

U.S. food safety system a good excuse for a bellyache

WASHINGTON—It is fitting that an investigation into inefficiency in America's food safety system is led by a panel with the less-than-trim name of U.S. Senate Committee on Governmental Affairs Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia.

But there the hypersyllabic panel was last week, providing a tidy example of tax dollars run amok, with lots of blame to share on a life and death matter. Food safety has apparently inspired decades of good intentions, world-renowned science, inept legislation, turf-conscious pencil-pushers and status quo-loving lobbyists.

By stomach-turning coincidence, Chairman Sen. George Voinovich (R-Ohio) several days earlier had called an Emergency Medical Services crew to

SUNDAYWATCH

James Warren

his home at 1:30 a.m. when his wife was struck with food poisoning. He was left wondering "how she got it and how she could avoid it," and thus is even more sensitized to the issue.

But rather than my faking knowledge of complex matters of food-borne pathogens and other hazards, which are said to prompt an estimated 81 million medical cases and 9,000 deaths a year in the United States, let me offer you a pizza. No, make it two pizzas: one cheese, the other pepperoni.

I do so after being served a slice of insight by Lawrence Dyckman, director of food and agriculture issues in the resources, community and economic development division of the General Accounting Office.

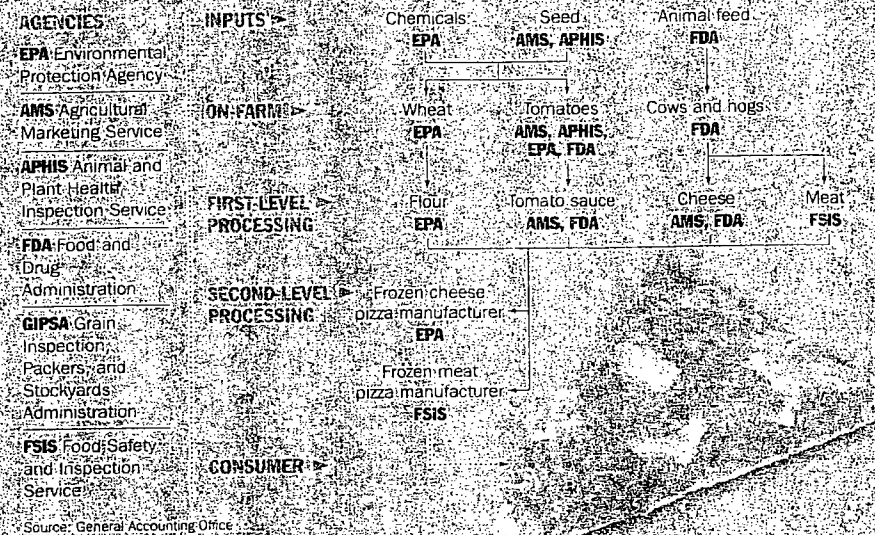
He brought a chart delineating the different federal agencies responsible for ensuring the safety of both a frozen cheese pizza and a frozen pizza with pepperoni. In all, there are six agencies; these check out the chemicals, seed and animal feed at the "input" level; the wheat, tomatoes and cows at the farm level; the flour, tomato sauce, cheese and meat at the initial stage of processing; and the actual manufacture of the pie at the final level of processing.

A pre-hearing perusal of a Dyckman graphic inspired Sen. Dick Durbin (D-IL), chief sponsor of legislation to radically simplify food regulation, to devise a prop in the form of a fake pizza, which opened up to display a chart of confusing regulations, all topped by this scrumptious oddity:

The Department of Agriculture, which has jurisdiction over frozen pepperoni pizza, inspects such pizza processors daily, while the Food and Drug Administration, which has responsibility for frozen cheese pizza, inspects those processors an average of just once every 10 years.

Ditto cheese and beef ravioli. As Durbin noted,

Federal agencies responsible for ensuring safe pizza



different agencies regulate each of them.

It turns out that there are 12 federal agencies overseeing at least 35 food safety laws. They include the following:

The Food Safety and Inspection Service, part of the Agriculture Department, is in charge of meat, poultry and some eggs and some egg products.

The Food and Drug Administration is responsible for the safety of most of the rest.

The Department of Health and Human Service's Centers for Disease Control and Prevention have a piece of the action, as do the Agriculture Department's Agricultural Marketing Service; Animal and Plant Health Inspection Service; Agricultural Research Service; and Grain Inspection, Packers, and Stockyards Administration.

The Commerce Department is also in the fray, via its National Marine Fisheries Service.

The Treasury Department figures via the U.S. Customs Service and the Bureau of Alcohol, Tobacco, and Firearms.

The Environmental Protection Agency and Federal Trade Commission round out this regulatory battery.

Then, Mr. and Ms. Taxpayer, be informed that the Food Safety and Inspection Service inspects daily those U.S. plants producing the following:

Open-face sandwiches, hot dogs in a pastry dough, corn dogs, dehydrated chicken soup, beef broth, spaghetti sauce with meat stock, beans with bacon (2 percent or more bacon), pizza with meat topping, and soups with more than 2 percent meat or poultry.

Now, be informed that the Food and Drug Administration has jurisdiction over, and inspects once every 10 years on average, those plants producing the following:

Sandwiches with two pieces of bread, hot dogs in a roll, bagel dogs, dehydrated beef soup, chicken broth, spaghetti sauce without meat stock, pork and beans (no limit on amount of pork specified), pizza without meat topping and soups with less than 2 percent meat or poultry.

And, fish lovers, be warned that oversight of chemical residues, and the methodologies for figuring out the amount of fish that can be safely consumed, is a mess too. Dyckman put it succinctly: "A fish considered unsafe to eat in one state may become safe to eat if it swims to another state."

Cheery, eh?

Even Durbin concedes that we have "the safest food supply in the world" but could be better, especially as we eat a greater diversity of food, with more of it prepared away from home. In addition, the number of virulent, food-borne pathogens has increased sharply.

And to say what plays out in food safety is wacky is not to degrade the serious and high-minded efforts of many federal officials and inspectors in the system. It is, instead, to see many of them as captives of bureaucratic history that has led to institutional irrationalities.

It's not that they are bad, conniving people undermining safety. No, it seems more as if there are generally well-intentioned souls who, of necessity, spend way too much time protecting turf and bad-mouthing competing agencies.

Retaining the status quo, for many government officials and industry lobbyists, seems paramount.

So the Clinton administration's suggestion of more cooperation, and creation of what it terms a "virtual food safety agency," struck Durbin as "impossible to defend as good government." There's less there than meets the eye, he believes.

Listening to testimony from top government officials and industry lobbyists, one heard their essential defense of much of the current system. The regulated industries tend to repeat a similar mantra, namely refine and improve but, heaven forbid, don't dramatically alter the system.

Their views were derided by Carol Tucker Foreman, who oversaw meat, poultry and egg inspection as a top Agriculture Department official during the Carter administration.

Freed from what she termed the "institutional imperative to defend the status quo," she made clear the "system is broke" and that nobody in his right mind, if asked to start a system from scratch, would come close to replicating the current mish-mash.

Back in Chicago on Friday, Durbin said, "I really like [Health and Human Services Secretary] Donna Shalala and [Agriculture Secretary] Dan Glickman but cannot get over their resistance to harmonizing and modernizing this. I really think you have to leave government before you look at this objectively."

In 1906, Upton Sinclair's book "The Jungle" led to the federal regulation of meat. Back then, the title referred to the Chicago stock yards.

An updated version might refer to the regulatory world it spawned.

Chicago Tribune
Dyckman graphic
8/8/99

Chicago Tribune

Sunday, August 8, 1999

Good
Sunny

Good
Sunny
Dinner



DEPARTMENT
OF AGRICULTURE



DEPARTMENT
OF COMMERCE

PRESIDENT'S COUNCIL ON FOOD SAFETY



DEPARTMENT OF
HEALTH & HUMAN SERVICES



ENVIRONMENTAL
PROTECTION AGENCY

MAR 15 1999

Food
Safety

The President
The White House
Washington, DC 20500

Dear Mr. President:

As co-chairs of your Council on Food Safety, we are pleased to submit to you the Council's assessment of the National Academy of Sciences (NAS) report *Ensuring Safe Food from Production to Consumption*. The NAS report provided the Council with valuable insight into the strengths and weaknesses of the current federal food safety system. The Council finds the NAS report to be a constructive contribution to improving the effectiveness of the federal food safety system through sound science and risk assessment, strategic planning, and better federal integration with state and local governments. The Council will consider the report's advice as it moves forward with the development of the comprehensive strategic plan as specified in Executive Order 13100.

Respectfully,

Neal Lane

NEAL LANE
Assistant to the President
For
Science and Technology

Donna E. Shalala

DONNA E. SHALALA
Secretary of
Health and Human Services

Daniel Glickman

DANIEL GLICKMAN
Secretary of
Agriculture



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

Mary-
FYI

Food
Safety

Cliff

The Honorable Richard J. Durbin
United States Senate
Washington, D.C. 20510

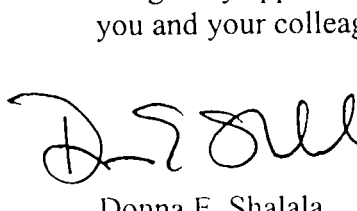
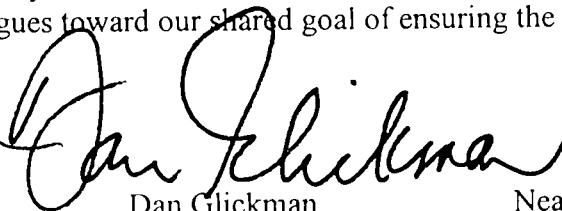
Dear Senator Durbin:

As we said in the Food Safety Council's response to the National Academy of Sciences' (NAS) report you referred to in your February 11 letter, the Clinton Administration is committed to the goal of a fully integrated food safety system in the United States. The Council is conducting an assessment of organizational structure options and other mechanisms that could strengthen the Federal food safety system through better coordination, planning and resource allocation, keeping in mind that the primary goal is food safety and public health.

The President undertook this Food Safety Initiative, first funded in fiscal year 1998, to address actions needed to reduce foodborne illness and to improve coordination among Federal agencies involved in food safety. This initiative set a course designed to advance a single, national food safety policy between the country's primary food safety agencies, the Department of Health and Human Services (HHS), the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA). In addition to stronger coordination at the Federal level, HHS recently extended efforts to improve Food and Drug Administration (FDA) coordination with State and local food safety agencies. USDA has a long-standing partnership with the States and continues to build on those associations. These efforts will ensure elimination of any duplication of efforts and facilitate development of a nationally integrated food safety system.

Under the direction of the President's Food Safety Council, we are rapidly moving toward creation of a virtual national food safety agency that provides a single voice on food safety issues. These efforts have resulted in the Federal food safety agencies working as one and complementing one another's efforts. Clearly, however, more work lies ahead to enhance and improve our achievements.

We greatly appreciate your demonstrated leadership in food safety and look forward to working with you and your colleagues toward our shared goal of ensuring the safety of our Nation's food supply.

Donna E. Shalala

Dan Glickman
Secretary of Agriculture

Neal Lane
Assistant to the President for
Science and Technology

Food
Safety

President's Council on Food Safety
Assessment of the NAS Report
Ensuring Safe Food from Production to Consumption

Americans have one of the world's safest food supplies. This is largely a result of sustained regulatory and education programs along the farm to table continuum as well as surveillance and research efforts. The federal food safety system, comprised of multiple agencies, is authorized by a diverse set of statutes and is supported by numerous key partnerships with state, local, and tribal governments. Together these agencies have created a system that has given U.S. consumers confidence in the safety of their food purchases.

As good as the nation's food safety system is, there is room for improvement. Illnesses and deaths due to contaminated food, while preventable, continue to cause considerable human suffering and economic loss. That is why, at the very beginning of his first term, President Clinton set a course to strengthen the nation's food safety system. Under the President's leadership, surveillance and research have dramatically increased, programs are better coordinated, and regulations are more prevention-oriented and science-based. But this is only the beginning. The Council on Food Safety, with the help of the public, will continue to identify problems and promote solutions.

The Council welcomes the findings and recommendations provided by the National Academy of Sciences in its August 1998 report *Ensuring Safe Food From Production to Consumption*. This report lays out a clear rationale for a national food safety plan, one that is based on science and risk assessment.

- The Council supports **NAS recommendation I**, which states that the food safety system should be based on science. In its assessment of the NAS report, the Council provides numerous examples in which this is already the case and examples of areas that need to be strengthened.
- The Council supports **NAS recommendation IIa**, which calls for federal statutes to be based on scientifically supportable assessments of risk to public health. In this regard, the Council will conduct a thorough review of existing statutes and determine what can be accomplished with existing regulatory flexibility and what improvements will require statutory changes.
- The Council supports **NAS recommendation IIb**, which calls for the production of a comprehensive national food safety plan. In fact, the development of such a plan is already underway and is one of the primary functions of the Council as specified in Executive Order 13100. One component of the plan will be exploring methods to assess the comparative health risks to the nation's food supply.
- The Council supports the goal of **NAS recommendation IIIa**. Here, the NAS calls for a new statute that establishes a unified framework for food safety

programs with a single official with control over all federal food safety resources. The report acknowledges that there may be many organizational approaches to achieving the goal of a “single voice” for federal food safety activities. The Council will conduct an assessment of structural models and other mechanisms that could strengthen the federal food safety system through better coordination, planning, and resource allocation, keeping in mind that the primary goal is food safety and public health.

- The Council supports **NAS recommendation IIIb**. This recommendation argues that agencies should have the legal authority and other tools needed to work more effectively with our partners in state, tribal, and local governments. Federal food safety agencies already have many of the tools identified by the NAS and have used them to establish extensive partnerships with state, tribal, and local governments. However, some tools are missing and much more needs to be done to better coordinate the federal government’s interactions with other levels of government. The Council agrees that the roles of state, tribal, and local governments in the food safety system are critical and that their efforts deserve the formal recognition that partnership in a national food safety system conveys.

Food
Safety

Administration Statement

on behalf of

The President's Council on Food Safety

**Before the Senate Governmental Affairs Committee
Subcommittee on Oversight of Government Management, Restructuring and
the District of Columbia**

August 4, 1999

I. Introduction

Mr. Chairman, Members of the Subcommittee, we are pleased to be here this morning to discuss the extremely important issue of protecting our nation's food supply – an area that is a very high priority for the Administration. I am Jane E. Henney, M.D., Commissioner of Food and Drugs, Food and Drug Administration (FDA), and I am Catherine E. Woteki, Ph.D., Under Secretary for Food Safety, U.S. Department of Agriculture (USDA). We applaud your continued interest in ensuring the safety of our nation's food supply and look forward to a full discussion of the issues you are raising today. In our testimony, we will discuss the current status of our nation's food supply and the complex challenges we face, the history of the food safety system, the substantial improvements we have made – particularly over the last several years, and the next steps we are taking to continue to improve the safety of our food.

The Food Safety Challenge

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 —mostly the very young, elderly, and immune compromised — die every year as a result. The threats are numerous and varied – among them are *Escherichia coli* (*E.coli*) O157:H7 in meat and apple juice; *Salmonella* in eggs, on vegetables and on poultry; *Vibrio* in shellfish; *Cyclospora* and hepatitis A virus on fruit; and *Cryptosporidium* in drinking water.

Today's challenges with respect to the food supply are complex. Much has changed in what we eat and where we eat. Americans are eating a greater variety of foods, particularly poultry, seafood and fresh fruit and vegetables. This is beneficial to our health, but presents greater food safety challenges. More consumers demand these foods year round, making safety issues surrounding transportation and refrigeration of increasing importance. And as international trade expands, shifting regional commerce and products to a global marketplace, our role in ensuring

the safety of food expands as well. Americans 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. This food is purchased not only from grocery stores and restaurants, but also is consumed in institutional settings such as schools, hospitals, nursing homes and day care centers. The result is that, as more people become involved in preparing our meals, the chance for disease-producing errors increase.

Our vulnerable population will be growing, with, increased longevity, and increasing numbers of immune-compromised individuals. Now nearly a quarter of the population is at higher risk for foodborne illness.

These are all important factors—different foods, more foods prepared outside the home, and increased vulnerable populations—but perhaps the most important elements in our changing world are the recognition that foodborne diseases are a substantial contributor to ill health, that these diseases are largely preventable, and that new and more virulent foodborne pathogens continue to emerge. We are aware of more than five times the number of foodborne pathogens in 1999 than we were in 1942. Many of these pathogens can be deadly, especially for people at highest risk. As the system of food production and distribution changes, we must be sure that the food safety system changes with it. There are many difficult challenges to preventing foodborne illnesses. To meet them, we need a strong science base that addresses all the complex issues involved in continuing to improve food safety and public health.

The Origins of the Federal Food Safety System

Until the first decade of the 20th Century, the regulation of food safety was primarily the responsibility of State and local officials. The Meat Inspection Act and the Pure Food and Drugs Act were both passed by Congress in 1906, establishing the federal framework which has survived to this day. From their inception, these laws focused on different areas of the food

supply, and they took different approaches to ensure food safety.

The Meat Inspection Act emerged in 1906, as a result of Congressional acknowledgment of risk after publication of Upton Sinclair's book The Jungle, which focused public attention on filthy conditions in Chicago's meatpacking plants. Infectious agents were the leading cause of human morbidity and mortality in this country, and the links between some animal diseases and human diseases, what we would now call zoonotic diseases, were known. This Act and its successors, required continuous inspection, including ante-mortem and post mortem inspection, to identify animal diseases, and prevent contamination during slaughter. It also created an inspector force, which continues to this day as the Food Safety and Inspection Service (FSIS) at USDA. Over the years FSIS was also given authority to oversee poultry and egg products via the Poultry Products Inspection Act and the Egg Products Inspection Act. Starting in 1967, the Acts provided for a shared funding and cooperative agreement system permitting States to operate meat and poultry inspection programs. Twenty-five (25) States have their own programs as of today.

The genesis of the original Pure Food and Drug Act of 1906 began with debates around substitute foods, such as margarine for butter, and the use of questionable "ingredients" or additives in foods, such as coal tar, borax, and colors. Thus, the Pure Food and Drugs Act, as originally enacted, forbade adulteration and misbranding of foods in interstate commerce, placing the initial responsibility on the food industry to produce safe and wholesome food, with the government in effect policing the industry. In addition to authority under the Federal Food, Drug, and Cosmetic Act (formerly the Pure Food and Drug Act), FDA has authority under the Public Health Service Act, which gives FDA two valuable additional tools: very broad authority to adopt regulations to control the spread of communicable disease when food is involved, and the ability to both provide assistance to, and accept assistance from, our state and local counterparts in the regulation of communicable disease.

II. The U.S. Food Safety Team

Despite split jurisdictions and differing statutory responsibilities across several Federal agencies, the Administration has adopted a farm-to-table approach that looks at food safety as an integrated and interdependent system.

Under the current structure, two Federal agencies have primary statutory responsibility for assuring the safety of our food supply – FDA of DHHS and FSIS of USDA. FSIS has regulatory and inspection responsibility for meat, poultry, and egg products, and FDA has regulatory responsibility over the remainder of the food supply.

FDA has jurisdiction over 78 percent of domestic and imported foods that are marketed in interstate commerce. FDA seeks to ensure that these products are safe, sanitary, nutritious, wholesome, and adequately labeled. FDA has jurisdiction where food is produced, processed, packaged, stored, or sold. FDA's jurisdiction includes much more than food processing plants; it also includes approval and surveillance for new animal drugs, medicated feed, and all food additives (including coloring agents, preservatives, food packaging, sanitizers and boiler water additives) that can become part of food. FDA shares with FSIS responsibilities for egg safety. FDA has authority for shell eggs and FSIS has authority for egg products.

FSIS is charged by statute to prevent the shipment of adulterated meat products to consumers, and to oversee appropriate labeling and provision of other consumer information. FSIS also has authority to oversee poultry and egg products, via the Poultry Products Inspection Act and the Egg Products Inspection Act. The acts also require any country wishing to ship meat, poultry or egg products to the U.S. to maintain an inspection program that is equivalent to the U.S. inspection. FSIS inspects each meat and poultry food animal, both before and after slaughter.

The Centers for Disease Control and Prevention (CDC), in DHHS, plays a critical and unique role as a disease monitoring, investigative, and advisory agency that is separate from – but works closely with – both food regulatory agencies. CDC leads Federal efforts to gather data on foodborne illness and investigate outbreaks, and monitors the effectiveness of prevention and control efforts. Through its on-going public health efforts, CDC also plays a pivotal role building State and local health department epidemiology and laboratory capacity to support foodborne disease surveillance and outbreak response.

The Environmental Protection Agency (EPA), another important partner, protects our water supply by setting drinking water standards under the Safe Drinking Water Act. It also regulates pesticide products used in this country and establishes tolerances or maximum limits for pesticide residues allowed on imported and domestic food commodities and animal feed.

State and local partners also have an important role to play in food safety. The Administration has a long history of reaching out to its State and local partners and has worked effectively with them utilizing a variety of mechanisms: cooperative agreements, contracts, grants, memoranda of understanding and partnerships.

Food safety can only be effective if it has a strong underpinning in scientific research and risk assessment. The Federal government has major capabilities to perform both basic and applied research related to food safety problems. Our Federal research resources include research conducted at CDC, NIH, and FDA, as well as that performed at FDA's National Institute for Food Safety Technology (Moffet Center), and that performed by USDA's Agricultural Research Service (ARS), and USDA's partnerships with the nation's land grant universities via the Cooperative State Research, Education and Extension Service (CSREES).

Together these Federal agencies promote food safety and prevent foodborne illness and food

hazards through inspections; surveillance; enforcement; research and risk assessment; premarket approval of food and color additives, pesticides, and new animal drugs; establishing controls for safe processing; working with State, local, and foreign governments; partnering with academia and the private sector, and education.

III. Building an Effective Food Safety System

The Administration has consistently worked to build an effective food safety system that is grounded in science and that includes strong surveillance, research, education, risk assessment, and enforcement. In January of 1997, the President directed three Cabinet members – the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency – to identify specific steps to improve the safety of the food supply. A program designed to fill the existing gaps was presented to the President in the May 1997 report entitled, “Food Safety from Farm to Table: A National Food-Safety Initiative.”

The goal of this initiative was to further reduce the incidence of foodborne illness due to microbial contamination to the greatest extent feasible. The initiative recognized foodborne illness as an emerging public health hazard that required aggressive government action, identified critical gaps in the food safety system for controlling or eliminating foodborne pathogens from the food supply, and proposed a strategy for closing those gaps. The initiative focused our efforts on hazards that present the greatest risk and sought to make the best use of public and private resources. These elements have been key to the success of our efforts. We will discuss later all of the Administration’s accomplishments in these areas.

The 1998 National Academy of Sciences (NAS) report, “Ensuring Safe Food from Production to Consumption” reaffirmed these principles. The NAS report defined the operational charge or mission of an effective food safety system as *“to protect and improve the public health by*

ensuring that foods meet science-based safety standards through the integrated activities of the public and private sectors." It defined the elements of a good system as:

- Adequate surveillance and monitoring
- A science-based foundation using risk analysis
- Focused education and research
- Effective and consistent regulation and enforcement
- Response and adaptation to new technology and changing consumer needs
- Adequate human and financial resources
- Partnerships with Federal, State, local and private sector stakeholders

Recognizing the need to go further, the President established the Council on Food Safety in August 1998, jointly chaired by Agriculture Secretary Glickman, Health and Human Services Secretary Shalala, and Dr. Neal Lane, the President's science advisor and Director of the White House Office of Science and Technology Policy. The Council's goal is to make the food supply even safer through a seamless, science-based food safety system supported by well-coordinated surveillance, standards, inspection, enforcement, research, risk assessment, education, and strategic planning.

IV. Accomplishments of the U.S. Food Safety System

Food safety has been a high priority for the Administration since it took office. Beginning in 1993, actions taken by the Administration have led to significant improvements in the safety of our food supply. These achievements range from regulatory initiatives including promulgating rules on seafood, meat, and poultry HACCP and declaring *E. coli* O157:H7 as an adulterant in raw ground beef – to statutory changes such as passage of the Food Quality Protection Act in 1996 and significant amendments to the Safe Drinking Water Act in 1996. This year, for the third consecutive year, the Administration has coordinated a multi-agency effort to protect the health of

the American public by improving the safety of the Nation's food supply. Through joint planning, coordination, and implementation, the Administration has worked to maximize the use of its resources and has continued to improve food safety.

Following on these efforts, the recommendations in the May 1997 report were comprehensive and ambitious and led to a needed shift in attention and resources toward the growing problem of microbial contamination of food. The recommendations included:

- Developing and expanding an early warning system for food-borne illness;
- Creating a national electronic network for fingerprint comparison;
- Improving outbreak containment through better Federal-State-local coordination;
- Establishing a risk assessment consortium;
- Improving pathogen detection methods;
- Understanding antibiotic resistance;
- Improving prevention techniques to avoid, reduce, or eliminate pathogens;
- Implementing seafood, meat, and poultry HACCP;
- Enhancing the safety of foods at retail;
- Enhancing coverage of imported foods;
- Improving consumer, retail, and food service education;
- Conducting research to identify barriers to safe food handling; and
- Developing a strategic plan.

In just two years the Administration has delivered on these extensive commitments. The vast majority of the recommendations have been implemented and already are leading to important improvements in our food safety system.

These successes were aided by the tremendous support we have received from Congress over the last several years.

The following examples highlight key achievements of this Administration – including

accomplishments under the Food Safety Initiative -- and demonstrate how the U.S. food safety system is founded on the elements of a good system consistent with those articulated by the National Academy of Sciences. (See also attached list of accomplishments.)

Surveillance, Monitoring, and Outbreak Response

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. Outbreak response is also critical because even an ideal food safety system will not be able to prevent all foodborne illness, but rapid action can contain an outbreak once it is identified.

FoodNet Surveillance Network. A strong food safety system starts with knowing where the problems are and identifying new problems rapidly. In July 1995, HHS and USDA began a collaborative project to collect more precise information on foodborne illnesses, and to conduct related epidemiologic investigations to help public health officials better understand the epidemiology of foodborne disease in the U.S. Now expanded under the President's Food Safety Initiative, 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. Recent results from FoodNet show a 44 percent decrease in the infection rate for Salmonella Enteritidis (SE), a serious infection associated with poultry and eggs, from 1996 to 1998 in the areas of the country under surveillance, and a 15 percent decline in illnesses caused by Campylobacter, the most common bacterial foodborne pathogen in the U.S. Also, FoodNet data help to document the effectiveness of new food safety control measures such as USDA's Pathogen Reduction and Hazard Analysis and Critical Control Points (HACCP) Rule as well as HACCP programs undertaken by the FDA for seafood and other food products. For example, some of the changes in rates of food-borne illness may reflect that FDA and FSIS prevention efforts are working.

PulseNet. PulseNet, developed by CDC, enables a national network of public health laboratories to perform DNA “fingerprinting” on bacteria that may be foodborne and compare results through an electronic database maintained by CDC. Now a collaborative effort among HHS, USDA and several states, PulseNet permits rapid and accurate detection of food-borne illness outbreaks and traceback to their sources, including detection of disparate multi-state outbreaks that may have gone undetected. PulseNet has been key in rapidly detecting and controlling numerous outbreaks of foodborne illness, including multi-state outbreaks. For example, last year PulseNet connected two seemingly independent *E.coli* O157:H7 outbreaks in Michigan to a common source-alfalfa sprouts; helped confirm that about 50 cases of *E. coli* O157:H7 in Wisconsin were attributable to cheese curds from a single facility, after initial inspections did not reveal the source of contamination; and connected *E.coli* O157:H7 outbreaks from ground beef with specific processors. In addition, without PulseNet, it is very unlikely that the recent outbreak of listeriosis from ready to eat meat products would have been recognized and identified as emanating from one source. Since the illnesses were dispersed across a wide geographic region, the comparative matching of pathogen strains via PulseNet facilitated the epidemiological investigation that led to the recall of contaminated product.

Antibiotic Resistance. The National Antibiotic Resistance Monitoring System (NARMS) was established in 1996 as an interagency cooperative activity to monitor emerging resistance to antibiotics in foodborne pathogens, beginning with *Salmonella*. The effort is coordinated and directed by HHS and USDA. NARMS was enhanced in FY98 to improve our ability to detect emerging antibiotic resistance among foodborne pathogens. Using NARMS, HHS and USDA collaborated in response to an outbreak of salmonellosis among residents of a Vermont dairy farm. NARMS helped determine that *Salmonella* Typhimurium DT 104 was widespread in the U.S., prompting CDC to warn State health departments of its presence and provide preventive steps to minimize its spread.

In addition, under the leadership of HHS, and with USDA as a full participant, a Task Force has been formed to produce a public health action plan to combat antimicrobial resistance. The Task Force is chaired by FDA, NIH and CDC. A public meeting was recently held in Atlanta with federal participants and experts from across the country. This public meeting covered many issues concerning human medical use and misuse, animal agriculture use and misuse, and plant protection uses of antimicrobial agents. Work to develop this action plan will proceed over the next year.

FORC G. In 1998, Vice President Gore announced the formation of the Foodborne Outbreak Response Coordinating Group (FORC G), a partnership of Federal, State, and local agencies established to better respond to foodborne illness outbreaks. The role of this interagency group is to coordinate and develop procedures for managing outbreaks, share information on potential sources of outbreaks and pathogens, and coordinate interdepartmental action on those issues when necessary.

Science-Based Foundation Using Risk Analysis

The Administration's food safety efforts are firmly grounded in science. Thus, we agree with the NAS report's focus on the use of scientific risk assessment to develop rules that will have the most positive influence on public health. Risk analyses are helpful in defining the extent of scientific certainty and in helping decision-makers make the tough decisions a science-based food safety system requires.

Risk Assessment Consortium. The Risk Assessment Consortium (RAC), formed in 1997, is composed of USDA, HHS, and EPA. The RAC has accomplished numerous interagency activities that have helped advance the science of microbial risk assessment. The RAC established an intramural research program with projects intended to provide data for use in

microbial risk assessment modeling. In addition, the Risk Assessment Clearinghouse was established, through FDA's joint Institute for Food Safety and Applied Nutrition (JIFSAN) to serve as a repository for data, methods, and tools for food safety risk assessment.

Risk Assessments. In 1998, USDA and HHS completed a farm-to-table quantitative risk assessment for *Salmonella Enteritidis* in eggs and egg products, which served as the foundation for both agencies' regulatory actions to address the safety of eggs and egg products. In addition, the Administration is conducting or supporting needed risk assessments and analyses on Bovine spongiform encephalopathy (BSE), *listeria monocytogenes* in food, *vibrio parahaemolyticus* in shellfish, antimicrobial resistance in food producing animals, and *E. coli* 0157:H7 in beef.

Focused Research

Since 1997, research has been a key component of the President's Food Safety Initiative and these efforts have been supported by Congress. From developing new tools to identify, prevent, or eliminate hazards from contaminated food, to performing basic research on pathogens and their impact on humans and animals, to researching and conveying important information for consumers about safe food handling methods, food safety research plays an integral role in the Administration's food safety strategy. The Administration has taken additional steps in recent years that have provided an expanded role for research in the U.S. food safety system. In 1999, Congress supported this effort and supplied to HHS and USDA additional funding for research and risk assessment. We are grateful for support for research in 1997 and 1998 as well, having received a total of \$68.7 million in 1997, \$83.8 million in 1998, and \$107.5 million in 1999.

Joint Institute for Food Safety Research. In July 1998, building on the work of the Interagency Working Group on Food Safety Research, the President directed the Secretaries of HHS and USDA to create the Joint Institute for Food Safety Research (JIFSR), through the President's Council on Food Safety. JIFSR will coordinate planning and priority setting for food safety

research among the two Departments, other government agencies, and the private sector and will foster effective translation of research results into practice. The JIFSR, expects to optimize food safety research investments, channel Federal resources to research that is needed to minimize the impact of current and emerging food safety problems, and avoid research redundancies. In addition, USDA through the direction of the Agricultural Research Service and its National Agricultural Library, is developing a national database on food safety research which will be housed under JIFSR. The database will contain information on all Federal food safety research and will attempt to document private sector investments in food safety research. The database will provide one additional mechanism for communicating the range of food safety research and potential applications.

Interagency Working Group on Food Safety Research. Late last month, the Interagency Working Group on Food Safety Research, through the National Science and Technology Council, completed its report documenting the government-wide inventory of microbial food safety research, which has helped identify information gaps and priorities for future research. The analysis contained in this report will contribute to the planning activities of JIFSR. The report should now be available on the OSTP homepage.

Advancements in Research. The investment in food safety research already is paying off for the industries. Some examples of recent research breakthroughs include the discovery by NIH of a potential vaccine for *E. coli* O157:H7; development by ARS of new animal drugs which can help preempt the growth of *Salmonella* in the intestines of newly hatched broiler chicks; the development of a five minute rapid test to identify generic bacteria on meat and an improved technique to directly detect and quantify harmful *E.coli* within 30 minutes (improved from previous times of 24 to 48 hours); and the isolation of Norwalk virus from shellfish by FDA. In addition, the FDA's Moffett Center is working on non-thermal processes, including ultraviolet light, high hydrostatic pressure, and antimicrobials, to improve the safety of juices that will not

receive heat treatment.

Effective and Consistent Regulation, Guidance, and Enforcement

The Administration has concluded that Hazard Analysis and Critical Control Point (HACCP) systems provide a more effective and efficient way to reduce hazards that may be present in food products. HACCP systems, which may be tailored to individual processing and distribution conditions, place emphasis on the prevention of contamination in processed foods. Because these systems attempt to identify and control microbial, chemical and physical hazards during processing, they significantly reduce the possibility that the final product will contain hazards that could cause human illness.

Pathogen Reduction and HACCP. In December 1995, FDA published its rule to assure seafood safety using HACCP principles. The program is a tool for the enforcement of FDA standards for toxins, pathogens, contaminants and residues. FDA has also proposed to expand HACCP to fruits and vegetable juices. In July 1996, USDA published its “Pathogen Reduction and HACCP” rule. The rule requires all industry plants that slaughter and process meat and poultry to implement HACCP systems as a means of preventing or controlling contamination from pathogens and other hazards. Initial reports following HACCP implementation are encouraging. An independent study conducted by the Sea Grant University at Stony Brook, N.Y., has reported that the seafood HACCP regulations are having a positive impact on the seafood industry. In addition, the meat and poultry performance standards, which require FSIS testing to determine if plants are meeting or exceeding standards for the occurrence of *salmonella* in a product, and its mandate that plants test for the occurrence of generic *E. coli* as an indicator of their controls for fecal contamination, have led to recognizable results as cited by CDC in March 1999. Also, as a result of pre HACCP testing and post HACCP implementation tests for performance, FSIS was able to report declines in salmonella on broilers by almost 50 percent.

Good Agricultural Practices (GAPs)/Good Manufacturing Practices (GMPs). In response to a Presidential directive, and after receiving significant public input, FDA, working with USDA, published its October 1998 Guide to Minimize Microbial Food Safety Hazards for Fresh 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. The agencies are now working together to educate the agricultural industry – both domestically and internationally – on the recommendations included in the guidance.

Improved Protection for Imported Foods. The increasingly global nature of the food safety system that FDA regulates presents significant challenges. On July 3, 1999, President Clinton directed FDA and the U.S. Customs Service to strengthen our border protection through all available actions – such as preventing “port shopping”, destroying imported food that poses a health risk, increasing the amount of bond posted for imported food to deter premature entry in the U.S., and enhancing enforcement actions, including increased civil monetary penalties. A report is due to the President in 90 days. The President also called on Congress to pass legislation that would further enhance Federal authority over FDA-regulated imported food – USDA already having adequate authority to inspect and enforce.

Responding and Adapting to New Technology and Changing Consumer Needs

Going beyond the basics of GAPs/GMPs, and HACCP approaches, the Administration also is working to encourage the application of new technologies to solve food safety problems. These efforts are focused in research and development, particularly on technologies suitable for small businesses, and in streamlining reviews in those cases where premarket approval is required for use of a new technology.

New Technology Development. Some of the exciting and new technologies developed by industry as well as our food safety agencies include irradiation, steam pasteurization for meat and

poultry carcasses, pulsed light to reduce pathogens on raw or cooked food products, hydrostatic pressure for shellfish, antimicrobial rinses to reduce pathogens on raw products, and competitive exclusion to reduce *Salmonella* levels in poultry on farms. FDA and EPA have also expedited premarket reviews of food additives and safer pesticides as a means to encourage development of these new technologies and tools.

Adequate Human and Financial Resources

The Administration has requested and Congress has funded increases for the food safety initiative over the last two fiscal years, which has served as the foundation for many of our successes.

Funding this year's request, an increase of more than \$70 million for the Initiative, is critical if we are to continue advancing our food safety agenda. Our food safety programs must be adequately funded so that the Federal agencies can meet their statutory responsibilities to protect American consumers.

One immediate organizational change that the Administration currently is seeking is the transfer of the Seafood Inspection Program (a voluntary fee-for-service program of the National Oceanic and Atmospheric Administration at the Department of Commerce) to FDA, which will consolidate all Federal seafood inspection activities into one agency. This voluntary program inspects and certifies fishing vessels, seafood processing plants, and retail facilities for federal sanitation standards, and bases its safety inspections on FDA's seafood HACCP standards. To achieve these efficiencies, the Administration's proposal is contingent on the President's request of \$3 million to effect the transfer.

Coordinated Budget. As part of Executive Order 13100, the President directed the Council on Food Safety to develop annual coordinated food safety budgets. The goal is to develop coordinated budgets that sustain and strengthen existing capacities, eliminate duplication, help identify priority areas for investment, and ensure the most effective use of resources for

improving food safety. Efforts are currently underway to develop a coordinated budget in FY 2001.

Education

Education is another key element of the President's Food Safety Initiative which has continued to receive Congressional support. The Administration has developed educational approaches that span the farm-to-table continuum – from educating farmers, producers, and distributors, to food handlers and preparers, to consumers.

Consumer Education. The President's Food Safety Initiative has spurred new consumer education programs within the Administration as well as expanded cooperative ventures with public and private partners, including other Federal agencies. One example is the "Fight BAC!" campaign sponsored by the Partnership for Food Safety Education, a public-private partnership, with participation of both USDA, HHS and the States. The campaign was created to reduce the incidence of foodborne illness by educating Americans about safe food handling practices.

Consumer Labels. In 1994, safe handling labels were mandated for meat and poultry at retail sale, to ensure consumers understood time and temperature requirements for safe cooking. The Administration also has adopted product-specific messages, including a warning label on unpasteurized juices and, just last month, proposed safe handling instructions for shell eggs.

Partnerships with State and Local Governments

The NAS report recognized the important role that State and local governments play in food safety. Both FDA, FSIS, and EPA historically have strong partnerships with States. For example, the states are directly involved with FDA in the regulation of milk and shellfish safety through the National Conference of Interstate Milk Shippers, and the Interstate Shellfish Shippers Conference, as well as through the Seafood HACCP Alliance, which provided extensive training

to seafood processors after publication of the final seafood HACCP regulation. Twenty-five States operate inspection programs for meat and poultry under cooperative agreements and with shared funding from FSIS.

Food Code. FDA and FSIS work with the States to encourage uniformity among the State laws affecting food safety in retail and food service establishments. The principal mechanism for this is the Food Code – a model code published by FDA intended for adoption by State and local authorities for use in regulating retail food and food service establishments. It is essential that the Federal government provide training both to the States and local governments, as well as to the retail and food service industry, to be sure that the critical elements of the Food Code are properly applied. Currently, 14 States have adopted the Food Code and adoption is pending in 22 others.

V. Where Do We Go From Here

At the beginning of his first term, President Clinton set a course to strengthen the nation's food safety system. Under the President's leadership, we have enhanced surveillance of foodborne disease and better coordinated our response to outbreaks. We have improved coordination of food safety programs, issued regulations that are science-based, and targeted important new research and risk assessment to critical scientific gaps. And, we have strengthened education and training, especially for those who handle food at critical points from the retail setting to the home.

The Administration is proud of all we have accomplished, particularly the great strides we have made over the last few years. However, this is only the beginning. As good as the nation's food system is, there is much more to be done. As the challenges to our food safety system continue to evolve, we must adapt our system to meet these changing needs. And, we must ensure that our food safety system is capable of responding to and preventing foodborne illness and food hazards through the most effective means possible.

For these reasons, the President directed his Council on Food Safety to develop a comprehensive strategic food safety plan. The plan will address the full range of food safety issues, long- and short-term, to further ensure the health and safety of the nation's food supply. The plan will help set priorities, improve coordination and efficiency, identify gaps in the current system and ways to fill those gaps, enhance and strengthen prevention and intervention strategies, and identify reliable measures to indicate progress.

As part of this process, the Council will conduct a thorough assessment of the existing statutes, evaluate the degree of regulatory flexibility that currently exists and determine what improvements will require statutory changes. In addition, the Council will conduct an assessment of structural and organizational options and other mechanisms that could strengthen the federal food safety system before recommending major legislative or administrative actions on reorganization.

To draft the strategic plan, the Council established an interagency Strategic Planning Task Force, which we co-chair. The Task Force, along with five working groups, has developed a draft set of goals and objectives which have been shared with various stakeholders to seek their input. Those stakeholders and Council representatives engaged on July 15, 1999 in an important exchange of views on the food safety system of the future at a public meeting in Washington. A second public meeting is scheduled for October 1999 to review strategic planning progress that will be made over the next few months. The Council expects to provide a draft plan to the public in early 2000 and invite additional comments. The final document is due to the President in July 2000.

We firmly believe that establishing a seamless, science-based food safety system is critical to ensuring the safety of our food supply and protecting public health. How we get there should be carefully thought through with all of our partners and stakeholders. We assure you that we are approaching this effort seriously and expeditiously, and are considering the full range of options

available to us.

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 the next steps to continue to improve the nation's food supply.

Clinton/Gore Administration Accomplishments in Improving Food Safety

Although our food supply is already among the safest in the world, the Clinton/Gore Administration has made further reductions in foodborne illness a national priority. The Administration has put in place improved safety standards for meat, poultry, and seafood products. Research, education, and surveillance efforts have also been greatly expanded. Here are some significant milestones in the Administration's food safety efforts.

August 1999. Completed review of one-third of all allowable pesticide residue levels on food by the August 3rd deadline, as called for by FQPA, and significantly reduced the use of two organophosphates used on foods eaten by children.

July 1999. Public meeting of the President's Council on Food Safety Strategic Planning Task Force goals.

July 1999. Established a control plan for *Vibrio parahaemolyticus* in oysters.

July 1999. Announced grants to five land grant universities that will serve as models for very small meat and poultry plants due to implement the final phase of HACCP.

July 1999: Advised consumers of the risks associated with eating raw sprouts.

July 1999. Proposed efforts to improve egg safety by requiring that shell eggs be stored at 45 degrees or below during transport, in warehouses, and at retail stores; and by requiring safe handling statements on egg cartons.

July 1999. Released Interagency Working Group on Food Safety Research report, which compiles an inventory of food safety research on microbial contamination.

July 1999. Directed the Departments of Health and Human Services and Treasury to explore additional actions they could take to protect U.S. consumers from unsafe imported foods, with reports due back to the President by late 1999.

July 1999. Directed the Strategic Planning Task Force of the President's Council on Food Safety to develop immediate recommendations concerning the regulation of eggs.

June 1999. PulseNet expanded to include Salmonella, Shigella, and Listeria, as well as E coli 0157:H7 bacteria fingerprinting.

May 1999. Published *Federal Register* notice advising meat and poultry plants to reassess their HACCP preventive control plans to ensure they are adequately addressing *Listeria monocytogenes* in ready-to-eat products, and provided guidance to industry recommending environmental and end-product testing for presence of *Listeria monocytogenes* in ready-to-eat products.

May 1999. Implemented extensive educational efforts targeted to at-risk consumers about *Listeria monocytogenes* in ready-to-eat products

Spring 1999. Held two public conferences to educate foreign and domestic agriculture communities on "Good Agricultural Practices/Good Manufacturing Practices" guidance document.

March 1999. FoodNet surveillance data announced by CDC that indicate important decreases in Salmonella

and Campylobacter infections since 1996, including a 15 percent decrease in Campylobacter and a 44 percent drop in Salmonella Enteritidis infections.

Feb. 1999. Proposed rule on irradiation for raw meat and meat products.

Feb. 1999. FSIS and FDA signed a Memorandum of Understanding (MOU) to facilitate the exchange of information at the field level about food establishments and operations that are subject to the jurisdiction of both agencies.

Jan. 1999. Implemented new procedures to expedite the review of food additives that are intended to decrease the incidence of foodborne illnesses through their antimicrobial actions against human pathogens that may be present in food.

Jan. 1999. Implemented HACCP in almost 3,000 small meat and poultry plants. Preliminary results from the 300 largest meat and poultry plants that implemented HACCP in 1998, show significant reductions in the prevalence of pathogens on meat and poultry products.

Jan. 1999. Announcement of new technique to detect DT104, a potentially deadly strain of Salmonella that resists many antibiotics.

Nov. 1998. FoodNet expanded to include an eighth state, and now represents more than 10 percent of the U.S. population.

Nov. 1998. Held "National Conference on Food Safety Research" with a goal of answering the question: "What should our food safety research be as we move forward?" Participants included Federal agency representatives as well as academics, and industry and consumer group representatives. Discussion focused on the research needs of regulatory and action agencies, and on the research needs for detection, prevention, and risk assessment.

Oct. 1998. Published guidance for growers, packers and shippers of fresh fruits and vegetables to provide information on agricultural and management practices they might apply to enhance the safety of fresh produce.

Aug. 1998. Finalized a regulation that requires eggs to be stored and transported at 45 degrees Fahrenheit or less. By law this regulation becomes effective in August 28, 1999.

Aug. 1998. Created the President's Council on Food Safety, which is charged with developing a comprehensive strategic plan for Federal food safety activities and with ensuring that all Federal agencies involved in food safety work together to develop coordinated food safety budgets each year.

Aug. 1998. Initiated a public awareness campaign on the risk that unpasteurized or untreated fruit and vegetable juices may present to vulnerable populations.

July 1998. Announced new warning labels that would be required on packaged fresh fruit and vegetable juices not processed to kill harmful bacteria.

July 1998. Announced the Joint Institute of Food Safety Research, which will develop a strategic plan for conducting and coordinating all federal food safety research activities, including with the private

sector and academia.

May 1998. Formed a national computer network of public health laboratories--called PulseNet--to help rapidly identify and stop episodes of foodborne illness. The new system enables epidemiologists to respond up to five times faster than before in identifying serious and widespread food contamination problems by performing DNA "fingerprinting" on foodborne pathogens.

April 1998. Proposed a regulation to require processors of packaged fruit and vegetable juices to implement HACCP to preempt contamination of their products.

April 1998. Implemented a pilot HACCP program for the retail sector of the food industry, including restaurants, grocery stores, institutional food service and vending operations.

March 1998. Isolated Norwalk viruses from shellfish by developing a rapid, sensitive and reliable method capable of detecting low levels in contaminated shellfish. Until this method was developed there was no direct proof that shellfish transmit viral disease to humans from contaminated waters.

Feb. 1998. Announced Administration's proposed food safety budget, which requests approximately \$101 million increase for food safety initiatives.

Jan. 1998. Implemented new, science-based HACCP system for 300 of the largest meat and poultry plants.

Dec. 1997. Implemented HACCP regulation for the seafood industry, a uniquely complex industry consisting of more than 4,000 domestic seafood producers – mostly small businesses – processing more than 300 varieties of seafood from numerous different habitats.

Dec. 1997. Approved irradiation for red meat as a food additive.

Oct. 1997. Issued Presidential Directive to improve the safety of domestic and imported fruit and vegetables.

Oct. 1997. Established the Partnership for Food Safety Education, an ambitious federal-private partnership to reduce the incidence of foodborne illness by educating Americans about safe food handling practices. The Partnership has launched a multi-year, broad-based public education campaign—Fight BAC! -- to teach Americans about safe food-handling practices. Federal partners include the U.S. Department of Agriculture, U.S. Department of Education, and U.S. Department of Health and Human Services.

May 1997. Reported to the President a comprehensive new plan to improve the safety of nation's food supply—"Food Safety from Farm to Table"--detailing a \$43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.

Jan. 1997. Unveiled National Food Safety Initiative, a five-point plan to strengthen and improve food safety. Working with consumers, producers, industry, states, universities, and the public, the administration recommended actions to reduce foodborne illness.

Jan. 1997. Announced new early warning system, the Foodborne Outbreak Response Coordinating Group (FORC-G), a partnership of federal and state agencies established to develop a comprehensive, coordinated national foodborne illness outbreak response system to increase coordination and communication among federal, state, and local agencies; guide efficient use of resources and expertise during an outbreak; and prepare for new and emerging threats to the U.S. food supply.

Aug. 1996. President signed Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants such as *Cryptosporidium*, and gives people the right to know about contaminants in their tap water.

Aug. 1996. President signed Food Quality Protection Act of 1996, which streamlines regulation of pesticides by EPA and puts important new public-health protections in place, especially for children.

July 1996. President announced new HACCP regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent *E. coli* bacteria contamination in meat.

April 1996. Established the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), a collaborative effort between FDA and the University of Maryland. JIFSAN will be a jointly administered multi-disciplinary research and education program.

Jan. 1996. Began collecting data through the Foodborne Diseases Active Surveillance Network (FoodNet), a collaborative effort among FSIS, FDA, and CDC along with state health departments and local investigators around the country to better track the incidence of foodborne illness and monitor the effectiveness of food safety programs in reducing foodborne illness.

Dec. 1995. Issued new rules to ensure seafood safety, using HACCP regulatory programs to require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety assurance actions.

Oct. 1995. Declared *E. coli* O157:H7 an adulterant in raw ground beef.

Spring 1994. Issued new rule requiring the application of safe handling instructions on labels on raw meat and poultry products.

1994. Embarked on strategic CDC program to detect, prevent, and control emerging infectious disease threats, some of which are foodborne, making significant progress toward this goal in each successive year.

1994. Reorganized USDA to establish the Office of the Under Secretary for Food Safety as a means of increasing the visibility of food safety within USDA and separating food safety functions from marketing functions carried out by other parts of USDA. Reorganization also created a new Office of Public Health and Science within FSIS to improve the scientific base needed to make good regulatory decisions that are based on public health.

1993. Vice President's National Performance Review issued report recommending that government and industry move toward a system of preventive controls for food safety.



Consumer Federation of America

Carol Tucker Foreman
Distinguished Fellow and
Director
The Food Policy Institute

September 13, 1999

AT Foreman
Food Safety

The Honorable Thad Cochran
Chairman, Subcommittee on Agriculture,
Rural Development and Related Agencies
326 Russell Building
Washington, DC 20510-2402

Dear Senator Cochran:

I am writing to you on behalf of Consumer Federation of America to urge you to support full funding for the President's Food Safety Initiative in the FY 2000 Agriculture Appropriations bill. CFA is the nation's largest consumer organization, representing 250 member groups and 60 million Americans. Our members include state and local consumer organizations, senior citizens groups, members of rural electric and other consumer cooperatives, family farmers and trade unionists.

Food-borne illness is a serious public health problem in the United States, claiming as many as 9,000 lives each year. The cost of medical care and lost wages associated with food poisoning is estimated to be between \$6.6 billion and \$37.1 billion annually. The Food Safety Initiative is a government wide effort to develop strategies and improve science in order to reduce this toll.

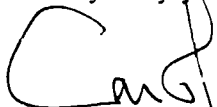
The House has already approved full funding of the Initiative. If the Senate also provides full funding, the FDA will have the funds necessary to increase inspections of high risk food processing facilities from once every three to four years to at least once a year and will also be able to double, from two percent to four percent, the imported food inspected at port-of-entry.

Full funding for the Initiative will also provide increased funds for the USDA's Food Safety and Inspection Service. USDA will use this increase to help very small meat processing plants make the transition from old, outmoded inspection regimes to the new Pathogen Reduction and HACCP Inspection system. This new system is already in effect in large and small plants and has been effective in reducing Salmonella contamination in meat and poultry products processed in those plants.

For many years, the U.S. government gave little attention to systems for reducing food-borne pathogens. Now the federal government is establishing the building blocks necessary

to combat the problem. Both industry and consumer groups have endorsed the effort to modernize food inspection and reduce the threat of food-borne illness. The new money is vital to continuing the progress that has begun. Please support full funding of the President's Food Safety Initiative.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Carol Tucker Foreman', written over a horizontal line.

Carol Tucker Foreman

 *** TX REPORT ***

Food Safety

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SENT BY: CSPI WASHINGTON DC ; 9-16-99 ; 16:24 ;

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CSPI CENTER
 FOR SCIENCE
 IN THE
 PUBLIC INTEREST
 Publisher of **Nutrition Action Healthletter**

PRESS RELEASE

FOR IMMEDIATE RELEASE

September 16, 1999

FOR MORE INFORMATION:

Colleen Dermody (202) 332-9110 x 370
 Caroline Smith DeWaal, x 366

"Play the Food-Safety Lottery: Odds are One in Four You'll Get Sick This Year"

Statement of Caroline Smith DeWaal

**Director of Food Safety for the Center for Science in the Public Interest
 on the Centers for Disease Control and Prevention's (CDC) New Foodborne Illness Estimates
 Washington, DC**

Today the CDC confirmed that the number of illnesses and deaths from contaminated food in the U.S. is unacceptably high. The odds are one in four that you'll get sick this year from contaminated foods. President Clinton and Congress should act now on proposals to fundamentally change federal food-safety programs.

Making food safer is achievable. The President's Food Safety Initiative has been the single biggest effort in decades to improve government food-safety programs. Congress should fully fund the Initiative this year.

Next year, the President should implement real reform, by combining food-safety functions into a single federal agency with a farm-to-table mission to reduce foodborne illnesses and deaths. Senator Richard Durbin (D-IL) and Representative Rosa DeLauro (D-CT) have introduced the Safe Food Act of 1999, to accomplish this.

In today's food-safety lottery, odds are 1 in 840 that you'll be hospitalized and 1 in 55,000 that you'll die from contaminated food, according to CDC's new data. Those odds go up for elderly consumers, children, or those who are immune-compromised. The food industry should lower the risk by reducing the amount of contaminated food that reaches consumers' plates. Consumers can improve their own odds by washing their hands frequently, using safe food handling practices, and making sure

SENT BY: CSPI WASHINGTON DC ; 9-21-99 ; 9:59 ;

Food
Safety

New York Times

Saturday, September 18, 1999

The Food Poisoning Toll

Disquieting figures released this week by the Centers for Disease Control in Atlanta confirm that food poisoning is far more prevalent than earlier studies have suggested. The agency now estimates that about 28 million Americans contract some sort of food-borne illness annually — more than double its previous estimate of 30 million.

These findings come at a critical moment for the food safety issue in Congress. A House-Senate conference committee is about to convene to decide how much money will be allocated for food safety efforts by the Agriculture Department and the Food and Drug Administration. Both chambers have passed budget measures that slash or food safety. Although President Clinton requested an increase of \$82 million to expand food inspections and research on how to minimize microbial contamination, the

House bill provides only \$35 million and the Senate bill only \$42 million.

The new figures from the C.D.C. should prompt the conferees to approve the full funding requested. It is a pittance compared with the huge financial costs imposed by food-borne illness in terms of lost work and medical care, estimated by some experts as exceeding \$8 billion a year.

Beyond the immediate budget battle, Congress needs to turn to structural reform. The current system for protecting the public from unsafe food is a dangerously inefficient jumble administered by a dozen different agencies. A promising measure pending in the Senate would create a streamlined system under the authority of a new independent Federal agency. The latest C.D.C. findings make it seem all the more timely.

CSPI

Science in the
Public
Interest

Publisher of

Nutrition Action HealthletterDate: 8-16-99Time: 2:30 PM

FAX COVER SHEET

TO: Tom FreedmanCompany: White House Domestic Policy CouncilFax Number: 456-7431 Phone Number: _____Total Number of pages INCLUDING this cover sheet: 11SENDER: Jennifer Santos for Darren MitchellSENDER'S Phone Number: (202) 332-9110

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SUBJECT: _____

COMMENTS: FYI: CSPI's comments on the President's
Food Safety Council's Strategic Plan

CSPI

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PUBLIC INTEREST

Publisher of ***Nutrition Action Healthletter***

USDA/FSIS Hearing Clerk
300 12th Street, SW
Room 102 Cotton Annex
Washington, DC 20250-3700

August 16, 1999

Docket No. 98-045N

FDA/Dockets Management Branch
(HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Docket No. 97N-0074

Electronic Docket No. OPP-00550
oppts.homepage@epa.gov

Re: President's Food Safety Council: Strategic Plan;
***Federal Register*, Vol. 64, No. 116 (June 17, 1999), pp. 32788-32790**

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to provide comments on the Draft Food Safety Strategic Plan developed by the President's Council on Food Safety (the Council). CSPI is a nonprofit consumer group with over one million members in the United States and Canada that focuses primarily on nutrition and food-safety issues.

While the Council and its workgroups are to be applauded for their efforts to devise a national strategic plan for food safety, it is clear that public input earlier in the process could have dramatically improved the product. Dialogue with interested groups was not sought until after the basic framework was put in place and workgroups on specific elements of the plan had begun their deliberations. We have numerous concerns about the draft strategic plan and would like to see fundamental changes made to its basic framework. It is important that these changes not be rejected simply because the process has moved too far along for our suggestions to be given serious consideration by the Council.

1875 Connecticut Avenue, N.W. / Suite 300 / Washington, DC 20009-5728 / (202) 332-9110 / FAX (202) 265-4954
On the Internet at www.csipinet.org • Executive Director: Michael F. Jacobson, Ph.D.

The draft strategic plan fails to communicate adequately with the public. The plan is not written so that it will be understood by consumers; instead, it is laden with overly complicated and bureaucratic language, and appears to have been drafted for an audience of Washington regulators and policy experts.

The draft strategic plan ignores the finding of the National Academy of Sciences. The plan fails to respond, as the administration said it would, to the findings and conclusions of the National Academy of Sciences (NAS) report "Ensuring Safe Food from Production to Consumption."¹ Most importantly, there is no attempt in the plan to create a food-safety system headed by "an identifiable, high-ranking, presidentially-appointed head, who would direct and coordinate federal activities and speak to the nation, giving federal food safety efforts a single voice," as called for by the NAS.²

The draft strategic plan fails to address the deficiencies in the current system that have been identified by CSPI and others. CSPI has documented numerous deficiencies in the existing system, as outlined in the attached Appendix. The General Accounting Office has also documented problems.³ The final strategic plan should address and correct those deficiencies.

The Council should rewrite the strategic plan to provide a road map for the establishment of a single, independent agency responsible for ensuring the safety of *all* foods. At a recent congressional hearing on overlap and duplication in the federal food-safety system, Dr. Catherine Wotecki, Undersecretary for Food Safety, U.S. Department of Agriculture, testified that such a plan is still under consideration by the Council.⁴

The Council must recognize that a single, independent agency would provide the most rational and effective solution to the country's food-safety problems and would correct the myriad shortcomings in the existing, highly fragmented system. Such an agency is also the best way to establish a single voice and single budget for federal food-safety policy, as recommended by the NAS.

¹ Institute of Medicine, National Research Council, *Ensuring Safe Food from Production to Consumption*, (Washington, D.C.: National Academy Press, 1998).

² *Ibid.*, p. 13.

³ Testimony of Lawrence J. Dyckman, Director, Food and Agriculture Issues, U.S. General Accounting Office, before the U.S. Senate Subcommittee on Oversight of Government Management, Restructuring, and the District of Columbia, (August 4, 1999).

⁴ Testimony of Catherine E. Wotecki, Ph.D., Undersecretary for Food Safety, U.S. Department of Agriculture, before the U.S. Senate Subcommittee on Oversight of Government Management, Restructuring, and the District of Columbia, (August 4, 1999).

CSPI urges the Council to replace its draft strategic plan with a new plan that better responds to the findings of the NAS, more clearly communicates the federal government's food-safety goals and objectives to the general public, and streamlines those goals and objectives into a more coherent and rational approach.

The revamped strategic plan should be based upon three primary activities:

- *Identification of food-safety risks.* This should include microbial, chemical, and physical risks. The tools for this include outbreak information from CDC and the states; illness information from FoodNet and PulseNet; and food contamination data from the agencies. The agencies should then do a risk assessment to identify the highest risk foods or processes.
- *Application of resources to control those risks.* The resources available to combat foodborne illnesses include not only those at the federal level, but also state food-safety programs, industry programs, consumers, and the research community. The tools include the new HACCP systems, new food-safety technologies, inspection, sampling, performance standards, and consumer education. Hurdles to achieving a risk-based inspection system should be identified and addressed in this part of strategic planning. The most streamlined approach to managing these resources at the federal level is by forming a single, independent food safety agency.
- *Measurement of the public-health outcomes.* The tools are the same as those used to identify risks: outbreak information from CDC and the states, illness information from FoodNet and PulseNet; and food contamination data from the agencies. This should tie back into the risk assessment process and trigger the process of reallocating resources.

Those three activities clearly communicate to the public how the agencies are planning to create a risk-based food safety regulatory system. While many of the objectives described in the *Federal Register* strategic plan are important components of such a plan, they should be incorporated into a much clearer framework.

In addition to the general comments provided above, CSPI has several additional comments concerning the draft strategic plan.

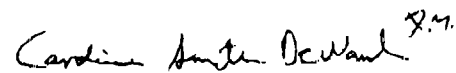
- The draft strategic plan premises its actions on the overstated need for more food-safety data. "Goal 1" of the strategic plan, relating to the development and use of a food-safety knowledge base, reads like a prerequisite before action may be taken on the plan's other goals. This goal implies that the federal government lacks the necessary scientific knowledge to act on important food-safety issues. That is not true: an adequate knowledge base to address many pressing problems does exist,

and the objectives of Goal 1 should be folded into the plan's other goals as supplemental objectives, not prerequisites for action.

- Goal 3 mixes principles of risk assessment and risk management that should be treated separately by the food-safety regulatory system; by contrast, under the framework proposed by CSPI, risk assessment would occur under the "Identify Risks" prong, while risk management would take place during the second, "Apply Resources" prong.
- Goal 5 has as an objective "Enhance international understanding and acceptance of food safety standards that are in accordance with U.S. statutes and international trade agreements." To the extent that this objective focuses on international trade issues involving U.S. food products, it should not be part of the federal government's strategic plan for food safety.
- Ensuring the safety of imported foods, however, must be an objective of the strategic plan. The federal government should have the authority and resources necessary to audit foreign governments and inspect foreign food manufacturers that export foods to the U.S., to ensure that the food meets safety standards that are equivalent to those in this country.

The draft strategic plan of the President's Food Safety Council represents a modest advance down the same road that the administration has been on for some time. It protects the current structures, while promising better coordination. The Council needs to look "outside the box" to find the answers to the current food-safety problems. Otherwise, consumers will be asked to live with a system that reacts to -- rather than prevents -- food-safety problems.

Very truly yours,



Caroline Smith DeWaal
Director of Food Safety



Darren Mitchell
Staff Attorney for Food Safety

Appendix

Under the current system, FDA is severely underfunded for its food-safety responsibilities. FDA's foods are generally, but erroneously, thought to pose a lower risk than the meat and poultry products regulated by USDA,¹ and Congress appropriates accordingly. FDA's budget for regulating foods is approximately one-third of USDA's food inspection budget.² In essence, FDA regulates more food with less money. FDA's food program also doesn't fare well when compared to other priorities at FDA. When you compare funding of the food program to that of the programs that approve drugs, biologics, and medical devices, the food-safety office at FDA only received 27% of the total program budget.³ This is despite the fact that food represents more than 50% of FDA's mission area.⁴

Under the current structure, food-safety problems fall through the cracks of agency jurisdiction. Lettuce and other fresh vegetables and fruits are essentially unregulated for safety. Last year, FDA proposed a number of guidelines for farmers,⁵ but they are entirely unenforceable. The use of animal manure on food crops is also not controlled. These are some of the problems that fall through the cracks of the current jurisdictional systems.

Under the current structure, multiple agencies fail to address glaring public health problems. Eggs are regulated both by FDA and USDA, but neither agency has developed an effective containment strategy to prevent the spread of *Salmonella enteritidis* (SE) in shell eggs. Instead, the agencies have acted like keystone cops, tripping over each other and bungling each attempt to control SE in eggs.⁶ Today, over twelve years since SE inside eggs was first identified as a public-health concern by the Centers for Disease Control and Prevention, consumers still

¹ Center for Science in the Public Interest, *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net*, (Washington, D.C.: Center for Science in the Public Interest, Updated August 1999).

² U.S. Department of Agriculture, "U.S. Department of Agriculture 1999 Budget Summary," available at <<http://www.usda.gov/agency/obpa...-Summary/1999/text.html#funding>>Internet; U.S. Food and Drug Administration, "FY 2000 Budget Request Table of Contents," available at <<http://www.fda.gov/oc/oms/ofm/budget/BudgetTOC.htm>>Internet [hereinafter cited as *FDA Budget*].

³ *FDA Budget*.

⁴ *The FDA Food Additive Review Process: Backlog and Failure to Observe Statutory Deadline*, Fourth Report by the Committee on Government Reform and Oversight, December 21, 1995, p. 8.

⁵ U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, *Guidance for Industry. Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, (Washington, DC: U.S. Food and Drug Administration, October, 1998).

⁶ U.S. General Accounting Office, *Food Safety and Quality: Salmonella Control Efforts Show Need for More Coordination*, (Washington, DC: U.S. General Accounting Office, April 1992).

await an effective strategy to eradicate SE in shell eggs.

Under the current structure, the same food-processing plant may get two entirely different food-safety inspections. The classic example is a processing plant that produces both pepperoni and cheese frozen pizzas. The pepperoni line will get daily visits from a USDA inspector to check on conditions in the plant as workers slice the pepperoni and apply it to the pizza.⁷ The cheese line will be subject to FDA inspection on average once every 10 years.⁸ The minimal difference in hazard between the processing of cheese and pepperoni pizzas is not enough to justify the vast disparity in government inspection. The recent memorandum of understanding (MOU) between USDA and FDA on inspection did nothing to address this disparity.⁹

Under the current structure, some food-processing plants may get no federal food-safety inspections. Due to resource constraints, FDA has turned some portions of its regulatory responsibility over to the states. The best example of this is in the area of shellfish production, where FDA relies totally on state inspections of shellfish packing houses. In other instances, FDA simply is unaware of plants that it is supposed to regulate. A 1991 Inspector General investigation documented that FDA's identifies food firms "by reviewing newspapers, magazines, phone books, industry publications, trade periodicals, surveillance reports and consumer complaints. Inspectors may also walk through stores looking for new products."¹⁰ The Inspector General reported that, under this system, some food plants escape detection for long periods of time.

Under the current structure, quality inspections occur more frequently than safety inspections. There are many shell-egg plants that receive regular inspections from U.S. government inspectors, but the inspections are for quality, not for safety. All plants shipping eggs between states are visited by the Agricultural Marketing Service (AMS) each quarter and many plants also participate in a voluntary grading program where they receive continuous

⁷ Michael R. Taylor, "Preparing America's Food Safety System for the Twenty-First Century -- Who is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?" *Food and Drug Law Journal*, Vol. 52, No. 1 (1997), p. 18 [hereinafter cited as *Preparing for the Twenty-First Century*].

⁸ U.S. Department of Agriculture, U.S. Department of Health and Human Services, U.S. Environmental Protection Agency, *Food Safety From Farm to Table: A National Food Safety Initiative. A Report to the President*, May 1997, p. 37 [hereinafter cited as *Food Safety from Farm to Table*], *Preparing for the Twenty-First Century*, p. 18.

⁹ U.S. Department of Agriculture, Food Safety and Inspection Service, U.S. Department of Health and Human Services, Food and Drug Administration, *Memorandum of Understanding*, Feb. 23, 1999.

¹⁰ Department of Health and Human Services, Office of the Inspector General, *FDA Food Safety Inspection*, August 1991.

inspection by AMS.¹¹ Under the voluntary AMS program, our government ensures that each has a yolk of the proper diameter, but nothing in the program checks for the presence of *Salmonella Enteritidis* (SE).¹² Nor does FDA, the agency charged with food-safety oversight of shell eggs, check for SE during its infrequent inspections.¹³

Under the current structure, HACCP is a different system at FDA and at USDA. The new HACCP systems for seafood, meat, and poultry share almost as many differences as similarities. For example, both frequent inspection and laboratory verification of product samples are essential to give the government appropriate oversight over plants utilizing HACCP. Otherwise, the HACCP program is little more than an industry honor system. While USDA requires both on-site inspection by government inspectors and two levels of laboratory verification of meat and poultry products, FDA requires neither for seafood products. FDA inspects seafood plants once every one to five years and made laboratory testing for HACCP verification optional for seafood processors.¹⁴

Multiple agencies may prolong the time it takes to bring the benefits of new technologies to the consumer. For example, last year, Agriculture Secretary Dan Glickman announced the commercial availability of a biological inoculation for young chicks against *Salmonella*.¹⁵ This product was developed by the USDA's Agricultural Research Service and then spent years being considered for approval at the Food and Drug Administration.¹⁶ For several other heralded technologies, like trisodium phosphate for poultry and irradiation for poultry and red meat, FDA approval is just the first step in implementation; there is often a public rulemaking process at USDA before products can be used in meat and poultry plants. This bifurcated process can take years to get through.¹⁷

¹¹ 7 C.F.R. § 59.28; Poultry Division, AMS, USDA, "Quality Eggs for Volume Buyers," Brochure No. AMS-627, August, 1996.

¹² *Ibid.*

¹³ Elizabeth Dahl and Caroline Smith DeWaal, *Scrambled Eggs: How a Broken Food Safety System Let Contaminated Eggs Become a National Food Poisoning Epidemic* (Washington, DC: Center for Science in the Public Interest, 1997), p. 11 [hereinafter cited as *Scrambled Eggs*].

¹⁴ Caroline Smith DeWaal, "Delivering on HACCP's Promise to Improve Food Safety: A Comparison of Three HACCP Regulations," *Food and Drug Law Journal*, Vol. 52, No. 3 (1997), pp. 331-335.

¹⁵ U.S. Department of Agriculture, "USDA Researchers Create New Product That Reduces *Salmonella* in Chickens," USDA Release No. 0121.98, March 19, 1998.

¹⁶ Telephone conversation with John DeLoach, MS BioScience, Inc., Dundee, IL, April 1998.

¹⁷ Rosanna Mentzer Morrison, Jean Buzby, and C. T. Jordan Lin, "Irradiating Ground Beef to Enhance Food Safety," *Food Review*, Vol. 20, No. 1 (1997), p. 34; U.S. Department of Health and Human Services, Food and Drug Administration, "Irradiation in the Production, Processing, and Handling of Food; Final Rules," *Federal*

Under the current structure, imported products are treated differently at FDA and USDA. Imported meat and poultry products are subject to a two-stage approval process by USDA. First, the exporting country's meat or poultry inspection safety system must be approved by USDA; then, the individual plant must be inspected by USDA before it can ship meat to the U.S. Even then, the meat is subject to random verification checks at the border. FDA meanwhile only has the authority to inspect food at the border but has the staff to check less than two percent of import shipments.¹⁸ FDA can't send inspectors to foreign countries except by invitation, even when they are checking the source of food involved in an outbreak in the U.S.

Under the current structure, we risk exporting our irrational food-safety system. There is increasing international pressure to "harmonize" our food safety systems with the systems used in foreign countries. "Harmonization" is the process of assuring that the systems in use in foreign countries provide an equally safe food product.¹⁹ With international trade in food products expanding rapidly, tremendous energy is being devoted to identifying and eliminating unnecessary barriers to trade and simplifying standard setting internationally, using organizations like Codex and the World Trade Organization.²⁰ We shouldn't harmonize internationally before we have harmonized our systems domestically, and this alone should provide some urgency to developing a more rational basis for our food safety system today.

Coordination with the state agencies that handle food safety is a nightmare. For example, state laboratories that analyze food samples for chemical or microbial contamination have complained about the lack of uniform testing methods and reporting requirements required by the federal agencies, including USDA, FDA, CDC, and the Environmental Protection Agency (EPA). This means that state labs may have to run multiple tests on a single food simply to meet the varying requirements of the federal agencies. In addition, they waste valuable staff time transmitting the same information to different agencies, which each have their own customized system for reporting lab results. The lack of common testing protocols and data requirements for

Register, Vol. 62, No. 232 (1997), pp. 64102-64121; Memo from Robert Sindt, Burditt & Radzius, to Caroline Smith DeWaal, April 1, 1998; Meeting with Robert Sindt, Burditt & Radzius, James Elfstrum, Rhodia, and Jerry Carosella, Consultant, Regulatory Microbiology, Washington, D.C., April 3, 1998.

¹⁸ U.S. General Accounting Office, "Food Safety: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable," (Washington, DC: U.S. General Accounting Office, April 1998), p. 5 [hereinafter cited as *Safety of Imported Foods*].

¹⁹ *Agreement on the Application of Sanitary and Phytosanitary Measures*, Article 3, GATT Doc. MTN/FA II-A1A-4 (Dec. 15, 1993) in *Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, GATT Doc. MTN/FA (Dec. 15, 1993) 33 I.L.M. 9 (1994).

²⁰ *Preparing for the Twenty-First Century*, pp. 26-27.

foods discourages many states from sharing their laboratory data with the federal agencies.²¹

In addition, there are not common laboratory certification standards for state laboratories that test food for contamination. This means that in many outbreak and recall situations, a state lab test result will have to be repeated by a federal agency. This can result in a several day delay in recalling food or informing the public, with the continuing risk to public health.

Confusing food-safety standards exist because agencies can't agree. FDA and EPA have different public health standards for the permissible methylmercury content of fish. Methylmercury is a potent developmental toxin that accumulates in fish from environmental sources.²² It can accumulate to toxic levels both in fresh water and ocean dwelling species. EPA has established a standard for recreationally caught fish that is more protective of public health than the standard that FDA applies to commercially caught fish. Efforts to set a single standard have resulted in a logjam, with Congress finally asking the National Research Council to mediate the squabble and set its own standard. Meanwhile, the public and the states are left to wonder what is the safe level for methylmercury in fish.

New technologies can completely escape government review for food safety, because of the complicated system of multiple reviews. For genetically modified foods, approval responsibilities for new plant varieties is done by three different federal agencies. USDA's Animal and Plant Health Inspection Service (APHIS) has a mandatory review process to protect against plant diseases and pests that might emerge from genetically modified seed stock. The EPA has a mandatory review process for genetically modified seeds with pesticidal qualities. FDA, meanwhile, utilizes a voluntary review process to address food-safety problems that might emerge from genetically modified foods. Under this system, FDA relies on an industry honor system that allows the biotech companies to decide whether and when they should consult with FDA prior to putting a product on the market.

This scheme certainly demonstrates that with respect to genetically modified foods, issues other than human-health issues have been the principle focus of government agencies so far. While every plant species using genetically modified techniques has to go through a review at APHIS to determine the impact on plant health, some of these species could escape any government review for food safety. Clearly, FDA has let resource deficiencies drive some policy issues. The agency simply has not had the staff to police emerging food issues properly. Given

²¹ "National Integrated Food Safety System. An Update on Work Group Activities: Laboratory Operations and Coordination," session at the 103rd Annual Educational Conference of the Association of Food and Drug Officials, June 5-9, 1999, San Antonio, TX; Association of Food and Drug Officials 1999 Resolution Number 99-09 Concerning National Standards for Computer-based Laboratory, Inspection and Surveillance Data Standards, June 7, 1999.

²² Institute of Medicine, *Seafood Safety*, (Washington, DC: National Academy Press, 1991), pp. 12, 116-117.

FDA's other priorities, it is unclear if it ever will.

Study Puts U.S. Food-Poisoning Toll at 76 Million Yearly

By DAVID STOUT

WASHINGTON, Sept. 16 — Although the United States has one of the safest food supplies in the world, about 76 million Americans suffer food poisoning each year and about 5,000 die from it, the Federal Government said today.

The Centers for Disease Control and Prevention in Atlanta said the estimates in a study it released today were the most complete ever compiled on food-borne illnesses (the agency avoided the everyday term "food poisoning") and were based on many sources, including death certificates, hospital surveys and academic studies.

"These new estimates provide a snapshot of the problem and do not measure trends and do not indicate that the problem is getting better or worse," Dr. Jeffrey Koplan, the centers director, said in a statement.

Dr. Paul S. Mead, a bacteria specialist at centers, an author of the study, said it contained no startling revelations from a scientific standpoint. But there are two conclusions that challenge earlier findings by the agency. The agency's estimate of annual illnesses caused by food poisoning is more than twice as high as that suggested in earlier studies,

which put the figure at 30 million. Its estimate of deaths, on the other hands, is much lower than the old figure of 9,000.

The study does not address the safety of imported foods. And it does not lay blame on farmers or poultry producers or beef processors or supermarkets or restaurants, or any other link in the American food chain, although Dr. Mead said in a telephone interview that updates of the study might do so in future years.

"It's important that people not be alarmed by these statistics," Dr. Mead said, "but it's also important they take steps to avoid becoming one of the statistics."

Many food-related illnesses can be avoided by cooking hamburger thoroughly, washing kitchen cutting boards well — especially after they are exposed to raw meat — and drinking only pasteurized milk, he said.

Donna E. Shalala, the Secretary of Health and Human Services, said the findings released today should persuade Congress to enact food-safety measures proposed by President Clinton. They include legislation to give Federal agencies greater authority over the food industry and expand inspections and research.

"The public-health burden of food-

borne disease is substantial," Dr. Shalala said, although she did not differ with the study's conclusion that American food, over all, is safe.

The Center for Science in the Public Interest, a Washington consumer group, said the report showed that more than common-sense kitchen hygiene is needed. "The odds are 1 in 4 that you'll get sick this year from contaminated foods," said Caroline Smith DeWaal, the center's food-safety director, using the Federal Government's estimate of 76 million illnesses a year. "In today's food-safety lottery, odds are 1 in 840 that you'll be hospitalized and 1 in 55,000 that you'll die. Those aren't good odds for the American public."

Ms. DeWaal urged Congress to approve all the money Mr. Clinton has requested for his program (more than \$100 million) and said the White House and Congress should go further by creating a single powerful agency with "farm-to-table" authority to regulate food.

The Grocery Manufacturers of America, a trade group representing many big food and beverage companies, said today that it welcomed the findings of disease centers study.

"We think this is long overdue," said Brian Sansoni, a spokesman for the group. But he said the group

opposed creation of a "super agency" as cumbersome and unneeded.

The Federal study said food-borne diseases had been grossly underreported, in part because milder cases might be mistaken for other illness, or because the sufferer simply did not bother to consult a doctor once the symptoms had gone away. Even if a sufferer does seek treatment and the illness is diagnosed as food-borne in nature, the doctor or laboratory do not always relay the information to public health agencies.

Deaths from food-related diseases — if overestimated in the past — have, paradoxically, also been underreported officially, the study found.

Dr. Mead said the study contained no striking findings about particular kinds of foods or specific bacteria, viruses or parasites. Not surprisingly, the study linked various strains of salmonella to a high percentage of food-related illness.

But Dr. Koplan said reliable information — surprising or not — had never been more important. New bacteria and viruses evolve, and old ones grow more resistant to treatment. Americans dine out more, thus entrusting their health to strangers.

And the baby-boomers are aging. The elderly, along with children, are the most vulnerable to food illness.

The New York Times

FRIDAY, SEPTEMBER 17, 1999

Food Safety

Storm Proves Less Devastating in Reality Than Many Had Feared

By DAVID W. CHEN

Hurricane Floyd raked a waiting and well-prepared New York region last night, delivering fierce winds and torrents of rain that pounded beaches, flooded highways and forced the evacuation of hundreds of people.

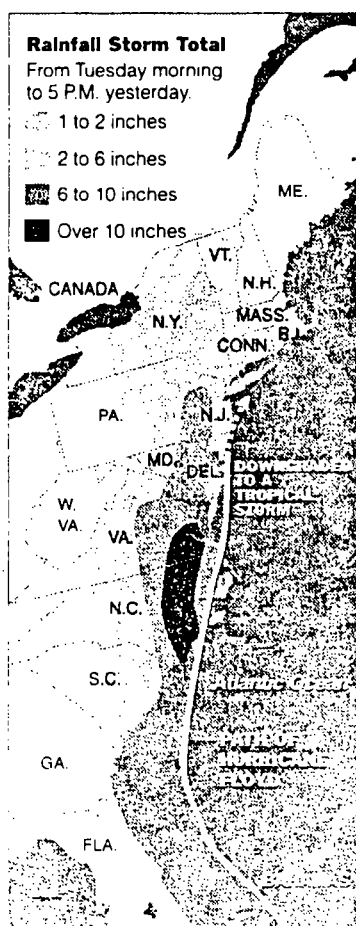
The bulk of the region, including New York City and Long Island, escaped the brunt of the storm and sustained untold inconveniences and sizable disruptions but little major damage. But in certain areas, particularly northern New Jersey and Rockland County, N.Y., the heavy rains turned tree-lined streets into raging rivers, flooding hundreds of homes and stranding hundreds of homeowners.

By late last night, the storm had stoked winds of up to 62 miles per hour and dumped more than 13 inches of rain in some areas. The center of the storm passed through central Long Island last night; the tail of the storm, meteorologists said, was expected to leave the area by early this morning.

But all through the day, a downgraded Tropical Storm Floyd — and the fear of Floyd — generated a host of disruptions that compromised life in the New York region.

New Jersey Transit suspended bus service from the Port Authority Bus Terminal in Manhattan. The region's three major airports suspended most operations. And last night, transit officials — fearful of flooded tracks — shut down Metro-North but ran limited service sporadically on two lines.

In Bergen County, rescue squads used boats to pluck residents trapped in flooded homes. In Clarkstown Township, in Rockland County, more than 1,200 people were trapped in their homes last night, surrounded by floods, waiting to be evacuated by the National Guard. And in Vineland, N.J., water was coursing so ram-bunctiously through the sewer system that it uncorked manhole covers.



However dramatic the storm, though, the reality turned out to be a little less devastating, perhaps, than the so-called storm of the century that some people had anticipated. As of late last night, there were no reported deaths related to the storm in the New York region and no interruptions to subway service.

If anything, New York City appeared to have been less discombobulated by the obsessively watched, Weather Channel-friendly trajectory of Floyd than it was three weeks ago when a surprising three-inch flash flood crippled the region's transportation network.

"I think the storm is about as we expected, maybe even a little less," Mayor Rudolph W. Giuliani said yesterday morning at a news conference at the city's crisis-management center.

Still, officials were nervously monitoring the flood damage late last night after girding for a storm, which, as a hurricane, had hammered the Carolinas on Wednesday night and forced the biggest evacuation in United States history.

According to Todd Miner, a meteorologist at Pennsylvania State University, the storm — which at one point covered as much area as the size of Texas — licked coastal areas yesterday as it churned quickly up the East Coast, losing strength along the way.

By last night, the storm, moving at 30 m.p.h., was passing through Long Island en route to Connecticut and central Massachusetts, said Peter Wichrowski, a meteorologist with the National Weather Service.

At 11 P.M., the heaviest rainfall in the region — 13.7 inches — had fallen on Brewster, N.Y., in Putnam County. The top figure for the city, the National Weather Service said, was 5.01 inches in Central Park.

For most of the day yesterday, meteorologists were predicting that the storm would wallop eastern Long Island, prompting officials there to evacuate residents and fortify low-lying areas with sandbags. But by late last night, it was clear that Long Island was largely spared, while New Jersey and the lower Hudson Valley were not.

Mr. Giuliani and other regional officials said that they anticipated that most services would return to normal today, though Metro-North officials said they were not sure whether all service would be restored by this morning. Schools, Mr. Giuliani said, are expected to reopen today. City and state officials were expected to resume normal workdays. And some of the smaller commodity markets that closed early yesterday — including the New York Mercantile Exchange — were expected to resume normal hours.

"We should have the city completely and absolutely returned to normal," Mr. Giuliani said late last night.

Across the New York region yesterday, officials stayed glued to their cellular phones, radio equipment and televisions in preparing for the storm, the first hurricane to touch the region since Hurricane Bob skirted eastern Long Island in 1991.

There were many unilateral acts of precaution. Gov. Christine Todd Whitman declared a state of emergency for all of New Jersey on Wednesday; Gov. George E. Pataki followed suit yesterday for New York City and Nassau and Suffolk Counties, deploying 1,500 members of the National Guard.

State and local officials ordered