

TESTIMONY**Statement of****Bernard A. Schwetz, D.V.M., Ph.D.****Acting Principal Deputy Commissioner****Food and Drug Administration****Before the****Committee on Governmental Affairs****Subcommittee on Oversight of Government Management, Restructuring
and the District of Columbia****United States Senate****October 10, 2001**

Good afternoon, Mr. Chairman and Members of the Subcommittee. I am Bernard A. Schwetz, D.V.M., Ph.D., Acting Principal Deputy Commissioner of Food and Drugs, Food and Drug Administration (FDA or Agency). Thank you for this opportunity to discuss the Federal food safety system and to provide testimony on behalf of the Department of Health and Human Services (HHS). Ensuring the safety of the food supply is a top priority for HHS and the Administration. I am pleased to be here today with my colleague, Dr. Elsa Murano, Under Secretary for Food Safety in the U.S. Department of Agriculture (USDA).

The American food supply continues to be among the safest in the world. Great strides have been made in recent years that have strengthened the Federal food safety system. The Federal food safety program includes new surveillance systems, better prevention programs, faster outbreak response, enhanced education, and better coordinated and focused research and risk assessment activities. Food safety agencies are working more closely together than ever before.

But our world is constantly changing, and we must continue to change with it. Indeed, we cannot rest until we have built a strong and credible food safety system that addresses the full range of food safety issues: one that is built on scientific expertise with recognized stature worldwide; that is risk-based and recognizes and responds to new risks; that provides a credible inspection and product sampling presence; that has the same level of protection to consumers from both domestic and imported food; that efficiently stewards new technologies to the market; and that effectively educates and communicates to consumers.

By way of background, while FDA has lead responsibility within HHS for ensuring the safety of food products, HHS's Centers for Disease Control and Prevention (CDC) has an important complementary and non-regulatory public

health role. As the lead Federal agency for conducting disease surveillance, CDC monitors the occurrence of illness in the United States attributable to the food supply. The disease surveillance systems coordinated by CDC are an essential information network for early warnings about dangers in the food supply and progress in reducing foodborne illness, and for indicating new or changing patterns of foodborne illness. Because CDC also detects and investigates outbreaks of foodborne illness through its networks, CDC is able to alert FDA and USDA to the implicated products and works closely with FDA agencies to take protective public health action. In keeping with its agency mission, CDC also identifies, evaluates, and offers expert scientific opinion on the effectiveness of foodborne disease prevention strategies. In addition, just as FDA works with State and local food safety counterparts, CDC works extensively with State and local departments to build their epidemiology, laboratory, and environmental health expertise in foodborne disease surveillance and outbreak response. All of these collaborations draw on and apply the unique expertise within HHS to address significant and emerging challenges posed by our food supply.

I will now discuss some of the challenges we face, describe the food safety system toward which we should strive, mention some recent food safety accomplishments, and describe where we need to go from here.

While much progress has been made in improving the safety of the food supply, it is important not to underestimate the significant challenges we face. I would now like to discuss some of these challenges.

Food Safety Challenges

While the American food supply is among the safest in the world, there are still too many Americans stricken by illness every year caused by the food they consume, and some die as a result. The CDC has estimated that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year. There are many reasons for this. People are eating a greater variety of foods, particularly seafood and fresh fruits and vegetables. As many of these foods are becoming available all year round, safety concerns associated with transportation and refrigeration arise. The rising volume of imported foods increases dramatically the number of potential sources of food contamination. People are eating more of their meals away from home. In fact, fifty cents of every food dollar is spent on food prepared outside the home. As more food workers become involved in preparing our meals, the opportunity for disease-causing errors also increases. This problem is especially important for persons at greatest risk who eat foods prepared in hospitals, nursing homes, and childcare centers. Indeed, persons at highest risk for foodborne illness – children, the elderly, pregnant women, and immuno-compromised persons – now comprise nearly a quarter of the population.

Other significant changes are the emergence of new foodborne pathogens and the ability of existing pathogens to overcome traditional food barriers such as temperature and acidity. We are aware of more than five times the number of foodborne pathogens today than we were half a century ago, and we continue to discover more. Many of these pathogens can be deadly, especially to those at highest risk.

Framework for a Strong and Credible Food Safety System

The goal of HHS is to strengthen our food safety system to address the full range of food safety issues. This system has three simple steps:

to identify risks;

to take action; and
to measure results.

In identifying risks, we must ensure a strong science base which is the foundation of any successful food safety system. We must also develop, enhance, and maintain surveillance systems that can quickly and accurately identify food safety risks in the human food and animal feed supplies and manage disease risks effectively. These surveillance systems are the key to an effective emergency response capability.

In taking action, we must start with prevention. That is how we, ultimately, will be most successful. We need strong risk-based prevention standards to prevent contamination of all human foods and animal feeds over the farm-to-table continuum. As these risk-based prevention standards are developed, we need education and training programs so that those in the industry and the public can effectively utilize them to reduce the risk of foodborne illness and minimize harm if illness develops.

Education is not enough. We need to verify. Domestic inspections of the food industry are essential to ensure application of appropriate preventive controls. And for imported food, we need a strong inspection and monitoring program to ensure that imported foods meet the same level of consumer protection as domestic foods. For both domestic and imported food, we need to maintain an adequate enforcement program to be sure the rules are followed.

Finally, we need science-based methods to measure results so we know how we are doing. The FoodNet system described below provides information on pathogens. We need similar mechanisms for other foodborne hazards. If implemented, such a framework would minimize foodborne illness and injury, maximize consumer safety and confidence, and enhance global competitiveness.

Recent Accomplishments

Even in the face of many challenges, there has been substantial progress in reducing to the greatest extent possible foodborne illness due to microbial contamination. Thanks to the budgetary support provided by Congress, this multi-agency effort has successfully built a strong foundation for a state-of-the-art, science-based food safety system and has promoted partnering among the key Federal agencies, States, academia, industry, and consumers. We intend to take a comprehensive approach that addresses all food safety hazards - microbiological, chemical, and physical - for products under FDA's jurisdiction.

As mentioned above, we now have in place newer surveillance systems, stronger prevention programs, faster outbreak response, and a risk-based philosophy that guides our research, risk assessments, and educational efforts. Preventive controls implemented by the Federal agencies, such as good agricultural practices for produce and eggs and HACCP systems for meat and poultry, have already shown results. There are also numerous interagency and Federal/State partnerships that have been formed to utilize more efficiently our collective resources.

I would now like to highlight just a few of the recent food safety achievements.

Surveillance

The primary objective of the American system of public health is to prevent disease before it occurs. Surveillance and monitoring are critical to meet this objective.

FoodNet Surveillance Network. A strong food safety system starts with knowing where the problems are and identifying new problems rapidly. The Foodborne Diseases Active Surveillance Network (FoodNet) is part of CDC's Emerging Infections Program. It is a collaborative project of the CDC, USDA, FDA, and nine States. This project began in 1995 to more precisely characterize the incidence and trends in foodborne illnesses, and to conduct systematic investigations to help public health officials better understand the epidemiology of foodborne disease in the U.S. Now expanded to nine sites covering 36 million people (13 percent of the U.S. population), FoodNet provides a strong network for responding to new and emerging foodborne diseases of national importance, monitoring the burden of foodborne diseases, and identifying the source of specific foodborne diseases, all with a view toward developing and implementing effective prevention and control measures.

PulseNet. PulseNet, developed by CDC, enables a national network of public health laboratories to "fingerprint" bacteria that may be foodborne and compare results through an electronic database maintained by CDC. Now a collaborative effort among CDC, FDA, USDA, and all 50 States, PulseNet permits early and accurate detection of food-borne illness outbreaks that in the past have often gone undetected or were not recognized until they became very large. PulseNet has been key in rapidly detecting and containing numerous outbreaks of foodborne illness, including multi-state outbreaks. For example, PulseNet aided in the identification of a multi-state outbreak of *Salmonella* Agona infections linked to toasted oats cereal. Since the illnesses were dispersed among 20 States, the comparative matching of the disease-causing organisms made possible via PulseNet facilitated the epidemiological investigation that led to the recall of two million pounds of contaminated product. Without PulseNet, it is unlikely that these cases would have been identified as coming from the same source. Similar systems are now under development for viruses and parasitic agents that produce foodborne illness.

eLEXNET. The electronic Laboratory Exchange Network (eLEXNET), a seamless, integrated, secure network, was developed by FDA to provide access to critical food testing data in Federal, State, and local food safety laboratories. eLEXNET has not only facilitated data information sharing and communication, but has also provided a means for collaboration among food safety experts. It has the potential to connect the nationwide food testing laboratories and provide an early warning notification system to identify potentially hazardous foods and more quickly contain their distribution and consumption.

To date, the eLEXNET system has been piloted with two Federal laboratories, four State laboratories, and two local laboratories. We are soliciting additional State and local participants. The initial pilot covered *Escherichia coli* O157:H7 but we are currently expanding it to cover three other pathogens - *Salmonella*, *Listeria*, and *Campylobacter*.

Antibiotic Resistance. The National Antibiotic Resistance Monitoring System (NARMS) was established in 1995 as an interagency cooperative activity between CDC, FDA, and USDA to monitor emerging resistance to antibiotics in foodborne pathogens, beginning with *Salmonella*. Since its inception, new sources of isolates, an increased number of isolates,

and additional disease-causing agents have been added to the system. NARMS facilitated the recognition that *Salmonella* Typhimurium DT 104, a strain highly resistant to antibiotics, was widespread in the U.S. This prompted CDC to warn State health departments of its presence and provide preventive steps to minimize its spread.

Prevention Standards

The most significant reduction in foodborne illness will be achieved through the development and implementation of successful prevention programs.

Hazard Analysis and Critical Control Point (HACCP). HACCP systems represent a systematic approach to the identification and control of the biological, chemical, and physical hazards that are reasonably likely to occur in a particular food in a particular production process. There are a vast array of microbiological, physical, and chemical hazards that have the potential to affect the safety of foods. HACCP is a risk-based, food safety management system that helps food manufacturers determine which hazards are reasonably likely to affect their products and then to develop safety assurance programs targeted to the specific steps that must be controlled to safeguard consumers. Because these systems are designed to identify and control microbial, chemical, and physical hazards that are reasonably likely to occur, they significantly reduce the risk that the final product will contain hazards that could cause human illness or injury.

FDA implemented seafood HACCP in December 1997. It requires all 4,100 seafood processors, covering 150 species of fish, to implement complete HACCP systems. Now in its fourth year, we are seeing across-the-board progress by the seafood industry and we have implemented a “mid-course correction” to focus that program where the public health issues are most significant. This year, FDA also finalized HACCP regulations for fruit and vegetable juices which will take effect next year. It is estimated that this will prevent at least 6,000 illnesses per year. FDA also has incorporated HACCP into its Food Code, a guidance document that serves as model legislation for state and territorial agencies that license and inspect food service establishments, retail food stores, and food vending operations in the U.S.

Good Agricultural Practices (GAPs). In 1998, FDA published a guide for growers and packers of fresh fruits and vegetables. The “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” provides science-based guidance to help reduce microbiological hazards common to the growing, harvesting, washing, sorting, packing, and transporting of fruits and vegetables. The guide addresses key areas where precautions should be taken to ensure safety: water quality, worker hygiene, field and facility sanitation, manure management, and transportation. This guide was produced in consultation with USDA and has been published in four languages. Since its publication, the agencies have been working together to educate the agricultural industry – both domestically and internationally – on the recommendations included in the guidance.

Sprouts. In 1999, in response to several foodborne illness outbreaks associated with sprouts, FDA issued a warning to consumers of the potential hazards associated with eating raw sprouts and issued guidance documents for the sprouts industry. These documents, “Reducing Microbial Food Safety Hazards for Sprouted Seeds” and “Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production” advise sprout growers and seed suppliers of the steps they should take to reduce microbial contamination.

In addition to issuing the guidance documents, last year FDA and the California Department of Health Services produced and distributed an educational video on good agricultural and manufacturing practices for sprout producers. To assess the extent to which the sprout industry is following the recommended practices, the Agency issued a special assignment last year to inspect 150 sprout producers. FDA is also working with academia and the sprout industry on research to identify techniques to prevent contamination.

Bovine Spongiform Encephalopathy (BSE). HHS, USDA, and other partners are working together to prevent BSE from entering the U.S. BSE is a fatal disease that causes progressive, neurological degeneration in cattle. It is one of a family of diseases called transmissible spongiform encephalopathies (TSEs). One TSE disease that affects humans is Creutzfeldt-Jakob Disease (CJD). A form of this disease, variant CJD (vCJD), appears to be related to the BSE disease of cattle. There is strong scientific evidence that the same agent that causes BSE in cattle is also the agent that causes vCJD in people. So far, there have been cases of vCJD reported in the United Kingdom and elsewhere in Europe, believed to occur in people who consumed beef products contaminated with the infective BSE agent. It is important to note that there are no reported cases in the United States of BSE in U.S. cattle or vCJD in Americans.

In January, HHS established an Interdepartmental Steering Committee for BSE/TSE Affairs. I chair this committee which includes representatives of FDA, CDC, the National Institutes of Health (NIH), USDA, the U.S. Trade Representative, the Office of Management and Budget, the U.S. Customs Service (Customs), the Department of State, the Department of Defense, the State Association of Feed Control Officials, the National Association of State Departments of Agriculture, and the White House Office of Science and Technology Policy. This committee assures ongoing coordination between agencies, integrated contingency planning in case BSE or vCJD is found in the U.S., and coordination of risk communication plans by the various agencies.

In addition, HHS is working closely with USDA in developing a report that USDA will submit to Congress regarding actions taken by Federal agencies to prevent foot and mouth disease, BSE, and related diseases. This report will discuss the economic impact, animal and human health risks, risk management, and steps to strengthen safeguards against these diseases.

Education

An essential element of ensuring the safety of the food supply is the education and training of industry, Federal, State, and local agriculture and health officials, and consumers in prevention programs across the farm-to-table spectrum. I have noted a couple of the educational materials developed for industry - good agricultural practices for fresh produce and guidance for the sprout industry to prevent contamination.

Enhancing school-based prevention efforts to educate the next generation about food safety is another important element. This month, in partnership with the National Science Foundation, the Agency is launching "Science and Our Food Supply," a curriculum for middle and high school students that will instruct our youth in the scientific principles of food safety and prevention. Also, in collaboration with FDA and several states, CDC is leading development of a model coordinated school health and food safety program.

An example of consumer education is the "Fight Bac" program to prevent illness by raising awareness of potential hazards in storing, cooking, and serving foods. This program is part of the Partnership for Food Safety

Education, a public-private partnership that includes HHS, USDA, the States, consumer groups, and industry. Consumer education efforts seem to be paying off. Surveys of consumer behavior indicate that more people are washing their hands and their cutting boards to prevent cross-contamination between raw and other foods. Fewer people are eating risky raw foods.

The foodsafety.gov web site, established in early 1999 by FDA in close cooperation with CDC and USDA, is visited an estimated 40,000 times each month. The site has information for consumers, industry, health professionals, food safety educators, and others. To raise awareness and educate health professionals, HHS and USDA also collaborated with the American Medical Association to develop a physician education program on the diagnosis and management of foodborne illness.

Research and Risk Assessment

Research and risk assessment are critical to ensuring the strong scientific basis necessary for our regulatory programs to be effective. The Department must be able to keep pace by learning more about foodborne diseases and their causes and by developing new scientific methods for detecting and preventing foodborne hazards. A strong science base is a prerequisite to meeting the food safety challenges and to maintaining our leadership role both nationally and in the new global economy.

In 1999, HHS and USDA created the Joint Institute for Food Safety Research (JIFSR). JIFSR coordinates planning and priority-setting for food safety research across government agencies and with the private sector. This coordination optimizes food safety research investments, channels Federal resources to research priorities, and helps avoid research redundancies. JIFSR also seeks to foster the effective translation of research results into practice along the farm-to-table continuum.

HHS has been a leader in food safety research and maintains technical expertise in a wide range of disciplines that affect the safe and wholesome production, packaging, and formulation of foods, dietary supplements, and cosmetics. FDA leads international standard setting efforts in food hygiene, food labeling, bioengineering of foods, and chemical contaminants. While FDA maintains a strong research and risk assessment program, the diversity and types of scientific expertise and knowledge are ever-expanding. Consequently, FDA recognizes it must leverage both academia and industry expertise as well and has done this through three cooperative agreements or consortia. The National Center for Food Safety and Technology (NCFST) at the Illinois Institute of Technology is devoted to research and evaluation of better food processing and packaging technology. The Joint Institute for Food Safety and Nutrition at the University of Maryland is devoted to risk assessment, agricultural practices and education, such as international Good Agricultural Practices training programs, and establishment of the Center for Risk Analysis and clearinghouse for risk assessment. The University of Mississippi has a collaborative program to work in the area of the safety of dietary supplements. FDA will work to strengthen these existing collaborations and will develop additional partnerships with other universities that have strong food safety research programs.

FDA has also strengthened its scientific foundation through extramural research grants to support research in the areas of BSE, produce safety, egg safety, HACCP system validation, food service or retail practices, and consumer practices. Examples of such projects include the development of simple, reliable methods for extraction and detection of viruses from a variety of food products, research to improve produce safety by developing and

applying novel non-thermal food processing technologies, and the development of improved sampling and detection methods of low levels of *Salmonella* Enteritidis in eggs.

CDC conducts a limited amount of applied research, particularly to understand and optimize public health practice for the prevention and control of diseases. Examples include efforts to develop assays for detecting and subtyping foodborne pathogens for which adequate testing methods do not currently exist; identify the causative agents for foodborne outbreaks of unknown etiology, as well as pathogens responsible for sporadic cases of foodborne illness; evaluate new strategies for reducing illness; and identify behavioral and other risk factors associated with foodborne disease. In addition, NIH also conducts scientific research on the health effects and genomics of foodborne pathogens.

Improved Protection for Imported Foods

The increasingly global nature of the portion of the food supply that FDA regulates presents significant challenges. To help keep unsafe foods out of U.S. markets, FDA works closely with Customs. FDA and Customs have established a procedure to prevent the distribution of unsafe imported food by requiring that shipments from “bad actor” importers be held in a secure storage facility at the importers’ expense until released by FDA. FDA has also established procedures to enhance interagency coordination and to efficiently use Customs’ civil monetary penalties procedures against importers who attempt to enter food into the U.S. by means of a material false statement, act, or omission. In January, FDA published a proposed rule to require marking food shipments refused entry for safety reasons to deter the practice of “port shopping” in which importers whose cargo is denied entry at one port attempt to re-introduce it at another port.

FDA has also led a series of food safety workshops literally around the world in Central America, South America, the Southern Pacific region, Asia, and Africa. These workshops educate foreign governments and food producers on the food safety standards needed to meet U.S. requirements. In addition, CDC has increased its efforts to build investigative capacity throughout the world and to expand systems such as PulseNet globally in order to rapidly identify international outbreaks. CDC is working in these areas in collaboration with the World Health Organization.

Next Steps

As stated earlier, HHS is committed to building a strong and credible food safety system. We must enhance our ability to identify risks, take action, and measure results. Specifically:

To enhance our ability to identify risks, we must strengthen our science base. We need to expand the FoodNet, PulseNet, and eLEXNET programs, described earlier, and assess adequate detection and response capacity in every State. Existing collaborations with our academic and private sector partners need to be strengthened and new partnerships need to be forged.

We need to take action to make improvements in inspections of domestic and imported foods. The Agency has redirected its field force to perform annual inspections of firms that produce foods at highest risk for microbiological contamination. FDA is working to enhance the infrastructure and capabilities of the field laboratory to increase the number of sample analyses of both domestic and imported foods. To help ensure that imported foods meet the same level of consumer protection as domestic foods, HHS is seeking to

increase its overseas presence and is providing technical assistance to foreign countries.
We will continue to measure results to ensure that the food safety activities are effective.

Thank you for the opportunity to discuss our food safety program and our continued efforts in this area. We look forward to working with the Subcommittee on ways to continue to improve the safety of the nation's food supply. I would be happy to answer any questions.

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