Progress and Perspective

Food Safety Initiative

FY '99 Annual Report

U. S. Food and Drug Administration

Making Progress Towards a Safer Food Supply

by Jane E. Henney, M.D., Commissioner, Food and Drug Administration

The protection of the nation's food supply has long been an important part of FDA's public health mission. As we enter the 21st century, the challenges facing the food safety system are constantly changing. We are eating a greater variety of foods throughout the year from all over the country and around the world. We are eating more and more foods prepared outside our own homes. Nearly a quarter of our population is considered "at-risk" for developing foodborne illness. And we are aware of more than five times the number of foodborne pathogens in 1999 than we were fifty years ago.

The most critical element of our nation's food safety system is a strong science base to underpin decision-making, from research and risk assessment, to surveillance, inspection, training, and education.

While the American food supply is among the safest in the world, we can always do more. This report, "Progress and Perspective," provides a snapshot of how FDA is meeting this challenge to ensure a safer food supply. The report explains not only what is being done, but also-–most importantly—how this effort is helping to reduce the incidence of foodborne illness.

In FY 99 there were significant accomplishments in all areas of food safety. A strong scientific base drives all of these programs. For example, we have created the National Antimicrobial Resistance Monitoring System to detect emerging drug resistance among foodborne pathogens. At the Illinois-based National Center for Food Safety and Technology, cutting-edge research is leading to food safety improvements. The internationally–recognized Seafood HACCP program has established a comprehensive, science-based program that is being adopted by more seafood processors every year. Experts from FDA provided training on good agricultural practices for international producers of fruit and vegetables. And, to better protect American consumers when problems do arise, FDA and the U.S Customs Service have developed a comprehensive plan to keep unsafe imported food from American consumers. Indeed, many of these activities require effective collaboration between and among many Federal, state, and local government counterparts.

This progress could not have taken place without the hard work and dedication of the entire FDA staff involved in the Food Safety Initiative, and the excellent leadership provided Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition (CFSAN); Dennis E. Baker; Associate Commissioner for Regulatory Affairs; Steven F. Sundlof, D.V.M., Ph.D., Director, Center for Veterinary Medicine (CVM); and Daniel A. Casciano, Ph.D., Acting Director, National Center for Toxicological Research. I also welcome Susan Alpert, Ph.D., M.D., to the position of Director of Food Safety for CFSAN Dr. Alpert brings a unique background in pediatrics, infectious diseases and microbiology to this critical job.

As President Clinton said during his radio address Dec. 11, 1999, "Food safety is part of our citizens' basic contract with the government." It is a contract FDA does not intend to break.

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Laura Fox / Writer
Center for Food Safety and Applied Nutrition
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Marcia Meltzer / Design
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Leading the Food Safety Initiative

Susan Alpert, Ph.D., M.D.

For Susan Alpert, Ph.D., M.D., leading the Food Safety Initiative (FSI) is an opportunity to blend her background in medical microbiology, pediatrics and infectious diseases with 12 years experience as an FDA regulator, most recently as director of the Office of Device Evaluation in the Center for Devices and Radiological Health. Appointed Director of Food Safety for the Center for Food Safety and Applied Nutrition in October 1999, Alpert provides leadership for the Food Safety Initiative as well as providing oversight for all medical and clinical aspects of food safety across the broad range of FDA's food safety responsibilities.

Alpert is optimistic about the opportunity the Food Safety Initiative creates for improving the safety of the food supply. "Food safety has been an important issue for FDA from its beginning in 1906. The initiative is providing us with an opportunity to lift the floor because of focus, attention and resources. We need to take advantage of this opportunity," she said.

What does Alpert think about the current safety of the food supply? "We need to reduce drastically the level of illnesses, hospitalizations and deaths from foodborne illness," she said.

"Bacteria are smarter than people. We will never totally eliminate them from the food supply. Where we can reasonably improve food safety by decreasing bacterial contamination we should. The challenge is to evaluate the entire farm-to-table process and find the places where we can take steps to decrease pathogens. I expect to see accomplishments in the areas of technology, science, risk assessment and education."

Alpert is placing a priority on working with the medical community. Health care providers today are focusing on preventive measures people can take to keep themselves healthy she explained. The medical community has an important role to play in educating the public about nutrition, safe food handling and food risks.

Alpert intends to engage the medical community by focusing on the clinical aspects of foodborne illness supported by the statistics of foodborne illness. "Infants and young children are at higher risk than average healthy adults. In addition, we are increasingly a population of at risk individuals—seniors, the immunocompromised, and those with chronic illness. We need better reporting of foodborne illness and we need to look to the medical community to assist us. We want doctors to think about foodborne illness when they see diarrheal diseases and take a food history. Where that raises suspicion, they need to culture for foodborne bacteria and report the findings."

Alpert explained that through the PulseNet system bacterial isolates can be linked. "We need this data to make the whole food safety system work. Underreporting of foodborne illness is a serious problem," she said.

"We Americans are lucky that we do not have to contend with many of the problems that consumers in other parts of the world face. For example, there are limits on the use of pesticides here, and we do not have many of the diseases that occur in other parts of the world. By addressing the risks we know about, such as *Salmonella*, *Listeria monocytogenes* and *E. coli* O157:H7, we can take a big bite out of foodborne illness," Alpert said.

Food Science – Perspective and Progress
An Interview with Robert Buchanan, Ph.D.

Dr. Robert Buchanan, senior science advisor to the Center for Food Safety and Applied Nutrition (CFSAN) of the Food and Drug Administration (FDA), shared his thoughts about advances in food science research and where science will lead us into the next century.

Q: Over the past 100 years what have been the major scientific breakthroughs in food science?
A: In 1906, with the passage of the Pure Food and Drug Act, the government was able to gain control over the economic adulteration of food and inappropriate use of chemicals. From there, the entire discipline of food science developed to the point today where there is a system in place that identifies risks in foods. We have moved from a system that began as "buyer beware" to HACCP—Hazard Analysis and Critical Control Points, which is based on the producer anticipating hazards and preventing them. There is now a safety net under the entire food system.

Microbiology was a new science at the turn of the century. Chemistry and toxicology had not been around too long. Here is a good example of the progress we are making: During the last 25 years the standard technique for isolating low levels of *Listeria* in food took one month. Now, gene-based systems can identify *Listeria* in six hours. This has helped reduce by 60 percent the incidence of listeriosis in the last 10 years.

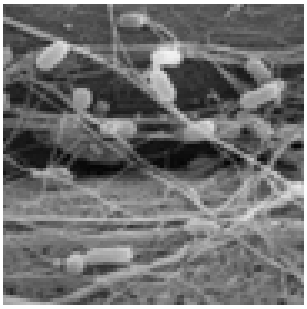
Q: Where do you expect science to take us as we look ahead to 2010—the first decade of the new century?
A: Nothing in the food industry stays the same. Food changes, the marketplace changes, the demographics of the population changes. This results in new challenges and new food safety problems. Science will provide us an ability to anticipate and rapidly respond to threats to public health. The translation of knowledge we've gained in the last ten years will turn into practical solutions in the next ten years. For example, in the 1990's it became apparent that foodborne pathogens start on the farm. It is now the job of science to identify those pathogens and identify methods for reducing or eliminating them.

Q: We hear talk all the time about a science-based inspection system. What does that really mean?
A: We will enhance the science-base of our food safety system by providing inspectors and investigators with scientific tools, new ways

of looking at information, and looking at information in a more scientific manner, such as risk assessment. We want to provide scientific data and concepts to the policy-makers so that regulations are sound.

Q: How will we know if the food supply is getting safer?
A: That question is fraught with dilemma. If you look at the incidence of disease, it is going down. However, we now have improved surveillance techniques and a greater ability to detect outbreaks. We are making improvements faster in surveillance than we are in prevention. I believe we will start to see the numbers drop—we already are—as the preventative strategies take effect. In the last few years, for example, we have seen the number of illnesses from *Salmonella* Enteritidis in eggs decline 44 percent.

Q: If there continues to be "emerging pathogens," will we ever "win the war" against foodborne illness? Can we come up with adequate prevention systems?
A: The continuing emergence of highly infectious pathogens presents new challenges. We can't rest on our laurels. We have learned some pretty important lessons about infectious disease in general. Now we are learning about multi-antibiotic resistant bacteria—an important area of concern. The globalization of the food trade results in unique challenges. We now must concern ourselves with emerging pathogens around the world because they will likely get to our borders. We no longer have geographical barriers to disease. We will need to develop other systems to replace those.



***E. coli* O157:H7**
A bacterium that can produce a deadly toxin.

To understand how much the world has changed we need to go back to the 1950's and the creation of the dinner salad. Before the 1950's raw salads were not a big item in the diet. Raw agricultural commodities were not readily available year-round. Even people who lived on farms ate very little fresh produce. People had to cook their food extensively to avoid getting sick.

Cantaloupe is another good example of how change in nutritional recommendations and consumer preference is creating challenges for food safety. If you go back 30 years, cantaloupes were available two weeks a year on a local basis. Now consumers want cantaloupes year-round and get them. They are available because of transportation improvements between North and South America.

I am not suggesting we give up fresh fruits and vegetables, they are a critical component of a healthy diet. However, we need to realize there will always be changes in the food system that will impact food safety, and we need to be ready for them.

Q: It seems as though the list of foods "at-risk" consumers should avoid is growing. Do you think that list will continue to grow?

A: No, I don't believe the list will continue to grow. As problems become apparent we mobilize the scientists to seek answers. For example, there is now a consumer advisory out about eating raw sprouts. Our researchers are working with industry to improve the safety of sprout production. The scientific knowledge gained has allowed FDA to recently develop and release detailed guidance on how to produce safer sprouts. Once industry conforms to those recommendations the public health advisory may no longer be needed.

Food Safety Research Begins on the Farm

In FY 99, FDA's Center for Veterinary Medicine (CVM) conducted food safety research programs in two distinct thematic areas: 1) antibiotic resistance in the pre- and post-approval animal production environments and 2) the microbial quality of animal feeds. Antibiotic resistance as it relates to zoonotic pathogens is directly related to CVM's mission, regulating the safe and effective use of drugs for use in food-producing animals. Development of antibiotic resistance in zoonotic pathogens is a critical human food safety issue impinging on the safe use of antimicrobials. CVM also regulates animal food. "As many feed components for food-producing animals harbor foodborne pathogens such as *Salmonella*, it is important to understand the potential role feed may play in transmission of zoonotic pathogens to man," stated David Wagner, Ph.D., a research animal scientist at CVM. Wagner also noted that "it is also important to understand how microbes associated with feed commodities influence the development and dissemination of antibiotic resistance within the environment."

Intramural research efforts on antibiotic resistance have centered on development of research to monitor, or identify, the patterns and types of antibiotic-resistant zoonotic pathogens at the retail and animal production levels and studies focusing on development and dissemination of antibiotic resistance within the animal production environment. "This two-pronged approach is designed to provide information about the types of resistant pathogens reaching the consumer which, when coupled with the other research results, will help to formulate prudent use strategies to minimize or mitigate resistance development," noted David White, Ph.D., a research microbiologist at CVM. Current monitoring activities are focused on characterizing the microbial quality of animal feeds and the types of antibiotic susceptibility patterns among *E. coli, Salmonella,* and

Enterococcus spp. isolates obtained from retail ground beef, ground turkey, ground pork and farm-raised fish. Additional monitoring activities are focused on characterizing susceptibility patterns to veterinary *E. coli, Salmonella,* and *Enterococcus* isolates from swine and poultry production facilities.

Another surveillance activity is CVM's participation in the PulseNet program sponsored by CDC. "CVM's involvement with this epidemiological surveillance tool provides a critical link to the animal production environment for traceback studies during outbreaks of foodborne illness. Research efforts on development and dissemination of antibiotic resistance in shiga-like toxin producing *Escherichia coli* (STEC), *Enterococci,* and *Salmonella spp.* as a consequence of antibiotic use in aquaculture, swine and poultry facilities are also underway.

Pamela Chamberlain, DVM, DABT, an FDA food safety toxicologist, collects blood from a lactating dairy cow for a study of drug clearance into milk.

CVM's extramural research program is designed to complement and augment its intramural research plan. Six of the FY 99 projects are designed to elucidate the prevalence and risk factors associated with the dissemination of antibiotic resistant *Salmonella, E. coli* O157:H7 and *Enterococci* within the animal.

Sprouts Safety – A High-Priority Area in FY 99

"It will take a multi-faceted approach to solve the international problem of sprout safety, but it can be done," said Michelle Smith, Ph.D., an FDA policy expert on sprouts. The need to find an answer is real. Since 1995 over 1,000 illnesses in the U.S. attributed to the consumption of raw sprouts have been reported.

"In FY 99 a comprehensive sprout policy was formulated that includes a mix of research, education, guidance, and if necessary, regulation," said Smith. "Recent surveys and research have provided valuable information on seed contamination, current industry practices, and treatments and tests that can reduce the risk of sprouts serving as a vehicle for foodborne illness."

Smith said laboratory science has built a solid foundation for understanding of the problem and will offer new strategies for the elimination of microbiological hazards on sprouts.

A Science-Based Food Safety System

Mary Lou Tortorello, Ph.D. and Karl Reineke harvesting sprouts at the National Center for Food Safety and Technology in Illinois.

Much of the sprout research is being conducted at the National Center for Food Safety and Technology (NCFST)—a consortium of government, industry and academia devoted to food safety research—in Summit-Argo, Ill. In FY 99, the center focused its work on prevention and intervention strategies and exploring alternatives to chlorination. These include thermal processing, disinfection with hydrogen peroxide and electron beam treatment. Most treatments would be affordable even by the small firms that dominate the industry. E-beam treatment would take place in bulk at a seed company or distribution plant.

NCFST also worked on validating rapid test kits for detecting pathogens in sprouts and spent irrigation water, the water that has flowed around and between sprouts during their production.

In FY 99 FDA collaborated with the California Department of Health and the sprout industry to produce a training video for sprout producers. The video is based on California's sprout training program and will be consistent with FDA's guidance. Distribution is scheduled to begin in Spring of 2000.

As FY 99 concluded, FDA was in the process of finalizing guidance for the sprout industry. In developing the guidance document FDA relied on the May 1999 paper, *Microbiological Safety Evaluations and Recommendations on Sprouted Seeds*, adopted by the National Advisory Committee on Microbiological Criteria for Foods. The report includes findings and recommendations to reduce microbial food safety hazards associated with sprouts.

Researching Prevention and Intervention Strategies for Unpasteurized Juice

Since Fall 1998, FDA has been conducting collaborative research to improve the safety of unpasteurized apple juice in response to its proposed requirement for a 5-log pathogen reduction process for juice producers who do not pasteurize their juice. Arthur Miller Ph.D., FSI research and risk assessment lead, identified six research goals:

(1) identify good harvest and manufacturing practices;
(2) develop tools to confirm effectiveness of pathogen control measures;
(3) determine the efficacy of current practices;
(4) establish critical control points;
(5) set critical limits; and
(6) identify technologies to lower incidence and levels of microbial pathogens in unpasteurized apple cider.

Research is being conducted at a leased commercial cider mill located near Placerville, Calif. Partners with FDA in this effort include the California Department of Health; the El Dorado County (Calif.) Department of Agriculture; the University of California at Davis; the Illinois Institute of Technology National Center for Food Safety and Technology; and USDA's Agricultural Research Service, Eastern Regional Research Center. FDA's mobile laboratory provided on-site analytical support to research teams.

The researchers have been counting bacteria, yeasts, molds and determining mycotoxin levels at several stages of juice making. The project covers several processing methods, including washing of apples using chlorination, ozone treatment, ultraviolet light treatment, and surface heat treatment, either by hot water or steam.

Miller said that many of the findings are not surprising, such as the fact that there are higher microbial loads on dropped apples versus tree-picked apples, and there are also significant increases in bacterial counts in fruit with bird pecks.

"A major achievement this year was the identification of a non-pathogenic *E. coli* with an antibiotic resistance marker. The strain has been inoculated onto apples and used to determine effectiveness of various intervention technologies," said Miller.

Cathy Melvin, an FDA microbiologist, samples apples at the Placerville, Calif., research facility

Promising pre-pressing research results include the use of hot water to wash apples, resulting in a 2-log reduction of bacteria on apple surfaces. Cornell University research on post-processing technologies indicates that UV light can produce up to a 5-log reduction.

Plant sanitation is an important factor in reducing the accumulation of bacteria, yeast and molds. Miller said that FDA research shows accumulation on the seam of the conveyor belt, dump tank, the hammer mill and filter cloths, pomace pump and collection and bottling tanks.

In July 1999, FDA hosted a meeting on improving the safety of fresh apple cider and shared research results with industry representatives.

"By next year there should be technologies that are validated and ready to go for industry to achieve a significant pathogen reduction," said Miller. "Without the use of heat pasteurization of cider, a combination of linked preventive and intervention measures will have to be used."

Baseline Data Gathered on Production of Fresh Produce in FY 99

Not all research is conducted in a laboratory. As part of the President's Food Safety Initiative, FDA and USDA's National Agricultural Statistics Service were directed to work together to establish a baseline description of current agricultural practices used in the production of fresh fruits and vegetables in the United States. Plans were to establish this baseline by interviewing growers and packers of fresh fruits and vegetables and to conduct a survey every two years to measure change in agricultural practices.

In FY 99 a pilot survey of growers and packers was conducted in California and New York. According to Sara Fein, consumer science specialist with FDA's Consumer Research Team, "The purpose of the pilot survey was to test the survey instrument, sampling procedures and data collection procedures to ensure the results will provide the desired information." California and New York were selected for the pilot because of the diversity of growing conditions, crops and industry characteristics.

The criteria used in selecting the targeted fruits or vegetables include: (1) produce that are included in the top 20 fruits and vegetables consumed in the United States; (2) produce that use the greatest number of planted acres in the United States; and (3) produce that is traditionally consumed uncooked.

In 2000, 14 states will be in the national survey. These states are

Arizona, California, Florida, Georgia, Michigan, New Jersey, New York, North Carolina, Oregon, Pennsylvania, South Carolina, Texas, Washington and Wisconsin.

Fein said the data from the national survey will be used to identify and support food safety research priorities and to develop educational outreach programs for growers and packers.

Three Risk Assessments Undertaken in FY 99

Risk assessment is a valuable tool for evaluating the public health impact of microbial contamination of food. In FY 99 three new risk assessments were undertaken.

- *Listeria monocytogenes* — a bacterium that occurs widely in both the agricultural and food processing environments. Although frequently present in raw foods of both plant and animal origin, it also can be present in cooked foods due to post-processing contamination. Ingestion of *L. monocytogenes* can cause serious human illness, particularly for pregnant women, the elderly or those who are chronically ill or have compromised immune systems. The risk assessment will seek and analyze three types of information: information concerning the epidemiology of foodborne listeriosis; information concerning the level of *L. monocytogenes* contamination of food and consumption levels of such foods; and information regarding the human health consequences of such exposure. The goal of this risk assessment is to provide FDA with the information needed to review current programs relating to the regulation of *L. monocytogenes* contamination in foods to ensure that such programs provide maximum public health protection.

- *Vibrio parahaemolyticus* — a bacterium that requires salt to grow. It is found in tidal water environments. It can be present in several types of seafood, including molluscan shellfish. The organism causes acute gastroenteritis in consumers, and, in some, can also cause septicemia and very rarely death. The risk assessment will determine the relationships between molluscan shellfish, *V. parahaemolyticus* and illness; assess the exposure to pathogenic *V. parahaemolyticus*; and produce estimates of illness for levels of pathogenic *V. parahaemolyticus* likely to be consumed by different subpopulations. FDA expects the risk assessment to provide the scientific underpinnings FDA needs to develop food safety policies that reduce the risk of disease resulting from the ingestion of *V. parahaemolytiocus* in molluscan shellfish and other seafood consumed raw.

- Foodborne pathogens associated with the use of antimicrobials in food producing animals — Food animals receive antimicrobials for growth promotion and control or treatment of infectious diseases. Food animals can carry organisms that are harmful to humans and these organisms may develop resistance when the animal is exposed to antibiotics. These resistant organisms can contaminate food products at slaughter and then infect humans who ingest the food. FDA is evaluating the risk to human health from resistant foodborne pathogens associated with the use of antimicrobials in food producing animals. FDA will use this formula to model the risk of increased duration of human illness due to resistant *Campylobacter* infections attributable to the use of fluoroquinolones in chickens. The model used in this assessment is a prototype for assessing risk due to the transfer of resistant foodborne pathogens from animals to humans. The goal is to protect public health by ensuring that significant human antimicrobial therapies are not compromised due to the use of antimicrobials in food animals, while providing for the safe use of antimicrobials in animals.

The Joint Institute for Food Safety Research

On July 3, 1998, President Clinton directed the Department of Health and Human Services (DHHS) and the Department of Agriculture (USDA) to develop a plan to create a Joint Institute for Food Safety Research (JIFSR). The goal of JIFSR is to (1) coordinate planning and priority setting for food safety research among the two Departments, other government agencies, and the private sector and (2) foster effective translation of research results into practice along the farm-to-table continuum.

In June 1999, the President received a report outlining the concept of JIFSR, and providing a proposed structure, operating principles, goals and outcomes and an implementation schedule.

"The result of a coordinated research effort will be the more efficient delivery of the scientific information needed to develop effective food safety guidance, policies, and regulations in support of public health goals," said V. Kelly Bunning, Ph.D., Food Safety Initiative (FSI) deputy lead scientist. Bunning explained that DHHS and USDA will have joint leadership of JIFSR and will use existing resources to support it.

PulseNet– Blending DNA, Computers and the Internet

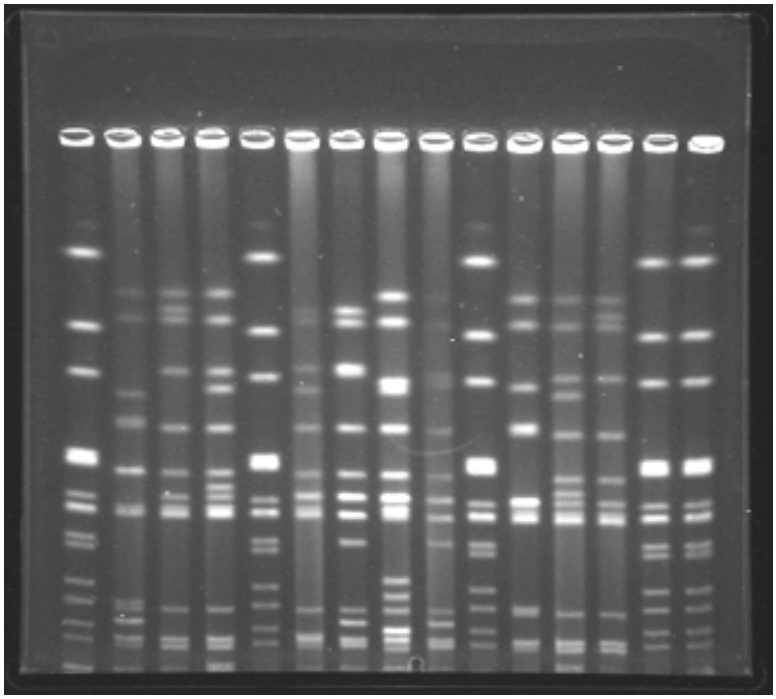
Detecting and responding to emerging pathogens in the food supply quickly and effectively is essential to preventing widespread illness. PulseNet—a collaborative project between CDC, FDA, USDA and state health departments—uses dedicated, high-speed Internet connections for the rapid comparison of DNA fingerprints of foodborne bacteria with those in an ever-growing database at CDC. When the system detects a match between fingerprints of bacteria isolated from different areas, an automated E-mail message is sent to all the participants alerting them of a possible multi-state outbreak.

Farukh M. Khambaty, Ph.D., is the microbiologist in charge of PulseNet at CFSAN. "Using the method of Pulsed-Field Gel Electrophoresis (PFGE) to generate DNA fingerprints of bacteria has proved to be the most reproducible and discriminatory solution for linking sporadic cases of foodborne illness with larger foodborne outbreaks," he said.

"With advances in the speed of computers and the development of the Internet, we can rapidly analyze and transfer huge files of information," he said. "Prior to 1997, a few gel tracks could be visually reviewed by a microbiologist. Now, we have a database with thousands of samples that will generate a report of strains that are identical or related."

In FY 99 an important case stands out as illustrative of the benefits of PulseNet. PulseNet proved useful in linking cases of *Shigella* infections in Minnesota, Massachusetts, California and Canada to fresh parsley from a single operation in Mexico. "A swift regulatory response from FDA staved off numerous more cases than would have otherwise resulted," said Khambaty.

In FY 99 PulseNet capability was expanded to FDA labs in Los Angeles; Brooklyn, N.Y.; Atlanta; Denver; Seattle; and Jefferson, Ark. They will fingerprint samples and transfer the information electronically to FDA in Washington for analysis. "This will significantly speed the process," said Khambaty.



A PFGE gel of multi-drug resistant Salmonella *strains; each vertical barcode-like pattern depicts the "DNA fingerprint" of a distinct isolate.*

Also in FY 99, two televised courses, which included information on PulseNet and the companion program FoodNet, were shown at more than 200 locations. FDA and state and local health department officials had an opportunity to learn how the programs operate.

Khambaty summed up the benefits of PulseNet by saying it allows us to do the detective work much faster, and thereby reduce significantly the number of illnesses and deaths from outbreaks.

The National Food Safety System Project — Improving Coordination and Communication

FDA is leading an effort to improve coordination and communication among public health and food regulatory officials, particularly around foodborne illness outbreaks. This effort, known as the National Food Safety System (NFSS) project, contributes significantly to more effective implementation of existing food safety programs. Work began in September 1998 with an FDA-hosted meeting of food safety and agriculture officials from all 50 states, Puerto Rico, and the District of Columbia; epidemiologists and laboratory staff from state and local health departments; and colleagues from CDC, USDA and EPA.

Discussions from that meeting led to the creation, in FY 99, of a nationwide Coordinating Committee and workgroups to generate ideas for activities that would promote an integrated national food safety system. Workgroups were established in six areas: Roles and Responsibilities; Outbreak Coordination and Investigations; Laboratory Operations and Coordination; National Uniform Criteria; Information Sharing and Data Collection; and Communication.

In FY 99 the Laboratory Operations and Coordination Workgroup developed a vision for a fully integrated national laboratory system. Marion Allen, FSI inspections coordinator, said “this system will assure competency, credibility and equivalency of test results among federal, state and local government laboratories that perform food safety testing. The Workgroup concluded that the best and most cost-effective approach to achieving this is to establish a network of accredited laboratories generating equivalent test results.”

In FY 99, two laboratory accreditation training programs were held. The first, in March, was for Workgroup members. The second, in June, was held in conjunction with the Association of Food and Drug Officials (AFDO) and preceded AFDO’s annual meeting. Over 70 federal, state, university and private laboratory personnel attended the workshop.

The Outbreak Coordination and Investigations Workgroup also

made progress in FY 99. Their goal is to develop a protocol on how to conduct multi-state outbreak investigations. Jack Guzewich, FDA's outbreak coordinator, said there needs to be greater clarity about the roles of various players in an outbreak situation and this initiative will address that.

A draft outline of a *Guidelines Manual for Coordinating Foodborne Outbreak and Traceback Investigations* was completed. Guzewich said the manual will take about a year to complete. FDA hired two new epidemiologists to work on writing the manual.

Also discussed at the Kansas City meeting was the need for on-going training of state and local officials. Responding to that need FDA produced two satellite video courses viewed by more than 6,000 people nationwide.

One course focused on conducting a traceback investigation using the procedures outlined in the FDA *Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations*. The training also covered the decision-making process for initiating tracebacks and the roles of producers, distributors, importers and investigators and how they fit into the overall traceback investigation. A foodborne illness course provided an opportunity to learn how to develop and maintain a surveillance system and how to apply epidemiological principles to an investigation. The role of the investigation team was also discussed.

FDA Assists Guatemala in Improving the Safety of Berries

In FY 99, FDA took several actions to help improve the safety of berries and other fresh produce exported from Guatemala to the United States. In 1996 and 1997, *Cyclospora* outbreaks during the spring and summer in the U.S. and Canada were traced to Guatemalan berry farms (primarily raspberry shipments, but also a few blackberry shipments).

FDA experts were sent to Guatemala to teach local inspectors to check implementation of that country's food safety program for fresh berries. "FDA also plans to evaluate how much progress the Guatemalan berry industry has made in adopting the Model Plan of Excellence (MPE) and train Guatemalan Ministry of Agriculture inspectors to check for correct implementation of safety measures designed to reduce the risk of *Cyclospora* contamination," said John Kvenberg, Ph.D., acting deputy director for the Office of Field Programs at FDA.

Growers are trying to implement the model program in an effort to obtain FDA permission for spring and summer export of their product.

In FY 99, FDA allowed raspberry shipments from four Guatemalan farms for the spring and summer season because these farms complied with all the requirements of the MPE. Only three farms actually exported to the U.S. and no reported outbreaks of cyclosporiasis were associated with raspberries from these farms.

National Antimicrobial Resistance Monitoring System

The United States now has in place a system that allows FDA to tell when foodborne bacteria that cause disease in humans begin to develop resistance to antimicrobials used in food animals. The system is called National Antimicrobial Resistance Monitoring System-Enteric Bacteria (NARMS-EB). It combines the resources of FDA, CDC and USDA to create a nationwide monitoring system. Linda Tollefson, DVM, MPH, director of Surveillance and Compliance at FDA's Center for Veterinary Medicine explained "under NARMS, isolates of *E. coli*, *Salmonella*, *Enterococci* and *Campylobacter* from humans and food animals are collected and tested to determine whether the bacteria are beginning to lose their susceptibility to antimicrobial drugs." The program alerts CDC and FDA to any change in bacterial response to antibiotics used in people.

Informed public health officials, responsible animal producers and drug manufacturers, and veterinarians can use this information to control and prevent harm from the use of antimicrobials in food animals through prudent antibiotic use practices. The system tests the three gram-negative bacteria for susceptibility to 17 different antibiotics and the susceptibility of gram -positive *Enterococci* to 27 antibiotics. The human isolates are tested by CDC, and the animal isolates by the Agricultural Research Services of USDA. FDA initiated the program in 1996 and significantly expanded it under the Food Safety Initiative in 1999 to collect more isolates from more locations and more types of bacteria from animals and humans.

U.S. Representatives Visit Mexico to Discuss NARMS

In June 1999, FDA representatives of the National Antimicrobial Resistance Monitoring System - Enteric Bacteria (NARMS-EB) Linda Tollefson, DVM, MPH and Kathy Hollinger, DVM, MPH visited Mexico to help start a monitoring system for antimicrobial resistance in *Salmonella* and *Campylobacter*. The representatives described the NARMS-EB and presented current data on multiple drug resistance in *Salmonella* from poultry slaughter isolates and on antimicrobial

resistance in *Campylobacter* from poultry.

Tollefson reported that "the project will begin with participation by sites in close proximity to the monitoring centers in five Mexican states with significant food animal agriculture." These sites are among fifteen collaborating laboratories situated throughout Mexico, Costa Rica, and Guatemala associated with the World Health Organization (WHO)-Resistnet group. This group was organized in 1996 to monitor resistance among the human pathogens *Salmonella*, *Shigella*, *Staphylococcus aureus*, *E. coli*, and *Pseudomonas aeruginosa*.

Tollefson noted that "the new project will first collect isolates from children in daycare settings to characterize the carriage rates of *Salmonella* in children and identify the antimicrobial resistance patterns of the isolates."

This collaboration between the U.S. NARMS-EB and the Mexican antimicrobial surveillance group represents the initiation of the first international human and animal monitoring system for foodborne antimicrobial drug susceptibility surveillance in the Americas.

FDA Funds 23 State Food Safety Task Forces

Working to improve coordination among state and local regulatory, industry, legislative and consumer organizations, FDA funded the establishment of 23 food safety task forces. "The goal is to create a better food safety system from the local level all the way up to the state level," said Richard Barnes, director of Federal-States Relations in FDA's Office of Regulatory Affairs.

During FY 99, organizational meetings were held to create the task forces. Participants included state departments of agriculture and health, local offices with responsibility for retail food protection programs, representatives of the retail food industry and consumer organizations. Topics for discussion included roles and responsibilities in retail food protection, adoption of the *Food Code* and its requirements and outbreak coordination.

ORA–Protecting the Nation's Food Supply at the Local Level

"Achieve effective and efficient compliance of regulated products through high quality, science-based work that results in maximizing consumer protection." That is the mission statement of FDA's Office of Regulatory Affairs (ORA), headed by Dennis Baker, associate commissioner for regulatory affairs. Specifically, that means that Baker is responsible for ensuring that FDA-regulated products (food, drugs, medical devices, cosmetics, radiation-emitting products such as microwave ovens, and feed and drugs for pets and farm animals) comply with the consumer protection laws and regulations the agency enforces. Approximately 900 investigators and 100 compliance officers in FDA offices around the U.S. are assigned to ORA.

Where food is concerned, FDA's presence is felt far and wide. "FDA inspects all food (except meat and poultry products) of domestic and foreign origin either directly or through contracts with state agencies. We want to make sure the food is wholesome and not misbranded. That responsibility includes food production, processing, distribution and sale at the retail level. We also investigate issues related to drug residues and pesticides in the food supply. We provide training to state health and agriculture officials and work for passage of the *Food Code*," said Baker.

Baker said that ORA's approach to food safety is risk-based. "We are targeting inspections to identify those products that have the highest level of contaminants and the highest level of food safety concern, such as low-acid canned foods or sanitation in the seafood industry," he said.

The following articles in this section illustrate ORA's accomplishments in the area of food safety.

Seafood Safety in FY 99

For the seafood industry, HACCP is paramount. HACCP, which stands for Hazard Analysis and Critical Control Points, is the science-based food safety system that the seafood industry is required to use to prevent the contamination of product.

FDA conducted the second year of rigorous seafood HACCP inspections, giving priority to processors with implementation problems. FDA inspectors evaluated the adequacy of HACCP plans for 11 types of hazards, ranging from pathogens and histamines to use of unlawful pesticides and food additives. Based on data available at the end of calendar year 1999, FDA found clear progress being made by most seafood processors; approximately 5 percent of seafood firms received warning letters for failure to comply.

Also, in FY 99, FDA worked with the Seafood HACCP Alliance to produce a training course for seafood processors on how to solve problems with the design and implementation of their HACCP plans. Phil Spiller, director of FDA's Office of Seafood, said that over 30 classes were taught around the country.

The New York Sea Grant Extension Program undertook an evaluation of the seafood HACCP program in FY 99. A survey taken of the seafood industry in seven New England and mid-Atlantic states found:

- Significant upgrades in facilities and equipment, primarily to enhance the ability to maintain proper temperatures. Time and temperature control is one of the keys to seafood safety for many products;
- Major changes in daily plant operations, relating to better temperature control, closer evaluation of the incoming products that arrive at the plant door, the use of test kits, sample analysis and other activities;
- Significant re-evaluation of cleaning and sanitizing practices in order to improve overall conditions in plants; and
- Overall, a better understanding of food safety hazards and how to control them.

The Sea Grant study observed that behavioral changes are being reported by the industry, along with the investment in tools needed to carry them out. This is likely to result in a significant improvement in the safety and quality of seafood products available in the marketplace. FDA is working with the Seafood HACCP Alliance, a consortium of government agencies, academia and trade associations to have the Sea Grant study replicated during FY 2000. "We look for-

ward to learning whether the rest of the nation is responding to HACCP as positively as processors in the northeast," Spiller said.

Vibrio parahaemolyticus Control Plan Adopted

At the 1999 Interstate Shellfish Sanitation Conference (ISSC), a plan to control *V. parahaemolyticus* in shellfish was adopted as interim guidance. Under the FDA plan, states are required to monitor shellfish for virulent strains of *V. parahaemolyticus* using state-of-the-art gene probe methodology, and to close shellfish harvest areas when virulent *V. parahaemolyticus* strains are detected. FDA is assisting states in implementing the control plan.

V. parahaemolyticus is a marine bacterium, not related to pollution, which caused four separate outbreaks of shellfish-related illness in the U.S. in 1997-1998. Prior to the summer of 1997, *V. parahaemolyticus* cases transmitted by shellfish occurred only sporadically.

The *V. parahaemolyticus* control plan will be voted on for permanent adoption into the Nation Shellfish Sanitation Program (NSSP) at the 2001 ISSC annual meeting. The NSSP, a federal-state cooperative program, was established in 1925 as a national program to address the safety of molluscan shellfish. Under this program, state regulatory agencies are responsible for classifying waters as suitable or unsuitable for the growing and harvesting of shellfish that may be consumed raw. The states are also responsible for monitoring shellfish growing areas, and inspecting processors of shellfish for sanitation and safe handling practices. In 1982, the ISSC was established to provide a forum for state regulatory officials to establish uniform national guidelines for assuring the safety of molluscan shellfish.

Voluntary National Retail Regulatory Standards Tested

Six jurisdictions began testing FDA's newly developed Voluntary National Retail Program Standards in FY 99. Richard Barnes, director of Federal-State Relations in FDA's Office of Regulatory Affairs, explained that the standards serve as a guide to regulatory retail food program managers in the design and management of a retail food program and provide a means of recognition for those programs that meet these standards.

The standards were developed with input from the retail foods regulatory community, industry and consumers. These standards reinforce sanitation, operational and environmental prerequisite programs; provide direction and focus to regulatory agencies and industry on the causes and contributing factors that lead to foodborne illness; and improve and build upon existing mechanisms and programs.

The six jurisdictions will be conducting self-assessments on their ability to meet the standards. The nine standards are: 1) regulatory foundation; 2) trained regulatory staff; 3) inspection program based on HACCP principles; 4) uniform inspection program; 5) foodborne illness response; 6) compliance and enforcement; 7) industry recognition; 8) program resources; and 9) program assessment.

The results of the tests will be discussed at the Conference for Food Protection's meeting in the year 2000.

FDA Using High-Tech Tools for Inspections and Assessments

Digital cameras and laptop computers are now tools of the trade for FDA staff conducting inspections and assessments on farms, processing plants and at the retail level.

Marion Allen, FSI inspections coordinator, explained that the digital cameras allow inspectors to document where problems may exist on a farm, or in the infrastructure of a plant, or with the labeling of a product. "The pictures taken by a digital camera can be downloaded directly into the lap-top computer and become a permanent part of the record. This provides FDA with a better record to support regulatory action," she said.

Access to laptop computers provides inspectors with resources such as the Code of Federal Regulations and the Food, Drug and Cosmetic Act, references they need on a daily basis.

REDUCING FOODBORNE ILLNESS FROM EGGS:

Although scientists have yet to discover which came first—the chicken or the egg—they have recently discovered that harmful bacteria can enter an egg through transovarian contamination before it is laid.

This discovery is a starting point in understanding how to reduce foodborne illness caused by *Salmonella* Enteritidis (SE) in eggs. It is estimated that 310,000 SE infections occurred in 1997. While more recent statistics from the Foodborne Diseases Active Surveillance Network (FoodNet) indicate a 44 percent decrease in the number of illnesses caused by SE from 1996 to 1998, the remaining public health burden requires additional action.

How FDA is proceeding in this matter illustrates what is meant by the term "science-based food safety system."

In FY 99, FDA issued a proposed regulation that would require safe handling statements on labels of shell eggs that have not been treated, such as with heat, to destroy *Salmonella* microorganisms. The agency also proposed to require that, when held by retail establishments, shell eggs be stored and displayed under refrigeration at a temperature 45 degrees F or less. FDA took those actions based on the number of outbreaks of foodborne illnesses and deaths caused by SE that are associated with the consumption of shell eggs that have not been treated to destroy this pathogen.

To come to this proposed regulatory decision, however, required looking at the scientific evidence. This evidence included a risk assessment on SE completed by the U.S. Department of Agriculture in 1998, in conjunction with FDA and CDC. Richard Whiting, Ph.D., senior scientist on the FSI staff, explained that the purpose of risk assessment is to identify steps in the processing and handling of eggs from farm to consumer that increase the risk of illness from this pathogen and to identify and evaluate potential risk reduction strategies. The SE risk assessment estimated that of the 47 billion shell eggs consumed annually as shell eggs, 2.3 million are SE-positive, exposing a large number of people to the risk of illness. The risk assessment also determined an 8 percent reduction in illnesses would occur when all eggs are maintained at an air temperature of 45 degrees F throughout shell egg processing and distribution system. Whiting said the risk assessment also concluded that to achieve a 25 percent reduction in human illnesses a broadly-based policy may be more effective than a policy directed solely at one area of the egg production-to-consumption chain. Consumer behavior research regarding the consumption of raw eggs also guided policy makers in developing the proposed safe handling labeling for shell egg packages.

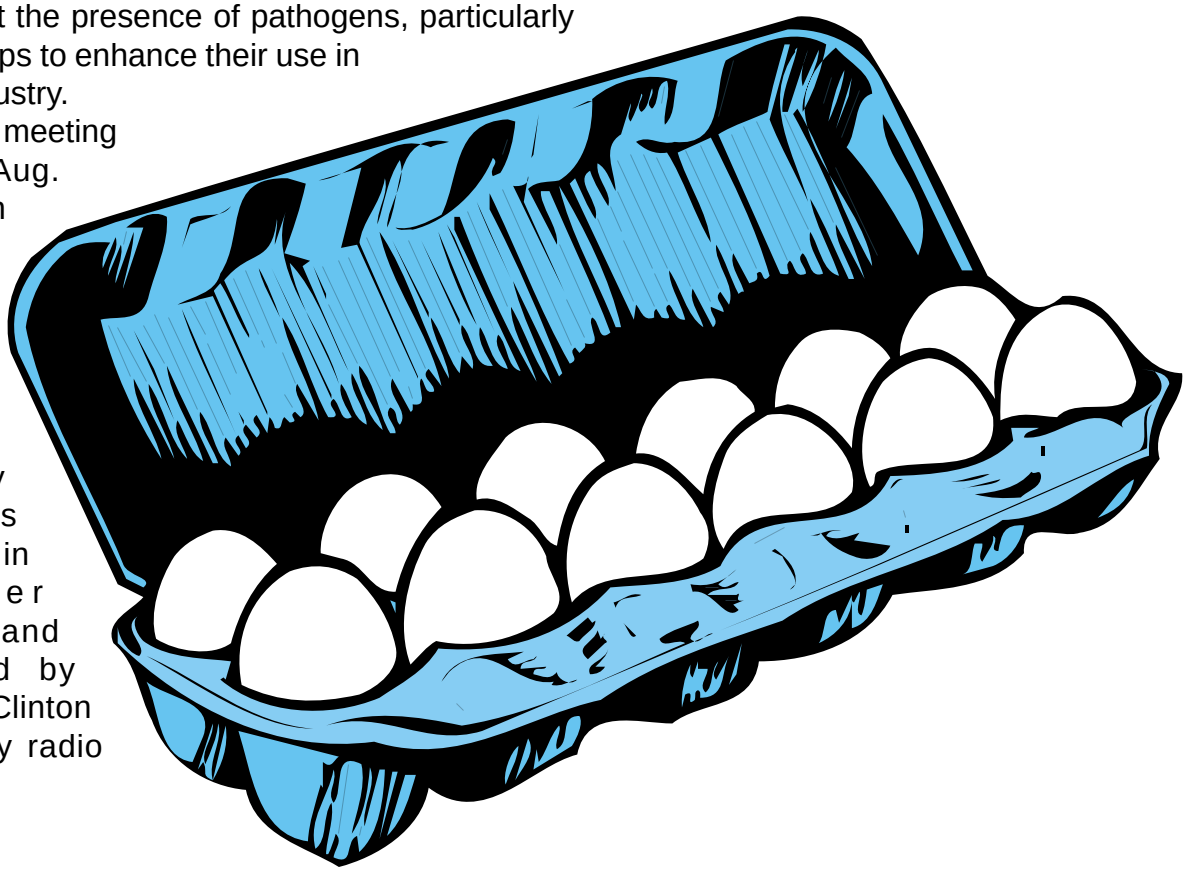
A COMPREHENSIVE APPROACH

(See Education, page 30, for more information on FDA's FY 99 activities to educate consumers and the food service industry on safe handling and preparation of eggs.)

"The issuance of the proposed regulations is not the end of the story," according to Lou Carson, deputy director of FSI. "It is a step in the process of assuring consumers a safer egg supply." A following step was the announcement in August by the President's Council on Food Safety—Strategic Planning Task Force—that an action plan on egg safety would be developed. Carson, who coordinated development of the egg safety action plan, said the plan examines the occurrence of SE in shell eggs and egg products using a farm-to-table approach, and steps which can be taken to reduce SE, including increased use of effective quality assurance programs at the producer level or on the farm. The Egg Safety Action Plan set goals of a 50 percent reduction in egg-associated SE illnesses by 2005, leading to the eventual elimination of SE in eggs as an important source of human illness by 2010 through science-based and coordinated regulation, inspection, enforcement, research, and education programs. The action plan also identifies new and existing technologies to control and prevent the presence of pathogens, particularly SE, and steps to enhance their use in the egg industry.

A public meeting was held Aug. 26 to obtain input on the plan's objectives and action items.

The egg safety plan was completed in December 1999 and announced by President Clinton in a weekly radio address.



The Safety of Imported Food—An Overview

At the port of Baltimore, in Maryland, huge cranes stand ready to unload cargo ships laden with food from around the world for American consumers. Spices from India, fish from Japan, baked goods from Europe—all destined for U.S. grocery stores or restaurants.

Spices from around the world await FDA approval before being released for further processing into jars and cans for grocery store shelves.

All imported products are required to meet the same food safety standards as domestic goods. Imported foods must be pure, wholesome, safe to eat, and produced under sanitary conditions. All products must contain informative and truthful labeling in English. The Food, Drug and Cosmetic Act, Section 801, directs FDA to refuse admission of any article that appears to be in violation of the Act.

To ensure that FDA is notified of all regulated products imported into the U.S., the importer, or his or her representative, must file an entry notice and an entry bond with the U.S. Customs Service pending a decision regarding admissibility of the product. FDA inspection and enforcement procedures for imports rely on coordination with Customs Service. For more information on coordination with the Customs Service, see page 24.

Dean Cook is an import investigator in FDA's Baltimore District office. He is one of 130 import investigators nationwide. Cook says he sees his job as the first line of defense in keeping unsafe imported products from American consumers.

As Cook describes it, import investigations is a two-step process with an immediate timeframe. Products cannot sit on the docks or in warehouses waiting for FDA to act. "The first step in an import investigation is the analysis of computerized data provided by OASIS (Operational and Administrative System for Import Support). The second step is product sampling," he said.

Each morning and then throughout the day, Investigator Cook and his colleagues Matthew Henciak and Nora Skerry review the OASIS

database. This is how the Customs Service notifies FDA of an entry. Based on a review of documents provided by the importer, product description, and a review of various databases, FDA makes a decision as to the product's admissibility. If FDA does not wish to examine the entry, the product is allowed to proceed into U.S. commerce. Cook says that it is important to determine if a product is on the Imports Alert listing. There are approximately 700 import alerts at any given time, which indicate products, firms, or countries that have exhibited past violations. A product that arrives in the United States that is on this list is detained without physical examination until private lab testing is performed. "The importer will have to prove the product is safe before it will be allowed into commerce," said Cook.

"If we decide to examine an entry, an import investigator will collect a sample from the shipment for laboratory evaluation. When we sample we look at products that may pose the highest health risk, those that contain harmful bacteria or acidified and low acid foods that may have been underprocessed. The samples are then sent to a laboratory for evaluation. During that time, the product must remain intact until the lab results are known. If the analysis indicates the product is in compliance, the shipment will be released into commerce. If there is a violation, the product will be refused admission," he said.

If there is a violation, the product will be detained. The importer of record then has the right to provide oral or written testimony to the FDA regarding the admissibility of the product or the manner in which the product may be brought into compliance. The product could ultimately be released if brought into compliance. If the product is not brought into compliance, it may be re-exported or destroyed under U.S. Customs supervision.

With four times the number of imported products entering the U.S. as in 1994, FDA has to be sure its import resources are targeted well.

Nora Skerry, an FDA import investigator, reviews the OASIS database to determine if an imported product is admissible for entry into the United States.

Imported Produce 1,000 Sample Survey

In March 1999, FDA initiated a 1,000 sample survey focused on high volume imported fresh produce: loose-leaf lettuce, cantaloupe, celery, strawberries, scallions/green onions, parsley, cilantro and broccoli. In ranking commodities selected for the produce survey, five risk factors were used: epidemiological outbreak data; structural characteristics; growing conditions; processing; and consumption.

These commodities were analyzed for *Salmonella*, *Shigella*, *E. coli* O157:H7, Aerobic Plate Count, and coliforms. Produce imported from Mexico, Canada, Costa Rica, Guatemala, The Netherlands, Honduras, Israel, Belgium, Chile, Italy, Nicaragua, Trinidad and Tobago, France, Korea, Columbia, Peru and the Dominican Republic was sampled.

Original plans called for 125 samples of each of the eight products. The quota of loose-leaf lettuce was completed by August 1999 and sampling of those products was discontinued. Because most broccoli is cooked prior to consumption, sampling of broccoli was discontinued after 36 negative samples. Collection of the remaining products was continuing into 2000.

Upon completion of the survey in early 2000, results of the entire survey will be released.

FDA-Customs Service Working Together for Imported Food Safety

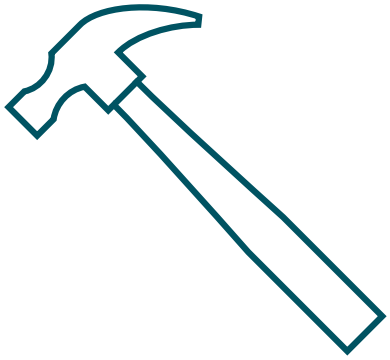
While most imported foods are safe, and most importers comply with U.S. food safety requirements, a few importers try to sidestep U.S laws to bring unsafe or contaminated food into the country. In December 1999, FDA and the U.S. Customs Service announced six steps that will be taken to better assure the safety of imported foods:

- Prevent distribution of imported unsafe food by means such as requiring food to be held until reviewed by FDA.
- Destroy imported food that poses a serious health hazard.
- Prohibit the re-importation of food that has been previously refused admission and has not been brought into compliance with U.S. laws and regulations, and require the marking of shipping containers and/or papers of imported food that is refused admission for safety reasons.
- Set standards for private laboratories for the collection and analysis of imported food for the purpose of gaining entry into the U.S.
- Increase the amount of the bond posted for imported foods when necessary to deter premature and illegal entry into the U.S.

- Enhance enforcement against violations of U.S. laws related to the importation of foods, including through the imposition of civil monetary penalties.

FDA planned a series of public meetings in February 2000 to receive public input on these action items. Final implementation on all actions will not take place until the fall of 2000.

BSE Educational Activities Gain Vice Presidential Award



On May 14, the FDA/Association of American Feed Control Officials (AAFCO) Bovine Spongiform Encephalopathy (BSE) Feed Regulation Team was honored with Vice President Al Gore's Hammer Award. The Hammer Award honors Federal employees and their partners who have joined forces to streamline procedures, put consumers first, and help build a better and more cost-effective government. The award citation reads "For making a significant contribution to reducing the possibility of bovine spongiform encephalopahty (BSE/Mad Cow Disease) becoming established and spread in the U.S." The BSE Feed Regulation Team used an innovative education-oriented partnership program to enforce an FDA regulation designed to control BSE.

The BSE regulation, now in effect for two years, restricts the use of mammalian protein in feeds for cattle and other ruminants. The regulation requires protein renderers, protein blenders, feed manufacturers and distributors to label feeds that contain prohibited material with the following warning statement: **"Do not feed to cattle or other ruminants."**

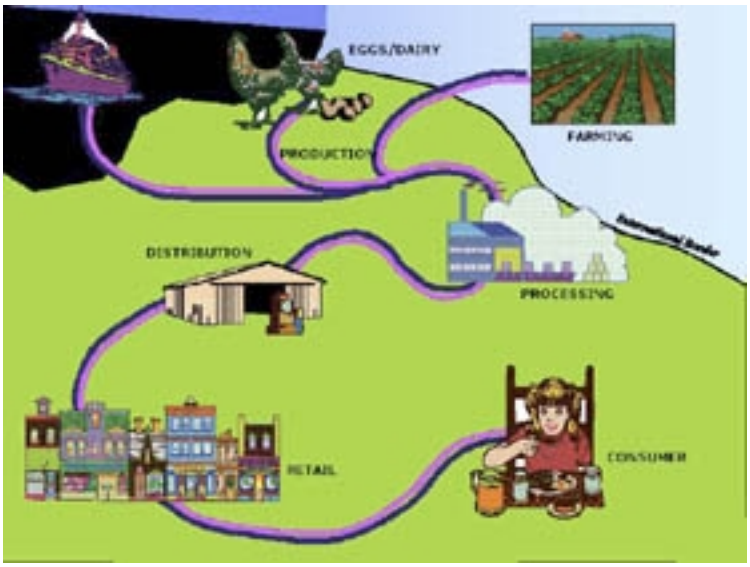
Gloria Dunnavan, director of FDA's Center for Veterinary Medicine, Division of Compliance, reports "the data shows that compliance rates for the first inspections of all but one industry segment equaled or exceeded 75 percent. Independent research has shown that major industry adjustments have been made to facilitate compliance with the regulations. FDA and state inspectors have conducted an unprecedented number of education-oriented inspections; a reinvented approach to doing inspections that has resulted in 70 percent savings in the cost of inspections."

"Thanks to the development of the BSE regulation, we can continue to say that there has not been a single case of BSE reported in the United States. Educational efforts with our regulatory partners will help assure that we can continue to make that claim," said Stephen F. Sundlof, D.V.M., Ph.D., director, Center for Veterinary Medicine.

EDUCATION

"The business of food safety education is to persuade or convince someone to change unsafe food handling behaviors. In this case there are many 'someones' along the farm-to-table continuum," says Marjorie Davidson, Ph.D., education team leader for FDA's Food Safety Initiative. "Not only must we provide people with information we must do it in a manner that results in changing unsafe food handling behaviors to safe food handling behaviors, " she said. "Constant reinforcement of educational messages is important to sustaining behavior change."

In FY 1999, producers, retailers, the food service industry and consumers were the focus of concerted efforts to change unsafe food handling practices into safe food handling practices. Sporting such names as GAPS and GMPS, and Fight BAC!™, research-based education was conducted all along the farm-to-table continuum.



Producer Education

Educating producers is a complex challenge due to the diversity of products, diversity of growing conditions and transportation systems, and perhaps the greatest challenge of all—diversity of language and culture of people around the world who grow and ship food to U. S. consumers. Producer education programs in FY 99 began to tackle these challenges. For international activities see page 27, International Outreach.

Expanded Producer Education Programs for GAPs

FDA provided funds to augment a Good Agricultural Practices (GAPs) Grant that the U.S. Department of Agriculture awarded to Cornell University to develop training programs and train domestic producers on GAPs. Producers in five key states — New York, Florida, California, Washington and Michigan — will be targeted for the training programs.

Retail Education

Food Safety Training and Education Alliance

Keeping consumers safe when they eat out of the home is the responsibility of many entities including retailers, food service vending operations, institutions and regulators. As part of the President's 1997 Food Safety Initiative, the Food Safety Training and Education Alliance (FSTEA) was established to share food safety training materials, promote and implement the *Food Code* and develop multicultural communication techniques.

How is that being accomplished? In FY 99, FSTEA launched a website as a method of sharing information with a large, diverse group of individuals with a common need. Accessible through www.foodsafety.gov, the website includes information on current activities, provides a link to databases of training materials and listings of available training courses.

Gary German, FDA's co-facilitator of FSTEA, said the alliance has been successful in developing competencies for regulators, trainers and industry officials. "These competencies provide national uniform education and experience standards that should be met by those who regulate the food industry, those who provide training for the food industry and those who work in the food industry," he said.

In addition to developing the competencies, FSTEA also developed criteria for reviewing the quality of education materials that are under development or completed.

Another project completed in FY 99 is the compilation of responses to the 1998 multi-cultural materials needs survey. The training materials identified in the survey are available from the National Agricultural Library.

Using video teleconferencing technology, FSTEA hosted a training program for trainers and educators in April 1999. The video conference attracted a nationwide audience who heard updates on FSTEA activities, training resources and information about National Food Safety Education Month.

Food Code "Train the Trainer" Courses Held in FY 99

Learning the content of the *Food Code*, a nationally-recognized reference published by FDA that guides retail outlets such as restaurants and grocery stores and institutions such as nursing homes on how to prevent foodborne illness, can be done by reading through the more than 400 pages of information it contains. Or, you can take a class.

In FY 99, FDA provided "Train the Trainer" classes on the *Food Code* to develop a cadre of qualified instructors to reach the local food service community. Six sessions were held across the country. The course covered instruction on effective training techniques and the requirements of the 1999 *Food Code*. Local, state and federal regulators use the *Food Code* as a model to help develop or update their own food safety rules and to be consistent with national food regulatory policy. Also, many of the over 1 million retail food establishments apply the *Food Code* provisions to their own operations.

"Participants who completed all five days of the course were expected to return to their respective organizations and conduct *Food Code* courses for their coworkers, industry and other interested parties," said Gary German, director of FDA's Division of Human Resources Development.

Consumer Education

For consumers, the food safety message was "risk". "We want consumers to understand why some are more 'at-risk' for foodborne illness than others and what foods are considered risky because of their association with foodborne illness," said Marjorie Davidson, Ph.D., FSI's team leader for education.

Keeping Vulnerable Seniors Safe from Foodborne Illness

Senior citizens are one such group that is at-risk for foodborne illness and for whom special education initiatives were developed in FY 99. A three-pronged approach is providing seniors with safe food handling information. Debuting in May 1999, the *Seniors and Food Safety* website is providing Internet-savvy seniors and others with specific information on why they are at-risk for foodborne illness; how changes in food distribution plays a role in food safety; and what steps they can take to keep food safe from the time it is purchased until it is consumed. The website is located on the Internet at www.foodsafety.gov and can be reached by clicking on Consumer Education.

A joint FDA-USDA video and companion publication targeted specifically to seniors was undertaken in FY 99. The video follows three sets of seniors as they learn about safe food handling. Printed information reinforces the four major points of safe food handling — clean, cook, chill and separate–don't cross-contaminate. Distribution of the video and publication will be completed in FY 2000.

Few Consumers Understand Risk of Eating Raw Eggs

Consumer behavior research indicates that many people are unaware of the dangers posed by eating raw or undercooked eggs. A specialized egg safety campaign was developed in an effort to reduce the incidence of foodborne illnesses caused by *Salmonella* Enteritidis. "The campaign kick-off was tied to FDA's proposed egg labeling and refrigeration rule. This provided an opportunity to inform consumers about safe handling and cooking of eggs," said Davidson. A video news release was developed and used by television stations with a rated viewership of more than 2 million persons. Two easily reproduced fact sheets were developed — *Playing It Safe With Eggs* for consumers and *Assuring the Safety of Eggs* for food service personnel. These fact sheets are on FDA's website and were mailed to institutions and organizations serving populations most vulnerable to foodborne disease such as day care centers, nursing homes, and area agencies on aging for redistribution to senior centers, congregate feeding programs, health care professional organizations, and to media. A news article was written in English and Spanish and distributed to small dailies, weeklies and local advertiser-type publications.

What's Cooking? National Food Safety Education Month — September 1999

"Cook It Safely" was the theme of FY 99's National Food Safety Education Month (NFSEM), an annual event to promote food safety to consumers and the food service industry. The President's Food Safety Initiative recognizes and encourages observance of this event, which was created by the International Food Safety Council. Special mailings were sent to over 100,000 food service directors for at-risk audiences—school food service directors and day care and nursing home food service directors—with special information about food safety.

FDA, in conjunction with USDA, developed and mailed an NFSEM consumer education planning guide to public health departments, FDA public affairs specialists and USDA extension agents, school nurses and school food service directors throughout the country. The 43-page guide contained reproducible activities and publicity ideas for food safety education during September. FDA public affairs specialists planned special programs in their communities during the month.

Bringing the Farm-to-Table Food Safety Initiative to Classrooms

"One of the best ways to develop safe food handlers is to educate students," said Laura Fox, an education specialist in FSI. In FY 99, work began on a supplementary food science curriculum aimed at middle and high school students. Through this program students will learn that foodborne illness may be caused by harmful bacteria that gets into the food supply anywhere in the continuum from farm-to-table. Students will also learn to prevent foodborne illness from occurring at home through proper food handling. Cosponsoring this program is the National Science Teachers Association. Components of the program will include an interactive website, a videotape, and printed teacher and student resource and activity guides. The program's content will meet the National Science Standards for Education.

FDA Support Grows for Partnership for Food Safety Education

FDA's support of the Partnership for Food Safety Education resulted in a further expansion of the Fight BAC!™ message to the public. In FY 99, the Partnership released a supplementary curriculum program for students in grades 4-6 to teach the four basic safe food handling messages through video and classroom activities and experiments.

"The influence of the Partnership is demonstrated by the number of other organizations who are coming to the Partnership with ideas for developing new initiatives," said Davidson. In FY 99, the Partnership joined forces with two major organizations—Pfizer and McDonald's—to provide food safety information to millions of consumers. Pfizer reprinted the Partnership's consumer brochure and made copies available to the public at its "Microbes" traveling science exhibit. McDonald's began its parent brochure "Playing it Safe at Home" with a section on food safety using Fight BAC!™ to deliver the four basic safe food handling messages. McDonald's printed 12 million copies for distribution in September and October 1999.

FDA Public Affairs Specialists Create New Education Projects

In FY 99, FDA public affairs specialists received funds from FSI to create 21 grassroots food safety education projects. Many of the projects utilize the Fight BAC!™ campaign materials, support National Food Safety Education Month, or focus on populations at severe risk from foodborne illness; people of low literacy; or multicultural populations. Howard Seltzer, education advisor on the FSI staff coordinates the funding of these grassroots projects. "An important aspect of the education program is getting materials to the people who need them in languages and approaches that are culturally appropriate. The FDA public affairs specialists understand the needs of consumers in the communities they serve," he said.

FDA's New Outreach and Information Center Ready for Business

"The FDA has continuously led the way in getting an effective food safety message out to the public. The Outreach and Information Center (O&IC) is an important, new resource that will help put the most up-to-date, reliable food safety information at the fingertips of those who need it most — American consumers," said Secretary of Health and Human Services Donna E. Shalala in announcing the opening of FDA's new Center.

Open for business on Sept. 14, 1999, the O&IC was created in part to enhance FDA's ability to provide accurate and meaningful information to the public about food safety. It is funded as one of the targeted projects for development under the Food Safety Initiative. The O&IC operates a newly expanded tollfree public information line 1-888-SAFEFOOD. The system includes more than 200 hours of newly recorded information. Between the hours of 10:00 a.m. and 4:00 p.m., EST, information specialists respond to calls directly from the public.

Outreach and Information Center

FDA Awards Food Safety Grants

FDA enhanced its ability to meet its goals by awarding grants to the food safety community at the state and local level and to academic institutions.

In FY 99, FDA awarded grants for innovative food safety projects to 11 state and local regulatory agencies. This pilot program is intended to complement, develop or improve state and local food safety programs that may also be used in other state or local jurisdictions. These grants, which total nearly $500,000 are for a one-year period and were awarded in four key areas: 1) inspection, 2) regulation and compliance, 3) information systems and 4) education and health information dissemination. Richard Barnes, director of FDA's Division of Federal-State Relations, said the other state and local agencies will be able to take the results of the projects and use them in their own areas.

Grants were also awarded to universities to support research in food safety to: 1) reduce the incidence of foodborne illness by improving the ability to detect and control pathogens in the food supply and 2) develop better data and modeling techniques to assess the exposure of the population to microbial contaminants and the range of health consequences of that exposure.

Nine proposals were funded for multi-year research projects. Marianne Miliotis, coordinator of FSI's extramural research said, "By establishing a collaborate effort between scientists and FDA, not only will we be able to meet our research goals, but we also expect to increase the dialog between government scientists and the greater scientific community for developing new technologies to keep the public safe from foodborne illness, and to stimulate interest in food safety research."

Multi-Lingual Materials on Produce Safety Initiative Completed

A new tool to help explain the Produce Safety Initiative was completed in FY 99. *Assuring Safer Produce: A Global Issue*, is a six-minute video that provides an overview of the good agricultural and good manufacturing practices outlined in FDA's *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*. The video was translated from English into Spanish, French and Portuguese for use worldwide. The guide is also now available in English, Spanish, French and Portuguese. The videos and English and Spanish guides are available on the Internet at www.foodsafety.gov.

International Conference Held on Safety of Fresh Produce

"Enhancing the Safety of Fresh Produce at the Source: Training Modalities and Methods, Needs and Opportunities," was the title of an international conference sponsored by FDA April 26-28.

"This landmark workshop, held at the University of Maryland, College Park, drew 175 participants from 24 countries on four continents," said Camille Brewer, FSI international activities coordinator. Attendees included government experts, education and training counselors, scientists, producers, worker groups, academic institutions and international organizations.

"The purpose of the workshop was to begin a process for determining how to develop an education and outreach program for growers and producers that will benefit public health and the marketplace," said Brewer. Topics discussed included minimizing microbial contamination through the control of water, manure, worker health and hygiene, field and facility sanitation and transportation.

"At the conference's conclusion we made progress identifying common elements of a good training plan, creating awareness of existing training programs, and identifying potential partnerships for the development of practical training modules," explained Brewer.

Training Provided to Improve Produce Safety in Central America

FDA participated in a planning meeting sponsored by the Food and Agriculture Organization in December 1998 to assess training needs and to begin to develop a core curriculum for regional train-the-trainer workshops on good agricultural practices for Central America.

FDA then provided instructors for the first of its kind Regional Course on the Assurance of the Quality and Safety of Fresh Fruits and Vegetables. The May 1999 training course, which was held in Costa Rica, brought together agriculture experts and health officials from Central America.

International Meetings Held on Produce Safety

In September 1999, FDA held two international meetings for mid-level government officials and industry representatives with food safety responsibilities. The first meeting in Mexico City was targeted to the countries of North and Central America and reached over 5,000 individuals through satellite link-up at 76 sites throughout Mexico. The second meeting in Chile reached more than 200 representatives from South America. Through general sessions and workshops, participants learned about the U.S. National Food Safety Initiative; Hazard Analysis and Critical Control Points principles in meat, poultry, seafood and juice industries; requirements and guidelines covering fruits and vegetables; research and risk assessment; the *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*; and food safety education and the role of government and the private sector in ensuring food safety.

Mary Ayling, FSI lead, produce inspection team, said the meeting provided an opportunity to discuss food safety concerns of the exporting countries.

A panel of experts from the U.S and Mexico discuss produce safety at the Regional Outreach Meeting on Food Safety in Mexico City.

U.S. and Mexico Formalize Food Safety Cooperation

In June 1998, the U.S. and Mexico issued a Joint Letter of Intent to Cooperate on Food Safety, in which they pledged to develop and implement collaborative projects. The goal is to develop a plan for working together on education, research and outbreak response. Several programs have been developed under the joint letter in the areas of education, outbreak response and research.

In September 1999, FDA participated in a training program on good agricultural practices sponsored by SAGAR (Mexico's) Ministry of Agriculture and Livestock, which was broadcast to 49 sites throughout Mexico.

A draft protocol between FDA and Mexico was developed to establish links when outbreaks occur in either country or positive lab samples implicate a particular commodity. "This protocol will formalize communications and ensure more rapid communication between the U.S. and Mexico," said Jack Guzewich, FDA's foodborne disease outbreak coordinator. Guzewich explained that a "Bilateral Foodborne Disease Outbreak Response Team" made up of federal, state and local representatives from Mexico will accompany FDA on investigations in Mexico. "We believe working together FDA can help Mexico improve the safety of their food supply."

FDA Staff Provides Expertise to Americas Region

FDA officials served as consultants to the Inter-American Bank, carrying out needs assessment of country capabilities for produce safety in Trinidad and Tobago, Honduras and Costa Rica.

FDA officials also served as consultants to the USDA on the Hurricane Mitch Reconstruction Project, assessing rehabilitation needs related to food safety in Honduras, Nicaragua, El Salvador and Guatemala.

Looking to the Future

A Message from Joseph A. Levitt

Director, Center for Food Safety and Applied Nutrition

As I reviewed this food safety accomplishment report for FY 99, I couldn't help but feel proud of what a productive and successful year it was. During the first year of the Food Safety Initiative (FY 98), the food safety foundation was built—programs put into place, research funded, partnerships established. In the second year, expectations were greater. We had to demonstrate that through the Food Safety Initiative, the safety of the food supply could be improved. After reading through this report, I hope you will agree with me that FDA is meeting that challenge.

Now it is time to look to the future. The year 2000 will see follow through on many important programs. These include the Egg Safety Action Plan, final regulations on juice safety and the use of new technologies to improve the safety of the foods we eat. A full listing of our 2000 program priorities can be found at http://vm.cfsan.fda.gov.

In July 2000 the President's Council on Food Safety will complete a comprehensive food safety strategic plan. Developed with input from all of our stakeholders, the goal of the strategic planning process is to create a comprehensive long-range plan that addresses the steps necessary to achieve a seamless food safety system including key public health, communications, and management issues regarding food safety. The plan will be used to set priorities, improve coordination and efficiency, identify gaps in the current system and mechanisms to fill those gaps, continue to enhance and strengthen prevention and intervention strategies, and develop performance measures to show progress.

So as we look to the future, let me extend my thanks and appreciation to our many colleagues throughout the Food and Drug Administration, the Centers for Disease Control and Prevention, the U.S. Department of Agriculture, the Environmental Protection Agency and the state and local agencies who are all working together to achieve one common goal: to improve the health of American consumers by reducing the incidence of foodborne illness.

www.FoodSafety.gov

Whether you're an industry representative, health professional, consumer or educator, you'll find something of interest at www.foodsafety.gov. This federal gateway site provides information on hot topics in food safety, links to key sites inside and outside of government and a search engine and index.