htm.

VIII. FDA's Outreach to the Device Community

Overview*:* FDA's Center for Devices and Radiological Health (CDRH) continues to be involved in the development and revision of consensus standards as well as federal guidelines related to security screening measures. These activities result in collaborative working relationships with many federal and state agencies as well as industry. Examples include:

A. Interagency Steering Committee on Radiation Standards -- CDRH is working with a subcommittee of the Interagency Steering Committee on Radiation Standards (ISCORS) to develop "Guidance for Security Screening of Humans Utilizing Ionizing Radiation" which is undergoing a final review. The purpose of the document is to provide a uniform set of guidelines for all federal agencies. The first part of the document provides a standard method for a federal agency to evaluate if a new security practice is justified. The second part of the document provides guidance on establishing a radiation safety program that is appropriate for the new practice.

B. American National Standards Institute -- CDRH continues to participate in the development of consensus American National Standards Institute/Health Physics Society N43 Radiation Safety Standards for Security Products that use Ionizing Radiation. ANSI/HPS N43.17-2002, *Radiation Safety For Personnel Security Screening Systems Using X-rays,* is currently undergoing a revision to address new system configurations and operating modes including portals, limited use systems, and products that use radioactive material as the radiation source. The new title is *Radiation Safety for Personnel Security Screening Systems Using X-ray, or Gamma Radiation*. There is also a new standard currently under development, ANSI/HPS N43.16, *Radiation Safety for X and Gamma Ray Cargo and Vehicle Security Screening Systems (Up To 10 MeV)*.

C. Biomedical Research Community -- Approximately 85% of FDA inspections of clinical research with medical devices reveal only minor problems with research conduct. However, in order to help improve the remaining research that may be problematic, the Division of Bioresearch Monitoring in CDRH has increased its educational outreach activities with the device research community including study sponsors, clinical investigators, study site staff, and institutional review boards. Division staff have participated in, and presented at, numerous trade association conferences and professional workshops with the Advanced Medical Technology Association, Association of Clinical Research Professionals, Harvard University's FDA Regulatory Symposium, Food and Drug Law Institute, Legacy Clinical Research and Technology Center, LifeScience Alley (formerly, Medical Device Alley), Medical Device Manufacturers Association, National Association of IRB Managers, New York State Bar Association, Orange County Regulatory Affairs Discussion Group, Public Responsibility in Medicine and Research, Regulatory Affairs Professional Society, Society of Clinical Research Associates, Society for Quality Assurance, and Washington University School of Medicine.

This outreach has focused on providing the device research community with information on good clinical research practice and suggestions for conducting successful device studies to improve research data quality. The Division recently published a guidance document for industry on the bioresearch monitoring review and inspection of premarket approval applications to improve the transparency of the marketing application review process. In addition, division staff has published several articles in professional journals and regulatory news bulletins to improve awareness of proper clinical research practices.

IX. The Future: Food and Drug Amendments Act of 2007

Overview: On September 27, 2007, President George W. Bush signed into law H.R. 3580, the Food and Drug Administration Amendments Act of 2007 (FDAAA). FDAAA adds many new provisions to the Federal Food, Drug, and Cosmetic Act. Certain existing laws were set to expire on September 30, 2007. Various changes to those laws were made, and new amendments added, to provide FDA with important resources and to strengthen the FDA's ability to safeguard and advance public health.

Provisions: Four of the provisions (or "Titles") included in FDAAA reauthorize existing laws:

- *Prescription Drug User Fee Act (PDUFA)* - allows FDA to collect fees from drug companies to help fund reviews of new drugs. The act enables shorter review times and a more predictable review process, while still maintaining high-quality reviews.
- *Medical Device User Fee and Modernization Act (MDUFMA)* - allows for user fees, and will allow FDA to make significant improvements in the medical device review program.
- *Best Pharmaceuticals for Children Act (BPCA)* - encourages more studies in children and promotes the development of treatments for children.
- *Pediatric Research Equity Act (PREA)* – continues FDA's authority to require studies in children concerning certain medical products and under other specific circumstances.

Additional Provisions: Among other things, the law also provides:

- Additional encouragement of specialized pediatric medical device development;
- Creation of a foundation (Reagan-Udall) to modernize product development, accelerate innovation, and enhance product safety
- Food safety provisions
- Advisory committee provisions
- Clinical trial registries
- Provisions intended to enhance drug safety

FDA has dedicated a web site at: http://www.fda.gov/oc/initiatives/advance/fdaaa.html. This web site is available to answer additional questions about the renewed legislation intended to improve the safety of FDA-regulated products.

References:

1. Statement by Secretary Mike Leavitt, Secretary of Health and Human Services, On Signing Memoranda of Agreement between the United States and The People's Republic of China to Improve the Safety of Food, Feed, Drugs and Medical Devices, December 11, 2007. To view the full text of the Statement, go to: http://www.hhs.gov/news/press/2007pres/12/pr20071211a.html.

2. Excerpts from Statement by Andrew C. Von Eschenbach, M.D., Commissioner of Food and Drugs, Department of Health and Human Services, on FDA's Food Safety Activities and the Transformation Initiative before Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, U.S. House of Representatives, Tuesday, July 17, 2007.

3. Excerpts from Statement of Andrew C. von Eschenbach, M.D. Commissioner of Food and Drugs, Department of Health and Human Services, before The Senate Agriculture, Rural Development, and Related Agencies Appropriations Subcommittee, Field Hearing at the West Madison Agricultural Research Center, Verona, Wisconsin, March 12, 2007.

   The full text of Dr. Eschenbach's testimony is available online at: http://www.fda.gov/ola/2007/foodsafety31207.html.

4. Excerpts from a Statement of David Acheson, M.D., F.R.C.P., Assistant Commissioner for Food Protection, Food and Drug Administration, before Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, September 25, 2007. The full text of the Statement is available online at: http://www.fda.gov/ola/2007/foodsafety092507.html.

5. Excerpts from a Statement by David Acheson, Assistant Commissioner for Food Protection Food and Drug Administration, U.S. Department of Health and Human Services on FDA Testimony for the Energy & Commerce Food Safety Hearing before Committee on Energy and Commerce Subcommittee on Oversight and Investigations, U.S. House of Representatives, Thursday, October 11, 2007.

   The full text of the Testimony is available online at: http://www.hhs.gov/asl/testify/2007/10/t20071011a.html.

6. Excerpts from "Ensuring the Safety of Imported Products, Questions and Answers." The full text is available online at: http://www.fda.gov/consumer/updates/imports101207.html.