S. Hrg. 106–366

"OVERLAP AND DUPLICATION IN THE FEDERAL FOOD SAFETY SYSTEM"

HEARING

BEFORE THE

OVERSIGHT OF GOVERNMENT MANAGEMENT, RESTRUCTURING AND THE DISTRICT OF COLUMBIA SUBCOMMITTEE

OF THE

COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

AUGUST 4, 1999

Printed for the use of the Committee on Governmental Affairs

U.S. GOVERNMENT PRINTING OFFICE
61–665 cc WASHINGTON : 2000

For sale by the Superintendent of Documents, Congressional Sales Office
U.S. Government Printing Office, Washington, DC 20402

COMMITTEE ON GOVERNMENTAL AFFAIRS

FRED THOMPSON, Tennessee, *Chairman*

WILLIAM V. ROTH, Jr., Delaware	JOSEPH I. LIEBERMAN, Connecticut
TED STEVENS, Alaska	CARL LEVIN, Michigan
SUSAN M. COLLINS, Maine	DANIEL K. AKAKA, Hawaii
GEORGE V. VOINOVICH, Ohio	RICHARD J. DURBIN, Illinois
PETE V. DOMENICI, New Mexico	ROBERT G. TORRICELLI, New Jersey
THAD COCHRAN, Mississippi	MAX CLELAND, Georgia
ARLEN SPECTER, Pennsylvania	JOHN EDWARDS, North Carolina
JUDD GREGG, New Hampshire	

HANNAH S. SISTARE, *Staff Director and Counsel*
JOYCE A. RECHTSCHAFFEN, *Minority Staff Director and Counsel*
DARLA D. CASSELL, *Administrive Clerk*

SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT, RESTRUCTURING, AND THE DISTRICT OF COLUMBIA

GEORGE V. VOINOVICH, Ohio, *Chairman*

WILLIAM V. ROTH, Jr., Delaware	RICHARD J. DURBIN, Illinois
JUDD GREGG, New Hampshire	ROBERT G. TORRICELLI, New Jersey

Kristine I. Simmons, *Staff Director*
Marianne Clifford Upton, *Minority Staff Director and Chief Counsel*
Julie L. Vincent, *Chief Clerk*

CONTENTS

"OVERLAP AND DUPLICATION IN THE FEDERAL FOOD SAFETY SYSTEM"

WEDNESDAY, AUGUST 4, 1999

U.S. SENATE,
OVERSIGHT OF GOVERNMENT MANAGEMENT, RESTRUCTURING,
AND THE DISTRICT OF COLUMBIA SUBCOMMITTEE,
OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:40 a.m., in room 342, Dirksen Senate Office Building, Hon. George Voinovich, Chairman of the Subcommittee, presiding.

Present Senators Voinovich and Durbin.

OPENING STATEMENT OF SENATOR VOINOVICH

Senator VOINOVICH. The hearing will come to order.

Good morning and thank you for coming. Today the Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia, holds the second hearing on the issue of food safety entitled, "Overlap and Duplication in the Federal Food Safety System."

The first hearing, which was held on July 1, examined Federal oversight of egg safety as a case study of the fragmentation and overlap in Federal food safety responsibilities. This hearing will not focus on a single food area, but rather it will examine the organization of all Federal food safety responsibilities.

I must say that a recent event in my life has influenced my thoughts on this issue. Last week, my wife came down with food poisoning and I became very sick. She had a couple of days of tests in the hospital and during the incident I kept wondering how did she get it and how could it have been avoided. I suspect that the source of the problem was not on the farm but rather in the handling of the food at the retail level. I am not saying that Federal inspectors should run out to all these retail establishments and do something about it. That is a county responsibility in our State. Nevertheless, that experience that I had really brought home to me—when you have to call emergency medical services at 1:30 in the morning and you have a very sick wife, you really understand the problem—much more so than someone that has not had that experience.

We have over 35 different laws that govern food safety policy, some of which are over 100 years old. Currently 10 different agencies, within four cabinet-level departments, as well as two independent agencies have some responsibility for food safety. The combined food safety budget is over $1 billion a year.

The Subcommittee will examine this issue with two questions in mind. First, if the Federal Government were to create a food safety system from scratch, start out right from the beginning, would it resemble the current system that we have? And, second, is this the best and most logical organization for Federal food safety agencies?

In addition, the Subcommittee will discuss S. 1281, the Safe Food Act of 1999, introduced by Senator Durbin that has been referred to our Committee.

According to the General Accounting Office, whose work on this issue has spanned more than two decades and included 49 reports, food safety is one of 33 program areas in the Federal Government in which there is substantial fragmentation and overlap. The longer I am here, I see what is going on in this area is going on all over the Federal Government.

As I mentioned earlier, four Federal departments, Agriculture, Commerce, Health and Human Services, and Treasury, as well as the Environmental Protection Agency and the Federal Trade Commission, have a role in food safety. Depending upon the department or agency, the Federal Government has vastly different approaches to food safety. For example, the Food Safety and Inspection Services in the USDA conducts continuous inspections at meat, poultry and egg processing plants around the country. The Food and Drug Administration, which is in Health and Human Services, on the other hand, conducts inspections of food processing plants within its jurisdiction once every 10 years, on average.

In addition, several analysts of Federal food safety policy argue that some of our efforts lack a scientific basis and should be focused on the most severe food-borne threats to human health, specifically micro-bio contamination.

I view this issue primarily as one of government management, and am most interested in learning how and why there are 12 different agencies involved in the oversight of food safety and what we can do to improve the current system.

I am here today to listen. I had not studied this issue in depth before learning of Senator Durbin's interest in this legislation. However, I do look forward to learning from our witnesses this morning whether there is any justification for the fragmentation which seems to exist and whether we can do better.

I would now like to yield to the Ranking Minority Member of this Subcommittee, Senator Durbin.

OPENING STATEMENT OF SENATOR DURBIN

Senator DURBIN. Chairman Voinovich, thank you for this hearing. I appreciate it very much and it is a topic which is near and dear to my heart and your family experience this last week, which you told me about just a few days ago, is repeated about 81 million times each year in the United States. And unfortunately, for 9,000 of those cases, it is fatal. Thank God it did not happen to your family nor has it happened to mine, but we will hear testimony today from a family where it has happened. It is a serious issue.

And it is one that, frankly, Congress really has no excuse to avoid any longer. In 1977, this same Committee issued a report about fragmentation in the food safety jurisdiction of the Federal Government. Twenty-two years ago we were dealing with this and

saying that we have to do something about it. And, sadly, we have done very little.

I want to say at the outset that the people who are testifying today, Dr. Henney, Dr. Woteki, folks from the General Accounting Office, as well as Carol Tucker Foreman, I believe are all sincere professional individuals who really have the public interest in mind. But I have to say that some of the best medical professionals when they get into the Federal bureaucracy kind of lose sight of the goal here. It all becomes a turf battle, a jurisdictional dispute and the same thing happens on Capitol Hill. Committee chairmen, everybody has got a piece of the action. Nobody wants to give it up. You go downtown, the USDA is afraid they are going to lose their employees if this goes to a single food agency. The FDA has the same fear and so do many other agencies.

And that competition has created gridlock and has created utter nonsense when it comes to the responsibility for food safety in America. We have on this table before you here some examples of the different jurisdiction for foods. And it is incredible to look at one pizza and decide that is the USDA's responsibility, another pizza is the FDA's and the list goes on and on.

And if you are out—I am kind of picking on Italian foods today, I do not mean to—but if you go out to the food store, and you buy beef ravioli and cheese ravioli, you have just bought two products that have different jurisdictions under the Federal Government.

Beef ravioli, Department of Agriculture, of course; cheese ravioli, why, of course, the Food and Drug Administration. You would not want the USDA to look at cheese ravioli, would you? Or you would not want the FDA to look at beef ravioli. And that just, I think, illustrates what has happened here.

Let me use one that comes from a little lighter vein and perhaps will betray my age a little bit. Forgive this, it may not be the best graphic, but one of my favorite routines on Saturday Night Live was Father Guido Sarducci, who had a routine entitled, "How Many Popes in the Pizza?" Well, we decided to take a look after the GAO report to find out how many different Federal agencies are responsible for making sure that the pizza that comes to your table is safe. You will notice that EPA, Agriculture Marketing Service, FDA, Animal Plant Health Inspection Safety, the Grain Inspection Safety Agency, and the Food Safety Inspection Service, all have a hand in inspecting this pizza on its way to our tables. Six different Federal agencies. How many bureaucrats in the pizza, I would ask Father Sarducci. And that is what it boils down to.

And what are we going to do about it? Frankly, we have not done enough. We have talked about it, we have studied it, we have issued all sorts of pious statements about how we have to get this under control and I am just not pleased with where we are today.

First, let me tell you why this is important. We do have the safest food supply in the world but it can be a lot safer. We do have a good food safety inspection system but it can be less bureaucratic, it can be more efficient, it can be driven by science and not by politics. And I think that is what every consumer wants.

In addition to that, we have to concede that we are entering into an era where food safety is a big ticket item, not just in terms of life and death for Americans, but also in terms of commerce. Do

you know what is going on in Europe today? We are in pitched battle in Europe today about the safety of food. And as a result, we are finding many of our exports from the United States that are being excluded, the Europeans will not buy them. They say they are dangerous. And the reason?

Frankly, there is no FDA or U.S. Department of Agriculture in the European Union that people trust. And, as a result, it takes nothing to panic the consumers in Europe away from products or toward products. It really argues, from my point of view, for us to have a science-based, coordinated, single agency effort here. We have to be able to defend the products that we sell to American families and the products we export around the world. And as long as you are dealing with six different agencies when it comes to pizza, you can see how we are fragmented and moving in so many different directions.

So, from the viewpoint of the 21st Century and the demands consumers will have worldwide for trust in the food that they eat, I think this concept is long overdue.

Let me show you a couple of other charts that illustrate some of the history of this.[1] I will go through them very quickly. We have had a series of GAO study reports. I am happy that GAO is here today. This has been an ongoing effort by the GAO. That just shows 5 or 6 years. All of them concluding that a single food safety agency was the way to go to try to make some sense out of the nonsense of our current bureaucracy.

The Governmental Affairs Committee, as I said, in 1977 and since has said repeatedly that dividing responsibility for food safety is not smart and we should put it in a single agency. The different reports by Vice President Gore on the same thing—this is from the National Academy of Sciences—I am going to be referring to this throughout the day because the industry people for some reason jumped on this report in August 1998 and said, proof positive, the White House is opposed to a single food safety agency. And, yet, if you will look through it, they talk about a single voice, a single unified agency, one official.

I really wish the people who are here representing the business community would not be so frightened by the idea of some change. This change could be for the better. You could have more confidence when it comes to consumers buying your product and you could have better results when you try to export overseas. But there has been this wall of resistance from the private sector side which just does not make sense.

We are more than happy to work with you. We are not trying to make your life any more difficult. We are trying to make it more sensible. If you make pizza and the USDA inspector shows up every day and the FDA inspector shows up every 3 years, 5 years or 10 years, how does that help you as a businessperson to make your plans and to go about your business? And I hope the private sector will be a little more open-minded as we get into this.

We have asked the former food officials who have been involved in this from FDA as well as different agencies, and Carol Tucker Foreman, of course, is quoted here, and we will hear from her in

[1] The charts referred to appears in the Appendix on page 41.

person. Dr. Kessler said it is ironic that the National Government deals with food safety issues in such a haphazard, inconsistent manner. And he goes on to say that we need a single agency with one mission and one consistent set of food safety goals. After the folks leave government they tell us this.

Sometimes, while they are there, but after they leave government they look back and say, why did I not do something about this tangled mess of Federal agencies stumbling over one another with the responsibility for food safety?

Well, I thank the Chairman for bringing this together today and a lot more will come out during the course of the hearing. I am looking forward to the testimony.

Thank you.

The prepared statement of Senator Durbin follows:

PREPARED STATEMENT OF SENATOR DURBIN

Mr. Chairman, I would like to thank you for calling this hearing on an issue of importance to every American virtually every time they eat. I appreciate your willingness to follow up on our hearing regarding egg safety with this more comprehensive look at the fragmentation in our Nation's food safety system.

This is not the first time this committee has studied the issue of food safety. Consider the following quote from a study produced by this committee in 1977:

> Divided responsibility between the Department of Agriculture and the Food and Drug Administration for food regulation has created a regulatory program which is often duplicative, sometimes contradictory, undeniably costly, and unduly complex.
>
> The current jurisdiction overlap has resulted in redundant inspections of the same plant, the shifting of responsibility of particular food items at various stages of production, and inconsistent food labeling policy. The recurrent problems of overlap, duplication, and concurrent jurisdiction are addressed by UDSA and FDA officials on an ad hoc case-by-case basis. There is currently no systematic or rational overall approach to Federal food regulation.
>
> *Committee on Governmental Affairs, United States Senate Study on Federal Regulation, Volume V, Regulatory Organization December 21, 1977, p. xv.*

Mr. Chairman, today this subcommittee revisits this issue and I am sad to report that the findings, reported by the Committee on Governmental Affairs over 20 years ago, remain an accurate description of the Federal food safety system of today. But we can change this situation. We currently have before us the Safe Food Act of 1999 (S. 1281)—a piece of legislation that can fundamentally set the course for a food safety system that is efficient, effective, based in science, and has the promise of maintaining the confidence of the consuming public.

Make no mistake, our country has been blessed with one of the safest and most abundant food supplies in the world. However, we can do better. Foodborne illness is a significant problem. While food may never be completely free of risk, we must strive to make our food as safe as possible. Americans at every level—Federal, State, and local government, industry, and the consuming public—share this responsibility.

The safety of our Nation's food supply is facing tremendous pressures with regard to emerging pathogens, an aging population with a growing number of people at high risk for foodborne illnesses, broader changes in food distribution patterns, an increasing volume of food imports, and changing consumption patterns.

The General Accounting Office (GAO) estimates that as many as 81 million people will suffer food poisoning this year and more than 9,000 will die. Children and the elderly are especially vulnerable. In terms of medical costs and productivity losses, foodborne illness costs the Nation up to $37 billion annually. The situation is not likely to improve without decisive action. The Department of Health and Human Services predicts that foodborne illnesses and deaths will increase 10-15 percent over the next decade.

In 1997, a Princeton Research survey found that 44 percent of Americans believe the food supply in this country is less safe than it was 10 years ago. American consumers spend more than $617 billion annually on food, of which about $511 billion

is spent on foods grown on U.S. farms. Our ability to assure the safety of our food and to react rapidly to potential threats to food safety is critical not only for public health, but also for the vitality of both domestic and rural economies and international trade.

Consumer confidence is important—just look what's happening in Europe, where Belgium has become embroiled in a dioxin crisis. Days before the national elections, poultry, eggs, pork, beef, and dairy products were withdrawn from supermarket shelves. Butcher shops closed and livestock farms were quarantined. Since then, countries worldwide have restricted imports of eggs, chickens, and pork from the European Union. Public outrage in Belgium over the dioxin scandal led to a disastrous showing by the ruling party in the national and European elections on June 14, and the government was forced to resign. Food safety concerns and fears are global.

Part of the controversy in Europe is the failure of government to win the confidence of the consumers. People lose confidence and panic unnecessarily when their government can't step up to its responsibilities. From "mad cow" disease to dioxin, we cannot afford to ignore these lessons regarding government's role in effectively and efficiently managing food safety. A credible Federal food safety system reassures consumers and makes our products more acceptable—here and abroad.

Today, food moves through a global marketplace. This was not the case in the early 1900's when the first Federal food safety agencies were created. Throughout this century, Congress responded by adding layer upon layer—agency upon agency—to answer the pressing food safety needs of the day. That's how the Federal food safety system got to the point where it is today. And again as we face increasing pressures on food safety, the Federal Government must respond. But we must respond not only to these pressures but also to the very fragmented nature of the Federal food safety structure.

Fragmentation of our food safety system is a burden that must be changed to protect the public health. Currently, there are at least 12 different Federal agencies and 35 different laws governing food safety, and 28 House and Senate subcommittees with food safety oversight. With overlapping jurisdictions, Federal agencies often lack accountability on food safety-related issues.

In a hearing last month, this subcommittee examined the way in which this fragmentation negatively affected the safety of the Nation's egg supply. *Salmonella* Enteritidis (SE) has been recognized as a cause of food-borne illness associated with mishandled or undercooked eggs since the mid-1980s. In 1997, SE may have caused about 300,000 illnesses, resulting in 230 deaths. Just last month, an International House of Pancakes restaurant in Richmond, Virginia was closed after 92 people contracted salmonella from eating eggs there. Seven people were hospitalized. Yet in over a decade since this problem first surfaced, the four Federal agencies with egg safety responsibility still have not implemented an effective comprehensive SE-prevention program.

At last month's hearing, the General Accounting Office (GAO) released its report, *U.S. Lacks a Consistent Farm-to-Table Approach to Egg Safety, which described the gaps, inconsistencies, and inefficiencies in the current egg safety system.*

The General Accounting Office has been unequivocal in its recommendation for consolidation of Federal food safety programs. GAO's April 1998 report states that "[s]ince 1992, we have frequently reported on the fragmented and inconsistent organization of food safety responsibilities in the Federal Government." In a May 25, 1994, report, GAO stated that its "estimony is based on over 60 reports and studies issued over the last 25 years by GAO, agency Inspectors General, and others." The Appendix to the 1994 GAO report listed: 49 reports since 1977, 9 USDA Office of Inspector General reports since 1986, 1 HHS Office of Inspector General report in 1991, and 15 reports and studies by Congress, scientific organizations, and others since 1981.

Again, earlier this year, GAO in its 21-volume report on government waste, pointed to the lack of coordination of the Federal food safety efforts as an example. "So many cooks are spoiling the broth," said the GAO while highlighting the absurdity of having one Federal agency inspecting frozen meat pizza and another inspecting frozen cheese pizza. But GAO is not the only agency calling for consolidation.

Last August, the National Academy of Sciences (NAS) released a report recommending the establishment of a "unified and central framework for managing Federal food safety programs," arguing that it should be "one that is headed by a single official and which has the responsibility and control of resources for all Federal food safety activities. . ." That report further states, "Many members of the committee are of the view that the most viable means of achieving these goals would be to create a single, unified agency headed by a single administrator. . ." I agree with this conclusion; S. 1281—the Safe Food Act of 1999—will do just that.

The administration has stepped forward on the issue of food safety—the President's Food Safety Initiatives and the President's Council on Food Safety have focused efforts to track and prevent microbial foodborne illnesses. I commend President Clinton and Secretaries Glickman and Shalala for their commitment to improving our Nation's food safety and inspection systems. I also acknowledge the long list of accomplishments by our agencies, represented today by Dr. Catherine Woteki, Under Secretary for Food Safety at the U.S. Department of Agriculture and Dr. Jane Henney, Commissioner of the Food and Drug Administration in the U.S. Department of Health and Human Services. I commend the dedication of the professionals in our Federal agencies who are committed to improving the safety of our food supply.

This administration has produced many food safety successes through a dedicated focus to coordinate agencies' efforts. Some suggest that this recent commitment to enhanced coordination is all that is needed. But this isn't the first time that coordination has been suggested. Again I refer to the 1977 Senate Governmental Affairs Committee report which says, "While we support the recent efforts of FDA and USDA to improve coordination between the agencies, periodic meetings will not be enough to overcome the problems outlined above." Coordination alone is not enough, as the NAS committee reports, "[T]he structure should also have a firm foundation in statute and thus not be temporary and easily changed by political agendas or executive directives." We must not retreat from recent food safety advances that have been made. We must provide the means to sustain this progress.

Dr. Sanford A. Miller, a former Director of the FDA Center for Food Safety and Applied Nutrition (1978 to 1987) who also served on the NAS study committee, was unfortunately unable to appear to testify today. His written statement is submitted for the record. Dr. Miller sums it up well in saying, "Each agency operates under a different mandate, governed by different laws and answering to different constituencies and traditions. To ask them to voluntarily ignore this history is naive. There needs to be a permanent structure focused on food safety to meet the enduring needs of the American people."

Earlier this year in response to the NAS report, even the President's Council on Food Safety stated its support for the NAS recommendation calling 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.

As directed by the President, the Council is currently developing a strategic plan. Three weeks ago, the council hosted a day-long meeting to gather public comment as part of that process. Food Chemical News reported that a "number of participants suggested that a single food safety agency would solve many of the problems by improving coordination and resolving uneven funding across agencies that makes it difficult to target resources based on food safety risks." I encourage the Council to seriously consider those comments.

An independent single food safety agency is needed to replace the current, fragmented system. The Safe Food Act of 1999 would combine the functions of USDA's Food Safety and Inspection Service, FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine, the Department of Commerce's Seafood Inspection Program, and the food safety functions of other Federal agencies. This new, independent agency would be funded with the combined budgets from these consolidated agencies.

With overlapping jurisdictions, Federal agencies many times lack accountability on food safety-related issues. There are simply too many cooks in the kitchen. A single, independent agency would help focus our policy and improve enforcement of food safety and inspection laws.

It's time to move forward. Let us stop using multiple Federal agencies to inspect pizza. Instead let us "deliver" what makes sense—a single, independent food safety agency.

A single, independent agency with uniform food safety standards and regulations based on food hazards would provide an easier framework for implementing U.S. standards in an international context. When our own agencies don't have uniform safety and inspection standards for all potentially hazardous foods, the establishment of uniform international standards is next to impossible.

Research also could be better coordinated within a single agency than among multiple programs. Currently, Federal funding for food safety research is spread over at least 20 Federal agencies, and coordination among those agencies is ad hoc at best.

New technologies to improve food safety could be approved more rapidly with one food safety agency. Currently, food safety technologies must go through multiple agencies for approval, often adding years of delay.

In this era of limited budgets, it is our responsibility to modernize and streamline the food safety system. The U.S. simply cannot afford to continue operating multiple systems. This is not about more regulation, a super agency, or increased bureaucracy, it's about common sense and more effective marshaling of our existing Federal resources.

With the incidence of food recalls on the rise, it is important to move beyond short-term solutions to major food safety problems. A single, independent food safety and inspection agency could more easily work toward long-term solutions to the frustrating and potentially life-threatening food safety issues we face .

Some individuals have argued that we don't need a whole new government bureaucracy, that moving boxes around on an organizational chart won't make food safer, and that if the system isn't broken then it doesn't need to be fixed. But what they don't appreciate is that the current fragmented system makes it impossible to apply resources to the areas of greatest need. The current fragmented system makes it difficult for the agencies to be held accountable. For example, the current fragmented system places food safety efforts in conflict with the mission for agricultural market promotion. A system that determines which agency inspects which plant based on whether the plant produces an open-faced sandwich rather than a traditional one is one which, if not broken, is certainly illogical.

A single, independent food safety agency will not have the burdens of our current fragmented system. Consolidation of food safety functions in a single, independent agency will preserve the expertise currently in our agencies in a manner that will promote more efficient and effective government. One agency instead of 12 or more handling food safety is a reduction in bureaucracy and red tape.

Mr. Chairman, we have before this subcommittee a bill, S. 1281, which can bring the various agencies together to eliminate the overlap and confusion that have at times, unfortunately, characterized our food safety efforts. We need action, not simply reaction. Our current fragmented food safety structure is not the best that we are capable of having and it certainly is not the most logically designed system. Members of the Senate Governmental Affairs Committee of 1977 understood the problem, and they were correct when they reported, "Responsibility for Federal food regulation, which is currently divided, should be assigned to a single agency." I hope we can finally achieve that goal.

I welcome today's witnesses and the insights they will share, and I look forward to working with you toward a more effective and less fragmented food safety system.

Senator VOINOVICH. Thank you, Senator Durbin.

I would like to now introduce the first panel of witnesses. Representing the administration are Dr. Jane Henney, who is the Commissioner of the Food and Drug Administration, U.S. Department of Health and Human Services; and Dr. Catherine Woteki, Under Secretary of Food Safety, U.S. Department of Agriculture. Lawrence Dyckman is the Director of Food and Agricultural Issues at U.S. General Accounting Office, and he is accompanied by Keith Oleson, Assistant Director, Food and Agricultural Issues.

And rounding out the panel is Carol Tucker Foreman, who is the Distinguished Fellow and Director of the Food Policy Institute at the Consumer Federation of America.

We thank all of you for coming this morning. It is the custom of this Subcommittee to swear in all witnesses. Therefore, I would ask you to stand and raise your right hands, and I would also ask the witnesses that will be on the second panel to stand, and I will swear all of you in.

[Witnesses sworn.]

Senator VOINOVICH. We will now call on our first witness, Dr. Henney. We are anxious to hear what you have to say.

TESTIMONY OF JANE E. HENNEY, M.D.,[1] COMMISSIONER, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. HENNEY. Thank you. Mr. Chairman, let me express on behalf of all of us on the panel we are very sorry to hear about your wife but glad that she has recovered well.

Mr. Chairman, and Members of the Subcommittee, we are pleased to be here this morning to discuss one of the administration's highest priorities, protecting our Nation's food supply. I am Dr. Jane Henney, the Commissioner of Food and Drugs at FDA and I am joined by Dr. Cathy Woteki, Under Secretary for Food Safety at USDA.

We appreciate 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. Although the American food supply is among the safest in the world, too many cases of foodborne illness occur in the United States each year.

Mr. Chairman, today Dr. Woteki and I will describe many of the achievements that have happened in the past several years but we will also look at the work that remains.

Today's food safety challenges are very complex. First, Americans are eating a greater variety of foods, particularly seafood, poultry, fresh fruit, and vegetables that are available throughout the year. Second, Americans are eating more of their meals that are prepared away from home. Third, nearly a quarter of the U.S. population—the very young, the old, the immune-compromised—is at higher risk for foodborne illness. And perhaps the most important element in our changing world is the emergence of new and more virulent foodborne pathogens.

Since 1942, the number of known foodborne pathogens has increased more than five-fold. Until the first decade of this century, the regulation of food safety was primarily the responsibility of State and local officials. The Pure Food and Drugs Act and the Meat Inspection Act were both passed by Congress in 1906. From the beginning, nearly 100 years ago, these laws focused on different areas of the food supply and each of them took a different approach to the food safety issues because of different problems that were present at that time.

The Pure Food and Drugs Act placed the initial responsibility for producing safe and wholesome food squarely on the shoulders of the food industry. The Federal Government's job, in effect, was to police the industry. Unlike FDA's law, the USDA's Meat Inspection Act requires continual government inspections in the slaughterhouse. These laws form the foundation of the food safety system today.

Under the current structure, FDA has jurisdiction over 78 percent of the Nation's food supply—all domestic and imported foods except for meat, poultry and egg products. FDA has jurisdiction where food is produced, processed, packaged, stored or sold. The USDA's Food Safety and Inspections Service has regulatory and inspection responsibility for meat, poultry and egg products.

---

[1] The combined prepared statement of Dr. Henney and Ms. Woteki appears in the Appendix on page 49.

And although the guiding statutes of the USDA and FDA approach food safety differently, today each agency relies on sound science and risk-based approaches to food safety. As our written testimony explains our efforts are strengthened by close working relationships with other Federal agencies such as the Centers for Disease Control and Prevention, the Environmental Protection Agency, and our State and local partners. Together we promote food safety and prevent foodborne illness and food hazards through coordinated and integrated activities.

Food safety has been a high priority for this administration. This year for the third consecutive year, the administration has strongly supported the multi-agency effort to protect the health of the American public by improving the safety of the Nation's food supply. This process began with the May 1997 report to the President entitled, "Food Safety: From Farm To Table," a national food safety initiative.

This report contained recommendations that are both comprehensive and ambitious, and implementation of the report has depended upon a food safety system that is integrated and interdependent.

The report has led to a very needed shift in our collective attention and resources toward the growing problem of microbial contamination of food. In just 2 years, the administration has undertaken the vast majority of the report's recommendations.

Last August the President established the Council on Food Safety, whose 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.

Dr. Woteki will be discussing this strategic plan. I would like to just briefly highlight a few of the administration's food safety successes. One, in July 1995, HHS and USDA began a collaborative project called FoodNet under this initiative. It provides a strong network for responding to new and emerging foodborne illnesses, for monitoring the burden of foodborne illness, and identifying the source of specific foodborne diseases. PulseNet was developed by the CDC and it is now joined by a collaborative effort with HHS and USDA, as well as several States, that enables a national network of public health laboratories to perform DNA fingerprinting on bacteria that may be foodborne. PulseNet permits rapid and accurate detection of foodborne illness outbreaks.

The National Antibiotic Resistance Monitoring Program was established in 1996 as a strong inter-agency cooperative initiative. There are more achievements than I can highlight in this short time. I want to leave time for Dr. Woteki to go through our strategic planning process and specifically some highlights of our successes in the area of research.

Thank you.

Senator DURBIN [presiding]. Thank you very much. Dr. Woteki.

TESTIMONY OF CATHERINE E. WOTEKI,[1] Ph.D., UNDER SECRETARY FOR FOOD SAFETY, U.S. DEPARTMENT OF AGRICULTURE

Ms. WOTEKI. Thank you very much.

Mr. Chairman, sorry you have to leave. Senator Durbin, I am pleased to be here as well, and I would like to echo the comment that Dr. Henney made about the commitments that we have within the administration to work together at all levels of government to strengthen our national food safety system. I have also brought with me today a couple of charts, as well, and I would like to draw your attention to the one that is over here on the side.

This is actually taken from the same report that you cited, that the National Academy of Sciences issued last year, in which they describe the attributes of an effective food safety system and this diagram tries to capture all of those elements.

I think what is important is to focus on the center oval in that diagram. Really the important focus of our food safety system and any other effective food safety system is on public health and improving human well-being. In addition, this chart illustrates that there are many different key players in the food safety system: The private sector, government, as well as consumers. And that they have independent functions but they are also interdependent in many ways.

They are all dependent on a science-based approach that depends on research and the provision of education and important information that each of these sectors needs in order to fulfill its roles and functions.

I think the chart also illustrates the fact that these groups have to work together through partnerships in order to achieve that central focus and goal: Improving public health.

Now, we believe, within the administration, that the activities that we have ongoing do meet these attributes of an effective food safety system. And, as Dr. Henney indicated in her testimony, we are trying to put our testimony together to actually highlight the accomplishments over the last several years with respect to furthering these attributes of an effective food safety system.

I would like to point out a second chart that we have brought along with us. It illustrates the logo for the Fight Bac campaign, which has been a very effective food safety education program that also has been science-based and has also been the result of a very effective partnership among the private sector, consumer groups, Federal agencies, and other organizations.

Now, before I continue where Dr. Henney left off, I would like to just briefly talk about the role of the Office of Food Safety within the Department of Agriculture because it is a new office that was created in the 1994 reorganization. We believe that the creation of this office has effectively laid to rest the complaints that have arisen in the past about the potential for conflict of interest within the department with respect to food safety. By separating the regulatory from the marketing functions, we believe that we have successfully put those complaints to rest.

---

[1] The combined prepared statement of Dr. Henney and Ms. Woteki appears in the Appendix on page 49.

The legislation that authorized the reorganization requires that the Office of Food Safety be filled by an individual who has a specific and proven public health or food safety background. And these changes have very substantially enhanced USDA's public health focus and also, I believe, fortified food safety's presence within the department's broad mission.

The Food Safety and Inspection Service does report to the Office of Food Safety. As you know, we have the responsibility for the inspection of meat, poultry and egg products sold in interstate commerce, and also for the inspection of imported products. The agency has approximately 7,000 Federal inspectors that are located in 6,000 plants and, subject to the authorizing legislation for the agency, conducts continuous inspections.

This amounts to approximately 8 billion poultry, 135 million livestock, as well as inspections that are conducted in processing plants.

Now, our testimony focuses on five additional attributes that the academy report listed for an effective food safety system. And I would like to just briefly describe them now.

The first is research. And since we have a science-based approach to food safety, we have continued to emphasize and even given more emphasis under the President's Food Safety initiative to the importance of R&D. And certainly through the appropriations, Congress has very substantially increased the amount of funding that is going to food safety research.

We also believe that these R&D activities are paying off in the development of new technologies that can be implemented farm to table to improve food safety. Another attribute that the academy report describes is effective regulation. And in the case of both the Food and Drug Administration and the Food Safety and Inspection Service, we are implementing new science-based, hazard analysis and critical control program approaches to improve food safety. So, we believe that we are making very substantial strides in effective regulation.

There are also independent reviews conducted both of the seafood inspection as well as of the meat and poultry HACCP implementations that are demonstrating the effectiveness of those programs.

New technologies are dependent on the science. And we are seeing the adoption of new technologies from steam pasteurization to anti-microbial rinses to the use of competitive exclusion products, to improve food safety, again, at the farm level as well as at the processing level.

We are also working on education and information programs to improve the amount and quality of science-based information that is available to the public as well as to all who are responsible for food safety in that continuum from farm to table. I mentioned the Fight Bac campaign at the beginning of my remarks. Clearly, we are also taking other steps through consumer labeling approaches and other information provision approaches.

Last, we recognize the importance of partnerships with State and local governments as well as other partners throughout the food system. Both FDA and FSIS historically have had very strong partnerships with the States. Two recent examples are the Seafood HACCP Alliance in which States worked closely with FDA and the

industry in the development of that new program and USDA's continued work with the 25 States that operate inspection programs.

Now, where do we go from here? Dr. Henney referred to the work of the President's Food Safety Council and of the Task Force that both Dr. Henney and I co-chair that is emphasizing the development of a strategic plan and budget to develop further improvements in our approaches to assure the public the safety of their food.

Now, to draft the strategic plan, the Council established the Task Force that Dr. Henney and I co-chair. We have through that Task Force, developed a draft set of goals and objectives. We have shared them with stakeholders in a meeting that was held last month to solicit their views and opinions and we have scheduled a second public meeting for October 1999, in just a couple of months.

We will be providing a copy of a draft plan to the public early in the year 2000 and our final report is due to the President in July of next year. Now, we firmly believe that a seamless, science-based food safety system is critical to ensuring the safety of our food supply and in protecting public health. How we get there should be carefully thought through with all of our partners and stakeholders. And I would like to assure you that we are approaching this effort very seriously and, we think, as expediently as we can and building in ample opportunities for consultation with stakeholders and partners. And we are considering the full range of options that are available to us and the recommendations of the academy.

I very much thank you for the opportunity to appear before you and to discuss our food safety programs and we are certainly looking forward to working with you in the future.

Senator DURBIN. Thank you.

I would like to thank you and Mr. Dyckman as well as Mr. Oleson, from the General Accounting Office, for the work that they have done on this issue. They have testified before and I welcome their return to the Subcommittee.

Mr. Dyckman.

TESTIMONY OF LAWRENCE J. DYCKMAN,[1] DIRECTOR, FOOD AND AGRICULTURE ISSUES, U.S. GENERAL ACCOUNTING OFFICE; ACCOMPANIED BY KEITH OLESON, ASSISTANT DIRECTOR, FOOD AND AGRICULTURE ISSUES, U.S. GENERAL ACCOUNTING OFFICE

Mr. DYCKMAN. It is always nice to be before this Subcommittee, Senator Durbin.

Much of what I have to say you have summarized so, if you will bear with me repeating your statements because I think we agree on many points. Millions of people become ill and thousands die each year from eating unsafe food. As we have stated in previous reports and testimonies, fundamental changes to the food safety system would minimize the risk of foodborne illnesses. These changes include moving to a uniform risk-based inspection system, administered by a single agency.

[1] The prepared statement of Mr. Dyckman appears in the Appendix on page 68.

My testimony today provides another view of our work on the problems resulting from the current fragmented food safety system and discusses our views on where in the Federal Government food safety responsibilities should reside.

As the chart up there shows and as you have already described, the Federal food safety system is very complex.

Senator DURBIN. I want to give you credit, the GAO credit for inspiring our pizza. That was your chart that did that. [Laughter.]

Mr. DYCKMAN. Yes. I actually liked your props a little better than ours. We do have a chart. There are 12 agencies involved with food safety. Thirty-five different laws ensuring the safety of cheese pizzas and meat pizzas, involves a half a dozen agencies.

Currently, food safety laws not only assign specific food commodities to particular agencies but also provide agencies with different authorities and responsibilities that reflect significantly different regulatory approaches.

The following samples from our prior work show some of the problems we found in reviewing the Nation's fragmented food safety system. Federal agencies are not using their inspection resources efficiently because the frequency of inspection is based on the agency's regulatory approach. Some foods and establishments may be receiving too much attention while others not enough. For example, USDA inspects meat and poultry plants, as we have said, at least daily; while FDA inspects firms that process foods with similar risks such as rabbit, venison, buffalo, and quail, on average, once a decade.

Senator DURBIN. Let me stop you, Mr. Dyckman, if I might for a moment. Going back to the illustration here of this cheese ravioli, the FDA responsibility, once in a decade they might come through the plant to look at this product?

Mr. DYCKMAN. That is our understanding.

Senator DURBIN. And on the beef ravioli, a daily inspection?

Mr. DYCKMAN. Yes.

Additionally, responsibilities for the oversight of chemical residues in foods are fragmented among three Federal agencies: The FDA, USDA, and EPA. As a result, chemicals posing similar risks may be treated differently by the agencies because they operate under different laws and regulations. This permeates down to the State level as well. For instance, because States use different Federal agency methodologies for determining tolerance levels, fish considered safe to eat in one State, can swim to the waters of another State and thus are considered unsafe.

Enforcement authorities granted to the agencies also differ significantly and obviously that is one of the underlying problems with this whole food safety mess or quagmire. For example, unlike FDA, USDA has authority to require food processors to register so that they can be inspected. USDA can also temporarily detain any suspect meat and poultry products.

We have also done work on imported foods and found that regulation of that is inconsistent and unreliable. For meat and poultry imports, USDA, by statute, can and does shift most of the responsibility for ensuring product safety to the exporting country and that is where we think it should be. In contrast, FDA must rely primarily on widely discredited port-of-entry inspections which cover

less than 2 percent of shipments entering the United States in 1997.

Fragmented responsibilities also cause problems for the food industry because there has not always been a complete clear, unified communication about health risks associated with contaminated food products.

So, how do we deal with all of these problems? Well, we believe the most effective solution is to consolidate food safety programs under a single agency with a uniform authority. It is not a new concept, it is not a difficult concept, and it is common sense. It was debated first in 1972 by the Congress with a proposed bill to transfer FDA's responsibilities, including its food safety activities to a new independent agency.

We have discussed today that the National Academy of Sciences mirrored much of the recommendations in our prior work and concluded that the current fragmented Federal food safety structure is not well equipped to meet emerging challenges and recommended that the Congress establish by statute a unified and central framework for managing Federal food safety systems. And the important thing and one that I want to stress is they recommended a system that is headed by a single official, not by several officials.

However, whether food safety responsibilities should be housed under an independent agency or an existing department is subject to debate. In this regard, I just want to point out that we reported recently on the experiences of four countries that have consolidated or in the process of consolidating their food safety responsibilities. Great Britain's and Ireland's efforts were responding to heightened public concerns about the safety of their food supplies and choose to consolidate responsibilities in the agencies that report to their ministers of health, because the public lost confidence in the agricultural ministries that had responsibilities for some food products.

While Canada and Denmark were more concerned about program effectiveness, cost savings, efficiencies, and they have consolidated their activities in agencies that already had those responsibilities, basically the agencies that report to the ministers of Agriculture.

But regardless of where a single agency is housed, what is most important in our opinion, is the adherence to four key principles. First, a clear commitment by the Federal Government to consumer protection. Second, a system that is founded on uniform laws that are risk-based. Third, adequate resources to carry out the system. Fourth, competent and aggressive administration of the laws by the responsible agency and effective oversight by the Congress.

If I could just make one more point, Senator Durbin, the original question was if we were asked to redesign the food safety system, how would we do it? If we had to start from scratch, as we enter the 21st Century, we would never build the present bifurcated system. It would not make any sense. I do not think if you asked a 100 people to start from scratch would they come up with what we have now. People are working hard, with best intentions, they are doing a fairly good job at what they do. But it is not that well coordinated.

It is not completely risk-based. Parts of it are, large parts of it are not. So, why should we be satisfied with it now? Why not trans-

form it? Why not transform it into the type of system and into the type of activities that your legislation calls for?

This completes our statement. And we would be happy to answer any questions.

Senator DURBIN. Thank you.

Carol Tucker Foreman, thank you for being with us.

TESTIMONY OF CAROL TUCKER FOREMAN,[1] DISTINGUISHED FELLOW AND DIRECTOR, FOOD POLICY INSTITUTE, CONSUMER FEDERATION OF AMERICA

Ms. FOREMAN. Thank you, Senator Durbin.

I am Carol Tucker Foreman. From 1977 to 1981 I served as Assistant Secretary for Food and Consumer Services at the Department of Agriculture with responsibility for meat, poultry and egg products inspection. I am here today to provide the perspective of one who has tried to make this system work for the American people but is now freed from the institutional imperative to defend the status quo.

Unlike the government witnesses, I can answer your question. If the Federal Government were to create a food safety system from scratch, would it resemble the current system? Is this the best and most logical organization for Federal food safety agencies? I think you know my answer to both of those questions would be an emphatic, no.

Two years ago Congress provided the National Academy of Sciences funds to examine the Nation's food safety system and recommend ways to improve it. In ensuring safe food from production to consumption the committee recommended that Congress create a unified and central framework for managing Federal food safety programs headed by a single Federal official who has both the authority and control of resources necessary to manage food safety efforts.

The committee also pointed out that ad hoc efforts—and I include in that the President's Food Safety Council—will not suffice to bring about the vast cultural changes and collaborative efforts needed to create an integrated system.

The problems with the present system are obvious. It does not produce an acceptable level of public health protection. Eighty-one million cases of foodborne illness and 9,000 deaths each year from food poisoning are not marks of success.

Second, the present food safety system does not use human or public resources well. In fiscal year 1998, FDA and FSIS spent just shy of $1 billion for food safety. USDA with the responsibility for only meat, poultry and eggs, got $746 million of that; FDA, with responsibility for all the other food products, got only $222 million. The fiscal year 1998 budget paid for 7,200 USDA inspectors, while FDA had only 250.

That disparity may explain why a Center for Science in the Public Interest analysis of CDC data showed that food products inspected by FDA were implicated in more foodborne illness outbreaks than foods inspected by USDA. The present system depletes the energies and demeans the talents of committed public servants

[1] The prepared statement of Ms. Foreman appears in the Appendix on page 81.

who spend way too much of their time bumping each other and jockeying for advantage.

The Commissioner of the Food and Drug Administration, the Under Secretary and the administrator of FSIS spend hours negotiating who is going to sign a letter, whose language is going to be used, who is going to get to sit at the table and where they will sit? What a waste of public funds and public talent.

In March 1999, President Clinton's Council on Food Safety committed to examining a unified system. The Council has not done that. The strategic plan does not say a word about it. It is gone. What a shocking lack of leadership. The Commissioner, the Under Secretary, and the trade associations, will testify here today, are going to urge you to ignore all the facts that have been laid out by the General Accounting Office.

Trade associations and the government will argue that tinkering around the edges and a little more cooperation will do the job.

With all due respect, that has been tried before. Fixing the present system by tinkering and nibbling is like trying to teach a pig to sing. It will not work, and the pig does not like it.

Our system is broke. If we are serious about protecting the public health we need to fix it. Consolidating food safety in one agency with one budget, one leader and, ultimately, one authorizing statute is the only way to do that.

A multitude of independent bodies, Congressional committees, the GAO, the National Academy of Science, and virtually all the public officials who have led these agencies and been asked about it after they have left government give you the same response I have.

Senator DURBIN. If I might interrupt for a second? The reason why the staffer is looking so nervous, as she is, is because I have 2 minutes left to vote. And I want to give you a chance to conclude. Are you near the end here?

Ms. FOREMAN. I am.

Senator DURBIN. OK, fine, thank you.

Ms. FOREMAN. The change can be accomplished in a phased manner that ensures an orderly transition. Talented and committed public servants can make this work if you tell them to make it work. They cannot make the present system work.

The American people deserve a better, more effective system, Congress can start down that road by passing the Safe Food Act, S. 1281.

Thank you.

Senator DURBIN. Thank you.

Thanks, everybody. I am going to call a recess here for a few minutes as I run off to vote. And you are welcome to snack, if you would like, and I will be right back.

[Recess.]

Senator DURBIN. I apologize for leaving but it is beyond my control. And I, again, apologize to Carol Tucker Foreman for interrupting you. Perhaps it gave more dramatic impact to your closing. [Laughter.]

Dr. Henney, when I use the term, virtual reality, what does that mean to you?

Dr. HENNEY. I do not have a lot of psychiatric training, but I would say, what does it mean to you? [Laughter.]

Senator DURBIN. Perfect answer.

My concept of virtual reality is this new technology where you put on this helmet and you feel like you are somewhere that you are not, that you are doing things that you are not doing. And that is why I was stunned when I received a letter, which I am going to make a part of the record—from two people I consider close friends and one I respect and do not know as well—Secretary Donna Shalala, Secretary Dan Glickman, and Neal Lane, Assistant to the President for Science and Technology.[1]

I wrote them a letter and asked them to respond to the National Academy of Sciences report, what the Food Safety Council had to say about fully integrating the food safety system in the United States. And I would like to read to you what they said as a group—I know these letters go through 85 different iterations and 85 different offices:

"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 Federal food safety agencies working as one, complementing one's efforts. Clearly, however, more work lies ahead to enhance and improve our achievements."

I am still wrestling with this virtual food agency. I want to deal in the real world here of a single food agency rather than a virtual reality. And as I listen to Dr. Woteki and Dr. Henney, I admire your efforts because you not only have an important mission, in this respect, the safety of food, you have an almost impossible assignment, to try to juggle all these agencies into one operation.

And it appears that the Food Safety Council is playing the role of a summit conference, bringing together all these different Federal agencies providing Esperanto texts and things so they can speak to one another and understand. And it strikes me that this memorandum of understanding which was issued in February of this year, between the Food Safety Inspection Service and the Food and Drug Administration is a lot like the Middle East peace accord. We finally have these two agencies willing to work.

Can you step back for a second? Can you say, let me think not as someone in government, but as someone outside government, that the thing you are proudest of is you have everyone speaking to one another? That you have people talking to one another?

It strikes me as impossible to defend to families across America that this is good government. It strikes me that you are doing the best you can with a terrible situation. How many different agencies dealing with one food product? Either beef ravioli should not be inspected every day or cheese ravioli should not be inspected once a decade. Something is wrong here. Somebody has got it wrong.

What I am suggesting is could we get together and talk? Could we try to deal with one agency here? You know what happened with the egg situation. We had that at the last hearing. We said to these agencies, tell us, here is the question. What temperature should we keep eggs at to keep them safe?

---

[1] The letter referred to appears in the Appendix on page 130.

Now, I am not a scientist. Cooked a lot of eggs, but I am not a scientist. And we said, work on this. Come up with it. How many years did it take the FDA? Eight years to come up with the answer to that question. And then they handed it over to the USDA to do their part of the calculation.

That is what is driving me crazy. And I think most of the people who watch this think, surely they are not defending this. This long lead time, this bureaucratic tangle that we have created when it comes to food safety inspection. I will repeat what I said at the outset. I really do trust both of you. I think you really do have the best of intentions in what you are trying to do and you have done your best. You are good professionals. But how—I mean step back for a second. Do you really think this is the most efficient way for us to inspect food in America?

Dr. Henney.

Dr. HENNEY. Well, Senator Durbin, you have raised a number of points. I think that we tried to outline in our testimony that where we come from on this is basically outlined for us in the laws and the jurisdiction that Congress provided to each of our agencies or the other agencies of government. I think when it comes to looking at ways in which we can make those function effectively, we have made, I would say, great strides in the last 3 to 4 years of getting this to be much better integrated, much better coordinated——

Senator DURBIN. Can we address that——

Dr. HENNEY [continuing]. As it needs to be. But I think that to the issue of jurisdiction, at an operational level that is why we have some of these memorandums of understanding. Our jurisdiction is very clear to us. It is how we work out in the field that we have had to have many discussions between and among ourselves as to how we can do that.

Senator DURBIN. There was a TV show, and I cannot remember which one, and the fellow used to get up and say, the Devil made me do it. And I do not know how long ago that was. And I have heard so many witnesses say, Congress made me do it. Do not blame us. Do not blame us about all these different laws and 10 years and one daily inspection, Congress made us do that.

And, you are right. Congress did make you do a lot of these things. Congress came up with these crazy ideas that do not mesh and do not make sense. I am talking about something fundamental—changing the law. And I cannot get over how professionals in this business are resisting efforts to change the law and get out of this crazy quilt of jurisdiction into something that makes sense.

So, I applaud you for taking this mish-mash of law that we have handed you and trying to make something good of it. Thank you.

But let us get beyond that discussion for a second. What should we do? What should the law say? As a medical professional, would it not make more sense to have one agency driven by science in a coordinated effort, a new law, a new way of looking at things?

Dr. HENNEY. I think that the—I will come back to something that Dr. Woteki said. And that is what we are driving toward are the best public health outcomes. We are looking within the context of the strategic planning group that we have. One of the things that we are specifically looking at is the laws that undergird all of

our operations, where we have gaps or possible overlap. And looking at the different models that might make us more effective.

I think that we have much to be proud of. There is clearly much that we can do and each one of these models that is suggested, whether it is total independence, consolidation or better integration, all have both merits and draw backs. And that is something that we are undertaking this year to really clarify for ourselves and the thing that we have been charged with doing is making recommendations to the council and to the President about that matter.

Senator DURBIN. Dr. Woteki, if you had to draw up that model, with your goal public health and well-being, would it look like the current system?

Ms. WOTEKI. No. It would not look like the current system.

Senator DURBIN. Why?

Ms. WOTEKI. Well, we explained in our written testimony. There are historical roots as to why this system has evolved to what it is today and why there are the separation of responsibilities that there are. But I do think that the report that the academy made that you referred to in your opening remarks and that I did as well actually did give some very serious consideration to what structurally might be a better replacement for what we have. And they came up with four different approaches and said that those four might not be the whole constellation either.

One of them is an independent agency, as you have proposed. But the other three would be a lead agency, nesting those responsibilities within one department, or the creation of a council. So, the academy report, itself, says that there are a variety of different means by which you could achieve that effective system and among the things, as Dr. Henney said, that we are doing is looking at that range of ideas in addition to some other ones that have come up through the public meetings that we have had. And, essentially are going to be working through the pros and cons.

Senator DURBIN. But do you not see that as you step back and look at your best efforts now and those of your predecessors that when the point that was made, and I think by Mr. Dyckman earlier, about imported food, it is just impossible for me to explain to people why your agency feels that the safest thing for American consumers is for us to inspect the plants in the country of origin and the Food and Drug Administration says, no, the safest way to deal with it is inspect the product as it arrives in the United States.

And it is a totally different approach. Scientifically, should we not be able to coordinate those? I mean clearly the food products involved are so similar, you cannot say, well, it makes more sense in one area but not in others. Should we not be able to at least come to a common ground, a common solution as to what the best scientific answer is to that question?

Ms. WOTEKI. Certainly the administration agrees that we have to have a better approach towards the safety of imported food. One of the things that for the Food Safety and Inspection Service has been very important has been the legislative authorities that permit that system of equivalency, that require us for imported meat and poultry products to make sure that the country exporting to us

has an equivalent system and permits us to do those inspections overseas.

FDA has been seeking similar authorities and perhaps Dr. Henney would like to expand on that.

Senator DURBIN. Sure, please.

Dr. HENNEY. Thank you.

I think that, yes, we have on many occasions over the course of the years sought additional authority in this area. I think that the President last month also called on us to, in the wake of no active legislation in this area, asked that we work closely with Customs to use any administrative tools at our disposal to look at how we could focus on the imported food issue in a stronger way. And we will be doing that. But this, again, is something where, as I think as Dr. Woteki points out, we would also need to be working with you and Congress about the needed statutory authorities that are really not present for us at the current date.

Senator DURBIN. Let me ask you this. One of the things that seems clear is that there is a lot of communication among the different Federal food safety inspection agencies. How many interagency coordination meetings on food safety are held each week? Does anybody know?

Dr. HENNEY. Let me just give you a few examples. I know that we held the strategic planning meeting, the Task Force, weekly, and we would be doing that this afternoon. I think between the Center for Foods, which is the lead agency for food safety out of the FDA, and the FSIS service, the lead officials there meet on almost a weekly basis.

We have strong interaction. I think, as we look at our other colleagues at CDC and EPA, in fact, we have a person from CDC who now has been located with us and we have sent a person down there. So, that there are, yes, there are many meetings weekly if not daily.

Senator DURBIN. That raises the obvious question. Would it not be better if we had fewer meetings and more enforcement? Would it not be better if we had one set of rules, scientifically based, that all of the agencies or a single agency was attempting to enforce? Would the consumers be better off if there was less time spent by people working in food safety at agencies trying to piece together all these different standards and all these different approaches?

Mr. Dyckman, would you like to respond to that?

Mr. DYCKMAN. Well, clearly, it would be better to have more enforcement. I guess from the efficiency standpoint regardless of whether this is food safety, aviation safety, environmental safety, I think that the track record will show that when you have an independent, unified agency that has responsibilities the better off you are. Now, of course, EPA is not perfect, but they do not have unified legislation. And we have done lots of audit reports on EPA and have recommended that. But at least all the environmental laws or most of them are housed at one agency, it is a lot easier to coordinate and communicate.

I wanted to address one other point. If I may take the liberty. I attended one of the strategic planning meetings, the open meeting that the President's Food and Safety Council had a few weeks ago and one of their goals is to create a national and to the extent

possible, a international seamless food safety system from farm to table. And I believe the meeting was to address how to organize or reorganize the Federal food safety system.

And quite frankly, I was disappointed that I did not even see on the table the option of consolidating all Federal agencies. There were proposals to make it more seamless, to better coordinate. But as we have heard today there were four options in the National Academy of Science report including a single food safety agency. But that fourth option which is a consolidated, unified single agency was not addressed.

Senator DURBIN. If I could go back then. Let me ask, there was a suggestion, I believe it was in Dr. Woteki's testimony, that we are approaching this effort seriously and expeditiously and considering the full range of options. Does that include a single food agency?

Ms. WOTEKI. Most definitely. We are considering all of the recommendations that were made by the academy report as well as the recommendations that are coming forward from these various meetings that we have had.

Senator DURBIN. Because Mr. Dyckman said it was not brought up.

Mr. DYCKMAN. Yes. I attended part of that and John Nicholson, sitting behind me, attended the whole day and we discussed it when he came back. And while we have heard officials say that is one of the options at the working session to get public input, it was not offered up on the table as a possible option, and it really surprised us.

Senator DURBIN. Carol Tucker Foreman, you have been on the inside, on the outside, and you addressed what you would have to just characterize as the politics of this situation here. Why are we running into this resistance? Now, people who are recognized professionals in the field and have to know in their heart of hearts that this is not the way to run a railroad. Why then do we have an administration which prides itself on food safety and is unwilling to move forward with the concept of this independent single agency?

Ms. FOREMAN. Could I say one other thing before I answer that?

Senator DURBIN. Sure, of course.

Ms. FOREMAN. Not only is the unified agency not part of the discussion but at the public meeting a number of people suggested that it should be and at the end of the meeting the two Secretaries went out, met with the media and said, we do not want a single food safety agency. It would be disruptive. Boy, you bet it would. It would disrupt this nice little club. It would make people's lives change. And I think out of that would come better food safety.

There is a wonderful guy at OMB years ago who said, in Washington where you stand depends upon where you sit and turf is the ultimate determiner of what your position is. These are people who are committed, but every statement that Dr. Henney made comes qualified with, we want to do these things but only with the structure that we have now.

We want better health, we want better science, but only with the structure that we have now. You cannot change the structure. It is the iron law of Washington.

Senator DURBIN. Well, let me address one specific concern that is legitimate, that would have to be resolved here. And that is the difference in responsibility between a public health agency, like the Food and Drug Administration, and an agency like the U.S. Department of Agriculture, which combines many different things relative to agriculture. In addition to promoting products, they are inspecting products.

Certainly FSIS has a health component to it, but it is a much different agency by mission. Is that part of the friction here? Is that part of the tension that we run into when we talk about a single agency?

Ms. FOREMAN. I do not think so. First, let me point out that Congress, by creating the Under Secretary for Food Safety began to address the conflict between USDA's different missions. The Under Secretary for Food Safety has only one responsibility, to protect public health. FSIS does not have to balance safety and marketing. Incidentally, I might point out, this is the highest ranking food safety officer in the U.S. Government by act of Congress. You still have to compete within the department.

On the other hand, FDA is required to accommodate the food industry, to encourage the food industry, and to encourage international trade. So, FDA has to balanced interests. If you want the best for food safety, the best for the American people, stop this virtual stuff, take these two agencies and put them together under a leader who does not have to go up the line to a Secretary.

Senator DURBIN. Dr. Henney, let us go right to that point.

Is that one of your concerns that if you move this out of the FDA, that it would compromise what you consider to be a central responsibility when it comes to public health? That it might go to an agency, a new one, an existing one which does not share that same public health commitment?

Dr. HENNEY. Senator Durbin, I have not foreclosed conclusions here. I think that if you look at the issue that we are both driving for, both the reorganization that was done at USDA and within our own organization, public health is the bottom line. We come from that at the FDA from a variety of standpoints. Our history is in public health, what we have always done is always geared at the public health. We are a science-based regulatory agency that has a very long and proud history in this regard and we are also advantaged, we believe, by our sister agencies within the health department such as CDC and NIH and the like.

I think that the working relationship that we have with the Agriculture Department for the other commodities that they regulate and the recent accommodation that was made in terms of public health being under the purview of the Under Secretary did separate that issue that had been present before in terms of marketing and public health.

But we feel proud, quite frankly, of the fact that our whole history has really been driven by this issue and will remain that.

Senator DURBIN. Well, Dr. Woteki, I would like you to have a chance to respond to this as well. This is something that is often—this is the bottom line here. The turf battle goes over a lot of different aspects but one of the most basic is whether or not your agency, the Department of Agriculture, for example, could even

take on this responsibility if it were given the entire food safety responsibility, because of some of the internal conflicts which have been written about over the years.

What are your thoughts on that?

Ms. WOTEKI. Well, I think that the greatest gains we are going to make in the future with respect to food safety are going to be ones that are premised on prevention. Techniques that we can put into place at the farm level as well as during processing and through the retail and preparation areas.

The greatest gains though I think are really going to come in the prevention on-farm as well as in the processing areas. And those are going to require an enormous amount of further scientific research to develop the new technologies that can be applied, that are going to be cost-effective, and that will continue to deliver to the American consumer a high quality and safer food product.

Senator DURBIN. But the basic bottom line—I am sorry.

Ms. WOTEKI. So, our whole approach that has guided what the Department of Agriculture has been doing for meat and poultry and egg product inspection and also that is guiding now the President's food safety initiative is this farm to table approach with a heavy emphasis on R&D as well as the adoption of science-based approaches in our regulatory systems.

Senator DURBIN. I guess the bottom line question though, is can your agency promote a product as well as oversee it, inspect it and do it with credibility?

Ms. WOTEKI. Well, I think you can look to our record of the last 5 years, since the reorganization. And the answer to that is, yes. We have implemented this new science-based HACCP approach in meat and poultry. We have seen a very high compliance rate in the industry and recent data from CDC has indicated that there is a dramatic decrease in salmonellosis that parallels the declines that we are seeing through our own performance testing on products. That has been done. There has been a high rate of industry compliance and it has been quite successful.

Senator DURBIN. Mr. Dyckman, you noted that several countries have started wrestling with this question on their own and have come to different conclusions on it, if I understood your testimony. It was a situation in England and Ireland that they move toward more of a public health orientation and if not, if I do not remember correctly, Canada and Denmark moved more toward the agricultural side of it.

Could you explain, if you have it there or if you know, what drove those decisions? I know the mad cow outbreak and other things were issues in England.

Mr. DYCKMAN. Well, it was obviously, distrust in England and Ireland for Federal regulators that dealt with food safety. And, so, they chose to place their responsibilities in a health oriented agency, that is under the Health Ministers. It was less of a concern for the other two countries. They were more concerned with economy and efficiency.

If I might return to your question that you asked the other two witnesses. GAO places a lot of emphasis on integrity and accountability. Integrity composes many aspects and it includes many

things. One of them is clearly an appearance of a conflict of interest and I think you alluded to that today.

There are questions, legitimate questions about whether or not an agency that promotes an industry should also regulate parts of that industry, even if there is a firewall. And I think Agriculture has a firewall. But still there are questions. Questions to the extent that if we were to start from scratch, we would avoid the appearance of conflicting interests.

Accountability is another important issue in government, not just in food safety but all aspects of government. The U.S. taxpayer has the right to demand answers from one official who could represent an issue or set of issues. We do not have that in food safety right now. It is spread across various agencies as we have discussed today. And that is why there is such an effort to coordinate.

Now, obviously, even if you put all food safety responsibilities or many of them in one agency there still would be a need to coordinate but at least you would be able to go to one agency official, to have one person testifying today on food safety representing the administration and would be able to say "yes," I can make that change or explain the reason for not making that change.

You would not have to go to several different agencies.

Senator DURBIN. I think that is the bottom line and the reason why, obviously, I am pushing for the idea that I believe in. But I also have the highest respect for all who have testified today who may see things differently. And I repeat what I said at the outset, I believe you are all professionals.

I think you are doing the very best in terms of food safety for this country. I just think we can do it better and I hope that perhaps your testimony today and this hearing will cause some within the administration to understand that what I have in mind is not disruptive but, in fact, will create a more efficient approach. And I thank the panel very much for your testimony.

Dr. HENNEY. Thank you.

Ms. WOTEKI. Thank you.

Senator DURBIN. The next panel that we have includes Nancy Donley of Chicago, President of Safe Tables Our Priority; Caroline Smith DeWaal, Director of the Food Safety Programs for The Center for Science in the Public Interest; Dr. Rhona Applebaum, Executive Vice President for Scientific and Regulatory Affairs of the National Food Processors Association; and Dr. Stacey Zawel, Vice President for Scientific and Regulatory Policy for the Grocery Manufacturers of America.

So, Nancy, if you are prepared, if you would lead off and then we will allow the others to join in.

Thank you for being here.

TESTIMONY OF NANCY DONLEY,[1] PRESIDENT, S.T.O.P., SAFE TABLES OUR PRIORITY

Ms. DONLEY. Thank you, Senator Durbin for inviting me here today and thank you for your years and ongoing many, many more, I hope, in leading such good efforts in food safety. It has not gone unnoticed. The American public thanks you for it.

[1] The prepared statement of Ms. Donley appears in the Appendix on page 92.

I was invited to testify here today on a subject that has become the single most important issue in my life and that is food safety. Until July 18, 1993, food safety was a non-issue as far as I was concerned. I did what most of the public does, I assumed that the food we fed our families was safe. I assumed that our government had the situation of ensuring the safest food safety possible well in hand. I assumed that the food industry was governed under the strictest of regulations to produce food of the highest safety level possible. I assumed that companies violating food safety law were dealt with swiftly and harshly. I assumed that there was an entity ultimately responsible for protecting my family from unsafe food. I assumed wrong on all counts, dead wrong.

On July 18, 1993, my only child, my 6-year old son, Alex, died a brutally painful death after eating *E.coli*, 0157:H7 contaminated hamburger. Alex wanted to be a paramedic when he grew up so that he could help people. So, when he died, we wanted to donate Alex's organs to fulfill his wish in helping others. We were told we could not. The toxins produced by *E.coli* 0157:H7 had destroyed his internal organs and they had liquified portions of his brain.

My son suffered horribly and I still suffer and grieve every day, 6 years later and I will for the rest of my life. And this happens to millions of people every single year.

After Alex's death I joined S.T.O.P., Safe Tables Our Priority. S.T.O.P. is a national nonprofit foodborne illness victims organization that was founded in the wake of the Jack-in-the-Box *E.coli* 0157:H7 epidemic in 1993 that killed 4 children and sickened over 700. Our founders include parents of children who died or were seriously injured from eating contaminated meat.

Since then our membership has expanded to include people impacted by many different foodborne pathogens from all food groups. Our mission is to prevent unnecessary illness and death from foodborne pathogens.

When I learned that Alex had died because his hamburger was contaminated with cattle feces, I was determined to understand where the system had failed and it has been an incredibly eye-opening experience for me. S.T.O.P.'s initial focus was on fixing the *E.coli* 0157:H7 problem, a problem then thought to be confined to beef. I learned that at the time of Alex's death meat inspection did not include any measures to address microbial contamination. So, I worked extensively during the rule making process for FSIS's pathogen, hazard analysis and critical control point regulation which mandated microbial testing for the first time in history.

Also, during this time, *E.coli* 0157:H7 was declared an adulterant in ground beef and safe food handling labels were required for all raw meat and poultry products sold at retail.

Things were definitely looking up in the hamburger disease fight as *E.coli* 0157:H7 was commonly referred to. But then we learned that *E.coli* 0157:H7 is not just a hamburger problem. The primary reservoir of 0157:H7 is found in cattle and the first incidence and outbreaks of *E.coli* poisoning were found in ground beef. But outbreaks have subsequently been linked to such diverse foods as lettuce, sprouts, cantaloupe and apple juice. Japan had a national epidemic that infected over 10,000 people with contaminated radish sprouts being the suspected vehicle.

Several months ago school children in Europe became sick from *E.coli* 0157:H7 contaminated goat cheese and *E.coli* 0157:H7 outbreaks have been linked to contaminated drinking water and in my home State of Illinois, children became very sick after swimming in a contaminated reservoir.

This single pathogen, which is why I went through this list, affects products that is regulated by the FDA, FSIS and EPA. So, while FSIS was dealing with the problem in meat, prevention strategies were not put in place for other products that could be affected by the same pathogen and that was because no one was looking at the overall big picture.

There appears to be a dangerous tunnel vision occurring within the individual agencies where they focus only on their small world and do not see how happenings in other areas might be of relevance to their own.

The invitation to this hearing contained the following questions: One, if the Federal Government were to create a food safety system from scratch, would it resemble the current system? And, two, is this the best and most logical organization for Federal food safety agencies?

If the Federal Government were to create a food safety system from scratch I cannot imagine it creating the fragmented system that exists today. The reason that it is so hodge-podge is that it was never planned. It just evolved into what it is today. Food safety was not the concern historically that it is today. Rather quality and labeling issues were the driving forces.

So, consolidating food safety activities into a single independent agency would elevate food safety, prevent duplication, and fill-in gaps that currently exist in our multiple-agency system. A single independent agency would be better prepared to handle emerging food safety issues. It would be more efficient, more effective, and more responsive.

The current structures of agencies within even larger departments undermines the importance of food safety because these departments have such broad and diverse agendas, but food safety always gets very—very often can get overlooked or does not receive the attention it deserves.

FSIS is a subset of the USDA, a huge department, whose responsibilities include everything from forestry to circus animals. It is even more complex with CFSAN, a subset of the FDA, which is a subset of HHS. When you are such a tiny piece of the pie you do not command much attention. And food safety deserves to be the entire pie.

It is time to face the fact that the current system of multiple agencies regulating food safety is simply not working. Victims are falling through the cracks because of the lack of a single cohesive food safety program. Imagine what might have happened if a single food agency had been implemented immediately following the Jack-in-the-Box epidemic. A single independent entity responsible for all foods including meat would have looked at the animal reservoir pathogens in a larger context. While developing a program to address the animal pathogens in meat, it would have logically and simultaneously looked at the potential of animal waste contaminating other foods as well and developed prevention strategies.

These produce-related foodborne illness outbreaks might have been avoided all together. Our organization has members who were victims of the juice and lettuce outbreaks who question why did not government anticipate such a problem occurring? They want to know who was in charge of the safety of the food that made their loved ones sick? The answer is, tragically, a dual one. There were too many in charge and yet no one in charge.

We strongly support the implementation of a single independent food safety agency. The safety of the food we feed our families is of critical importance and deserves the uncompromised scrutiny and attention of an agency unencumbered with other conflicting responsibilities such as trade and marketing issues.

Now, many industry associations support the status quo of the marketers.

Senator VOINOVICH [presiding].

Ms. Donley, your time is almost up.

Ms. DONLEY. Oh, I am sorry.

In conclusion, we oppose such an arrangement to have conflicting agendas within agency. So, I would just like to say that it is time to acknowledge that we are beyond fixing the current situation and we really hope that turf wars will be set aside and just focus on protecting the common people. That is what we count on government to do.

Senator VOINOVICH. Thank you very much. Ms. DeWaal.

TESTIMONY OF CAROLINE SMITH DeWAAL,[1] DIRECTOR, FOOD SAFETY PROGRAMS, CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Ms. DEWAAL. Thank you very much and I want to thank Senator Durbin for his tremendous leadership and Senator Voinovich for your willingness to look at this question. I am Caroline Smith DeWaal. I am Director of Food Safety Programs for The Center for Science in the Public Interest.

CSPI is a nonprofit organization based in Washington and we have been working for over 25 years to help improve the public health largely through our work on nutrition and food safety issues. We are supported by over a million subscribers to our Nutrition Action Health Letter. Food safety experts believe that contaminated food causes up to 81 million illnesses and 9,000 deaths each year.

While these estimates illuminate the magnitude of the problem, for many consumers these aggregate numbers mean less than the specific outbreaks and recalls, such as the Jack-in-the-Box outbreak, the outbreak from Odwalla juice, the Hudson Food recall where millions of pounds of ground beef were recalled or the most recent Bil Mar outbreak linked to listeria in processed meat products.

These well-publicized cases have awakened consumers to the fact that contaminated food is a greater risk than we thought. Food contamination problems are cropping up in such health foods as apple cider and alfalfa sprouts to such traditional favorites as ham-

[1] The prepared statement of Ms. DeWaal appears in the Appendix on page 96.

burgers and hot dogs. It is hard to know any more what is safe to serve your kids or your aging parents.

CSPI has been collecting data on foodborne illness outbreaks for several years. Today we are releasing an updated version of this data in a report called, Outbreak Alert: Closing the Gaps in Our Federal Food Safety Net. In this listing of over 350 outbreaks FDA regulated foods were identified in three out of four of the foodborne illness outbreaks.

Yet, FDA receives roughly one out of every four dollars appropriated for food safety regulation. This disparity is only one of many created by our current system, which spreads responsibility for food safety among numerous Federal agencies.

Senator Voinovich asked us to address the following questions. If the Federal Government were to create a food safety system from scratch, would it resemble the current system and is this the best and most logical organization for the Federal food safety agencies?

The answer to both of those questions is a resounding, no. It makes no sense when food safety problems fall through the cracks of agency jurisdiction. It makes no sense when multiple Federal agencies fail to address glaring public health problems. It makes no sense to have a single food processing plant get two different, entirely different food safety inspections while other plants get no Federal inspection at all.

It makes no sense that the widely touted HACCP program is markedly different at the Food and Drug Administration and at the Food Safety and Inspection Service. It makes no sense that new food safety technologies face multiple hurdles at various agencies before they can benefit consumers.

It makes no sense that the United States inspects imported food differently depending on which regulatory agency is in charge. Quite simply, the current food safety system makes no sense for today's consumers.

CSPI documented these problems last year for the National Academy of Sciences panel that wrote "Ensuring Safe Food from Production to Consumption." This year we have documented even more problems.

For example, for State laboratories there are no minimum testing requirements when they are checking food. They actually have to run different testing protocols depending on which agency they are running the test for. This means that contaminated food recalls and outbreak announcements can be delayed for several days while Federal agencies retest products to confirm the findings of the State laboratories.

Another example is genetically modified plant species. These are subject to a mandatory review at our APHIS, our Animal and Plant Health Inspection Service, to ensure plant health and safety. But only a voluntary review at the Food and Drug Administration to ensure human health.

The agencies want us to believe that they can coordinate their way out of these problems. It is true that the Clinton Administration has worked hard to address many pressing food safety problems. Despite their best efforts, however, coordination will never provide the whole solution. While a joint FDA–FSIS egg safety task

force has been meeting for years, neither agency has proposed on-farm controls for *Salmonella* that infects eggs.

In addition, a memorandum of understanding between FSIS and FDA on inspection issues failed to net any meaningful change because USDA is statutorily limited to conducting only meat and poultry inspections. These examples show that coordination cannot ultimately address many of the problems with the current system.

In Vermont, where I grew up, there is a joke a city slicker who asks directions from an old Vermont farmer. The punch line is, you cannot get there from here. Today we all want the safest possible food supply. But like that old Yankee farmer, I am afraid that you cannot get there from here. That is why CSPI strongly supports the Safe Food Act of 1999.

Thank you very much for your time and attention.

Senator VOINOVICH. Thank you very much. Dr. Applebaum.

TESTIMONY OF RHONA APPLEBAUM,[1] Ph.D., EXECUTIVE VICE PRESIDENT FOR SCIENTIFIC AND REGULATORY AFFAIRS, NATIONAL FOOD PROCESSORS ASSOCIATION

Ms. APPLEBAUM. Thank you, Mr. Chairman.

My name is Rhona Applebaum and I serve as the Executive Vice President for Scientific and Regulatory Affairs for the National Food Processors Association.

NFPA appreciates this opportunity to offer comments on the organizational structure of our Nation's food safety system. Because our primary mission is food science and food safety, we have a very direct interest in providing input on this proposal.

In the few minutes I have this morning, I will briefly address the effectiveness of our current food safety system and some of the challenges to public health that system faces as well as why we believe a single food safety agency is not necessary to meet those challenges.

While NFPA does not endorse S. 1281, the Safe Food Act of 1999, we commend its author, Senator Durbin, for his legislation's goal of enhancing food safety, an objective shared by the food industry.

Our means to the end is where we differ. Our approach embraces a single food safety policy not a single food safety agency. If the Federal Government were to start from scratch to establish a food safety regulatory system would it resemble the current system? Probably not. But then numerous other government agencies, whose missions parallel and/or compete with one another might also look differently with the benefit of a clean slate.

We should be mindful that our existing food safety system has evolved over many decades and enjoys the confidence of the overwhelming majority of the American public. In short, the system works and it continues to evolve toward an even more effective system in the future.

Rather than focusing our efforts on creating a new agency, our energies would be of greater benefit if we focus on enhancing the strengths of the existing system. The current regulatory framework in the United States, with shared oversight of food safety by FDA,

[1] The prepared statement of Ms. Applebaum appears in the Appendix on page 119.

USDA, and several other agencies, has resulted in Americans enjoying one of the safest food supplies in the world.

So, while there may be ways to improve the current system, it is not accurate to say categorically that the system is broken and needs to be replaced.

There are two primary reasons why our current system works well. The first is that safety is the food industry's No. 1 concern, our principal focus. Safety is job one, as the saying goes.

Second, the current food safety system is largely based on sound science and a mutual commitment to food safety by both food companies and all agencies involved in their regulation. But can the system be improved? Absolutely.

Our plea is to work together to enhance not demolish the existing framework. NFPA believes that it is unnecessary to have a single food agency to improve the system. Three goals should be considered when discussing improvements to our current system.

These include, first, better coordination among various Federal, State and local government agencies. Second, a single scientifically based Federal food safety policy which ensures uniform and consistent food safety guidelines and requirements.

Third, and of extreme importance, is that sound objective science must be the basis for any changes and improvements to our food safety system. This view is endorsed by both the National Academy of Sciences and the President's Council on Food Safety.

Sound science must be the tool used in determining the allocation of resources in the food safety regulatory framework.

Mr. Chairman, in closing, NFPA believes that incorporating better agency coordination and more consumer education along with increased surveillance and better agency resource allocation in terms of risk assessment to consumers will go a long way to enhance the safety of the U.S. food supply and work is underway to see these actions realized.

NFPA recommends that Congress examine the recommendations of the National Academy of Sciences and the changes being designed and implemented by the President's Food Safety Council before considering such drastic measures as the creation of a whole new government bureaucracy.

As stated in our written comments, our system is not so flawed that it needs to be razed. It simply needs an upgrade and some remodeling.

Again, Mr. Chairman, I thank you for the opportunity to provide testimony to this Subcommittee and welcome any questions you or other Members may have.

Thank you.

Senator VOINOVICH. Thank you. Dr. Zawel.

TESTIMONY OF STACEY ZAWEL,[1] Ph.D., VICE PRESIDENT FOR SCIENTIFIC AND REGULATORY POLICY, GROCERY MANUFACTURERS OF AMERICA

Ms. ZAWEL. Thank you, Mr. Chairman and Senator Durbin for the opportunity to come before you today to talk about this very important issue. As you know, my name is Stacey Zawel, and I am

[1] The prepared statement of Ms. Zawel appears in the Appendix on page 124.

Vice President of Scientific and Regulatory Policy for the Grocery Manufacturers of America.

And like I said, I definitely welcome the opportunity to come to talk to you and recommend ways to refine but not replace our Nation's food safety system. If we were starting from the beginning and had the luxury of creating a food safety system from scratch, GMA would recommend that the system be based on four fundamental principles.

First, regulatory controls would rest on science-based assessments of risk, not speculative hazards. Second, education about proper methods of food handling and preparation would be provided at all stages of the food chain.

Third, adequate staffing and resources would be provided to administer this food safety system. And, fourth, industry and all sectors of government would pledge to work together in a coordinated manner to maximize food protection.

But the fact of the matter is we are not starting from scratch. We already have a food safety system in place. Critics argue that it is fatally flawed by a lack of coordination among the responsible agencies and senseless duplicative effort. They are wrong. The existing system is a successful partnership among government, industry and consumers, the diversity of the regulatory players adds a breadth and a depth of experience that is crucial in addressing the multi-faceted nature of the food safety challenge.

The President's Council on Food Safety, which includes Secretary Shalala and Secretary Glickman, is working on a strategic food safety plan that will focus on enhancing cooperation among the responsible Federal agencies. Planned measures include a unified food safety budget and a single research plan. In the face of this commitment to enhance coordination at the highest levels of government, it is simply ludicrous to suggest that the present food safety system must be entirely scrapped.

We need to work with the successful system we have, giving the Council on Food Safety time to make the adjustments necessary to perfect it. Any other course would be enormously disruptive and very expensive.

GMA believes, therefore, that the question we should be asking today is not necessarily how can we build a food safety system from scratch but how can we assist the Council on Food Safety in improving the one that we have?

GMA would suggest a renewed focus on the four basic principles I discussed earlier. The first one being that the food safety system must be based on science. Especially as food production, processing and distribution increases in complexity and sophistication, we must rely upon scientific techniques to detect and address potential food safety hazards. We have to identify and fight the true causes of foodborne illness with the right scientific weapons and those weapons can only be developed and refined through laboratory research and practical testing.

We are starting to achieve some of the benefits a science-based approach can bring and every effort should be made to ensure that this direction continues. For example, new techniques to reduce bacterial contamination such as irradiation and certain chemical compounds are being developed that offer encouraging results.

USDA's adoption of the hazard analysis critical control point systems approach, a process control originally developed and used voluntarily by the industry has the potential to transform the antiquated meat and poultry inspection system from one based on sight, smell and touch to one founded on science-based assessments of risk. Although implementation challenges abound this technique and others do show some promise.

USDA, FDA, and other Federal agencies, working with the States and industry, must continue their focus on the science and research.

The second one is education and proper handling must be promoted. The handling of foods at all stages of the farm to table production chain affect safety. And everyone has a responsibility for and must be educated with respect to the proper and safe methods for handling food products.

Third, adequate resources are definitely needed and have to be properly employed. Without properly trained personnel, state-of-the-art equipment and the necessary funds an emphasis on science and research is meaningless. Although FDA has historically enjoyed respect throughout the world, the agency's reputation is being threatened by a depletion of resources for food safety.

Similarly, although FSIS is better funded, the agency's labor-intensive is both costly and antiquated.

Fourth, Federal food safety agencies must also work cooperatively. Coordination is a challenge in a food safety system that draws upon these multiple disciplines, expertise, and history of several executive agencies. But replacing the successful system we have with a single agency is not a magic bullet for enhancing food safety. Moving boxes around on the government's organizational chart simply will not make food any safer.

And in conclusion, what I think we need to do is focus on the Council on Food Safety that has already created a coordinated food safety system, united by a single budget and a research plan that the proponents of S. 1281 are seeking. Before embarking upon an expensive, disruptive reorganization, we owe it to the American people to see if the Council's strategic plan and related activities can address any challenges that exist and move the country to a new level of food safety and protection.

That concludes my remarks and thank you very much for the opportunity to testify today.

Senator VOINOVICH. Thank you.

My impression is that the problem today in the country is a lot more severe than it was, say, 25 or 30 years ago, in terms of more food being processed and more people buying pre-packaged things and the rest of it.

That is the first impression I have gotten from this testimony. Second, that the diseases that are out there are a little more rampant than they were in the past and are more diversified than what we have encountered in the past.

When did the Council on Food Safety get organized? When were they brought together to talk about looking at this, do you know?

Ms. APPLEBAUM. Approximately a year ago.

Senator VOINOVICH. A year ago. The President has been in office 7 years. Go back and look at the studies about this problem which

is, by the way, like so many other problems in the Federal Government. Just unbelievable. GAO report after GAO report after GAO report says that this is something that should be done and everyone says they are going to do something about it, but it does not happen.

From what I can see from listening to this testimony, this is all over the lot. Dr. Zawel, why is it that you think that it would be terribly disruptive and cause all kinds of problems and so forth? I agree with a lot of what you said. This should be done, and this should be done, and this should be done. But, you know something? It hasn't been done for a long time.

I know from my experience in government that when you have people all over the lot, everybody has got to get coordinated. We have, frankly, Senator Durbin, too many committees looking at too many things, and you cannot coordinate. It is just mind-boggling.

Dr. Applebaum, why don't you think it makes sense to take this stuff, get it on the table, try to reorganize it and get one agency and start from scratch and get the job done and do it right?

I would think that industry would welcome it. You have one group coming in, another group coming in. I was just talking to the Ohio director of agriculture, and they are trying to get the State organized because it is not as coordinated as it ought to be.

I would like your comments.

Ms. ZAWEL. Well, let me just reflect some of what I said in my statement which is that our, I guess, opposition to a single food safety agency does not, at the same time, reflect that we do not think there are problems with the current system. There are some real challenges and that the system has been developed, as Dr. Applebaum has said, through a long history of events, which has brought us to where we are today. And, so, I do not think that I will necessarily go to the mat and say, every single aspect of today's current system is definitely ideal. I think we definitely need increased coordination, and all the other things that we called for.

What I think would be terribly disruptive is to just decimate everything that we have, build brand-new infrastructures and build brand-new agency with a single head. I do not know. I am truly not convinced that that, in and of itself, is going to result in all this food safety challenge just going away.

Senator VOINOVICH. Well, one thought that I have had is that if you are going to do this, I am not sure you would create a whole new agency. I would probably determine what agency is most involved in this area, perhaps the Department of Agriculture, and say, they are the most into this and then try to figure out how FDA could be folded into that. I would not start with a brand-new infrastructure. I do not think that would make the most sense, and would try to work out some system of doing it that way.

Ms. ZAWEL. I think that with respect to coordination, which I think is probably one of the biggest challenges that any infrastructure has and certainly this one where we have multiple agencies, it is a challenge to coordinate. But at the same time if you look at any one organization, whether it is Congress or whether it is one single company, there is always challenges to coordinate. There are always going to be turf battles. So, the key to necessarily decimating all the turf battles is well—which I think is one of the big-

gest issues that you guys have in recommending the agency and making it more effective. I am not sure that that key is one agency, in and of itself.

Senator VOINOVICH. I would add that it depends on where these responsibilities are in an agency. I have been through this as governor, and we formed cabinet councils to coordinate, but the issues that we were coordinating had relative priority in those agencies.

The issue is where does this particular matter fit into the overall structure of an agency, and is it way down in Health and Human Services, which has tremendous responsibility?

You just wonder how much attention does this particular area get from that agency, and would it receive a lot more attention if it were, say, located in the Department of Agriculture?

Any other comments, Dr. Applebaum?

Ms. APPLEBAUM. Yes, Mr. Chairman, if I could just make some comments in regards to your observation. There seems to be, I will use the term, an epidemic, if you will, that you relate to foodborne disease. In that regard there is heightened awareness. The public is more aware of the fact that there is illness that can be conveyed through the food. So, there is a heightened awareness and people are more aware of the fact that there could be a food-related issue associated with the disease.

And there are also more virulent organisms that we have to be cognizant of. The organisms that we are dealing with today are not the same ones we dealt with 25 or 50 years ago. But we also must be cognizant of the fact that there are different practices that we are following as consumers.

We are looking more and more towards less processed. We do not necessarily cook our food like we did in the past. There are differences in education that was done in the past than that done currently.

So, there are a whole lot of factors involved in terms of what is being implicated and blamed on, if you will, the increases in illnesses. The food industry does not take even one illness with any type of frivolity or look at it in a trivial way. We are very much concerned with that and it is very important.

I want to get back also to the second point that you raised with Dr. Zawel; that is, Do you not think that the best way to the end, the means to the end in this regard, is just to focus everything on one particular agency? Let us have one body, one entity, a body that we can go to and then we can get all these things fixed.

I think we all share the common goal of enhancing and improving the safety of our food supply. That is first and foremost in NFPA's concern and the members that both Dr. Zawel and I represent. The difference here is that we feel the solution to this problem needs a plan first, and the plan we view is a single food safety policy. Put the policy in place. Then, in terms of whatever house it is in, that will come later.

We are looking now in terms of the advancements that have been done to date related to the NAS report as well as the President's Food Safety Council. There have been advancements made; even though they have only been in place for a year, progress is being made.

We are looking at this, I am looking at this, our association is looking at this in terms of the advancements being made. Our food supply is not perfect, but there are things that have to be done. Better coordination, better integration, having everything based on sound science. But do we pull back and stop the advancement when there is advancement being made only to retract and take another direction that has no justification? There is not any evidence as to whether or not a single food safety entity is the best means to the end.

That is our basic difference in this regard. We would like a plan. We would like the plan based on a single food safety policy; then enact that policy. It is the policy that is going to ensure the safety of the food supply, not a single entity, not a single agency, in and of itself. Can there be consolidation? Absolutely. Can there be consolidation of current statutory authority? Absolutely.

We have been working on that for quite a long time. But to just demolish a system that is working and working effectively and is the model that the rest of the world is looking towards in order to pattern themselves, we do not think makes a lot of sense.

Senator VOINOVICH. Thank you.

Yes, Ms. DeWaal.

Ms. DEWAAL. Thank you, Senator Voinovich.

I want to introduce, to pick up on another line that you were talking about and that is the relationship with the State Governments. I went to a meeting of the Association of Food and Drug Officials and these are the State people who really spend a lot of time regulating food. And they spent a lot of time talking to me about their concerns about the current Federal system.

The State lab example I have given you. They have four different testing protocols depending on which Federal agency they are preparing a food sample for.

In the area of outbreak investigation, the State will initiate an outbreak investigation but until they know what food is implicated, who do you call? And there is no ghost busters here. There is no food busters. They cannot even call a Federal agency, regulatory agency until they know whether it is a USDA or an FDA regulated food.

In the area of State inspection there was a lot of concern right now USDA and FDA are developing new systems. And I am really encouraged that they are doing that to work more closely with their State partners. So, if a State inspector goes into a food plant you will not have a Federal inspector go in the next day.

Well, the way they are doing this is with little laptop computers that these State inspectors will carry around with them and they will link-in electronically with the Federal system.

Well, what if we have a laptop which is the USDA laptop and a laptop which is the FDA laptop and then they still have got their State laptops. There has to be a better system.

We have 50 States who work on food safety. Every State has food safety responsibilities. And they are trying to link up with these multiple Federal agencies and they are having a hard time.

I just want to talk on the Department of Agriculture issue. I understand that it is very appealing to think that you could maybe house everything over at USDA. And I think there is a big trust

issue, though. And when President Nixon thought about forming the Environmental Protection Agency there were environmental functions spread out all over the Federal Government. And many of them were at the Department of Agriculture. But he decided that they needed, first of all, to create a new infrastructure to get the right focus on environmental protection and we have seen real results from that.

And, second, he did, he formed the structure first. We just heard from NFPA that they want the plan first and the structure second. Well, that is not what happened when President Nixon looked at it. He formed the structure first and then Congress passed the laws that developed the plan. The Clean Water Act, the Clean Air Act, and many other laws which that agency now enforces.

So, and in Canada, today, they are looking at more gradually combining food safety functions but they formed the structure, an independent inspection agency first and now they are just getting around to changing the laws.

So, I think those are some things that you should think about as you consider that. Forming a plan first may take us 10 years. I am not sure that we can afford that.

Senator VOINOVICH. Any other comments? I know that Senator Durbin has some questions.

Ms. DONLEY. I would just like to, if I might, Senator Voinovich, to your point of I wrote down here that it sounded like you were suggesting perhaps to fold it into an existing agency or department. And then you mentioned a point that I brought up as well that there in HHS, for instance, you used the example that it is so huge, it has so many responsibilities that there is a lack of attention. And I say that that is also the case in USDA.

But if we are really going to do something and really take it the next step I think we should take it completely and make the next step that, make the complete move. And give something that is going to give the public confidence. The public is concerned with what it views as a conflict of interest in agencies that have marketing responsibilities and trade responsibilities also being the regulators. And, therefore, that is why we really see the need for this agency to be independent.

Senator VOINOVICH. Thank you.

Senator DURBIN. I would like to note that we have got a vote. The buzzer is coming up.

Senator DURBIN. That is good news for the panel. [Laughter.]

Because I will try to wrap up very briefly.

Senator VOINOVICH. Yes. Because I think after that we probably should adjourn.

Senator DURBIN. I will. I will just ask a few questions and then we can both leave to vote or you can leave early if you would like. It is your decision, Mr. Chairman.

Thank you for your testimony. I appreciate all of you being here and Nancy Donley, an old friend, thank you for reminding us that this is a life and death issue because your family was touched by that tragedy. And I have never forgotten the first hand-written letter you sent me so many years ago which brought my attention to this issue.

And I just want to say very briefly, I agree with you. I think that we really have to think about the agency and its responsibilities so the mission is clear and the people understand what that mission is.

USDA, by virtue of numbers and responsibility, looks like the obvious place to turn. But it does have some conflicting responsibilities here, at least responsibilities that are not necessarily complementary to a regulatory attitude. And that is something that I would look at very carefully. As much as I like the USDA, I would have to look at that very carefully.

FDA, a smaller part of the pie, one-fourth, I think when it comes to the employees involved in it, has a major part of their responsibility, as Caroline Smith DeWaal has said, with three out of the four of the outbreaks coming through foods that were inspected or should have been inspected by that agency. And they certainly do not receive the money they deserve for the important responsibilities that we send their way.

I would like to say to the two witnesses that come from the private side, because I only have a couple of minutes here, rather than being discouraged or upset or angry or confrontational I am encouraged by what you had to say. I do not know if this is a conscious decision or maybe I am looking for that pony on Christmas morning, but I really sense that there is a change in attitude here and it is a good one and more open-mindedness about this. And I do not disagree at all with what you have said.

I mean it is really a chicken and egg, I guess it is a good analogy here, as to whether we are going to start the structure and then bring policy or start with policy and then bring structure. My guess is we are going to end up at the same place, either way.

Because once we sit down and try to explain to your manufacturers and processors why we have an inspection of one of these products every day and another one every 10 years, it is going to come together when we say there is only one way to decide this and that is science. Any other way is pure politics or commercialism. It has to be science. What is the scientifically defensible approach to this?

We are trying to sell that to Europe now so our products have a chance. We are as inclined to hyperbolic rhetoric as anybody on this side and I plead guilty. But we are not trying to do anything drastic or demolish or disrupt.

I really think that if this is going to be done sensibly that it is going to have to be a reasonable transition here. We are bringing together a lot of ideas, a lot of science, a lot of agencies, and a lot of players trying to make this thing work better for American families. If we do not do it carefully we could lose ground rather than gain ground.

So, more than anyone here as the champion of this cause, I will tell you I am determined to make sure it is done right if it is ever done at all. And that is not an overnight, super agency, conceived and created by one piece of legislation. I do not think it will ever happen that way, nor should it.

We should really think this thing through and make sure when it is done that the change is for the better.

The last point I will make, and I will give you a couple of minutes to respond if you would like, is I met with an executive of a

major company, and I will not go any further to identify him, last year for breakfast. And he said, what are you working on? And I said, food safety. And his company makes a lot of food products. He laughed at me. Why are you doing this? He said, we have the safest food supply in the world. Cannot you find something better to do with your time?

And that kind of took me aback and I did not quarrel with him, I respect him very much. And I said, well, I think it is an important issue. It was not but weeks later that he got hit with a major, multi-million dollar problem in this company involving food safety. And he was on the phone to me talking about food safety.

As confident as we are of the goodness of our food supply, as much as we want to see it continue to be good, we know that terrible things can happen and we want to do our best to avoid them. And that is really what I am about here.

I do not think that there is strength in the diversity of regulatory players, as has been said here, in one of the testimonies. I really think we have too many different voices. This Tower of Babel mentality where these coordinating meetings are going on night and day to try to keep these agencies working together. Would it not make a lot more sense to bring them all under one roof, on a science-based, sound theory and approach on food safety?

I hope it will.

Senator VOINOVICH. I would like to make one point before we have to go vote on the agriculture bill.

We talked about the needs and so forth. But one of the big areas that we need to be concerned about is exporting our products. We are seeing more and more artificial barriers put up to our products, saying they are not healthy or they are this or they are that. I think that we need to be a lot more authoritative and united in terms of the quality of our products in terms of how to deal in the world market place. Because they are going to find any excuse they can to keep us out of that market place today.

So, it is just another ingredient that may not have been around 25 or 30 years ago.

Senator DURBIN. That is all I have.

Senator VOINOVICH. Any comments?

Senator DURBIN. Rebuttal?

Ms. ZAWEL. I would just conclude and say that I think that we have the same interests in mind in terms of assuring that we have the utmost safest food supply in the United States and obviously we would certainly encourage, as we have, multinational companies that we represent, that that same product is safe as it goes across the oceans. And, initially I think Senator Durbin, you had said that you wished the industry would stop resisting or Chairman Voinovich, I cannot remember which one. And, I think that that is not necessarily, and I hope you recognize, where we are at. We definitely want to work towards ensuring and enhancing the food supply as much as we possibly can further. But that we believe, with all due respect to Caroline, that the plans and the policies that change and affect that system to make it better are really what is key and not necessarily the structure.

Senator VOINOVICH. I would like to finish with one remark. I have a lot of confidence in the food industry that wants to put out

the best products it can. They want quality products. They know that if they have problems that it is going to hurt the business. I think that sometimes those of us in government forget that the private sector is doing everything it possibly can to make sure that there are healthy products out there. Because they understand how important it is to the safety of the public and also to their businesses.

Thank you very much.

The meeting is adjourned.

[Whereupon, at 12:54 p.m., the Subcommittee was adjourned.]

Consolidation of Food Safety Regulation: Not Just A New Idea

Divided responsibility for regulating food production has resulted in a regulatory program which is often duplicative, sometimes contradictory, undeniably costly, and unduly complex." . . . We believe the bifurcated food regulation system should be **unified in a single agency**."

[Senate Committee on Governmental Affairs, "V. Regulatory Organization, Chap. 4 "Food Regulation: A Case Study of USDA and FDA" in *Study on Federal Regulation*, 95th Cong., 2d sess., **December 21, 1977**, S.Rept. 95-91, p. 139]

Recommendations for the Department of Health and Human Services:
"HHS03: Develop a National, Uniform Inspection System to Ensure a Safe Food Supply: Responsibility for food safety should be **consolidated into a single agency**, and policies and inspection systems should be implemented on an objective, scientific basis."

["*From Red Tape to Results: Creating a Government That Works Better and Costs Less*" Report of Vice President Al Gore and the National Performance Review, Appendix A: Major Recommendations By Agency, **September 7, 1993**, p. 140]

(A)

What Former Food Safety Officials Say . . .

"Such fundamental structural reform may be in order. The current system does not make the best possible use of available resources, it complicates the implementation of consistent food safety strategies, and it is at odds with the clear assignment of responsibility and accountability . . ."

Michael R. Taylor
Deputy Commissioner for Policy, FDA, 1991 to 1994
Administrator of FSIS, USDA, 1994 to 1996
Food and Drug Law Journal, Volume 52, Number 1 (1997)

"Each Agency operates under a different mandate, governed by different laws and answering to different constituencies and traditions. To ask them to voluntarily ignore this history is naive. There needs to be a permanent structure focused on food safety to meet the enduring needs of the American people."

Sanford A. Miller, PhD.
Director, Center for Food Safety and Applied Nutrition, FDA, 1978 to 1987
Testimony, U.S. Senate subcommittee hearing, August 4, 1999

—continued on next chart

(B)

What Former Food Safety Officials Say . . .

"It is ironic that the national government deals with food safety issues in such a haphazard, inconsistent manner. The food industry long ago mastered the problem of mass-producing and shipping products all over the world. Meanwhile, the federal government has failed to keep pace with this revolution. Perhaps it is time to take a serious look at combining the food safety resources of the federal government under one roof. Perhaps we need a single agency with just one mission and one consistent set of food safety goals."

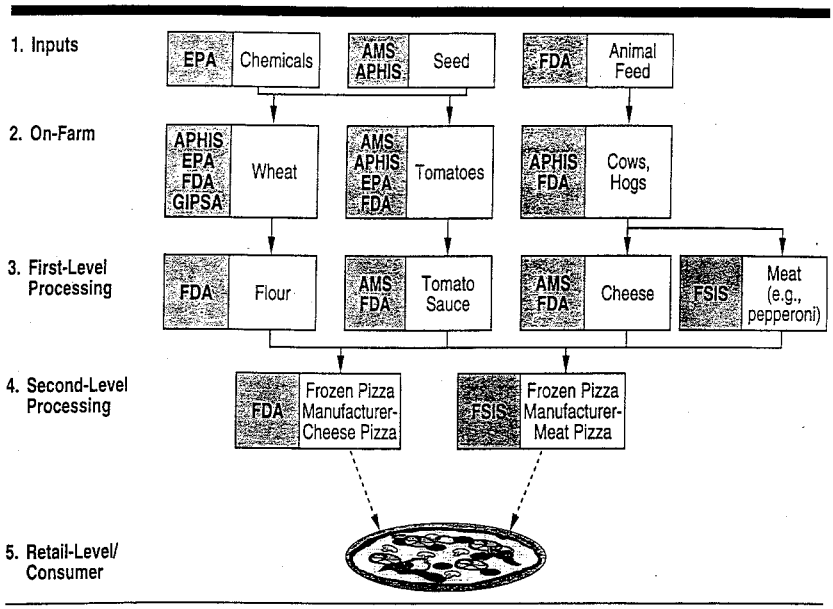
David A. Kessler, MD
Commissioner of the Food and Drug Administration, 1990 to 1997
Comments given at "Food Irradiation: The Next Step in Food Safety"
April 7, 1998

"The proposed Safe Food Act responds to the NAS recommendation. It applies to government the same standard government applies to the food industry in the Hazard Analysis and Critical Control Point regulatory system. It would create a structure that has clear lines of responsibility and accountability."

Carol Tucker Foreman
Assistant Secretary of Agriculture for Food and Consumer Services, 1977 to 1981
Testimony, U.S. Senate subcommittee hearing, August 4, 1999

FRAGMENTATION NO MATTER HOW YOU SLICE IT

Figure 1: Federal Agencies Responsible for Ensuring Safe Pizza



Ensuring Safe Food from Production to Consumption

Institute of Medicine, National Academy of Sciences
August, 1998

Recommendation IIIa:

"To implement a science-based system, Congress should establish, by statute, a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education."

"The committee found that the current fragmented regulatory structure is not well equipped to meet the current challenges. The key recommendation in this regard is that in order for there to be successful structure, one official should be responsible for federal efforts in food safety and have control of resources allocated to food safety."

"This recommendation envisions 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."

"[T]he structure should also have a firm foundation in statute and thus not be temporary and easily changed by political agendas or executive directives."

"Many members of the committee are of the view that the most viable means of achieving these goals would be to create a single, unified agency headed by a single administrator. . ."

Food Safety Under a Single, Independent Agency
Not a New Idea

1969	White House Conference on Food	Recommended that there be one federal regulatory policy with respect to safety, sanitation, identity, and labeling of foods. Recommended consideration of the establishment of a single federal regulatory agency for foods.
1970	GAO — Food Inspection Report	Criticized the overlapping inspection activities of USDA, FDA, and other federal agencies and the lack of consistency in their requirements, procedures, and concepts.
1972	Ralph Nader Report —Sowing the Wind	Found that food inspection "remains embarrassed by departmental conflicts of interest and overlapping jurisdictions in USDA and FDA." The report recommended the creation of a new food safety agency to enhance protection of public health.
1977	Senate Governmental Affairs Report	"We believe that the bifurcated food regulatory system should be unified in a single agency."
1992	GAO — Risk-Based Food Safety Inspection Report	Recommended that "Congress hold oversight hearings to evaluate options for revamping the federal food safety and quality system, including creating a single food safety-agency responsible for administering a uniform set of food safety laws."
1998	National Academy of Sciences — *Ensuring Safe Food from Production to Consumption*	Recommended the establishment of a unified and central framework for managing federal food safety programs. "Many members of the committee are of the view that the most viable means of achieving these goals would be to create a single, unified agency headed by a single administrator."
1999	GAO Performance & Accountability Series	" . . . The highly fragmented federal food safety structure needs to be replaced with a uniform, risk-based inspection system under a single food safety agency."

GAO's Consistent Call for Single Food Safety Agency

"To develop a uniform, risk-based inspection system, we recommend that the Congress hold oversight hearings to evaluate options for revamping the federal food safety and quality system, including (1) creating a single food safety agency responsible for administering a uniform set of food safety laws...."

GAO/RCED-92-152, June 26, 1992, p. 6

"Duplicative inspections by federal agencies also result in an inefficient use of resources. . . . Instead, a single agency could take the lead responsibility for inspecting to ensure that food establishments comply with all food safety laws and regulations, ceding when necessary to the enforcement authority of the appropriate agency if violations are found."

GAO/RCED-92-152, June 26, 1992, p. 45

"In 1977, the Senate Committee on Governmental Affairs recommended that the responsibility for food regulation be unified under a single federal agency and federal statute....This argument has become even more convincing since 1977."

GAO/RCED-92-152, June 26, 1992, pp. 57-58

"Our analysis of the advantages and disadvantages of the three options indicates that creating a single food safety agency is the most effective way for the federal government to resolve long-standing problems, deal with emerging food safety issues, and ensure the safety of our country's food supply."

GAO/RCED-92-152, June 26, 1992, p. 61

"GAO believes that creating a single food safety agency is the most effective way for the federal government to overcome long-standing problems, deal with emerging food safety issues, and guarantee the safety of the nation's food."

GAO/T-RCED-94-71, November 4, 1993

"In our view, creating a single food safety agency is the most effective way for the federal government to resolve long-standing problems, deal with emerging food safety issues, and ensure the safety of our country's food supply."

GAO/T-RCED-94-223, May 25, 1994, p

"In previous reports and testimonies, we concluded that the most effective way for the federal government to resolve long-standing problems, deal with emerging food safety issues, and ensure a safe food supply is to create a single food safety agency responsible for administering a uniform set of laws."

GAO/T-RCED-94-223, May 25, 1994, p. 1

"Our testimony is based on over 60 reports and studies issued over the last 25 years by GAO, agency Inspectors General, and others." The report's Appendix lists:

- 49 GAO reports since 1977
- 9 USDA Office of Inspector General Reports since 1986
- 1 HHS OIG Report in 1991
- 15 Reports and studies by Congress, Scientific Organizations and Others since 1981

"To resolve long-standing problems and guarantee the safety of the food supply, a single food safety agency administering a uniform set of laws should be created."

GAO/T-RCED-94-223, May 25,1994, p.1

"Ideally, as GAO has stated in the past, food safety would be better ensured if the Congress created a single food agency responsible for carrying out the requirements of a cohesive set of food safety laws."

GAO/RCED-94-192, September 26, 1994, pp. 5, 44

"We believe the existing federal food safety structure needs to be replaced with a uniform, risk-based inspection system under a single food safety agency."

GAO/T-RCED-98-24, October 8, 1997, p.1

"Since 1992, we have frequently reported on the fragmented and inconsistent organization of food safety responsibilities in the federal government... To address this problem, we recommended the formation of a single food agency."

GAO/RCED-98-103, April 30, 1998, p. 14

"In the past, we have recommended a single food safety agency to correct the problems created by this fragmented system."

GAO/RCED-98-224, August 6, 1998, p.4

SINGLE FOOD SAFETY AGENCY CALL -- NOT A NEW IDEA: PIZZA TOPPING DISCREPANCY CITED OVER TWO DECADES AGO

1999:

"Subtle differences in food products often dictate which agency regulates a product and what actions it takes. A case in point: USDA is responsible for inspecting plants that produce open-faced meat sandwiches and pizzas with meat toppings. It conducts these inspections at least once each operating shift. On the other hand, the Department of Health and Human Services' Food and Drug Administration (FDA) is responsible for inspecting plants that produce traditional meat sandwiches and non-meat pizzas. It conducts inspections of plants under its jurisdiction, on average, once every 10 years. . . ."

". . . The highly fragmented federal food safety structure needs to be replaced with a uniform, risk-based inspection system under a single food safety agency. . . .

[GAO Performance and Accountability Series, Major Management Challenges and Program Risks: Department of Agriculture, January 1999].

1977:

". . .the current food regulatory system results in duplication and inconsistency. As a result of the dual food inspection system, more than 2,000 plants are considered joint USDA-FDA responsibilities, and are subject to inspection by both agencies. The waste which stems from these duplicative inspections is undoubtedly excessive. Precious resources needed for effective food regulation are squandered."

"One case involved Saluto, a medium sized producer of frozen pizzas. About 99 percent of the firm's products are meat pizzas and the other 1 percent contain only cheese. The firm is under continuous USDA inspection and is also inspected by FDA. The resident USDA Inspector told GAO that he performs the same plant sanitation inspection regardless of whether meat or non-meat pizzas are produced. GAO found that the FDA's inspection of plant sanitation conditions resulted in a duplication of effort."

". . .When FDA learns that adulterated canned mushrooms are in the possession of a sausage pizza manufacturer, immediate enforcement action depends upon FDA's prompt notification of USDA (although FDA could itself take enforcement action if the mushrooms were purchased for the non-meat pizza)."

[Senate Committee on Governmental Affairs, "Study on Federal Regulation"; Volume V, Regulatory Organization, December 1977]

U.S. Department of Agriculture

Department of Health and Human Services

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), Department of Health and Human Services (HHS), 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 increasingly important. 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 inspection 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 margerine 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 program. 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 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 later discuss 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; and
- 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 foodborne 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 are already 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 epidemiological 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 foodborne 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 foodborne 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 additional funding to HHS and USDA for research and risk assessment. We are grateful for Congressional 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 consumers 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 distributers, 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 handling and cooking requirements. 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.

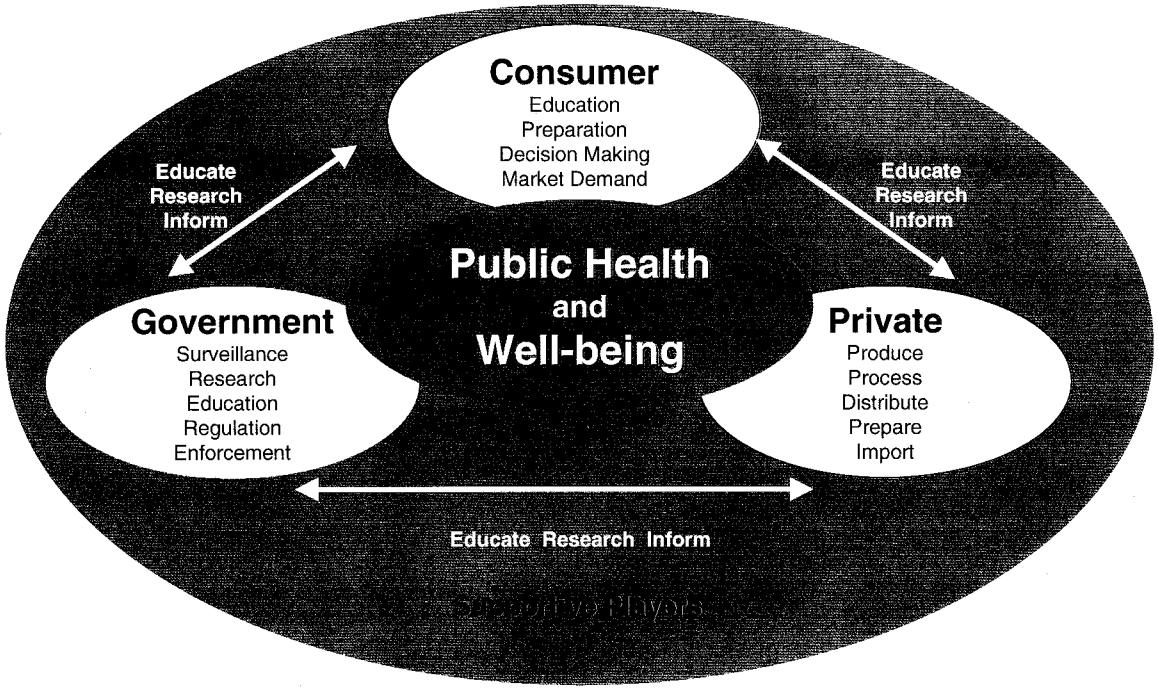
As part of this process, the Council will conduct a thorough assessment of the existing statutes, evaluate the degree of regulatory flexibility that currently exists and determine what improvements will require statutory changes. In addition, the Council will conduct an assessment of structural and organizational 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.

An Effective Food Safety System



From: Ensuring Safe Food, National Academy Press, 1998.

U.S. Department of Agriculture

Department of Health and Human Services

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 plans 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 eight 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.

United States General Accounting Office

GAO

Testimony

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

For Release
on Delivery
Expected at
10:30 a.m. EDT
Wednesday
August 4, 1999

FOOD SAFETY

U.S. Needs a Single Agency to Administer a Unified, Risk-Based, Inspection System

Statement of Lawrence J. Dyckman,
Director, Food and Agriculture Issues
Resources, Community, and Economic
Development Division

GAO/T-RCED-99-256

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the need to revamp the federal food safety system. Each year, millions of people become ill and thousands die from eating unsafe foods. As we have stated in previous reports and testimonies, fundamental changes to the food safety system are needed, including moving to a uniform, risk-based inspection system, administered by a single agency. (See Related GAO Products.). My testimony today provides an overview of our work on the problems resulting from the current fragmented food safety system and discusses our views on where in the federal government food safety inspection responsibilities should reside.

In summary, the structure of the current food safety system—which costs the federal treasury more than $1 billion annually—hampers efforts to address public health concerns associated with existing and newly identified food safety risks. The fragmented system was not developed under any rational plan but was patched together over many years to address specific health threats from particular food products. Efforts to address food safety concerns—particularly changing health risks—are hampered by inconsistent and inflexible oversight and enforcement authorities, inefficient resource use, and ineffective coordination.

A single food safety inspection agency responsible for administering a uniform set of laws is the most effective way for the federal government to resolve these long-standing problems, deal with emerging food safety issues, and better ensure a safe food supply. While we believe that this would be the most effective approach, we recognize that there are short term costs and other considerations associated with setting up a new government agency. A second option, though less desirable, would be to consolidate food safety activities in an existing department. In such an event, consolidating these activities--either in the U.S. Department of Agriculture (USDA) or the Department of Health and Human Service's (HHS) Food and Drug Administration—presents benefits and drawbacks. Regardless, it is unlikely that fundamental, long-lasting improvements in food safety will occur until food safety activities are consolidated under a single agency and the current patchwork of food safety legislation is altered to make it uniform and risk-based.

BACKGROUND

Twelve different agencies administer as many as 35 laws that make up the federal food safety system. Two agencies account for most federal spending on, and regulatory responsibilities for, food safety: The Food Safety and Inspection Service (FSIS), under USDA, is responsible for the safety of meat, poultry, and some eggs and some egg products, while FDA is responsible for the safety of most other foods. Other agencies with food safety responsibilities and/or programs include HHS' Centers for Disease Control and Prevention; USDA's Agricultural Marketing Service, Animal and Plant Health Inspection Service, Agricultural Research Service, and Grain Inspection, Packers, and Stockyards Administration; the Department of Commerce's National Marine Fisheries Service; the Department of the Treasury's U.S. Customs Service and Bureau of Alcohol, Tobacco, and Firearms; the Environmental Protection Agency (EPA); and the Federal Trade Commission. Appendix I describes the food safety roles and responsibilities of these 12 agencies and shows each agency's food safety funding and staffing level for fiscal year 1998.

Despite the more than $1 billion spent annually on the current food safety system, food safety remains a concern. For example, in late 1998, 101 people became ill from eating hot dogs contaminated with listeria—a pathogenic bacterium. Of those who became ill, 15 died and 6 suffered a miscarriage or stillbirth. In May and June of this year, about 120 people became ill in the Richmond, Virginia, area because they ate at a local restaurant where some of the food contained eggs contaminated with the pathogenic bacterium Salmonella Enteritidis. Because many cases of foodborne illness go undiagnosed, estimates of the actual number of incidents that occur nationally each year cover a wide range–from a low of 6 million cases to a high of 33 million cases, leading to about 9,000 deaths annually, according to CDC. In medical costs and productivity losses, foodborne illness costs the nation between $7 billion and $37 billion per year, according to USDA estimates.

CURRENT FEDERAL FOOD SAFETY SYSTEM NEEDS OVERHAUL

During the past 25 years, we and other organizations, such as the National Academy of Sciences, have issued reports detailing problems with the federal food safety system and made numerous recommendations for change. While many of these recommendations have been acted upon, improvement efforts have fallen short, largely because the separate agencies continue to operate under the different regulatory approaches implicit in their basic authorities. Consequently, it is unlikely that fundamental, lasting improvements in food safety will occur until systematic legislative and structural changes are made to the entire food safety system.

The federal regulatory system for food safety evolved haphazardly. As the understanding of foodborne hazards grew, food safety concerns changed. Addressing one new worry after another, legislators amended old laws and enacted new ones. Programs emerged piecemeal, typically in response to particular health threats or economic crises. The laws not only assigned specific food commodities to particular agencies but also provided the agencies with different authorities and responsibilities, reflecting significantly different regulatory approaches. The resulting inflexible and inconsistent oversight and enforcement authorities, inefficient resource use, and ineffective coordination efforts have hampered and continue to impede efforts to address the public health concerns associated with existing and newly identified food safety risks. The following examples represent some of the problems we have found in reviewing the nation's food safety system:

- Federal agencies are not using their inspection resources efficiently. Because the frequency of inspection is based on the agencies' regulatory approach, some foods and establishments may be receiving too much attention while others may not be receiving enough. Firms that process food products posing similar health risks to the public are inspected at widely different frequencies, depending on which agency—and thus which regulatory approach—governs them. Although the level of health risk is similar for all animal products, meat and poultry plants regulated by FSIS are inspected at least daily, while firms that are under FDA's jurisdiction such as, processors of rabbit, venison, and quail, are generally inspected, on average once every ten years. Furthermore, food establishments are sometimes inspected by more than one federal agency because they participate in programs or process foods that are under the jurisdiction of different agencies.

- Responsibilities for the oversight of chemical residues in foods are fragmented among FDA, USDA, and EPA. As a result, chemicals posing similar risks may be treated differently by the agencies because they operate under different laws and regulations. Furthermore, the states use different methodologies for determining the amount of fish that can be safely consumed. For example, under the Clean Water Act, EPA is required only to consider risks to human health and aquatic life when conducting water quality assessments. However, under the Federal Food, Drug, and Cosmetic Act, FDA is allowed to consider both health risks and benefits in establishing tolerances for chemical contaminants in food. Therefore, as we reported in 1994,[1] FDA standards for some chemicals are often less stringent than those developed by EPA. This inconsistency is often reflected in the methodology the states use to determine the levels of fish consumption considered safe. According to EPA officials as of 1998, about 30 states use a methodology similar to EPA's and about 20 states use a different methodology such as one similar to FDA's.[2] Thus a fish considered unsafe to eat in one state may become safe to eat if it swims to another state.

- Enforcement authorities granted to the agencies also differ. USDA agencies have the authority to (1) require food processors to register so that they can be inspected, (2) presume that food firms are involved in interstate commerce and are thus subject to regulation, (3) prohibit the use of processing equipment that may potentially contaminate food products, and (4) temporarily detain any suspect foods. Conversely, FDA, without such authority, is often hindered in overseeing food processors.

- Oversight of imported food is inconsistent and unreliable.[3] To ensure the safety of meat and poultry imports, FSIS has a statutory mandate to require that each of the countries exporting meat and poultry to the United States demonstrate that it has a food safety system that is equivalent to the United States' system. Under the equivalency requirement, FSIS has shifted most of the responsibility for ensuring product safety to the exporting country. The exporting country performs the primary inspection, allowing FSIS to leverage its resources by focusing its reviews on verifying the efficacy of the exporting countries' systems. In contrast, FDA lacks the legal authority to require that countries exporting foods to the United States have food safety systems equivalent to ours. Without such authority FDA must rely primarily on its port-of-entry inspections, which covered less than 2 percent of shipments in 1997, to detect and bar unsafe foods. Such an approach has been widely discredited as resource-intensive and ineffective.

- Fragmented federal responsibilities also cause problems for the food industry because communication about health risks associated with contaminated food

---

[1] Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food, (GAO/RCED-94-192, Sept. 26. 1994).

[2] EPA officials stated that further review of the 20 states using a methodology different than EPA's may reveal that some of them are actually using a methodology similar to EPA's.

[3] Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable (GAO/RCED-98-103, Apr. 30, 1998).

products is impaired. As we reported in April 1998,[4] nearly every day during May, June, and early July 1997, officials from FDA, FSIS, and the Environmental Protection Agency participated in conference calls to discuss the latest developments in the investigation of animal feeds contaminated with dioxin (a suspected carcinogen) to determine what actions, if any, the agencies needed to take to protect consumers. While FDA and FSIS worked together to make decisions on the preferred course of action, each agency was responsible for communicating its decisions to the producers or processors under its jurisdiction. However, complete information was not communicated to all affected parties. For example, when officials from FDA, the agency responsible for regulating animal feed, met with meat and poultry producers, their primary concern was with the contaminated feed, not with the animals that had consumed it. Thus, they did not necessarily tell these producers of the actions they should take for their affected animals. FSIS, the agency responsible for regulating meat and poultry processors, sent word of the testing requirements to meat and poultry processors and to trade associations, but it did not notify meat and poultry producers. FSIS has jurisdiction over processing plants, but not producers.

- The agencies have made attempts to coordinate their activities to overcome the fragmentation and avoid duplication or gaps in coverage, but history has shown that as time passes, such efforts frequently prove to be ineffective. We have reported in the past that unsafe conditions in food processing plants have gone unaddressed because the notifications required by coordination agreements do not always take place or the problems referred to the responsible agency are not promptly investigated.[5] As we testified before this Subcommittee last month, egg safety remains questionable, despite FSIS' and FDA's efforts to coordinate their activities on egg and egg product safety—a shared responsibility between the two agencies.[6] In 1991, an amendment to the Egg Products Inspection Act mandated that federal regulations be issued requiring the refrigeration of shell eggs. Eight years later, FSIS regulations, effective August 27, 1999, set refrigeration requirements for eggs from the packing plant through transportation to the retail level. However, FDA, which has responsibility for egg safety at the retail level has not enacted similar regulations; therefore, refrigerating eggs at the retail level is not yet required.[7]

These problems, which apply to many food products, are clearly illustrated in the regulation of pizza. Figure 1 shows the federal responsibilities for ensuring the safety of a frozen meat pizza and a frozen cheese pizza.

---

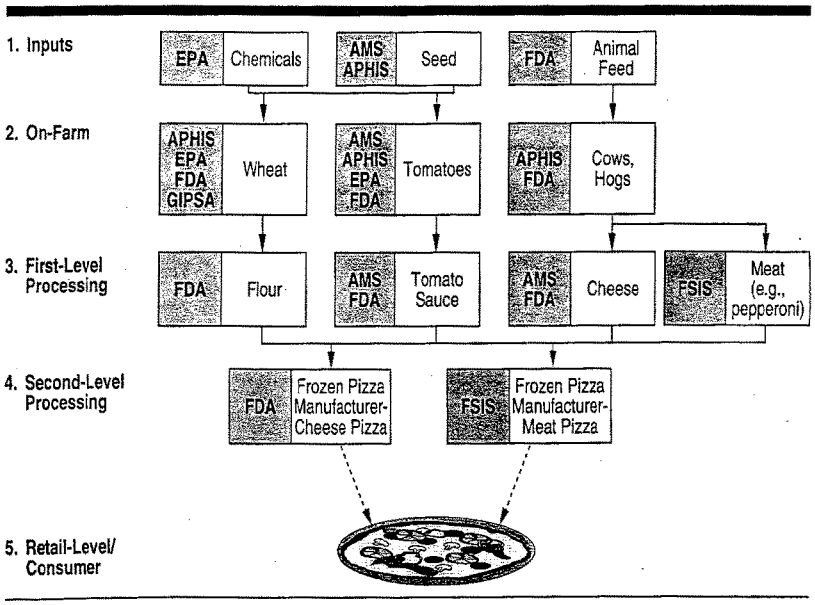
[4] Food Safety: Agencies' Handling of a Dioxin Incident Caused Hardships for Some Producers and Processors (GAO/RCED-98-104, Apr. 10, 1998).

[5] Food Safety and Quality: Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

[6] Food Safety: U.S. Lacks a Consistent Farm-to-Table Approach to Egg Safety, (GAO/RCED-99-184, July 1, 1999).

[7] On July 1, 1999, FDA announced proposed regulations for ensuring the safety of eggs that contained, among other things, refrigeration requirements for eggs at the retail level.

Figure 1: Federal Agencies Responsible for Ensuring Safe Pizza



A SINGLE AGENCY WOULD ENHANCE FOOD SAFETY

The most effective solution to the current fragmentation of the federal food safety system is consolidating food safety programs under a single agency with uniform authority. Consolidating food safety activities is hardly a new concept. Such a concept was debated in 1972 in connection with a proposed bill to transfer FDA's responsibilities, including its food safety activities, to a new independent agency, called the Consumer Safety Agency. This new agency was to be responsible for, among other things, ensuring the safety of the nation's food supply, although meat and poultry inspection was to remain in USDA.

Whether an independent single agency is preferable to a component of an existing department, as we testified in 1972,[8] is a matter of judgment upon which opinions differ. However, we continue to believe, as we testified in 1994,[9] that a single independent food safety agency administering a unified, risk-based food safety system is the preferred approach, although we recognize the difficulties in establishing a new government agency. Regardless of where a single agency is housed, what is most important are certain principles, including a clear commitment by the federal government to consumer protection, a system that is founded on uniform laws that are risk-based, adequate resources devoted to that purpose, and competent and aggressive administration of the laws by the responsible agency. Although these principles can be influenced by organizational placement, commitment to them probably depends more on public and political concern for the importance of the mission.

In this regard, we recently reported on the experiences of four countries that have consolidated or are in the process of consolidating their food safety responsibilities.[10] Two of the four—Great Britain and Ireland—were responding to heightened public concerns about the safety of their food supplies and chose to consolidate responsibilities in the agencies that report to their ministers of health. For example, the British plan to consolidate food safety activities into a single agency was largely a result of the government's perceived mishandling of an outbreak of Bovine Spongiform Encephalopathy (commonly referred to as "mad cow" disease). Public opinion viewed the agriculture ministry, which had dual responsibilities to promote agriculture and the food industry and to regulate food safety, as slow to react because it was too concerned about protecting the cattle industry.

The other two countries—Canada and Denmark—were more concerned about program effectiveness and cost saving and accordingly consolidated activities in agencies that report to their ministers of agriculture, who already control most of the food safety resources. For example, Canada did not face a loss of public confidence, as did Great Britain and Ireland, but instead faced a budgetary crisis; it therefore sought ways to reduce federal expenditures. By combining the various elements of its food inspection services, Canada expected to save about 13 percent of its food inspection budget, or $44 million Canadian ($29 million U.S.) per year.

---

[8] Hearings on the Consumer Safety Act of 1972 before the Subcommittee on Executive Reorganization and Government Research, Senate Committee on Government Operations (1972).

[9] Food Safety: A Unified, Risk-Based Food Safety System Needed, (GAO/T-RCED-94-223, May 25, 1994).

[10] Food Safety: Experiences of Four Countries in Consolidating Their Food Safety Systems, (GAO/RCED-99-80, Apr. 20, 1999).

We are not alone in calling for fundamental changes to the federal food safety system. In an August 1998 report, the National Academy of Sciences concluded that the current fragmented federal food safety structure is not well equipped to meet emerging challenges.[11] As such, the Academy report recommended that the Congress establish, by statute, a unified and central framework for managing federal food safety programs, one that is headed by a single official and has the responsibility for, and control of, resources for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.

According to the Academy report, many members of the committee believed that the most viable means of achieving food safety goals would be to create a single, unified agency headed by a single administrator—an agency that would incorporate the several relevant functions now dispersed, and in many instances separately organized, among three departments and a department-level agency. However, designing the structure and assessing the associated costs involved were not possible in the timeframe given the committee, nor were these tasks included in the committee's charge. As such, the committee did not recommend a specific organizational structure but instead provided several possible configurations for illustrative purposes. These were

- forming a Food Safety Council of representatives from the agencies, with a central chair appointed by the President, reporting to the Congress and having control of resources;
- designating one current agency as the lead agency and making the head of that agency the responsible individual;
- establishing a single agency reporting to one current cabinet-level secretary; and
- establishing an independent single agency at the cabinet level.

In response to the National Academy's report, the President established a Council on Food Safety and directed it to provide him with an assessment of the Academy report within 180 days.[12] The council was also charged with developing a comprehensive strategic plan for federal food safety activities and making recommendations to the President on how to implement the plan.

In its March 1999 report to the President,[13] the Council agreed with the goal of the Academy's recommendation that there should be a fully integrated food safety system and undertook to assess structural models and other mechanisms that could strengthen the federal food safety system through better coordination, planning, and resource allocation. In its analysis, the council said it plans to determine whether certain models of reorganization would have advantages for coordination and allocation of resources

[11] Ensuring Safe Food From Production to Consumption (Institute of Medicine, National Research Council, National Academy Press, Washington, D.C., Aug. 1998).

[12] The President's Council on Food Safety comprises, among others, the Secretaries of Agriculture, Health and Human Services, and Commerce, and the Administrator of EPA.

[13] President's Council on Food Safety Assessment of the NAS Report: Ensuring Safe Food from Production to Consumption, (President's Council on Food Safety, Mar. 1999).

while also considering how each agency's responsibilities that are not driven by food safety might affect food safety responsibilities.

To conclude, Mr. Chairman, as the United States prepares to enter a new millenium, we believe the Congress has an opportunity to transform our present food safety system into one that better protects consumers' health. Creating a single agency to administer food safety activities that are uniform and risk-based is the most effective way for the federal government to resolve long-standing problems, deal with emerging food safety issues, and better ensure the safety of our country's food supply. This completes our prepared statement. We would be happy to respond to any questions.

Contact and Acknowledgement

For future contacts regarding this testimony, please contact Lawrence J. Dyckman at (202) 512-5138. Individuals making key contributions to this testimony were Keith Oleson and John Nicholson

Food Safety Responsibilities and Fiscal Year 1998 Funding and Staffing Levels at 12 Federal Agencies

Dollars in millions

Agency	Fiscal year 1998 funding[a]	Fiscal year 1998 staffing
Food and Drug Administration (FDA), within the Department of Health and Human Services (HHS), is responsible for ensuring that domestic and imported food products (except meat, poultry, and processed egg products) are safe, wholesome, and properly labeled. The Federal Food, Drug, and Cosmetic Act, as amended, is the major law governing FDA's activities to ensure food safety and quality. The act also authorizes FDA to maintain a surveillance of all animal drugs, feeds, and veterinary devices to ensure that drugs and feeds used in animals are safe and properly labeled, and produce no human health hazards when used in food-producing animals.	$254[b]	2,796[b]
Centers for Disease Control and Prevention (CDC), within HHS, is charged with protecting the nation's public health by providing leadership and direction in preventing and controlling diseases and responding to public health emergencies. CDC conducts surveillance for foodborne diseases; develops new epidemiological and laboratory tools to enhance the surveillance and detection of outbreaks; and performs other activities to strengthen local, state, and national capacity to identify, characterize, and control foodborne hazards. CDC engages in public health activities related to food safety under the general authority of the Public Health Service Act, as amended.	15	50
Food Safety and Inspection Service (FSIS), within the U.S. Department of Agriculture (USDA), is responsible for ensuring that meat, poultry, and some eggs and egg products moving in interstate and foreign commerce are safe, wholesome, and correctly marked, labeled, and packaged. FSIS carries out its inspection responsibilities under the Federal Meat Inspection Act, as amended, the Poultry Products Inspection Act, as amended, and the Egg Products Inspection Act, as amended.	676	9,702
Animal and Plant Health Inspection Service (APHIS), within USDA, is responsible for ensuring the health and care of animals and plants. APHIS has no statutory authority for public health issues unless the concern to public health is also a concern to the health of animals or plants. APHIS identifies research and data needs and coordinates research programs designed to protect the animal industry against pathogens or diseases that are a risk to	[c]	[c]

humans to improve food safety.		
Grain Inspection, Packers and Stockyards Administration (GIPSA), within USDA, is responsible for establishing quality standards and providing for a national inspection system to facilitate the marketing of grain and other related products. Certain inspection services, such as testing corn for the presence of aflatoxin, enable the market to assess the value of a product on the basis of its compliance with contractual specifications and FDA requirements. GIPSA has no regulatory responsibility regarding food safety. Under a memorandum of understanding with FDA, GIPSA reports to FDA certain lots of grain, rice, pulses, or food products (which were officially inspected as part of GIPSA's service functions) that are considered objectionable under the Federal Food, Drug, and Cosmetic Act, as amended, the U.S. Grain standards Act, as amended, and the Agriculture Marketing Act of 1946, as amended.	[c]	[c]
Agricultural Marketing Service (AMS), within USDA, is primarily responsible for establishing the standards of quality and condition and for grading the quality of dairy, egg, fruit, meat, poultry, seafood, and vegetable products. As part of this grading process, AMS considers safety factors, such as the cleanliness of the product. AMS carries out its wide array of programs to facilitate marketing under more than 30 statutes—for example, the Agricultural Marketing Agreement Act of 1937, as amended; the Agricultural Marketing Act of 1946, as amended; the Egg Products Inspection Act, as amended; the Export Apple and Pear Act, as amended; and the Export Grape and Plum Act, as amended. AMS is largely funded with user fees.	10[d]	42[d]
Agricultural Research Service (ARS), within USDA, is responsible for conducting a wide range of research relating to the Department's mission, including food safety research. ARS carries out its programs under the Department of Agriculture Organic Act of 1862; the Research and Marketing Act of 1946, as amended; and the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended.	55	167
National Marine Fisheries Service (NMFS), within the Department of Commerce, conducts its voluntary seafood safety and quality inspection programs under the Agricultural Marketing Act of 1946, as amended, and the Fish and Wildlife Act of 1956, as amended. In addition to the inspection and certification services provided for fishery products for human consumption, NMFS provides inspection and certification services for animal feeds and pet foods containing a fish base.	13[d]	174[d]
Environmental Protection Agency (EPA) is responsible for regulating all pesticide products sold or distributed in the United States and setting maximum allowed residue levels—tolerances—for pesticides on food commodities and animal feed. EPA's activities are conducted under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and the	127	970

Federal Food, Drug, and Cosmetic Act, as amended.		
Federal Trade Commission (FTC) enforces the Federal Trade Commission Act, which prohibits unfair or deceptive acts or practices. FTC's food safety objective is to prevent consumer deception through the misrepresentations of food.	[c]	[c]
U.S. Customs Service, within the Department of the Treasury, is responsible for collecting revenues and enforcing various customs and related laws. Customs assists FDA and FSIS in carrying out their regulatory roles in food safety.	[c]	[c]
Bureau of Alcohol, Tobacco, and Firearms, within the Department of the Treasury, is responsible for administering and enforcing laws covering the production (including safety), use, and distribution of alcoholic beverages under the Federal Alcohol Administration Act and the Internal Revenue Code.	[c]	[c]
Total	$1,150	13,901

[a]Fiscal year 1998 appropriated funds.

[b]FDA's data includes funding and staffing for various programs across FDA that are involved with food safety activities, including the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, the field components for these centers, as well as overall agency-wide support.

[c]The agency did not specify its food safety resources.

[d]Agencies' funding and staffing levels are for both safety and quality inspection activities.

[e]We did not obtain these agencies' food safety budgets due to the small amount of funds for these activities in previous years.

Source: GAO's analysis of federal agencies' data.

RELATED GAO PRODUCTS

Food Safety: U.S. Lacks a Consistent Farm-to-Table Approach to Egg Safety (GAO/RCED-99-184, July 1, 1999).

Food Safety: Experiences of Four Countries in Consolidating Their Food Safety Systems (GAO/RCED-99-80, Apr. 20, 1999).

Food Safety: Opportunities to Redirect Federal Resources and Funds Can Enhance Effectiveness, (GAO/RCED-98-224, Aug. 6, 1998).

Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable, (GAO/RCED-98-103, Apr. 30, 1998).

Food Safety: Agencies' Handling of a Dioxin Incident Caused Hardships for Some Producers and Processors (GAO/RCED-98-104, Apr. 10, 1998).

Food Safety: Information on Foodborne Illnesses, GAO/RCED-96-96, May 8, 1996).

Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food (GAO/RCED-94-192, Sept. 26, 1994).

Food Safety: A Unified, Risk-Based Food Safety System Needed (GAO/T-RCED-94-223, May 25, 1994).

Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry (GAO/RCED-94-110, May 19, 1994).

Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

(150152)

Consumer Federation of America

STATEMENT OF CAROL TUCKER FOREMAN[1]
BEFORE THE
SUBCOMMITTEE ON GOVERNMENT MANAGEMENT, RESTRUCTURING AND THE DISTRICT OF COLUMBIA
U.S. SENATE COMMITTEE ON GOVERNMENTAL AFFAIRS

AUGUST 4, 1999

Mr. Chairman and members of the Committee, I am Carol Tucker Foreman, distinguished fellow and director of the Food Policy Institute, Consumer Federation of America. From 1977-81 I was assistant secretary of the U.S. Department of Agriculture with responsibility for meat, poultry and egg products inspection. I appreciate the opportunity to appear before you today on the subject of the Overlap and Duplication in the Federal Food Safety System.

In your letter of invitation you asked me to address two questions,

> First, "If the federal government were to create a food safety system from scratch, would it resemble the current system?"
>
> Second, "Is this the best and most logical organization for federal food safety agencies?"

---

[1] Carol Tucker Foreman is distinguished fellow and director of the Food Policy Institute, Consumer Federation of America (CFA). CFA is the nation's largest consumer organization with 250 member organizations representing over 60 million Americans. From 1977-81, Foreman was assistant secretary of agriculture for food and consumer services. Her responsibilities included the meat, poultry and egg products inspection programs of USDA.

She is a member of the National Advisory Committee on Meat and Poultry Inspection, the advisory committee of the Joint Institute for Food Safety and Applied Nutrition, the FDA's research institute at the University of Maryland and the Partnership for Food Safety Education. She was a member of the task forces that prepared *Foodborne Pathogens: risks and consequences*, for the Council on Agricultural Science and Technology (CAST) in 1994 and 1998.

Foreman was editor of Regulating for the Future published by the CNP Press in 1989. The Center for the Study of American Business at Washington University in Saint Louis has published the March 1999 debate between Foreman and Professor Murray Weidenbaum, "Regulation-Benefit or Bane."

In 1986, Foreman founded the Safe Food Coalition, a group of consumer, public health, senior citizen and trade unions that campaigned successfully to persuade USDA to abandon its 20 year position that it had no authority to regulate the presence of pathogens in raw meat and poultry products and to adopt the Pathogen Reduction and HACCP system.

1424 16th Street, N.W., Suite 604 • Washington, D.C. 20036 • (202) 387-6121 • www.consumerfed.org

The answer to both questions is an emphatic "No." That view is shared by most of the individuals who have had responsibility for administering food safety laws and, over a period of 50 years, from an impressive array of expert bodies, presidential commissions, this Committee, the U.S. Senate, and again and again, the General Accounting Office. The structure of our food safety system is in serious disarray, has been for some time and there is reason to believe that some of the illness and deaths associated with food-borne disease stem directly from the failure to address these issues.

The most recent and impressive case for serious structural change was made by a committee appointed by the National Academy of Sciences. At the request of Congress, the Institute of Medicine and the National Research Council formed the Committee on Ensuring Safe Food from Production to Consumption to examine these issues and make recommendations on changes needed to assure an effective system.

The Committee issued its report in August 1998, one year ago. The Academy reported that the nation's food safety structure is characterized by poor use of public resources, overlapping jurisdictions and gaps in protection. The Committee noted that food safety functions of the federal government are divided among 12 agencies and governed by 35 different laws and 50 memoranda of understanding.

To address these problems, the Academy recommended:

> The nation's food safety system should be based on science and able to apply resources where the risk is greatest
>
> Congress should establish a "unified and central framework for managing federal food safety programs, headed by a single federal official who has both the authority and control of resources necessary to manage food safety efforts. "
>
> Congress should change federal statutes so that inspection, research and enforcement are based on scientifically supportable assessments of risk.
>
> A comprehensive national food safety plan should be developed.

Finally, the Committee noted that ad hoc efforts such as President Clinton's Food Safety Initiative "will not suffice to bring about the vast cultural changes and collaborative efforts needed to create an integrated system."

Sadly, it now appears that the Administration has chosen to duck the most important of the NAS recommendations. Congress should and must have the courage to act on them. The issues raised are extremely important--to the health of the

American people, to those who raise and process and sell food, and to our nation's role in a global market place.

PROBLEMS WITH THE CURRENT SYSTEM
The Existing System is Not Effective in Securing Safe Food

Americans are told we have the safest food in the world, but we are surrounded by evidence that it is not safe enough. There is agreement that food-borne illness causes up to 81 million illnesses (Archer and Kvenburg, 1985) and 9,000 deaths (CAST, 1994) each year in the united States. The annual cost of of medical treatment and lost productivity from illness caused by seven major pathogens ranges from$6.6 bill to $37.1 billion (Buzby and Roberts, 1997.)

We are subjected to weekly reports of contaminated food recalled by government and industry. We eat from an international plate, laden with products from some countries with food safety systems far less sophisticated and competent than our own. Americans visiting developing countries are told not to drink the water, but we go to the store and purchase and eat raw fruits and vegetables raised in those countries and washed in that very same water. We are confronted with a constant stream of new food products and processes. Each new introduction is greeted by the promise from one group that this is the greatest advance to date in nutrition and health and by the vociferous charges of others that the new product will bring us nothing but grievous harm.

In recent months we have seen the devastating effect on the food industry, consumers and even governments, that failure to deal with food safety threats can bring. In Belgium the government fell after officials first failed to discover a serious dioxin contamination of feed and then attempted to conceal it from the public. In the United Kingdom public confidence in the safety of the food supply has been seriously undermined by government's mishandling of bovine spongiform encephalopathy

The Existing System Developed Incrementally, With No Plan

The Food and Drug Administration is the nation's primary food safety agency. Meat, poultry and eggs are inspected by USDA. The basic charters for these two programs were signed on the same day back in 1906. They share the same definition of food adulteration. Both laws originally were administered by the Department of Agriculture, but by different divisions.

Each division adopted entirely different regulatory approaches. The Pure Food and Drug Act prohibited companies from shipping misbranded and adulterated foods in interstate commerce. FDA has developed a system of standards companies must meet. The Meat Inspection Act required government inspectors to examine all animals before and after slaughter and to provide continuous inspection through each step of further processing.

The Pure Food and Drug Act was assigned to USDA's Bureau of Chemistry. Because most of the human health threat from meat products were a result of animal disease, the Meat Inspection Act was assigned to the Bureau of Animal Husbandry.

The Bureau of Chemistry became the Food and Drug Administration and ultimately became an agency of today's Department of Health and Human Services. For most of the last 92 years, meat and poultry inspections have been overseen by animal health experts and viewed as adjuncts of USDA's marketing efforts.

The Environmental Protection Agency sets limits on pesticide residues in food products *treated with pesticides*. FDA enforces EPA's limits. FDA also sets the limits on pesticide residues in foods *because they persist in the environment*. The Center for Veterinary Medicine sets limits on residues of animal drugs in meat and poultry products and USDA enforces them.

Food safety research, the foundation for an effective and rational system, is conducted in 21 federal agencies. The Centers for Disease Control has primary responsibility for surveillance of food-borne illness, but if there is a food poisoning outbreak, the FDA and FSIS to determine what regulatory action is needed.

The Present System Produces Serious Gaps in Public Health Protection and Undermines Public Confidence in Food Safety and Government

Present food safety laws produce not just overlaps and duplication, but leave serious gaps in public health protection. The laws do not allocate resources based on risk and do not provide a rational division of responsibilities. Frequently, in the words of Charles Dickens, the law is a ass, a idiot."

Some of the examples are well known by now. A processing plant makes two kinds of pizza. Pepperoni is subject to the federal Meat Inspection Act. The line where pepperoni pizza is made must be inspected at least daily by a federally sworn USDA inspector. The processing line in the same plant that is makes pizza with just cheese and no pepperoni falls under the jurisdiction of the FDA. An inspector from FDA may visit that line once a year or even less.

This squanders both money and public confidence, but there are more serious problems where gaps and overlaps almost surely result in illness and death.

This committee recently held hearings on the failure of either USDA or FDA to regulate egg safety effectively. Shell eggs are subject to FDA regulation. In the mid-1980's *Salmonella enteritidis* became a major food-borne disease. Four federal agencies have some role in regulating eggs. However, they were unable to decide which should deal with a disease that infected chickens (but didn't make the chicken sick) and was passed through to the eggs (which could and did make humans sick). FDA has jurisdiction over shell eggs but not hen houses. The Animal and Plant Health Inspection Service of

USDA has responsibility for animal health and safety, but *SE* didn't make the chickens sick. USDA's Agricultural Marketing Service provides voluntary egg grading but doesn't regulate for safety. The Food Safety and Inspection Service inspects pasteurized processed egg products, but pasteurized eggs do not usually carry *SE*. The result was and is that no agency has pursued an effective program to clean up egg safety.

The Center for Science in the Public Interest has petitioned the FDA to undertake rulemaking. No final rule has been promulgated. Thirteen years have passed since the first major outbreak of *SE* traced to eggs. The agencies have stood around acting like they had a hot egg--juggling it for a minute and then tossing it to the next guy.

In a recent risk assessment USDA reported that *SE* contaminated eggs cause over 661,633 illnesses each year and 331 deaths.

Inspection resources are not allocated according to the risk they present to human health. Federal law requires continuous inspection of meat and poultry. Every one of the two billion chickens, ducks and turkeys slaughtered each year is examined--inspected inside and out, its viscera probed--by a federal inspector. This system was devised primarily to prevent the spread of poultry disease, not human illness. It has been effective. Today the disease rate in poultry is less than one percent and only one disease known to occur in poultry can be passed on to humans. However, 2,500 of USDA's inspectors stand on poultry lines all day every day probing chickens for diseases that aren't there, and wouldn't make humans sick if they were.

On the other hand, raw and partially cooked molluscan shellfish is a high risk food. Taken from contaminated waters, it may harbor Hepatitis B. Shellfish fall under the jurisdiction of the Food and Drug Administration and the Interstate Sanitary Shellfish Commission. Inspection is sporadic. There is nothing, under the present system, that can be done about this. FDA can't borrow money or inspectors from USDA to increase shellfish inspection.

To improve nutrition, the federal government urges Americans to eat more fruits and vegetables. The Center for Science in the Public Interest analyzed food-borne illness outbreak data from the Centers for Disease Control and found that, between 1990 and1998, fruits, vegetables and salads were the second most likely group to be linked to a food-borne illness outbreak, causing 48 of the 225 outbreaks reported. Raw fruits and vegetables are terribly susceptible to bacterial contamination. They are subject to the most cursory inspection. FDA has issued "guidance" for these products. There are no regulations, no HACCP, no performance standards for limited bacterial contamination.

Finally, the irrational division of responsibility raises the risk that new food products will be approved without adequate oversight investigation and safety testing. This may have serious human health consequences. At the very least it undermines public confidence in the safety of the food supply and makes its impossible to defend against charges of

danger. Within the next two to three years it is estimated that half of our corn, soybean and cotton crops will be produced using genetically modified organisms. Critics argue that these crops are a danger to the environment and to human health. The regulatory structure for reviewing and approving genetically engineered foods contributes to the confusion and fear. Three separate agencies share responsibility for regulating GMOs. In order to protect plant species, APHIS must review new GMOs to assure that these products do not present a risk to other plants. In order to protect the environment, EPA must approve any genetically modified plant that defends itself against pests. FDA has responsibility for protecting human safety. FDA does not require that GMOs be reviewed before they are sold and used. FDA's process is voluntary. If a company thinks its product is safe, it just tells FDA that is the case and then offers it for sale. This is not reassuring to the American people, nor to our trading partners.

There are other irrationalities. FDA sets standards for milk safety. State governments enforce them. When a cow is slaughtered for food, she becomes the jurisdiction of the USDA's Food Safety and Inspection Service.

Federal inspectors examine every steer, cow, pig, lamb, chicken, turkey and duck at slaughter and at every step of further processing, applying uniform federal standards However, once the products are fully processed and go to a restaurant or retail store safety responsibility passes to state and local governments and the quality and frequency of inspection varies widely. A steak will emerge from a slaughterhouse that is operated under almost surgically clean conditions. However, if it doesn't sell after a few days in the retail meat case, it may be taken to the back room and ground up for hamburger and offered for sale again. The grinding may be done in a setting and with equipment that are rarely inspected by local authorities.

None of these problems is new. The GAO has filed report after report with Congress outlining the problems and recommending change.

The Existing System Results in Misallocation of Scarce Public Resources

Resources allocated to food safety are governed by placement and politics rather than by the risk to human health.

Food safety responsibilities at the Department of Agriculture have been consolidated in the Food Safety and Inspection Service, led by a career employee under an appointed under secretary. The FSIS budget for FY 1998 was over $650 million. The agency has 7,200 inspectors monitoring safety in 6,200 meat and poultry plants.

Food safety at the Department of Health and Human Services is a subunit of the Food and Drug Administration, which is under the Public Health Service. The FDA has an appointed commissioner a step lower than an under secretary.

FDA has jurisdiction over some 55,000 establishments. Its FY 1998 budget was

$925 million, but food safety commanded only $161 million of that. FDA employed

about 250 inspectors that year, who conducted 5,000 inspections. Several years often pass between FDA inspections of a particular food processing facility.

The Existing System Protects Institutional Imperatives First

The Department of Agriculture was established to protect and assist food producers, and its institutional bias remains true to that goal. Production agriculture has been the Department's first concern. No agriculture secretary has ever had a background primarily in human health, food safety and nutrition. The Department's food safety programs are overseen by the congressional agriculture committees, whose members' first concern is *not* food safety. Between 1980 and 1992, the secretaries of agriculture included a hog farmer, a former president of the meat industry trade association, and a cattle rancher. Their perspectives about food safety were informed by their previous endeavors.

The present Administration and secretary have given food safety the highest priority. Secretary Glickman brought to the position a long standing interest in food safety and nutrition and has been actively involved in shaping the Department's action in the field. At least temporarily, institutional history and priorities can be reshaped by personal commitment. But the present emphasis is the exception to the rule. There is no guarantee that the Department's leadership will not revert to placing a priority on promoting agricultural products.

Congress has made one encouraging change at USDA. The Department of Agriculture Reorganization Act of 1994 took food safety out of the Department's marketing agency and, by statute assigned it to a new Under Secretary for Food Safety. The law requires that the individual filling the position be qualified by training or experience and states that food safety is the Under Secretary's only concern.

The FDA benefits from being within the human health bureaucracy, along with the Centers for Disease Control, the Public Health Service and the National Institutes of Health. The institutional ethos is human health. But there are two problems. First, FDA is buried two levels down in the Department, one of several agencies under the Assistant Secretary for Health. Food safety is a subunit of FDA, down another level. Second, FDA as a regulatory agency, has attempted to wall itself off from the rest of the Department. The goal is to protect decision making from politics. That hasn't usually been effective. It has been effective in assuring that secretaries are not involved in and knowledgeable about FDA issues.

Food safety is often the poor stepsister at FDA, with most of the attention and resources devoted to concerns over drugs and medical devices. Further within the Center for Food Safety and Applied Nutrition, prestige has usually attached to the staff reviewing new food additives. Food inspection has not been a high priority. In fact, the

Agency's food inspection staff is assigned to FDA's enforcement apparatus, not CFSAN, and inspectors review food, drug and device companies.

The Existing System Offends Every Rule of Effective Organization and Management

The existing food regulatory system offends every rule of good organization and management. There is no clear statement of mission for protecting the public. Each agency operates under different statutes. There are no clear lines of authority and responsibility. Resources are not allocated according to need and priority. There is no clear standard for success.

The Government Performance and Results Act of 1993 doesn't help in this situation because responsibility is too diffuse. Each agency may take the steps required by the strategic planning exercise is limited to achieving goals within the agency's existing structure and authority. The agencies may succeed in following the law, but they are failing the public.

The existing food regulatory system also fails the test this Administration established for Reinventing Government, to make government both less expensive and more efficient...to redesign, to reinvent, to reinvigorate the entire federal government. Although the Administration appeared ready to tackle the problem in 1994 when it recommended moving meat and poultry inspection from USDA to FDA, it has subsequently abandoned that idea.

The strategic plan being drafted by the President's Food Safety Council is not an adequate substitute for organizational structure. The Plan does not override statutory authority and to date, the plan assumes that existing law will govern all food safety activity under the plan. The plan does not include any standards for judging success in meeting its requirements.

Only Major Structural Change Will Address These Problems

The list of people favoring major change is impressive. It includes not just the GAO and outside experts brought in to observe the problems. It also includes those of us who have had the experience of trying to make the existing system work. Those include former CFSAN director, Professor Sandy Miller who could not be here today; former FSIS Administrators Lester Crawford, Russell Cross and Michael Taylor. It includes former FDA Commissioner, Dr. David Kessler and it certainly includes me.

I could cite numerous instances in which the public got less than the best from USDA and FDA during my time in government because of different statutory mandates, misallocated resources and plain old turf battles. When I arrived at USDA, the agency staff rarely communicated with FDA. The dozens of "Memoranda of Understanding" between the two agencies were scrap paper. During my first two years at the

Department, Commissioner Donald Kennedy was eager for us to work together. When our staffs insisted something could not be done, we could often meet and find a way to do it. But that always took time and meant decisions had to be kicked up to the top instead of being resolved at lower levels. When Dr. Kennedy left, he was succeeded by a Commissioner whose interest in food was limited and whose patience for negotiating agency compromise was nonexistent.

However, the most useful example of the hopelessness of securing real coherence between two agencies is illustrated by the dispute between USDA and FDA over the appropriate nutrition labeling for fat in ground beef. FDA was charged by Congress in the Nutrition Labeling and Education Act with developing labels. Meat and poultry were not covered by the Act because they were administered by USDA. FDA worked out the label regime for fat and cholesterol. USDA staff declined to follow that regime, urging a completely different system for describing the amount of fat in ground beef. The agencies were unable to reach an agreement. The subcabinet officials were unable to reach an agreement. Secretary Louis Sullivan met with Secretary Ed Madigan. They could not reach agreement. This negotiation continued over most of 1992 and resulted in complete stalemate. In the end, the decision went to the President of the United States. President Bush, after the November 1992 election, met with his two Cabinet officers, heard each one's case and made the decision. The President of the United States had to decide the appropriate wording for nutrition labeling of the fat content of meat.

Today you will hear witnesses who oppose meaningful structural change. There are two groups that oppose change. Present government officials and industry lobbyists.

Industry witnesses will not assert that this is the best system. In the past they have simply argued that changing it requires too much time and energy and they propose instead that agencies change their focus and cooperate with each other and the industry more.

In truth, some in the industry have no interest in more regular or effective government regulation and inspection. Perhaps most importantly, trade associations and industry lawyers have spent many years developing direct lines to the people they need to deal with. Change might disrupt those lines of communication, at least temporarily.

Unfortunately, the other group opposing meaningful statutory structural change includes the government officials now running the programs. Two weeks ago the secretaries of Agriculture and Health and Human Services made their views clear in media interviews. They said creating a single food safety agency would be "disruptive."

Representatives of USDA and FDA appear here today to tell you that the Food Safety Council is the best way to proceed. It is my understanding they have written to Senator Durbin, committing to the creation of a "virtual" food safety agency.

It is time for some reality and some honesty here. "Virtual" is not reality. It only seems to be. Underneath the seeming agreement between the agencies, there is constant competition and conflict. That's why it took them several months to prepare that letter to Senator Durbin. FDA complained bitterly when Sec. Glickman suggested recently that we should consider labeling genetically engineered foods. That's their jurisdiction.

FDA staff fret that USDA has stopped being the advocate for producers and started protecting consumers. They believe Agriculture is trying to steal their turf. They warn darkly that USDA doesn't have good science and can't be trusted with food safety. There is real distress that a number of FDA's top staff have left the Agency to work for the Food Safety and Inspection Service.

USDA staff complain that FDA cannot come to a conclusion on any issue and that the Agency does not want to change the way it does anything in order to cooperate. Both departments argued against having White House staff serve as a co-chair of the President's Food Safety Council. Each group expressed fear that having the White House staff involved would introduce "politics" into food safety decision making.

As one old Washington wag said, "In government, where you stand depends upon where you sit." Protecting the home turf will almost always outweigh all other considerations. It makes otherwise responsible people do and say strange things--how else to explain two cabinet secretaries rejecting single food safety agency because it would be "disruptive." I think the case has been made. The public interest would be served well by disrupting a system that results in 9,000 deaths each year. When we get to the point of having "virtual" food poisoning, we can get along with a "virtual" food safety agency.

Over a 50 year period the people who argue for little or no change have won this debate. The problems have just gotten worse. During that time thousands of people have died. The time has come to try it another way.

The proposed Safe Food Act responds to the NAS recommendation. It applies to government the same standard government applies to the food industry in the Hazard Analysis and Critical Control Point regulatory system. It would create a structure that has clear lines of responsibility and accountability.

The Safe Food Act would begin to straighten our the problems with the present system. It will not be easy to pass this legislation. Today's arrangements have evolved over 90 years; people and programs have found comfortable niches; change threatens positions and relationships and scares just about everyone. Many disdain efforts to develop a better structure as time wasted moving boxes around on an organization chart. But the existing framework is the result of historical accident with no relevance to today's public health needs. It is not efficient or effective in protecting public health.

GIVE CONSUMERS AN EFFECTIVE, EFFICIENT FOOD SAFETY SYSTEM

The American people should expect their tax dollars to support a food safety apparatus that has human health as its primary goal and commands the resources and attention necessary to achieve its objective. The Safe Food Act will create such a structure. Congress should pass the Safe Food Act of 1999 so we can enter a new century with the institutional structure necessary to provide the American people the safest and most nutritious food possible.

S.T.O.P. - Safe Tables Our Priority

P.O. Box 46522 Chicago, IL 60646 www.stop-usa.org
Telephone 312/957-0284 Fax 312/427-2307 Victim Hotline 800/350-STOP

Testimony of Nancy Donley before the
Subcommittee on Oversight of Government Management, Restructuring
and the District of Columbia
United States Senate
August 4, 1999

"Overlap and Duplication in the Federal Food Safety System"
and
S. 1281 "The Safe Food Act of 1999"

I would like to thank Senators Voinovich and Durbin for inviting me to testify here today on a subject that has become the single most important issue in my life-food safety. Until July 18, 1993, food safety was a non-issue as far as I was concerned. I did what most of the public does--I assumed that the food we fed our families was safe. I assumed that our government had the situation of ensuring the safest food supply possible well in hand. I assumed that the food industry was governed under the strictest of regulations to produce food of the highest safety level possible. I assumed that companies violating food safety law were dealt with swiftly and harshly. I assumed that there was an entity ultimately responsible for protecting my family from unsafe food. I assumed wrong on all counts. Dead wrong.

And then came that most awful week in July when my only child complained of painful abdominal cramping. I immediately took Alex to his pediatrician. I thought that six-years-old was awfully young for appendicitis but what else could it be? Alex was immediately admitted to Children's Memorial Hospital in Chicago when he spent four days in agonizing pain before dying from E. coli O157:H7 poisoning. In an effort to escape the continuous, racking abdominal cramping, Alex curled up in a fetal position and begged me to hold him. I stroked his face, attempting to calm him, to soothe him. I watched in horror his life hemorrhaging away in the hospital bathroom; bowl after bowl of blood and mucus gushed from his little body. Later, I helped change blood-soaked diapers that he had to wear after he could no longer stand or walk. Alex's screams were followed by silence as the evil toxins attacked his brain causing him to lose neurological control. His eyes crossed and he suffered tremors and delusions. He no longer knew who I was.

I sat with my only child as the monitors registered organ failure after organ failure. His body swelled uncontrollably as his kidneys shut down. I lost count of the units of blood and platelets being intravenously fed to him. His little body had a hole dug into his side where the

doctors frantically shoved a hose to re-inflate his collapsed lung. Holes for brain shunts were drilled into his head to relieve the tremendous pressure. I screamed for the nurses as he suffered a massive seizure that left him on a respirator. I watched his brain waves flatten. My vibrant little boy, with his beautiful red hair and heartwarming smile, was reduced to a shell of a corpse as his father, his doctors and I all stood helplessly by.

Alex's last words to me were, "Don't cry Mommy" as I couldn't stop the tears from silently flowing down my cheeks. His last act before slipping into a coma was to mouth a kiss to his father.

From the age of three, Alex wanted to be a paramedic so that he could help people. So when he died, we wanted to donate Alex's organs, to fulfill his wish of helping others. We were told we couldn't. The toxins produced by E. coli O157:H7 had destroyed all his internal organs. They had liquefied entire portions of his brain.

After Alex's death I joined S.T.O.P.-Safe Tables Our Priority. S.T.O.P. is a national non-profit foodborne illness victims organization that was founded in the wake of the Jack-In-The-Box E. coli O157:H7 epidemic in 1993 that killed four children and sickened over 700. Our founders include parents of children who died or were seriously injured from eating contaminated meat. Since, then, our membership has expanded to include people impacted by many different foodborne pathogens from all food groups. Our mission is to prevent unnecessary illness and death from foodborne pathogens and we use a three-prong approach in efforts to achieve our goal-policy advocacy, public education and victim assistance and support.

When I learned that Alex had died because his hamburger was contaminated with cattle feces I was determined to understand where the system had failed. It has been an incredibly eye-opening experience for me. S.T.O.P.'s initial focus was "fixing" the E. coli O157 problem, a problem initially thought to be confined to beef. I learned that at the time of Alex's death, meat inspection did not include any measures to address microbial contamination. So I worked extensively during the rulemaking process for FSIS' Pathogen Reduction/Hazard Analysis and Critical Control Point regulation which mandated microbial testing for the first time in history in slaughter facilities. Also during this time, E. coli O157:H7 was declared an adulterant in ground beef and safe food handling labels were required for all raw meat and poultry sold at retail. Things were definitely looking up in fighting "The Hamburger Disease" as E. coli O157:H7 was commonly referred to.

But O157 is not just a hamburger problem as initially thought. The primary reservoir of E. coli O157 is found in cattle. The first incidents and outbreaks of E. coli poisoning were found in ground beef, but outbreaks have subsequently been linked to such diverse foods as lettuce, alfalfa sprouts, cantaloupe and apple juice. Japan had a national epidemic that infected over 10,000 people with contaminated radish sprouts being the suspected vehicle. Several months ago, school children in England became sick from E. coli O157:H7-contaminated goat cheese. E. coli O157:H7 outbreaks have also been linked to contaminated drinking water and in my home state

of Illinois, children became very sick after swimming in a contaminated reservoir. This single pathogen affects product regulated by FSIS, FDA and EPA. While FSIS was dealing with the problem in meat, prevention strategies were not put in place for other products that could be affected by the same pathogen. That was because no one was looking at the overall big picture. There appears to be a dangerous tunnel vision occurring within the individual agencies where they focus only on their small world and don't see how happenings in other areas might be of relevance to their own.

The invitation to this hearing contained the following questions:
1. If the Federal Government were to create a food safety system from scratch, would it resemble the current system?
2. Is this the best and most logical organization for Federal food safety agencies?

If the Federal Government were to create a food safety system from scratch, I can't imagine it creating the fragmented system that exists today. It wouldn't make any sense to. Food safety wasn't the concern historically that it is today. Consolidating food safety activities into a single independent agency would elevate food safety, prevent duplication and fill in gaps that currently exist in our multiple agency system. A single independent agency would be better prepared to handle emerging food safety issues. It would be more efficient, more effective and more responsive. The current structure of agencies within even larger departments undermines the importance of food safety because these departments have such broad and varied agendas that food safety gets overlooked or doesn't receive the attention it deserves. FSIS is a subset of the USDA, a huge department whose responsibilities include everything from forestry to circus animals. It is even more complex with CFSAN, a subset of the FDA who is a subset of HHS. When you are such a tiny piece of the pie you don't command much attention. Food safety deserves to be the entire pie.

It is time to face the fact that the current system of multiple agencies regulating food safety is simply not working. Victims are falling through the cracks because of the lack of a single, cohesive food safety program. Imagine what might have happened if a single food agency had been implemented immediately following the Jack-In-The-Box epidemic. A single independent entity, responsible for all foods including meat, would have looked at animal-reservoir pathogens in a larger context. While developing a program to address animal pathogens in meat, it would have logically and simultaneously looked at the potential of animal waste contaminating other foods as well and developed prevention strategies. These produce-related foodborne illness outbreaks may have been avoided altogether. Our organization has members who were victims of the juice and lettuce outbreaks who question why didn't government anticipate such a problem occurring? They want to know who was in charge of the safety of the food that made their loved one sick? The answer is tragically a dual one; there were too many in charge and yet no one in charge.

S.T.O.P. strongly supports the implementation of a single, independent food safety agency. The safety of the food we feed our families is of critical importance and deserves the

uncompromised scrutiny and attention of an agency unencumbered with other conflicting responsibilities such as trade and marketing issues. Many industry associations support the status quo of the marketers also being the regulators. The public is strongly opposed to such an arrangement. The USDA has attempted to separate the marketing functions from the regulators through the establishment of FSIS, however trade discussions still enter into policy meetings.

There comes a time when you have to acknowledge that something is beyond fixing. That inherent flaws make it impossible to fix and that you need to start from scratch. It's time for agency and department officials to put aside their egos and refrain from turf wars in order to create a food safety structure that will better protect the common people. That's what the public counts on its government to do.

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

Testimony of Caroline Smith DeWaal
Director of Food Safety
before the
Senate Committee on Governmental Affairs
on
"Overlap and Duplication in the Federal Food Safety System"

Washington, DC
August 4, 1999

My name is Caroline Smith DeWaal and I am director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a non-profit organization based in Washington, D.C. Since 1971, CSPI has been working to improve the public's health, largely through its work on nutrition and food-safety issues. CSPI is supported primarily by the one million subscribers to its *Nutrition Action Healthletter*, the largest circulation health newsletter in North America.

Food-safety experts believe that contaminated food causes up to 33 million illnesses and 9,000 deaths each year.[1] These estimates illuminate the magnitude of the problem with food-borne illness in the US. For many consumers, the aggregate numbers mean less than the specific outbreaks and recalls, which have awakened them to the fact that the risk from contaminated food is greater than they thought. Parents shouldn't have to fear the consequences of serving

[1] Council for Agricultural Science and Technology, *Foodborne Pathogens: Risks and Consequences*, (Ames, IA: Council for Agricultural Science and Technology, 1994), p. 4.

their children apple cider or a meal out at a local restaurant. Yet, food poisoning outbreaks have taught us that today we must.[2]

In the last thirty years, the US consumer has seen many changes in the way food is produced that impact food safety. Food production has evolved from a local industry to one where production and processing is centralized in different regions of the country. Improved transportation also has given consumers greater access to foods from around the world, with both their benefits and the potential hazards. The increase in imported foods presents new challenges because it is especially difficult to police the safety of food grown and processed in foreign countries.

Other changes are affecting US consumers as well. Foodborne pathogens have developed increased virulence,[3] while the public has grown more vulnerable to foodborne illnesses due to the aging of the population.

While the food marketplace has changed dramatically, the regulatory tools available to the federal government to prevent food poisoning have changed only minimally. The advent of new systems of preventive controls -- so called "HACCP" systems -- coupled with the expanded

---

[2] *Eg.*, Centers for Disease Control and Prevention, "Outbreaks of *Escherichia coli* O157:H7 Infection and Cryptosporidiosis Associated with Drinking Unpasteurized Apple Cider -- Connecticut and New York, October 1996," *Morbidity and Mortality Weekly Report*, Vol. 46, No. 1 (1997), pp. 4-9; Centers for Disease Control and Prevention, "Outbreaks of *Shigella sonnei* Infection Associated with Eating Fresh Parsley -- United States and Canada, July-August, 1998," *Morbidity and Mortality Weekly Report*, Vol. 48, No. 14 (1999), pp. 285-289.

[3] Robert V. Tauxe, "Strategies for Surveillance and Prevention," *The Lancet*, End of Year Review, Vol. 352 (1998), p. 10.

use of new technologies have the potential to enhance the safety of food.[4] But these benefits will not be fully realized until the underlying regulatory systems are modernized as well.

One area of food-safety oversight that needs improving is the area of surveillance. Foodborne-disease outbreak investigations tell the stories of who gets sick from food and why. Today, while headline after headline alerts consumers to food-poisoning outbreaks, no agency in the federal government maintains a comprehensive and current inventory of these outbreaks. Such an inventory would allow policy makers, the food industry and the public to monitor trends, issue public-health alerts, change production practices, and, ultimately, reduce the number of illnesses and deaths caused by contaminated food.

The Centers for Disease Control and Prevention (CDC) is the only entity that would be capable of releasing comprehensive and timely information on foodborne-illness outbreaks, but it discontinued its annual listing of foodborne-illness outbreaks in the 1980s.[5] To fill this gap, CSPI has been maintaining its own list of foodborne-illness outbreaks that have occurred from 1990 to the present. Today we are releasing an updated version of this list with over 350

---

[4] US Department of Agriculture, Food Safety and Inspection Service, "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule," *Federal Register*, Vol. 61, No. 144 (1996), pp. 38806-38989.

[5] Telephone conversation with Dr. Patricia Griffin, Chief of Foodborne Diseases, Foodborne and Diarrheal Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, GA, January 14, 1999; *eg.* Centers for Disease Control, "Line Listing of Foodborne Disease Outbreaks, 1982," *Foodborne Disease Surveillance, Annual Summary 1982*, (Atlanta, GA: Centers for Disease Control, September 1985), pp. 19-24.

outbreaks.[6] This list is the only one of its kind available, but even it includes only a small fraction of the outbreaks being reported to CDC and the other federal agencies.

Outbreaks are defined generally as two or more illnesses from a single source.[8] The outbreaks on CSPI's list were those that could be relatively easily identified, such as highly publicized, novel, or large outbreaks. We also used CDC lists for *Salmonella enteritidis* (SE) and *E. coli* O157:H7. Here are our most recent findings:

First, looking at the data in the context of our current regulatory system, over three times as many outbreaks were linked to Food and Drug Administration (FDA)-regulated foods as were linked to US Department of Agriculture (USDA)-regulated foods (See Appendix A). FDA regulates all foods other than meat, poultry, and some processed egg products. This doesn't mean that meat and poultry products are safer than we thought. In fact, data on individual illnesses that is collected by CDC's FoodNet system clearly demonstrates that *Campylobacter* and *Salmonella*, two pathogens commonly found on chicken, are the principle cause of individual cases of food poisoning.[9] Instead, the outbreak data make it clear that FDA-regulated foods represent a significant public-health problem that is not being addressed adequately.

---

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

[7] *Ibid.*, p. 3.

[8] Centers for Disease Control and Prevention, "Surveillance for Foodborne-Disease Outbreaks -- United States, 1988-1992," *CDC Surveillance Summaries, Morbidity and Mortality Weekly Report*, Vol. 45, No. SS-5 (1996), p. 1.

[9] Centers for Disease Control and Prevention, "Incidence of Foodborne Illnesses: Preliminary Data from the Foodborne Diseases Active Surveillance Network (FoodNet) -- United States, 1998," *Morbidity and Mortality Weekly Report*, Vol. 48, No. 9 (1999), p. 191.

Out of 277 outbreaks linked to FDA-regulated foods:

- **123 outbreaks were linked to eggs and egg dishes.** Most of the egg-related outbreaks were caused by *Salmonella enteritidis*, a bacterium that can survive in raw or undercooked eggs and egg dishes. Egg dishes involved in several outbreaks include pudding, stuffing, baked ziti, and ice cream made with shell eggs.
- **42 outbreaks were linked to produce,** including cantaloupe, tomatoes, strawberries, watermelon, potatoes, scallions, lettuce, raspberries, sprouts, basil, and parsley.
- **39 outbreaks were linked to seafood,** including mahi mahi, salted whitefish, tuna, buffalo fish, blue marlin, surgeon, grouper, ahi, crab, and shrimp. **Of the seafood outbreaks, 19 were linked to shellfish,** including oysters, clams, and mussels.
- **14 outbreaks were linked to game,** including venison, bear meat, and cougar meat.
- **12 outbreaks were linked to dairy products,** including cheese, pasteurized and raw milk, and ice cream.
- **Eight outbreaks were linked to juices,** including apple cider, apple juice, and orange juice.
- **39 outbreaks were linked to FDA-regulated foods with multiple ingredients.** These include salads, baked goods, and soups.

Out of 78 outbreaks linked to USDA-regulated foods:

- **50 outbreaks were linked to beef, including 38 to ground beef.** Other types of beef were prime rib, roast beef, corned beef, raw beef, sliced beef, and beef jerky.

- **27 outbreaks were linked to meats other than beef, including chicken, pork, turkey, and multiple-meat products.** Poultry products caused 14 of these outbreaks and pork caused 10. Although *Campylobacter* is the leading bacterial cause of foodborne diarrhea and current data suggest that more cases are linked to poultry than to any other food, outbreaks linked to poultry are rarely recognized. The illnesses resulting from poultry products are more likely to occur individually or as part of a family outbreak that is never reported, according to CDC.[10]

Contrary to our findings, FDA's foods are generally, but erroneously, thought to pose a lower risk than the meat and poultry products regulated by USDA, and Congress appropriates accordingly. FDA's budget for regulating foods is approximately one-third of USDA's food inspection budget (See Appendix B).[11] In essence, FDA regulates more food with less money.

FDA's food program also doesn't fare well when compared with 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

---

[10] Telephone conversation with Dr. Patricia Griffin, Chief of Foodborne Diseases, Foodborne and Diarrheal Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, GA, January 14, 1999.

[11] US 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; US 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*].

program budget (See Appendix C).[12] This is despite the fact that food represents more than 50% of FDA's mission area.[13]

These data show that there is a big imbalance in the way Washington directs food safety resources. If food-safety resources were applied either equitably or on the basis of risk, FDA's food program would receive a much bigger budget.

While CSPI has broken down the data on foodborne illness outbreaks into nice, neat little categories, let's not forget the impact that each outbreak has on consumer perceptions of food safety. Consumers have to eat and feed their families several times a day. They want to know that everything is being done both by the food industry and by the government to assure the safety of that food.

Public concern about the safety of the food supply has increased, especially following the Jack in the Box outbreak in which fast-food hamburgers were linked to over 700 illnesses and 4 deaths.[14] In poll after poll, food safety ranks high on the list of things that consumers would like to see improved. Consumers' concerns are registering with the White House and with many in the government who are promoting new programs that will enhance food safety. Over the last three years, a national initiative on food safety has resulted in over $110 million in new federal dollars going to the food-safety programs, and we are urging Congress to add another $75 million this year. In addition, the Clinton administration has racked up an impressive number of food-

---

[12] *FDA Budget.*

[13] *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.

[14] Suzanne Marks and Tanya Roberts, "*E. coli* O157:H7 Ranks as the Fourth Most Costly Foodborne Disease," *Food Review*, Vol. 16, No. 3 (1993), p. 1; Centers for Disease Control and Prevention, "Outbreaks of *E. coli* O157:H7 Infections Reported to CDC for 1993," (unpublished).

safety accomplishments, including new regulatory, research and education programs. There has also been great emphasis on improving communication between the multiple departments with food-safety responsibilities.

While these initiatives are good, they are not enough. The National Academy of Sciences (NAS) completed a report last August, called *Ensuring Safe Food From Production to Consumption*, that concluded that the "current fragmented regulatory structure is not well equipped to meet the current challenges."[15]

Last year, I enumerated CSPI's concerns about the current structure for the NAS panel. One year later, little has changed. CSPI remains concerned that:

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,[16] 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

---

[15] Institute of Medicine, National Research Council, *Ensuring Safe Food From Production to Consumption*, (Washington, DC: National Academy Press, 1998), p. 12 [hereinafter cited as *Ensuring Safe Food*].

[16] US 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: US Food and Drug Administration, October, 1998).

attempt to control SE in eggs.[17] 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 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.[18] The cheese line will be subject to FDA inspection on average once every 10 years.[19] The minimal difference in hazard between the processing of cheese and pepperoni pizzas is not enough to justify the vast disparity in government inspection.

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 inspectors. 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,

---

[17] US General Accounting Office, *Food Safety and Quality: Salmonella Control Efforts Show Need for More Coordination,* (Washington, DC: US General Accounting Office, April 1992).

[18] 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*].

[19] US Department of Agriculture, US Department of Health and Human Services, US 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.

trade periodicals, surveillance reports and consumer complaints. Inspectors may also walk through stores looking for new products."[20] 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 US 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 inspection by AMS.[21] 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 SE.[22] Nor does FDA, the agency charged with food-safety oversight of shell eggs, check for SE during its infrequent inspections.[23]

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.

---

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

[21] 7 C.F.R. § 59.28; Poultry Division, AMS, USDA, "Quality Eggs for Volume Buyers," Brochure No. AMS-627, August, 1996.

[22] *Ibid.*

[23] 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*].

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.[24]

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*.[25] 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.[26] 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 bifurated process can take years to get through.[27]

---

[24] 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.

[25] US Department of Agriculture, "USDA Researchers Create New Product That Reduces *Salmonella* in Chickens," USDA Release No. 0121.98, March 19, 1998.

[26] Telephone conversation with John DeLoach, MS BioScience, Inc., Dundee, IL, April 1998.

[27] 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; US Department of Health and Human Services, Food and Drug Administration, "Irradiation in the Production, Processing, and Handling of Food; Final Rules," *Federal 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.

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.[28] 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.[29] 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.[30] 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.

---

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

[29] *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).

[30] *Preparing for the Twenty-First Century*, pp. 26-27.

In the year since CSPI first enumerated our concerns to the National Academy of Sciences, little has changed. In addition, we have documented other examples:

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 data requirements for foods discourages many states from sharing their laboratory data with the federal agencies.[31]

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

---

[31] "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.

sources.[32] 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

---

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

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

In its report last summer, the NAS found similar glaring disparities resulting from the multiple agency system of food-safety regulation and concluded that:

> "[A]n identifiable, high-ranking, presidentially-appointed head, [is needed] who would direct and coordinate federal activities and speak to the nation, giving federal food safety efforts a single voice. The structure created, and the person heading it, should have control over the resources Congress allocates to the food safety efforts; [and] the structure should have a firm foundation in statute . . .. Many members of the committee are of the view that the most viable means of achieving these goals would be to create a single unified agency headed by a single administrator -- an agency that would incorporate the several relevant functions now dispersed ... among three departments and a department level agency."[33]

The NAS also issued a call for new federal food-safety statutes so that resources could be better allocated according to assessments of risk to public health.

The NAS has provided further documentation of the problems that drove CSPI and other consumer organizations to call on President Clinton in April 1997 to form a single independent food-safety agency.[34] But NAS was hardly the first major advisory body to call for fundamental reform of our food-safety agencies.

---

[33] *Ensuring Safe Food*, p. 13.

[34] Memorandum from S.T.O.P.--Safe Tables Our Priority, Center for Science in the Public Interest, Consumer Federation of America, Public Voice for Food and Health Policy, Government Accountability Project, and the United States Humane Society to President Bill Clinton on the President's Food Safety Initiative, April 2, 1997.

In 1969, the White House Conference on Food recommended that there be one federal regulatory policy with respect to the safety, sanitation, identity, and labeling of food and advised consideration of the establishment of a single federal regulatory agency for foods.[35]

In 1972, Ralph Nader published a report, *Sowing the Wind*, that found that food inspection "remains embarrassed by department conflicts of interest and overlapping jurisdictions in USDA and FDA." The report recommended the creation of a food safety agency to enhance the protection of public health.[36]

In 1977, the Senate Government Affairs Committee issued a report that said, "We believe the bifurcated food regulatory system should be unified in a single agency."[37]

The United States General Accounting Office (GAO), which advises Congress, has consistently documented problems with the current food-safety structure and has recommended that Congress evaluate options for revamping the federal food-safety and quality system. In 1993, the GAO concluded that:

> "[C]reating a single food safety agency is the most effective way for the federal government to overcome long-standing problems, deal with emerging food safety issues, and guarantee the safety of our nation's food."[38]

---

[35] *White House Conference on Food, Nutrition, and Health. Final Report*, (Washington, DC: White House, 1969), pp. 118-119.

[36] Harrison Wellford, *Sowing the Wind: A Report from Ralph Nader's Center for Study of Responsive Law on Food Safety and the Chemical Harvest*, (New York: Grossman Publishers, 1972), p. 354.

[37] Senate Committee on Governmental Affairs, "V. Regulatory Organization," *Study on Federal Regulation*, 95th Cong., 2d sess., December 1977, S.Rept. 95-91, p. 140.

[38] General Accounting Office, "Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety," (Washington, DC: US General Accounting Office, 1993).

The GAO has reiterated this finding in numerous reports and testimonies before Congress since the early 1990's.

Two years ago, legislation calling on the President to establish a single, independent food-safety agency at the federal level was introduced in Congress by Senator Richard Durbin and Representative Vic Fazio.[39] Senator Durbin has played a leading role in examining the effectiveness of our current food-safety system and initiating this legislation, which is called the Safe Food Act. The Safe Food Act also was introduced in the House by Representatives Rosa DeLauro, a Connecticut Democrat, and Tom Latham, an Iowa Republican. This bill represents the most far-reaching change to the federal food-safety system that have been proposed in the last several decades.[40]

Last August, President Clinton appointed a Food Safety Council, which is charged with responding to the findings of the National Academy of Sciences. The agencies have responded by promising to coordinate their way out of these problems.[41] Despite their best efforts, however, coordination does not seem to be working. Following a multi-year effort at solving the SE problem in eggs, neither agency had proposed on-farm controls for SE.[42] In addition, a

---

[39] H.R. 2801, "Safe Food Act of 1997," 105th Cong., 1st Sess.; S. 1465 "Safe Food Act of 1997," 105th Cong., 1st Sess.

[40] H.R. 2345, "Safe Food Act of 1999," 106th Cong., 1st Sess.; S. 1281, "Safe Food Act of 1999," 106th Cong., 1st Sess.

[41] President's Council on Food Safety, "President's Council on Food Safety Assessment of the NAS Report: *Ensuring Safe Food from Production to Consumption*," last updated on March 19, 1999, available at <http://www.foodsafety.gov/~fsg/creport2.html>Internet.

[42] US Department of Agriculture , "New Egg Safety Steps Announced, Safe Handling Labels and Refrigeration Will be Required," USDA Release No. 0271.99, July 1, 1999, US Department of Health and Human Services, "New Egg Safety Steps Announced, Safe Handling Labels and Refrigeration Will be Required," HHS News No. P99-11, July 1, 1999; *Scrambled Eggs*, pp. 8-9.

Memorandum of Understanding between FSIS and FDA on inspection issues failed to net any meaningful change.[43] USDA is statutorily limited to conducting only meat and poultry inspections, and can not expand their inspection scope to cover FDA-regulated foods. These examples show that coordination cannot ultimately address many of the problems with the current system.

Others have expressed concerns that the agencies currently are in the process of implementing HACCP and cannot adapt to the other changes at this time. However, the fact that HACCP systems are being implemented at both FDA and USDA for seafood, meat, and poultry should be a driving force for making the shift to a single food-safety agency. FDA's weak regulatory program may jeopardize the credibility of HACCP with the American public. Seafood plants inspected last year showed a distressingly low level of compliance with the new HACCP regulation. Approximately 70% of seafood plants inspected by FDA were not fully in compliance with FDA's seafood HACCP rule.[44]

While FDA's recent failure at HACCP implementation is troubling, many hope that the widespread use of regulatory HACCP can and will fundamentally change government's role in food-safety oversight. It won't happen without more uniform enforcement.

HACCP may also help to free up some USDA inspectors to do other jobs. For example, technological innovation may make our current system of inspecting poultry obsolete within the

---

[43] US 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.

[44] Testimony of Jane Henney, Commissioner, US Food and Drug Administration, before the Committee on Agriculture, Rural Development, and Related Agencies, US Senate, March 16, 1999 in response to a question from Senator Durbin.

next few years. Those inspectors are urgently needed to provide inspections at the tens of thousands of food plants under FDA's jurisdiction. However, given the agency split, you cannot simply transfer inspection resources across agencies to the areas of greatest risk. Appropriate, efficient, and flexible utilization of this inspection resource in the next century requires the reorganization of the government structure.

Another driving force to change our current inspection program is the increase in imported food products. Imports have increased dramatically in the last few years due to several trade agreements that have expanded food trade with our closest neighbors.[45] This is creating a tremendous problem, especially for the Food and Drug Administration, because of the acute lack of resources directed towards food safety at that agency. For example, FDA inspects fewer than 2% of food products coming into the US, not including meat and poultry.[46] Several major outbreaks in the last few years have demonstrated the weaknesses in FDA's system of inspecting imports.[47] Clearly, the increasing number of food imports demands a more systematic and uniform approach to import inspection than we have today.

While it clear that a creating a single food-safety agency must be done thoughtfully, it is also clear it should be done soon. Consumers can't afford to wait years and even decades for the agencies to work out policies on every food-safety question. The current system is highly inefficient, and that inefficiency is putting consumers at risk.

---

[45] *Preparing for the Twenty-First Century*, pp. 26-27; *Food Safety from Farm to Table*, p. 41.

[46] *Safety of Imported Foods*, p. 5.

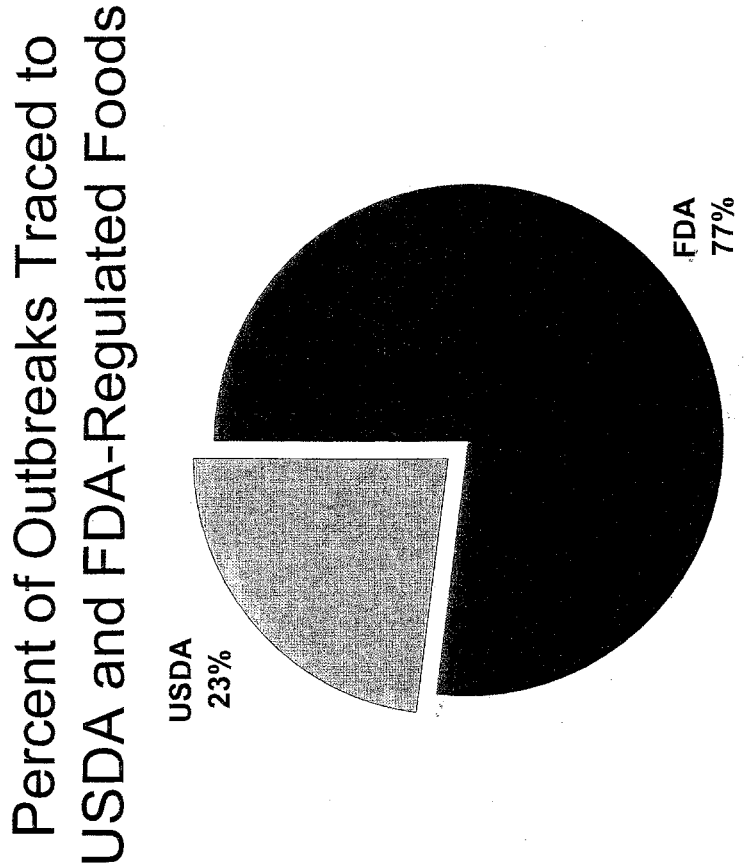
[47] *Ibid.*, p. 47.

The Committee asked us to answer the questions: If the federal government were to create a food-safety system from scratch, would it resemble the current system? Is this the best and most logical organization for the federal food-safety agencies? As this testimony has amply demonstrated, the answer to both questions is a resounding NO.

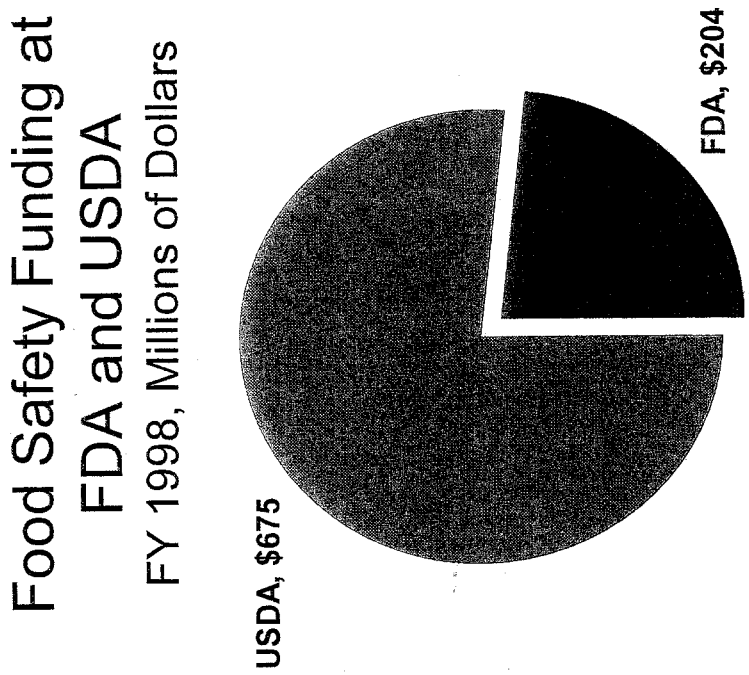
In Vermont, where I grew up, there is a joke about a city slicker who asks directions from an old Vermont farmer. The punch line is: You can't get there from here. Today we must ask whether we can achieve a safer food supply in the 21st century without radically redesigning the current food-safety regulatory system? Like that old Yankee farmer, I am afraid that you can't get there from here.

Thirty years ago, the White House Conference on Food first recognized the need for a single food-safety agency. We are hopeful that now Congress will lead the way to a more coherent food-safety system. It is time to respond with actions and not mere words.

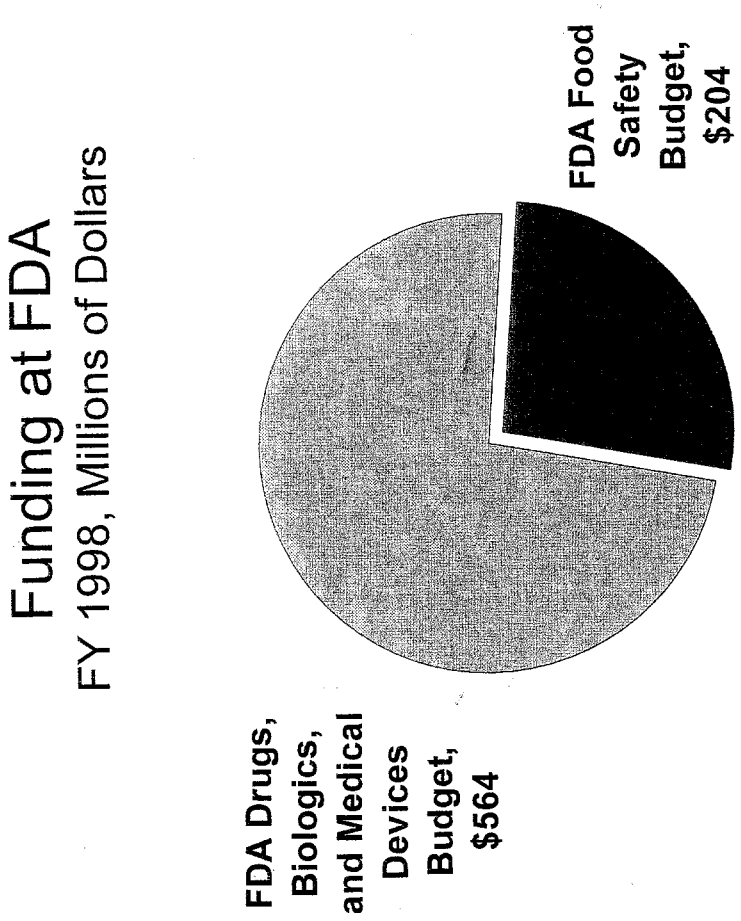
Appendix A


Percent of Outbreaks Traced to
USDA and FDA-Regulated Foods
USDA
23%
FDA
77%

Appendix B


Food Safety Funding at FDA and USDA
FY 1998, Millions of Dollars
USDA, $675
FDA, $204

Appendix C


Funding at FDA
FY 1998, Millions of Dollars
FDA Food Safety Budget, $204
FDA Drugs, Biologics, and Medical Devices Budget, $564

NFPA
The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

1350 I Street, NW
Suite 300
Washington, DC 20005
202-639-5900

WASHINGTON, DC
DUBLIN, CA
SEATTLE, WA

Testimony of the National Food Processors Association
Before the
Subcommittee
On Oversight of Government Management,
Restructuring and the District of Columbia
Committee on Governmental Affairs
United States Senate
Regarding the Federal Food Safety System
August 4, 1999

My name is Rhona Applebaum and I serve as the Executive Vice President for Scientific and Regulatory Affairs for the National Food Processors Association. I thank the Subcommittee and you, Mr. Chairman, for the opportunity to offer comments on the organizational structure of our nation's food safety system – a system we believe provides U.S. consumers with one of the safest food supplies in the world.

Before beginning my testimony I would like to note that NFPA serves as the scientific and technical trade association for the $460 billion U.S. food processing industry. We operate three laboratory centers and employ approximately 60 scientific and regulatory experts. NFPA's primary mission focuses on food science and food safety, so we have a very direct interest in providing input on this proposal.

Today, I would like to address the effectiveness of our current food safety system, and some of the challenges to public health that system faces. And, I would like to address why we believe a single food safety agency is not necessary to meet those challenges. While NFPA does not endorse S. 1281, the Safe Food Act of 1999, we commend Senator Durbin for his legislation's goal of enhancing food safety – an objective shared by the food industry.

My purpose today is to advance the deliberations of this Committee by providing constructive recommendations to improve the overall food safety system without a potentially disruptive restructuring of our current framework.

STRENGTHS OF EXISTING SYSTEM

The current regulatory framework in the United States, with shared oversight of food safety by FDA, USDA and several other agencies, has provided what is generally regarded as one of the safest, if not the safest, food supplies in the world. So while there may be ways to improve the current system, it is not accurate to say categorically that the system is broken and needs to be replaced.

There are two primary reasons why our current system works well. The first and primary reason is that safety is the food industry's number one concern. Food companies have a vested interest in the safety of their products. Any company that takes unnecessary chances on the safety of its product will not, and should not, be in business for very long. Second, the current food safety system is based in large part on sound science and a mutual commitment to food safety by both food companies and the agencies that regulate them—agencies at all levels of government—local, state and federal. This system to a large-degree is free from the hype and mischief that can wreak havoc on the collaboration and coordination that underpins this system—that makes the system work. Interference based on political agendas—not food safety constructs—does nothing to enhance or improve safety, or retain or increase the confidence of the American people in the safety of our food supply.

Recall Coordination

Another aspect of the current system that works well is the approach to handling food safety problems once they are identified. The systems in place at FDA and USDA's Food Safety and Inspection Service result in both industry and the agencies acting quickly and effectively to protect consumer health when potential problems arise. Handling of product recalls and withdrawals continue to be accomplished effectively under government's broad existing authority. Further, in the event a company refuses to cooperate with FDA or FSIS – something that is essentially unheard of – federal agencies can call on the states for assistance in assuring a potentially dangerous product is removed from the marketplace. And, let's not forget the power of the media. Nothing would be more detrimental to a company than negative media coverage detailing its refusal to cooperate with a government agency regarding the safety of its product.

These factors suggest the current food safety system is a strong and effective one.

ENHANCING THE EXISTING FRAMEWORK

While NFPA believes that the level of food safety in the U.S. is unprecedented, we acknowledge that a range of public health challenges face the current system. Mr. Chairman, the question is, how do we meet those challenges? It is not necessary to have a single food agency to do this; what is needed is a logical coordinated approach to food safety systems. Let me provide you with a few examples that will help to explain this statement.

Better Coordination

First, NFPA believes that a logical coordinated approach to food safety is the best way to improve upon the system already in place. Better coordination among various federal, state and local government agencies responsible for ensuring the safety of the U.S. food supply is needed to improve upon the effectiveness of existing programs. NFPA is supported in this assessment by the 1998 National Academy of Sciences report *Ensuring Safe Food from Production to Consumption*, which called for better coordination among federal agencies, but not a single food safety agency.

Further, NFPA believes what is needed is a single, science-based federal food safety policy. Uniform requirements will ensure that the same food safety guidelines will be followed and enforced. The President's Council on Food Safety – created in the wake of the NAS report - also supports a comprehensive food safety plan, and is working to develop such a plan as part of its mission. A unified policy is needed to provide cohesion and promote the sharing of technology, information, and resources to better ensure food safety.

There is a precedent for this approach, in nutrition labeling. Both FDA and USDA under separate authorities and with different processes, enforce virtually identical nutrition labeling rules. States are limited to promulgating and enforcing rules identical to the federal rules, by preemption provisions of the federal statutes, which ensure uniformity. The Nutrition Facts label for foods works exceedingly well, enforced by different federal agencies. Why can't there be a similar strategy for Good Manufacturing Practices, HACCP and other food safety requirements, along with similar inspection procedures for like products? In short, there needs to be a single, scientifically based federal food safety policy.

Changes Must be Science-Based

Another point that must be addressed is that any changes and improvements to our food safety system must be grounded in scientifically sound, objective science. Both the National Academy of Sciences and the President's Council on Food Safety endorse actions to ensure that our federal statutes are based on sound science. Scientifically-based risk assessment should determine the allocation of resources in the food safety regulatory framework. The system must identify real public health risks to consumers and focus on these risks. This is the basic premise of changes now being implemented in the current system, and we must avoid the temptation to abruptly change and follow a singular agenda, or set of agendas, in determining our nation's food safety policy.

Consumer Education

I must also stress the importance of enhancing efforts to educate consumers on proper food preparation and handling techniques. Many food safety problems can be prevented through appropriate handling and preparation. Enhanced educational efforts will help reduce the risk of foodborne illness at home. Increased regulatory power or more inspections would not adequately address this problem. Consumers recognize government agencies as credible sources of information on food safety. Food safety experts in government should be more proactive in promoting safe food practices in the home. To this end, we applaud efforts, proposed by experts at USDA, to include safe food handling practices as a separate guideline in revisions to the *Dietary Guidelines for the Year 2000*. American consumers need such information to ensure to the extent possible that the foods they eat constitute a nutritious, healthful and above all safe diet. In addition, government needs to be more public in its support of new technologies, such as irradiation, that can significantly enhance food safety for the good of all. Such technologies need vocal government support to assure acceptance by the American public.

NFPA believes that incorporating better agency coordination and more consumer education along with increased surveillance, and better agency resource allocation in terms of risk to consumers, will go a long way in enhancing the safety of the U.S. food supply.

If the Federal government were to start from scratch to establish a food safety regulatory system, would it resemble the current system? Perhaps not, but then numerous other government agencies whose missions parallel or compete with one another might also look differently with the benefit of a clean slate. We should be mindful that our existing food safety system has evolved over many decades, and enjoys the confidence of the overwhelming majority of the American public. The evolution is ongoing toward an even more effective system in the future.

CONCLUSION

Mr. Chairman, in closing I would like to point out that neither the National Academy of Sciences nor the President's Council on Food Safety feel a single food safety agency is necessary. In fact, the President's Council has stated "many food safety issues would be difficult to resolve by a reorganization." The President's Council is working to develop a comprehensive food safety plan and advising agencies of priority areas for investment in food safety. The Council is also working to ensure that agencies work toward better coordination of food safety activities. In light of these facts, we feel that it would not be wise to reorganize our highly successful food safety system in favor of a single food safety agency with the potential disruptions that would result from such a "sea change."

Instead, NFPA recommends that Congress examine the recommendations of the National Academy of Sciences and the changes being designed and implemented by the President's Food Safety Council before considering such drastic measures as the creation of a whole new government bureaucracy.

As a broad-based trade association with members regulated by both FDA and USDA, we at NFPA perceive wide cultural differences between these industry segments and their respective regulatory agencies. These cultural differences have, in our opinion, developed because of the different regulatory philosophies that have become ingrained in these various segments and agencies over many years. While we would like to see a reduction in the differences between the agencies in terms of their policies and approaches, we feel this can be effected through cooperative efforts between the agencies, as well as increased harmonization in certain regulatory requirements and statutory authorities. Proceeding without regard to the dynamic that exists in the factories that produce food, would, we believe, be detrimental to the objective of producing the safest foods possible.

In closing, The National Food Processors Association would like to leave you with the following analogy. We have identified in general terms what we believe is needed to improve and enhance the current food safety system---in brief, a more efficient scientific approach to assessing real risks, focusing attention and resources on these risks, and striving for better communication and coordination among all interested parties. So, we urge an alternative. Why expend resources to essentially demolish structurally sound buildings and replace them with an expensive new high-rise to house all functions under one roof? Why not just knock down a few walls, open a few pathways between buildings, and – better yet – put in a more efficient, uniform computer system? This will allow everyone to work together as a team, following the same directions to meet the same goal. The architecture of the nation's food safety system is not so flawed that the building needs to be gutted. It simply needs an upgrade in technology, and some remodeling.

Breaking down this science-based food safety system and rebuilding it under one potentially politicized agency is not prudent. Effectively building upon ninety years of food safety regulation, which has produced a food safety system that is among, if not the world's best, would achieve better results.

Again, Mr. Chairman I thank you for the opportunity to provide testimony to this committee, and welcome any questions you or other members may have.

GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

1010 WISCONSIN AVE., NW
NINTH FLOOR
WASHINGTON, DC 20007
PHONE (202) 337-9100
FAX (202) 337-4508
www.gmabrands.com

Remarks of Stacey Zawel, Ph.D.
Vice President, Scientific and Regulatory Policy
Grocery Manufacturers of America, Inc.
before the Senate Committee on Governmental Affairs,
Subcommittee on Oversight of Government Management,
Restructuring, and the District of Columbia

"Overlap and Duplication in the Federal Food Safety System"

August 4, 1999

Good morning. My name is Stacey Zawel; I am Vice President, Scientific and Regulatory Policy for the Grocery Manufacturers of America. Thank you for this opportunity to recommend ways to refine, but not replace, our nation's food safety system.

GMA is the world's largest association of food, beverage and consumer brand companies. With U.S. sales of more than $450 billion, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific, and political expertise from its member companies to vital food, nutrition, and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency, and growth in the food, beverage and consumer products industry.

If we were starting from the beginning, and had the luxury of creating a food safety system from scratch, GMA would recommend that the system be based on four fundamental principles. First, regulatory controls would rest on science-based

assessments of risk, not speculative hazards. Second, education about proper methods of food handling and preparation would be provided at all stages of the food chain. Third, adequate staffing and resources would be provided to administer the food safety system. And, fourth, industry and all sectors of government would pledge to work together, in a coordinated manner, to maximize food protection.

But we are not starting from scratch. We already have a food safety system in place. Critics argue that it is fatally flawed by a lack of coordination among the responsible agencies and senseless duplicative effort. They are wrong. The existing system is a successful partnership among government, industry, and consumers. The diversity of the regulatory players adds a breadth and depth of experience that is crucial in addressing the multi-faceted nature of the food safety challenge.

The President's Council on Food Safety -- which includes Secretary Shalala and Secretary Glickman -- is working on a strategic food safety plan that will focus on enhancing cooperation among the responsible federal agencies. Planned measures include a unified food safety budget and single research plan.

In the face of this commitment to enhanced coordination at the highest levels of government, it simply is ludicrous to suggest that the present food safety system must be scrapped entirely. We need to work with the successful system we have, giving the Council on Food Safety time to make the adjustments necessary to perfect it. Any other course would be enormously disruptive and expensive.

GMA believes, therefore, that the question we should be asking today is not how can we build a food safety system from scratch but how can we assist the Council on

Food Safety in improving the one we have? GMA would suggest a renewed focus on the four basic principles I discussed earlier.

The Food Safety System Must Be Based on Science

Especially as food production, processing, and distribution increases in complexity and sophistication, we must rely upon scientific techniques to detect and address potential food safety hazards. We have to identify and fight the true causes of foodborne illness with the right scientific weapons. Those weapons can only be developed and refined through laboratory research and practical testing.

We are starting to achieve some of the benefits a science-based approach can bring, and every effort should be made to ensure that this direction continues. For example, new techniques to reduce bacterial contamination, such as irradiation and certain chemical compounds, are being developed that offer encouraging results. USDA's adoption of the Hazard Analysis Critical Control Point Systems approach -- a process control originally developed and used voluntarily by the food industry -- has the potential to transform the antiquated meat and poultry inspection system from one based on "sight, smell, and touch" to one founded on science-based assessments of risk. Although implementation challenges abound, this technique and others show promise.

USDA, FDA, and other federal agencies, working with the states and industry, should continue their focus on science and research. All of the agencies with food safety regulatory responsibility, with industry's support, must look to science as the key to accomplishing their shared mission. And they must do this cooperatively, not competitively.

Education in Proper Food Handling Should be Promoted

The handling of foods at all stages of the farm-to-table production chain affects safety; accordingly, everyone has a responsibility for and must be educated with respect to the proper and safe methods for handling food products. Using tools like the FightBAC program, classroom education, advertising and other means at our disposal, we simply must get the word out to all Americans, including individual consumers.

But food safety education is a shared responsibility. The food industry is committed to this effort, through programs like FightBAC, and it should be encouraged to do more. At the same time, however, federal and state government must play its part in this process. Too often educational efforts at the federal level have faltered. The "education" component of the Nutrition Labeling and Education Act is a good example. Federal educational programs are important, and they should be fostered and funded.

Food Safety Agencies Need Adequate Resources Properly Employed

Without properly trained personnel, state of the art equipment, and the necessary funds, an emphasis on science and research is meaningless. Although FDA has historically enjoyed respect throughout the world, the agency's reputation is being threatened by a depletion of resources for food safety. The agency needs adequate funding for its science-based activities, strong leadership and adequate staffing. The food industry and consumers are best served by a strong FDA that develops policy based on the best science, and enhances public confidence in the safety of the food supply.

Similarly, although FSIS is better funded, the agency's labor intensive system is both costly and antiquated. FSIS continues to implement command-and-control regulations, creating a layering effect of cumbersome regulatory controls over an incrementally modernized food safety scheme. The agency's effectiveness and efficiency

could be enhanced considerably -- and its scarce resources optimized -- by streamlining the current inspection system, and focusing on products, processes and facilities presenting the most significant risks.

Federal and State Food Safety Agencies Must Work Cooperatively

Coordination is a challenge in a food safety system that draws upon the multiple disciplines, expertise and history of several executive agencies. But replacing the successful system we have with a single agency is not a magic bullet for enhancing food safety. Moving boxes around on the government's organizational chart simply won't make food any safer.

The President has appointed a Council on Food Safety and charged it with drafting a single, comprehensive strategic plan for unifying and improving the national food safety system. This plan will make improving cooperation and coordination one of its cornerstones. The Council's strong commitment to coordination is reflected in its plans develop a unified federal food safety budget, and through the Administration's recent creation of the Joint Institute for Food Safety Research.

In short, the Council on Food Safety is already creating the single food safety system -- united by a single budget and research plan -- that the proponents of S. 1281 are seeking. Before embarking upon on an expensive, disruptive reorganization -- a purely bureaucratic initiative with no guaranteed improvements in food safety -- we owe it to the American people to see if the Council's strategic plan and related activities can address any challenges that exist and move the country to a new level of food safety and protection.

FDA, USDA, and the other agencies with responsibility for food safety already have the legal authority and expertise needed to improve further the safety of the food Americans eat. Where changes in enabling legislation are necessary to maximize the agencies' effectiveness, and to allow them to make decisions based on science-based assessments of risk, those changes should be made. For example, legislation introduced by Senator Roberts this spring that would establish national, uniform standards with respect to when foods (other than meat and poultry) would be considered adulterated and, therefore, subject to enforcement action would substantially boost FDA's effectiveness in enforcing the law's food safety protections, and would enhance the cooperative role of state and local governments in a coordinated nationwide regulatory scheme.

GMA recognizes that ongoing concerns about food safety are somewhat more acute in the wake of unfortunate incidents of foodborne disease. A single food agency, however, would do nothing to reduce the risk of foodborne disease. It would only reshuffle government workers and offices, at a cost in terms of dollars and personnel time we can ill afford as the country seeks to ensure the safety of its food supply in an era increasingly characterized by global movement of foodstuffs and centralization of production and processing.

Summary

In short, America's food safety system needs the right focus, not a new structure. Scientific research, education, adequate resources and coordination should be its guiding principles. Creating another government agency to do the job of food safety simply is unnecessary.

GMA is eager to cooperate with Congress, the regulatory agencies, and all other appropriate stakeholders in refining the focus of our food safety system and assisting the agencies in using their resources in the most effective and efficient manner possible. Thank you for this opportunity to testify today.

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

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

U.S. Senate Testimony

By

Sanford A. Miller, Ph.D.
Professor and Dean
Graduate School of Biomedical Sciences, MC 7819
University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, Texas 78229-3900

Testimony before the Subcommittee on Oversight of Government Management, Restructuring, and the District of Columbia, hearing entitled, "Overlap and Duplication in the Federal Food Safety System," August 3, 1999, U.S. Senate, Washington, D.C.

STATEMENT BEFORE THE SENATE OVERSIGHT COMMITTEE

Thank you Mr. Chairman. My name is Sanford A. Miller and I am Dean of the Graduate School for Biomedical Sciences at the University of Texas Health Science Center at San Antonio. I served for nine years as the Director of the Center for Food Safety and Applied Nutrition at the FDA. Prior to that assignment, for more than 20 years, I was Professor of Nutritional Biochemistry at the Massachusetts Institute of Technology. I also served on the Institute of Medicine/National Academy of Science committee whose work resulted in the report, "Ensuring Safe Food". Although I will refer to the report, I do not represent the IOM or the NAS or the committee.

I am pleased to have this opportunity to discuss with you some of the issues associated with the assurance of safe food for the American public, in particular those dealing with the structure of food safety institutions in the US. In its report, the IOM/NAS committee described the current system and identified some of the attributes of a successful and effective food safety structure. The report pointed to several areas where the current organization fell short of the ideal and offered a number of recommendations to improve the current system. The committee's suggestions were reasonably comprehensive and covered most of the important areas.

In my opinion, three fundamental themes dominated their proposals. First, an effective food safety system must be based on science. Second, to accomplish this goal, the underlying statutes must be revised to permit flexibility and to permit, in regulation, recognition of the changing nature of scientific inquiry. Third, to implement these concepts, reorganization of national food safety institutions was recommended.

In the time that has passed since the publication of the report, nothing has occurred to change my view that the principal recommendations of the report still are sound and need to be implemented. Specifically, the recommendations for a statutorily-based single voice for food safety efforts, that is, a single point of responsibility both for programs and resources, has not been implemented.

This is not to say that the Administration and the Congress have taken no action; they have. The President, for example, has created the Joint Institute for Food Safety Research and the President's Council on Food Safety. Most recently, he directed the Secretary for Health and Human Services to work with other food-related agencies to develop programs (and, I assume, identify resources,) to ensure the safety of imported foods. The development of a nation-wide, early warning system for foodborne disease is another initiative of value, particularly in its effort to bring state agencies into the program.

Yet, none of these actions provides a permanent structure and a single point of responsibility to meet the needs identified, not only by the IOM/NAS committee, but also by many other thoughtful scholars of food safety. The rules of action and process can change with each Administration. Moreover, much depends on the goodwill expended by the leadership in each Agency to assure success of the overall program in meeting national goals.

In my experience, as long as the leadership has respect and good personal relations with each other, the system will work. When there are professional and personal conflicts, it will not. When resources are readily available and hard choices are not required, this system will work. When they are not available, it will not work. Each Agency operates under a different mandate, governed by different laws and answering to different constituencies and traditions. To ask them to voluntarily ignore this history is naive. There needs to be a permanent structure focused on food safety to meet the enduring needs of the American people.

It is important to recognize that this possible reluctant response to a request for collaboration, consolidation and of sacrifice of resource is not the reaction of stubborn bureaucrats. The professionals in the Agencies are hard working, extremely competent and, in many cases the world experts in their area of expertise. They have strong professional, ethical and social views on how to protect the public. Having been in their position, I understand the pressures they must work under. They must respond to and act under the existing acts even though they might personally believe that these statutes are not based on science and are inappropriate. They must respond to their constituents and the Courts. They are also clearly aware that every four years, a new Administration comes to office with ideas that may be significantly different than those they have been working under.

There are other, equally important reasons why new structures for food safety need to be explored. For example, a single point of responsibility can more readily reallocate resources, among and within agencies, as they are needed than under today's fragmented system. The need for adequate resources is an ongoing problem for regulatory agencies. There is a tendency for both Congress and the Administration to mandate programs without consideration for the source of support. It is also sometimes surprising to note the reluctance of the food industry to support a well-funded regulatory activity even though they often express the need for a strong FDA or FSIS. Our colleagues in multinational companies know best the difficulty of operating in European countries in which the regulatory agencies have lost credibility with the public. A strong, competent, well-funded food safety organization having a single focus for assuring a safe food supply is one way to attain a high level of credibility and support from the public. Indeed given the inexorable move towards a truly global food supply, there is need for a parallel global food safety structure. A single US focus would make it far easier to speak in this arena with a single authoritative voice.

It seems clear to me that there is a need for statutory change that recognizes the changing challenges of the new millennium. New science, globalization of the food supply, the emergence of new and more potent foodborne disease organisms, new genetic and conventional technologies bringing new foods to the table, the increased desire for the consumer to self medicate to prevent disease often through changes in the diet, all require a new, bold concept in organizing food safety efforts in the US. This concept must recognize the need for rapid decision making and action as food safety issues arise.

Given the general recognition that structural changes are required if we are to continue to identify the risks and to assure the safety of the food supply, what are the criteria that should be used to determine the validity of the proposed changes? Among many others, the most perplexing and potentially controversial could be the nature of the scientific

disciplines underlying food safety science and risk assessment. Today, risk assessment and food safety science are confederations of sciences. Few attempts have been made to identify the basic precepts for a new field of inquiry into food safety that would incorporate risk assessment and would provide the foundation for an agenda of research for this new field. Disciplines evolve from earlier fields of investigation. Nutrition is the child of physiology, and biochemistry descended from nutrition. Molecular biology and genetics, in turn, resulted from the extension of biochemistry and cell biology to the resolution of new unexplored problems in biology. Food safety science is at a similar period in its development. We are seeing a new science at the moment of its birth. Today, its knowledge base consists of toxicology, microbiology, nutrition, environmental sciences, food science, and public policy among others. We need now to define the process by which they can be integrated in a consistent program that can be used to educate a new generation of scientists who have the skills to rapidly and directly predict, prevent and resolve the new problems in food safety that will result from the global application of new technology. Clearly, there are many questions that need to be answered to meet the goals of safe food for all. There are no proposed solutions that do not require continued careful investigation and discussion. This is as true for the evolution of a new discipline of food safety science as it is for the structure of food safety institutions.

For the development of this new field of investigation, I strongly recommend the calling of a national conference to define the components of this new field and the curriculum that would support it. The conference would also be asked to generate an agenda that establishes priorities for the vital areas of investigation needed to meet the requirements of the future.

In its deliberations, the IOM/NAS committee considered the nature of the structural changes that could help resolve the issues raised in its report. Recognizing the complex nature of this task, the committee strongly recommended the funding of a second study, focused on the structure of food safety programs in the US. While the committee recommended the need for a single voice and point of responsibility for food safety at the Federal level, it also recognized that the actual form of such a structure required more effort and time than it had at its disposal. I continue to support this position and firmly believe that the next step in this evolutionary process needs to be a careful consideration of the organizational needs to assure for the American people what is their right, a safe food supply. It is for this reason that I ask your support to fund such a study at the IOM/NAS and to also consider funding a National Conference to consider the development of food safety science. Finally, for all of our colleagues, let me quote from Roger Bacon, the great medieval philosopher and scientist, "He that will not apply new remedies must expect new evils".

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

The Honorable George V. Voinovich
Chairman, Subcommittee on Oversight of Government Management,
Restructuring, and the District of Columbia
601 Hart Senate Office Building
Washington, DC 20510

Dear Senator Voinovich:

Thank you for your letter of September 8, 1999, in which you included follow-up questions from Senator Durbin stemming from the Subcommittee's August 4, 1999 hearing on food safety. We share your concerns about food safety and are committed to ensuring that our food supply remains the safest in the world. We appreciated the opportunity to testify before the Subcommittee and apologize for the delayed response to the following questions.

1. **In response to a question, you indicated that it is possible for USDA to regulate, inspect and promote products and do so with credibility. To illustrate that point, you mentioned the successful implementation of a science-based HACCP approach in meat and poultry, with high industry compliance rates and a dramatic reduction in *Salmonellosis* as measured by FSIS performance testing and recent CDC surveillance data. Yet meat and livestock industry associations have recently complained to Congress that FSIS is not fully enforcing the same HACCP program and salmonella testing standards for foreign plants importing meat and poultry into the United States.**

   This prompted Congresswoman Carrie Meek to introduce legislation that in effect would require USDA to enforce these standards for imports. In a May 25, 1999, letter to Congressman Charles Stenholm, Ranking Member of the House Committee on Agriculture, FSIS Administrator Thomas J. Billy responded to this issue by writing, "The U.S., which is a major exporter of meat, poultry, and other agricultural products, is protected and benefits by the right to demonstrate equivalence of our inspection system in gaining access to foreign markets. We expect other countries adopting new regulations to continue to accept our exports while they conduct the deliberate process to determine the equivalence of our measures."

   Does this indicate a conflict of interest? If not, why is it necessary to allow foreign meat and poultry producers more time than domestic producers to fully comply with HACCP program and pathogen reduction regulations?

   To answer the first part of your question, we do not believe there is a conflict of interest within USDA in regard to the regulation, inspection, and promotion of agricultural products. USDA is not unique in being a Cabinet-level Department with multiple responsibilities in a given area. For example, the Department of Health and Human Services (HHS) has jurisdiction over the research and testing of drugs, as well as drug approval. The Federal Aviation Administration (FAA) is responsible for transportation management as well as the investigations into transportation-related accidents. We believe the agricultural expertise residing at USDA allows the Department to handle a full range of programmatic responsibilities without conflict of interest and with credibility.

As for the role of the Office of Under Secretary for Food Safety at USDA, in the 1994 USDA reorganization, the food safety regulatory function was separated from the marketing function, effectively eliminating any questions from years past about the appearance of an intra-departmental conflict of interest. The reorganization legislation mandated that the office be occupied by an Under Secretary who has specific, proven public health or food safety background. These changes have enhanced USDA's public health focus and fortified food safety's presence within the Department's broad mission. I am very honored to be the first person to occupy this job.

In answer to the second part of your question, foreign meat and poultry producers were provided with the same amount of time in complying with HACCP requirements, as were domestic producers. Countries exporting meat or poultry to the United States must have a food regulatory system that has been judged equivalent to the FSIS domestic system. Prior to the World Trade Organization (WTO) Agreement on Sanitary and Phytosanitary measures, also known as the SPS Agreement, FSIS evaluated foreign food regulatory systems under provisions in U.S. inspection laws that required programs to be "at least equal to" the U.S. system.

The eligibility of countries to export meat or poultry to the United States was initially evaluated on a case-by-case basis through analysis of applications followed by on-site audits. Consequently, all "at least equal to" countries that were eligible to export meat or poultry to the United States, when the SPS Agreement was ratified in 1994, were automatically judged to be "equivalent."

From this baseline of equivalence, FSIS has sought to ensure that equivalence is maintained. For example, when FSIS implements new sanitary measures domestically -- such as the Pathogen Reduction/HACCP final rule -- notice is given to each exporting country that the new measures must be adopted by the foreign food regulatory system in either the same way or in an equivalent manner. Exporting countries are asked first to provide FSIS written assurance that the new requirement will be implemented and second to submit documentary evidence to support equivalence. FSIS reviews this documentation on a country-by-country basis and makes a determination of whether the foreign countries' measures appear, on their face, to be equivalent. During the next on-site foreign inspection system audit, the implementation of that measure is verified.

It is important to note that FSIS does not stop trade with exporting countries while the document analysis and verification process is underway. Nor do U.S. exports of meat or poultry cease when FSIS receives new import requirements from countries to which U.S. establishments export their products.

Three circumstances could, however, result in an interruption of trade. One is where an emergency sanitary measure is implemented by FSIS to address a hazard that is so severe that no product can enter the marketplace from a foreign establishment until the control is in place. The second is where an exporting country does not provide satisfactory documentary evidence of an equivalent sanitary measure. The third is where a system audit reveals that an exporting country is not implementing a sanitary measure in the manner that FSIS initially determined to be equivalent.

In the case of FSIS's Pathogen Reduction/HACCP sanitary measures, the first circumstance did not apply because none of the requirements were of an emergency nature. Thus, FSIS proceeded to evaluate documentation from each exporting country that explained the country's method of implementing Pathogen Reduction/HACCP sanitary measures. On-site verification was also conducted. By November 1999, FSIS had completed its review of the documentation submitted by exporting countries and on December 14, 1999, FSIS held a public meeting in Washington to release information on the status of foreign countries equivalence with HACCP requirements.

In addition to reporting the Pathogen Reduction/HACCP equivalence status of each exporting country at the public meeting, FSIS officials explained the rationale for acceptance of alternative

Pathogen Reduction/HACCP sanitary measures, and received public comments on the state of FSIS equivalence activities.

Of the thirty-six foreign countries eligible to export meat and poultry to the U.S., 32 countries submitted documentation regarding the implementation of Pathogen Reduction/HACCP sanitary measures. Four countries -- Dominican Republic, Guatemala, Honduras, and Slovenia -- did not submit documentation and voluntarily delisted all establishments that had been certified for the U.S. market. These countries will continue to develop HACCP programs and the U.S. will not accept product from these countries until full documentation is received and evaluated to determine whether the foreign HACCP program meets domestic requirements. Paraguay has not fully implemented Pathogen Reduction/HACCP requirements or equivalent measures and has been suspended from eligibility to ship product to the United States.

2. **Another area of concern regarding perceived conflict of interest involves the relationship of agricultural use of antibiotics and the development of antibiotic-resistant strains of specific foodborne pathogens that affect humans. According to a recent General Accounting Office report on this issue, USDA and FDA have differing positions on this issue. While FDA believes that regulatory steps based on scientific evidence are needed now to reduce the antibiotic use in food animals, USDA believes that more research is needed before decisions are made regarding further regulation. Is this a fair characterization of USDA's position? What evidence does USDA have to reject the conclusions of FDA?**

Many scientists within agencies at USDA and the Department of Health and Human Services (HHS) acknowledge that the issues associated with understanding the causal relationships between many agricultural uses of antibiotics and cases of drug-resistant bacterial disease in humans are complex and multifactorial. USDA and HHS scientists are working together as part of a government-wide taskforce to develop an action plan to combat antimicrobial resistance. This taskforce held a public meeting in July 1999 to solicit suggestions from a wide range of stakeholder groups and from the general public about important issues in antimicrobial resistance and steps that Federal agencies could take to begin to address these issues. USDA and HHS are working through the Taskforce to consider the stakeholder suggestions and additional ideas, and will work together to develop a plan that will specify practical implementation steps to combat antimicrobial resistance. This plan is expected to be released for public review in the early part of 2000.

3. **The recent dioxin residue incident in Belgium highlights the need for a mechanism for rapid dissemination of residue food safety information to prevent unsafe residues in the United States food supply. In the U.S., is the Food Animal Residue Avoidance Databank (FARAD) program an effective source of food safety residue information to help avoid and mitigate residue problems? How readily available is it to U.S. producers, extension agents, and food-animal veterinarians? Is it true that FARAD, through its newly established global FARAD centers in Europe, provided information useful in response to the Belgian crisis? Is this program adequately funded? Should funding for FARAD be expanded and made permanent?**

The Food Animal Residue Avoidance Databank (FARAD) originated with the 1982 Residue Avoidance Program sponsored by FSIS and was designated to be a repository of residue avoidance information and educational materials. Over the past 17 years, FARAD has evolved into an expert-mediated residue avoidance decision support system for food animal agriculture. It is the best source of professional advice available to practicing food animal veterinarians for determining how animals withdraw from medication and to ensure that animals are residue-free when going to slaughter.

FARAD received approximately $200,000 per year through FY 1998 from USDA's Cooperative State Research Education and Extension Service (CSREES). In FY 1999, this amount was increased to $500,000. For FY 2001, FARAD will have to compete for funding under the new Integrated Research, Education and Extension Food Safety Program.

FARAD was developed as a resource to be used by practicing food animal veterinarians. Although there have been frequent interactions between FARAD staff and those of the public health regulatory agencies, FARAD experts are not normally used by public health regulatory agencies, such as FSIS, to extrapolate food safety data in support of regulatory decisions.

Regarding FARAD's involvement in the Belgian dioxin case, since FARAD is a drug residue monitoring program and dioxin is not a drug, we would not expect FARAD to find or look for dioxin residues.

4. **The recent Belgian dioxin crisis also raises the concern about animal feed as a potential source of contamination to the human food supply. Which agencies are responsible for the safety of animal feeds, and how is this responsibility handled? Is there a single federal official with the authority to provide one voice on the food safety implications related to the animal feed supply? If so, why?**

The Food and Drug Administration (FDA) has primary responsibility for the safety of animal feed in the U.S. However, both USDA and the Environmental Protection Agency (EPA) also have a part in protecting the animal feed supply.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), FDA has the responsibility to ensure pre-harvest food safety. Within FDA, the Center for Veterinary Medicine (CVM) is responsible for regulating the levels of contaminants in animal feeds to ensure that the food for animals and food for humans derived from animals is safe and free of unsafe amounts of drugs, industrial chemicals, pesticide residues, and harmful bacteria.

USDA's Animal and Plant Health Inspection Service (APHIS) has responsibility for preventing the transmission of animal diseases among animals, including through animal products. FSIS conducts residue testing of meat and poultry products at slaughter for the presence of illegal drug residues. FSIS has the authority to refuse product for use in the human food supply if residues are present. The EPA establishes tolerances for pesticides on raw agricultural commodities and for residues in edible animal and vegetable products. FDA and FSIS enforce these tolerances.

Despite split jurisdictions and differing statutory responsibilities across several Federal agencies, the USDA and HHS, through the President's Food Safety Initiative, have adopted a farm-to-table approach in protecting the food supply.

5. **What safeguards exist to ensure against dioxin or PCB contamination of animal feeds, either accidental, intentional or by natural causes? To what extent are contaminated animal feeds implicated and what safeguards are in place to ensure that animal feeds are not a source for spreading pathogens such as *E. coli* O157:H7?**

Since FDA has primary responsibility over the protection of animal feeds, we defer to FDA on this issue.

6. Which agency regulates genetically modified foods? Does FDA review the food safety impacts of each new product before it comes to market? Does the USDA have a role? Are labeling requirements under consideration? For imported genetically modified products, do importers have to make any declarations prior to shipping food to the U.S.?

Under the coordinated Federal framework for the regulation of biotechnology, the Environmental Protection Agency (EPA), the Department of Health and Human Services' Food and Drug Administration (FDA), and USDA's Animal and Plant Health Inspection Service (APHIS) work to ensure that genetically engineered organisms do not adversely impact people or the environment---including other plants, insects, and animals. Federal regulations require that a thorough examination be conducted to determine possible environmental impacts of genetically engineered plant varieties before they can be field tested, and then again before the new varieties can be used commercially.

APHIS is authorized by the Federal Plant Pest Act to require scientific researchers to obtain permits or provide notification prior to introducing genetically engineered organisms that are, or could be, considered plant pests. When a company, academic research institution, non-profit organization, or public sector scientist wishes to field test a genetically engineered plant, they must first contact APHIS for permission.

APHIS can allow researchers to field test a genetically engineered plant product in one of two ways. The first entails applying for an annual permit from APHIS prior to testing. Researchers must provide APHIS specific information about the plant variety being tested, including the purpose of the test; how testing will be conducted; and specific precautions that will be taken to prevent the escape of pollen, plants, or plant parts from the field test site. APHIS officials take into account the biology and nature of the plants being altered, the characteristics and origin of the genetic material used in altering the plants, and the environment that the genetically engineered plant would be introduced to. All permit applications are examined for possible effects on the environment, endangered or threatened species, and non-target species, and the potential for any gene transfer to cultivated, wild, or weedy species. For example, in cases where plants are genetically altered to produce pesticide characteristics, APHIS requires data that demonstrates the pesticide will have minimal adverse impacts on diverse groups of organisms including, among others, insects, earthworms, birds, fish, mammals, and humans.

Alternatively, when there is certainty, based upon experience, that the field testing of a specific genetically engineered plant variety will meet APHIS safety standards and pose no plant pest risk, researchers can initiate field testing using a simplified procedure. Under this procedure, researchers must notify APHIS before a genetically engineered plant is moved or field tested. Afterward, APHIS has 30 days to review the notification prior to the initiation of testing. Field tests conducted under this notification process are required to remain in compliance with the same safety standards used in trials approved through the permit process.

If APHIS approves a new genetically modified plant for field testing, APHIS officials and their State counterparts may inspect the field test site before, during, and after a test to ensure that it is conducted and managed safely. After several years of such testing, a developer may wish to commercialize the genetically modified plant variety.

If a developer petitions APHIS to obtain a non-regulated status to release a genetically modified plant product for commercial agricultural use, APHIS prepares an environmental assessment that thoroughly examines any potential risks to the environment. Agency officials evaluate all available scientific information regarding the new plant variety and its possible effect on other plants, including the information contained in the petition itself. During the evaluation period, APHIS also publishes a notice in the *Federal Register* announcing that the petition is available for public review and comment. APHIS fully considers all such comments in the decision-making process.

APHIS will grant the petition for non-regulated status for a genetically engineered plant only if the Agency determines that the plant poses no significant risk to other plants in the environment. A determination of non-regulated status allows the plant to be grown in the same manner as other plants of that species. All new plant varieties that receive such determinations also must conform with State and Federal marketing standards and State seed certification laws, as well as the Federal Food, Drug, and Cosmetic Act, the Federal Insecticide, Fungicide, and Rodenticide Act, and other applicable statutes.

I hope this information is helpful to you and your staff. If I can be of further assistance, please don't hesitate to contact me.

Sincerely,

Catherine E Woteki

Catherine E. Woteki, Ph.D., R.D.
Under Secretary
Food Safety

CSPI Center for Science in the Public Interest
Publisher of *Nutrition Action Healthletter*

September 24, 1999

The Honorable George V. Voinovich
Subcommittee on Oversight of Government Management,
Restructuring and the District of Columbia
601 Hart Senate Office Building
Washington, DC 20510

Dear Senator Voinovich:

Thank you for holding the hearing on food safety on August 4 in the Senate Governmental Affairs Committee, Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia. I am happy to answer additional questions from the Committee.

Question 1. You mentioned in your testimony that in poll after poll, food safety ranks high on the list of things that consumers would like to see improved. Could you provide this public opinion data for the record? Does recent polling data indicate changes in consumer confidence in the safety of the US food supply or a change in consumer confidence in the US government agencies responsible for food safety? What actions would you recommend that Congress or the Federal agencies take to maintain or improve confidence in the safety of the food supply?

Every year, the Center for Science in the Public Interest (CSPI) polls a representative sample of our members/donors on which food and nutrition issues they believe are most important to address during the coming year. Improving food safety has been our members' top priority since 1988. This year's mail-in survey was conducted in January and garnered 18,000 responses. (See attachment A.)

While responses from our members clearly indicate the views of consumers that are most concerned about food and nutrition issues, other opinion polls have generally reflected similar concern among consumers. For example, a 1999 nationwide survey of consumers by CMF&Z Food Practices Consulting Group found that food safety was ranked as "very important" by 83% of the respondents. Drinking water safety, crime prevention, and health and nutrition were statistically even: "very important" garnered 86%, 83% and 81% percent of respondents, respectively. Protecting the environment was rated as "very important" by 69%. This nationwide poll was completed in July and included 400 consumers. (See attachment B.)

In 1998, a poll by the same organization showed that consumers' concerns about food safety (89% ranked it as "very important") surpassed their concerns about drinking water safety (85%) and crime prevention (82%). The areas of greatest concern were *E.coli*, Hepatitis,

Tel: (202) 332-9110
Fax: (202) 265-4954
Home Page: www.cspinet.org
E-mail: cspi@cspinet.org

Suite 300
1875 Connecticut Ave., N.W.
Washington, D.C. 20009-5728

Michael F. Jacobson, Ph.D.
Executive Director

pesticide residues, and *Salmonella*. The survey found that nearly two thirds of the public said food safety regulations were not tough enough, while one third thought they were just right. The telephone survey of 300 people was conducted in June 1988. (See attachment C.)

A 1998 survey by *Restaurants and Institutions* magazine on consumer attitutes toward restaurant food safety found that 43% of consumers thought the likelihood of contracting foodborne illness from food prepared in a restaurant or a food service establishment has increased over the past five years. Consumers identified the following initiatives to increase food safety: improved methods to detect harmful foodborne bacteria (55%); more frequent inspection of restaurants (52%); more frequent inspection of food processing plants (48%); programs to educate workers in the food service industry (45%); more inspection of foods that are imported into the U.S. (39%). This mail-in survey was completed by 738 households during May and June, 1998. (See attachment D.)

Another survey, conducted in 1997, found that consumers viewed food safety as needing "a lot of regulation to protect consumers' interests," which surpassed all other issues. In this survey of over 600 consumers, food safety garnered a 64% response, higher than airline safety (61%), environmental hazards (57%), health plans and health insurance (46%), and automobile safety (44%). This telephone survey was conducted in December 1997. (See attachment E.)

Finally, in a 1999 survey conducted annually by the Food Marketing Institute, product safety was ranked among the most important attributes in choosing food by 70% of supermarket shoppers. In surveys going back to 1990, product safety is always among the top three attributes listed. Between 1990 and 1999, it was chosen consistently by between 69% and 75% of those surveyed. The 1999 telephone survey included over 2000 households, and was conducted in January. (See attachment F.)

These surveys repeatedly show that food safety is a significant concern for consumers, one that must be addressed by governmental action. In one survey, when consumers were asked who was doing the best job of assuring food safety, government agencies ranked among the lowest (named by only 39% of respondents), behind farmers (60%), supermarkets (56%), consumers (53%), food processors (45%), and restaurants (44%). Meat packers scored the lowest, identified by only 38% of consumers. (See attachment B)

It is time for Congress to step in to ease consumers' concerns about food safety. It is time to merge the existing federal food safety agencies into a single agency with a farm-to-table mission to reduce the numbers of foodborne illnesses and deaths.

Question 2. In your written testimony, you mentioned that in the 1980s, the Centers for Disease Control and Prevention (CDC) discontinued their annual listing of food-borne illness outbreaks. What is the value of having such information made available on a timely basis?

The "Jack in the Box" outbreak in the early 1990s, in which over 700 people became ill and four children died from *E. coli* O157:H7 in hamburgers, illustrates the importance of thorough and coordinated outbreak investigations. In that outbreak, the first death was recorded in late December 1992, but California health officials failed to identify the source and alert the public. For the next three weeks, consumers in four western states continued to eat hamburgers contaminated with the deadly *E. coli* O157:H7. Ultimately, three more children died. Finally, on January 22, 1993, health officials in Seattle, Washington, announced that the Jack in the Box restaurant chain had been identified as the source of the contaminated hamburgers and the outbreak was stopped.[1] While CDC and the states have been working to improve communication on outbreak surveillance since 1993, the system has not improved sufficiently to ensure that long delays in identifying the cause of an outbreak and alerting the public will not occur again.

Just as a prompt alert to the public can help stop an outbreak, prompt information on outbreak trends is also critical to preventing illnesses. Outbreak information provides an early warning of new hazards in the food supply and allows federal and state health officials to look for related outbreaks both nationally and in their communities.[2]

With headline after headline reporting food-poisoning outbreaks[3], the public certainly expects that some government agency maintains a comprehensive inventory of foodborne-illness outbreaks in the U.S. Such an inventory would allow policy makers, the food industry, and the public to monitor trends, issue public health alerts, change production practices, and, ultimately, reduce the number of illnesses and deaths caused by contaminated foods. Publishing outbreak information can also help alert the public to the emergence of a new pathogen, or to the

---

[1] U.S. Department of Agriculture, "USDA Fights Foodborne Illness in Washington State," *USDA News*, Release No. 074.93, January 22, 1993; State of Washington, Department of Health, "Illnesses in Western Washington Linked to Jack in the Box," No. 93-04, January 18, 1993; "State Officials Announce Levels of Coliform Contamination in Beef," No. 93-05, January 22, 1993.

[2] CSPI's outbreak lists show three examples of outbreak clusters: Lettuce, summer and fall 1995; apple cider, fall 1996; alfalfa sprouts, summer 1997 through summer 1998. In these instances, harmful bacteria appeared on products that health officials would be less likely to suspect.

[3] "Outbreaks" are when two or more consumers become ill from a specific contaminated food item. "Cases" represents the number of individual illnesses that occur, either individually or as part of an outbreak.

appearance of a familiar pathogen on a new food source. Surprisingly, though, no federal agency maintains a comprehensive list of food-related outbreaks.

The Centers for Disease Control and Prevention (CDC) is the nation's primary disease monitor, a job that includes reporting on foodborne hazards. One might expect CDC to maintain a list of outbreaks caused by contaminated food in order to identify new hazards in the food supply. However, despite the relative simplicity of creating and maintaining a list of foodborne-illness outbreaks, CDC has determined that doing so is not a priority. While CDC is getting new funding to enhance its surveillance of foodborne illness, most of that funding is being spent on the agency's sentinel surveillance project, which studies foodborne illness intensively in a few "sentinel" sites. The basic functions of collecting and publishing information on outbreaks from around the country remain unfulfilled.

To help fill this key gap in CDC's current system, CSPI has been maintaining its own partial inventory of foodborne-illness outbreaks that occurred since 1990, which is available in our report *Outbreak Alert*. CSPI's inventory is the only one of its kind available today, but even it includes only a small fraction of the outbreaks being reported to the CDC and other federal agencies; in turn, those outbreaks represent only a small fraction of all foodborne-illness outbreaks that occur.[4] CSPI's information on outbreaks has been collected from numerous medical journals, government reports, and other sources.

In the early 1980s, CDC published annual summaries of foodborne diseases that included a "Line Listing of Foodborne Disease Outbreaks." That listing is comparable to the inventory CSPI has developed. Unfortunately, CDC's listing was discontinued during the 1980s due to budget constraints.[5] Today, the CDC compiles foodborne-illness data in many formats, but doesn't maintain a comprehensive list of outbreaks available to policy makers or the public. For example, the *Summary of Notifiable Diseases* and the *Surveillance Summaries on Foodborne-Disease Outbreaks* both list the total number of cases of illness linked to reported outbreaks from various pathogens and foods, but they are published months or sometimes years after the outbreaks.[6] Also, those summaries don't give information linking the food with the pathogen for

---

[4] *Surveillance for Foodborne-Disease Outbreaks, pp.13-15.*

[5] Telephone conversation with Dr. Patricia Griffin, Chief of Foodborne Diseases, Foodborne and Diarrheal Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, GA, January 14, 1999. E.g., Centers for Disease Control, "Line Listing of Foodborne Disease Outbreaks, 1982," *Foodborne Disease Surveillance, Annual Summary 1982*, (Atlanta, GA: Centers for Disease Control, September 1985), pp. 19-24.

[6] *Surveillance for Foodborne-Disease Outbreaks*; *Summary of Notifiable Diseases.*

each outbreak. The *Surveillance for Foodborne-Disease Outbreaks -- United States, 1988-1992* includes only brief descriptions of a few highlighted outbreaks by year, and the *Summary of Notifiable Diseases, United States, 1997* briefly describes only one foodborne-illness outbreak.[7]

Some reports of individual outbreak investigations conducted by CDC are published in its *Morbidity and Mortality Weekly Report* or in peer-reviewed journals.[8] However, without an outbreak inventory to put these reports in context, it is difficult to know whether the outbreaks that are described in those journals are truly illustrative of the most important trends.

Rather than leaving the job of compiling food poisoning outbreak information in the hands of a private organization like CSPI, CDC should serve as a clearinghouse for information on foodborne-illness outbreaks. CDC currently receives more outbreak information from state and local health departments than any other federal agency, so it is best situated to collect and release all available information. CDC should put a high priority on encouraging states to report all foodborne-illness outbreaks and, once this data is obtained, on compiling the numbers and promptly reporting on the trends observed. CDC should make information acquired during foodborne-illness outbreaks fully available to other government agencies, to the public, and to the food industry so that prompt action could be taken to prevent future outbreaks.[9]

To remedy this problem, CSPI has developed the following recommendations:

- **CDC should maintain a comprehensive inventory of foodborne-illness outbreaks and issue timely reports on those outbreaks.**

CDC should regularly collect reports from the states and publish (in written reports and over the Internet) quarterly lists of outbreaks and annual reports on outbreak trends. Funding should be provided in the National Food Safety Initiative to ensure that CDC has adequate staffing to handle those responsibilities.

---

[7] *Surveillance for Foodborne-Disease Outbreaks*, pp. 4-9; *Summary of Notifiable Diseases, 1997*, p. xii.

[8] CDC "Trip Reports" also are informative. These reports are written by the lead CDC Epidemic Intelligence Service (EIS) Officer on a foodborne-illness outbreak investigation. While Trip Reports are not publicized or indexed, they are available from CDC if requested for a specific outbreak.

[9] For example, following several outbreaks associated with fresh juices, the Food and Drug Administration required unpasteurized juices to bear a warning label to alert consumers to the hazards associated with these products. Department of Health and Human Services, Food and Drug Administration, "Food Labeling: Warning and Notice Statement; Labeling of Juice Products," *Federal Register*, Vol. 63, No. 130 (1998), pp. 37030-37056.

- **States should report all foodborne-illness outbreaks to CDC.**

States should send reports to CDC of all investigations of outbreaks conducted by state and local health departments. An electronic reporting system should be developed to minimize the burden on health departments and on CDC. CDC should also actively monitor media reports and request information from health departments, as it does for the FoodNet surveillance programs.[10]

- **Congress should fully fund the National Food Safety Initiative, a program coordinated by the White House to develop and fund projects to reduce the incidence of foodborne illness.**

The Clinton administration has requested $105 million in new food-safety funding in its fiscal year 2000 budget request, including $40 million for the Department of Health and Human Services, the parent agency of CDC. CDC needs additional funding to improve its surveillance systems and to develop a clearinghouse on foodborne-illness outbreaks. In addition, the funding sought for FDA to enhance inspection of both domestic and imported food is vitally important to reduce the number of outbreaks linked to FDA-regulated foods.

Respectfully submitted,

Caroline Smith DeWaal

Caroline Smith DeWaal
Director, Food Safety
Center for Science in the Public Interest

---

[10] U.S. Department of Health and Human Services, "FoodNet: CDC's Emerging Infections Program," updated April 1998, available at <http://www.cdc.gov/ncidod/dbmd/foodnet/foodnt498.htm>.

Issues Survey of CSPI Members/Donors

September 24, 1999

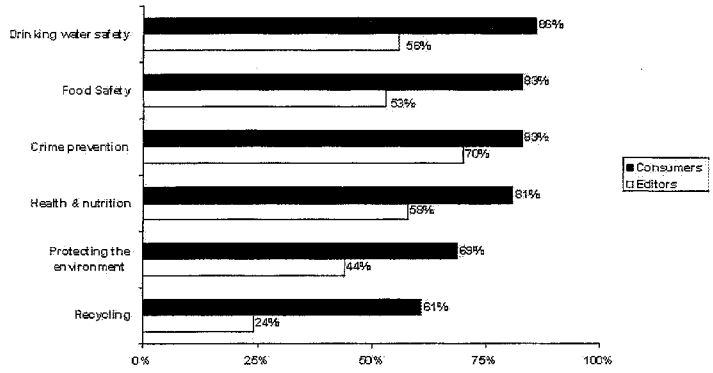
Issue	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	U.S. 1999
Safe Food	1	1	1	1	1	1	1	1	1	1	1	1
Food Additives	**								2*	2	2	2
Food Labels	2	3	2	3	2	2	2	2*	2*	3	3	3
Food Ads	3	4*	3		3	3		2*	2*			
Children Nut.		4*	4	4	4	4*						
ConsumrNutEd	4		5			4*		3	4	5		5
Alcohol	5			5								
Saturated Fats		2										
Food Testing				2		4*						
Fast Food					5							
Supplements					6	6						
Restr. Food						7	4	3	5			
Restr.Fd Safty										4		
Internat.Threat												4

* virtual tie.

*** We survey on a limited number of issues each year, so there is no data for many of these categories for certain years.*

Attachment B, Page 1

Food Safety Ranks Among Top Public Issues
(Rating of "Very Important")

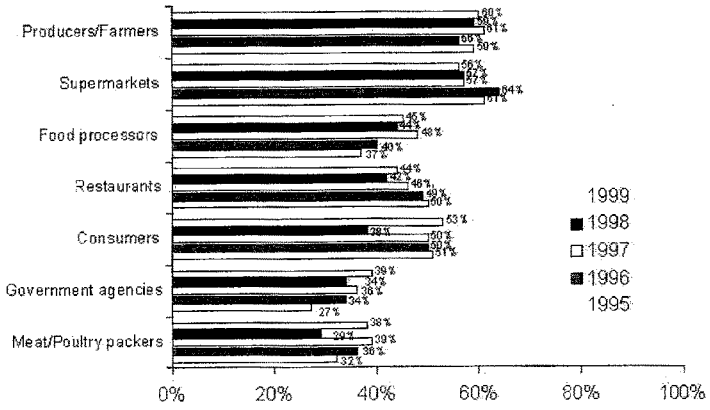


Back to the Results Table of Contents

Back to Food Safety

Attachment B, Page 2

Who's Doing the Best Job of Assuring Food Safety?



Back to the Results Table of Contents

Back to Food Safety

1999 Food Safety Survey Abstract:

The anticipated commercialization of food irradiation requires processors to proactively manage the responses that will impact their businesses. The Food Issues Survey provides perspectives on consumer attitudes toward irradiation and processor accountability and effectiveness in impacting food safety.

1999 Food Safety Survey Objectives:

- Identify food issues and trends of greatest concern and importance to the public and the media.
- Explore attitudes toward the role and credibility of interest group industry participants.
- Assess public perceptions of media credibility and influence on consumer food purchases.

1999 Food Safety Survey Methodology:

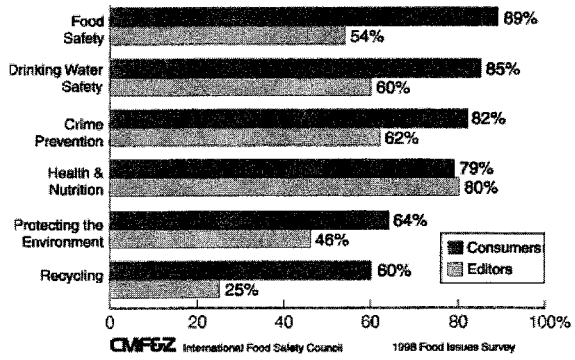
- CMF&Z's Market Research Group has conducted the annual survey since 1993.
- It is based on a nationwide, random sample of 400 consumers and 150 editors, and is conducted by telephone each spring.
- Trend analysis is performed annually.
- Margin of error on consumer surveys is + 4.9%.
- Margin on error on editor surveys is + 8%.

Back to Food Safety

Attachment C, Page 1

Consumers & Editors Rank Public Issues

For the first time, consumers ranked food safety higher than other issues addressed by this survey. Previously, crime prevention, safe drinking water and general health and nutrition were considered more important than food safety. The importance consumers placed on food safety surpassed the expectations of food editors, who continued to place more emphasis on other public issues.



Back to the Results Table of Contents

Back to Food Safety

1998 Food Issues Survey Objectives & Methodology

1998 Food Issues News Releases

1998 Food Issues Survey Objectives:

- Identify trends in the perceived importance of food safety to the American public and print media.
- Explore editors' beliefs on how informed the American public is about food safety and food-related issues.
- Identify food-safety-related issues of greatest concern and potential action.
- Identify the public's perceptions of media credibility on food safety issues.
- Explore consumer and editor attitudes toward the role and credibility of interest groups.
- Determine how well various groups do in communicating with media.

1998 Food Issues Survey Methodology:

- 300 telephone interviews are conducted for the survey -- 150 with a random sample of newspaper editors or food safety writers, and 150 with a random sample of the general public.
- The interviews for the 1998 Food Safety Survey were conducted in June of 1998.
- The survey has a margin of error of + 8 percentage points.

Back to Food Safety

1998 Food Issues Survey News Releases

1998 Food Issues Survey Results

Des Moines Register Sept 22, 1998 p1&5

Food safety consumers' top concern

■ E-coli, hepatitis, pesticides and Salmonella rank highest in a new survey.

BY ANNE FITZGERALD
REGISTER AGRIBUSINESS WRITER

U.S. consumers are more concerned about food safety than crime prevention or water quality, according to a new survey being released this week.

When asked to rate the importance of food safety as a public issue, 89 percent of the consumers surveyed rated it as very important, while 85 percent said the same about drinking water safety, and 82 percent about crime prevention. The study listed consumers' top concerns as E-coli viruses, hepatitis, pesticide residues and Salmonella.

More than half the consumers surveyed said farmers (69 percent) and supermarkets (57 percent) do an excellent job of ensuring a safe food supply. Only a third (34 percent) gave the same credit to government agencies. Meat and poultry processors ranked the lowest, with 29 percent saying they do an excellent job on food safety.

Conducted in June by CMF&Z, a marketing and public relations firm with offices in Des Moines and Cedar Rapids, the telephone survey of 150 U.S. consumers was co-sponsored by the International Food Safety Council, a coalition representing the restaurant and food service industries. It is the fourth annual survey of consumers' attitudes on food safety conducted by CMF&Z since 1995.

In earlier surveys, food safety ranked high, but this marks the first time it has ranked No. 1, said CMF&Z spokesman Bill Brewer.

A companion survey of 150 food editors across the country was conducted at the same time to gauge newspaper editors' perceptions of public attitudes toward food safety issues. Both surveys had an 8 percent margin of error.

In the new public survey, nearly two-thirds said food safety regulations were not tough enough, while one-third rated regulations "just right."

Three-fourths (77 percent) of consumers said media reports of food-borne illness affected their consumption.

In several cases, the responses of consumers differed markedly from those of editors.

For example, 54 percent of the editors said food safety was very important as a public issue, compared with 89 percent of consumers. Also, when both groups were asked to rate their levels of concern on 15 different food-safety issues; consumer concern ranked higher in all cases except one: fat content.

Two-thirds (67 percent) of the editors listed fat content as an issue of high concern, while just half (51 percent) of consumers did.

On most of the other issues, though, the levels of concern among consumers ran 15 to 25 percentage points higher than among the editors.

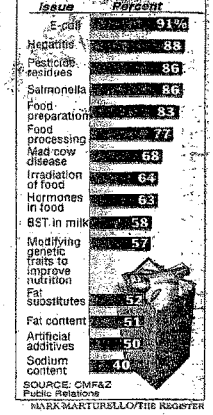
Both groups, however, agreed on which issue is of the most concern: E-coli contamination. They also agreed on which issue is of least concern: sodium content.

Sharon Pilmer, manager of consumer research at CMF&Z in Des Moines, said she thought the editors' responses differed from consumers in part because of their proximity to news and access to more information about the issues explored in the survey.

Agribusiness writer Anne Fitzgerald can be reached at (515) 284-8122 or fitzgeralda@news.dmreg.com

Consumer concerns

■ **Each of the** 150 people interviewed for the survey was asked to rank issues on a scale of one to five, where one represented "not concerned" and five was "very concerned." Listed below are the percent that listed their level of concern as either a four or a five. The margin of error for the survey is plus or minus 8 percent.



SOURCE: CMF&Z Public Relations

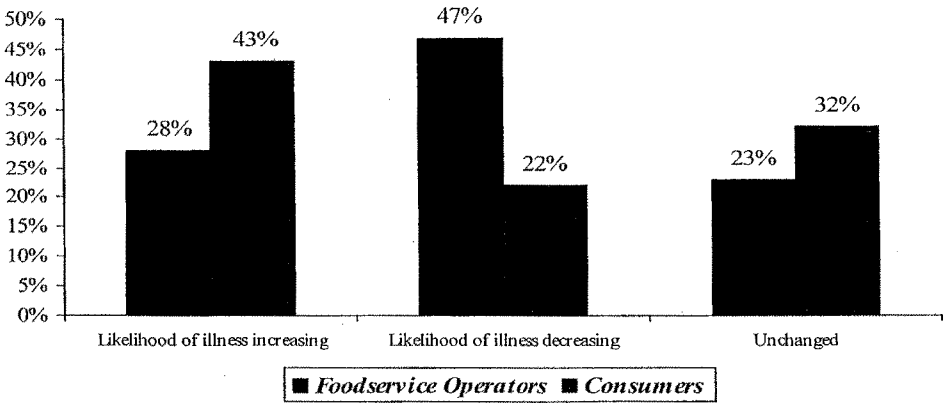
MARK MARTURELLO/THE REGISTER

Under the Microscope: Food Safety Perceptions and Practices

Barbara Allelujka
Research Director
Food & Lodging Group
Cahners Business Information

RESTAURANTS & INSTITUTIONS

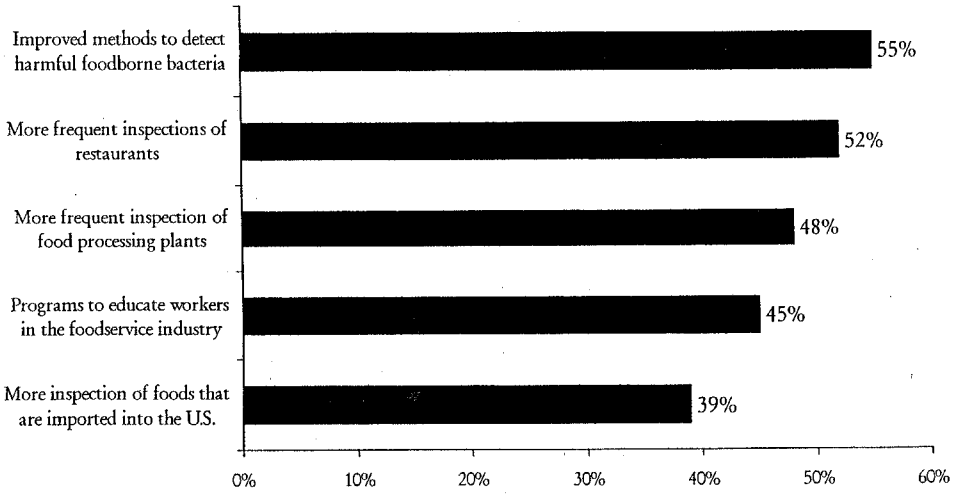
Perceived Likelihood of Contracting a Foodborne Illness from Food Prepared at a Restaurant/Foodservice Establishment*



*Compared to 5 years ago.

RESTAURANTS AND INSTITUTIONS

Consumer Opinions: Top 5 Initiatives That Definitely Will Increase Food Safety



Base: 738 consumers

RESTAURANTS AND INSTITUTIONS

Attachment E, Page 1

Health Care

PUBLIC AGENDA ONLINE
The Journalist's Inside Source for Public Opinion and Policy Analysis

Survey Organization: Princeton Survey Research Associates
Sponsored by Kaiser Family Foundation, Harvard University

Question: To begin, please tell me how much government regulation you think is needed to protect consumers' interests in some different areas. In general, how much government regulation is needed to protect consumers' interests in the area of [INSERT ITEM]? Would you say a lot, some, very little, or none?

	A lot	Some	Very little	None	Don't know
Food safety	64%	[illegible]	4%	[illegible]	2%
Airline safety	61%	[illegible]	5%	[illegible]	3%
Environmental hazards	57%	[illegible]	6%	[illegible]	3%
Health plans and health insurance	48%	[illegible]	9%	[illegible]	3%
Automobile safety	44%	[illegible]	9%	[illegible]	2%

Sample: 1,204 Adults
Methodology: Telephone Interview Conducted December 12-30, 1997
Asked of half sample
Margin of error for half sample +/- 4

Understanding the Issue:
Overview | Notable & Newsworthy | Fact File | Framing the Debate | Sources & Resources | Story Angles |

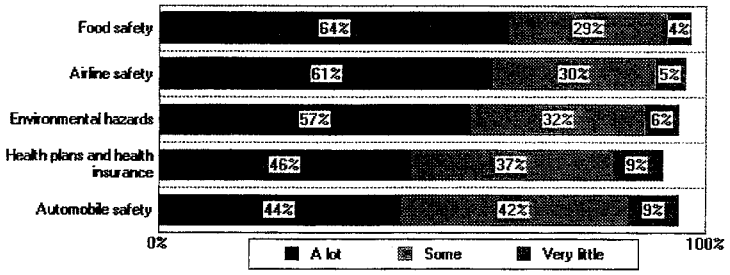
Public Opinion:
People's Chief Concerns | Major Proposals | Who Should Decide? | A Nation Divided? | Red Flags | Selection Criteria

Attachment E, Page 2

Health Care: Red Flags

People are less likely to support extensive government regulation of health care than of some other major industries

Please tell me how much government regulation you think is needed to protect consumers' interests in some different areas.



Source: Princeton Survey/Kaiser/ Harvard 12/97

For more details

Trends in the United States

Consumer Attitudes & the Supermarket, 1999

Conducted for the Food Marketing Institute

By Research International USA

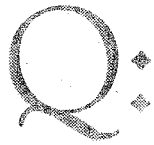
Price $35 Members
$90 Nonmembers
Multiple-copy discounts available

Published by:
The Research Department
Food Marketing Institute
800 Connecticut Avenue, NW
Washington, DC 20006

Printed on recycled paper

TABLE 46

IMPORTANCE OF VARIOUS FACTORS IN FOOD SELECTION, 1990-1999



I'd like to start by reading a list of food related factors that may or may not be important when a person shops for food. For each factor please tell me whether it is very important, somewhat important, not too important or not at all important to you when you shop for food.

Base: 1,002 shoppers

	Very Important									Jan. 1999				
	Jan. 1990 %	Jan. 1991 %	Jan. 1992 %	Jan. 1993 %	Jan. 1994 %	Jan. 1995 %	Jan. 1996 %	Jan. 1997 %	Jan. 1998 %	Very important %	Somewhat important %	Not Too important %	Not At All important %	Not Sure %
Taste	88	90	89	91	90	90	88	87	89	92	7	1	1	*
Nutrition	75	75	77	75	76	74	78	77	76	70	25	4	1	*
Product safety	71	72	71	72	69	69	75	73	75	70	20	6	2	3
Price	66	71	75	74	70	69	66	66	64	63	30	5	1	*
Storability	43	43	46	45	41	41	43	44	45	42	35	15	5	3
Ease of preparation	33	34	36	37	34	35	36	37	37	35	45	14	6	1
Food preparation time	36	38	41	36	36	35	36	39	36	35	43	16	5	1
Product packaging that can be recycled	x	48	45	41	38	34	34	31	31	29	37	22	12	*

x Not asked.
* Less than 0.5 percent.
May not add to 100 percent due to rounding.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable George V. Voinovich
Chairman, Subcommittee on Oversight
of Government Management, Restructuring,
and the District of Columbia
Committee on Governmental Affairs
United States Senate
Washington, D.C. 20510-6250

Dear Mr. Chairman:

Thank you for your letter of September 8, 1999, in which you submitted questions that Senator Richard Durbin raised as follow-up to the August 4th food safety hearing. We regret our delay in responding. We appreciated the opportunity to testify before your Committee at that hearing and look forward to working with you and your staff on these issues. Our responses to the five questions are below.

1. **The recent Belgian dioxin crisis raises the concern about animal feed as a potential source of contamination to the human food supply. Which agencies are responsible for the safety of animal feeds, and how is this responsibility handled? Is there a single federal official with the authority to provide one voice on the food safety implications related to the animal feed supply? If so, who?**

The Food and Drug Administration (FDA or the Agency) has primary responsibility in the Federal government for the safety of animal feed in the United States. Both the United States Department of Agriculture (USDA) and the Environmental Protection Agency (EPA), however, have a part in protecting the animal feed supply.

FDA is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA mandate under the FFDCA includes widespread responsibilities to help ensure pre-harvest food safety. In fact, the FFDCA defines "food" as "articles used for food or drink for man or other animals." Within FDA,

the Center for Veterinary Medicine (CVM) is responsible for regulating the levels of contaminants in animal feeds to ensure that the food for animals and food for man derived from animals is safe and free of unsafe amounts of drugs, industrial chemicals, pesticide residues, and harmful bacteria.

USDA has responsibility for preventing the transmission of animal diseases among animals, including through animal products. USDA also samples meat and poultry products at slaughter for the presence of illegal drug residues and notifies FDA for follow-up investigation/action as necessary. The EPA establishes tolerances for pesticides on raw agricultural commodities and for residues in edible animal and vegetable products. FDA enforces these tolerances.

The Commissioner of Food and Drugs is the single person with the authority to provide one voice on food safety implications related to the animal feed supply. The most recent example of this authority was the drafting, publishing, and implementation of the regulation (21 CFR 589.2000) relating to Bovine Spongiform Encephalophy (BSE). FDA was the lead agency in the preparation of this rule because the spread of BSE in the United Kingdom was clearly related to feeding ruminant meat and bone meal (a feed ingredient) to cattle. Both USDA and the Centers for Disease Control and Prevention (CDC) participated in the rule making process because of the potential transmission of an animal disease (BSE) and a human disease (new variant Creutzfeldt-Jakob).

2. What safeguards exist to ensure against dioxin or PCB contamination of animal feeds, either accidental, intentional or by natural causes? To what extent are contaminated animal feeds implicated and what safeguards are in place to ensure that animal feeds are not a source for spreading pathogens such as E. coli O157:H7?

FDA, through its Feed Contaminants Program administered by CVM, routinely collects surveillance samples of feed ingredients and complete feeds and analyzes them for pesticides, chemicals, mycotoxins, and microbial contaminants. Polychlorinated biphenyls (PCB) are one of the groups of chemicals for which these samples are analyzed. In addition to FDA, many States have feed contaminants programs that also collect and analyze samples for potential contaminants. Industry, particularly the animal rendering industry, routinely screens the fats and oils for pesticide and PCB contamination. Until the recent Belgian

dioxin incident and the dioxin contamination of ball clay in the United States (U.S.) in 1997, there were no reports of dioxin problems in the U.S. food supply for over 10 years. Because dioxin had not been a problem for a number of years, FDA had limited its surveillance efforts. When FDA became aware of the ball clay problem, we acted quickly to identify the source and prevent further use of the product in animal feed. Since the initial problem with ball clay, we have collected additional clay samples for dioxin analysis and provided guidance to industry on the potential for naturally occurring dioxin in other clay products. FDA has worked closely with EPA on the analysis of the clay samples. The two agencies met in October to discuss further surveillance sampling. FDA and EPA have agreed upon the type of samples to be collected and the regions within the U.S. from which to collect the samples. FDA is in the process of preparing an assignment to our field force to collect these samples. Under this joint effort by EPA and FDA, EPA will analyze the samples collected by FDA.

Animal feeds have not been implicated in spreading *E. coli* O157:H7. For FY2000, feed ingredients and completed feeds collected under the Feed Contaminants Program will be analyzed for *E. coli* O157:H7 in addition to *Salmonella*. A direct link between pathogenic organisms in feed contaminating animals and the edible product from these animals resulting in human disease is difficult to establish. The most often cited example of this direct link occurred in the 1970's when *Salmonella Agona* in fishmeal was linked to the same organism in poultry, and the poultry was implicated in a human disease outbreak. FDA continues to monitor feed ingredients and complete feed for *Salmonella* and handles reports of a positive finding on a case-by-case basis.

3. Which agency regulates genetically modified foods? Does FDA review the food safety impacts of each new product before it comes to market? Does the USDA have a role? Are labeling requirements under consideration? For imported genetically modified products, do importers have to make any declarations prior to shipping the food to the U.S.?

Which agency regulates genetically modified foods?

FDA, USDA, and EPA each have delineated responsibilities for the regulation of genetically modified foods. In 1986, the Office of Science and Technology Policy published a comprehensive federal regulatory policy for ensuring the safety of biotechnology

research and products. That policy, the "Coordinated Framework for Regulation of Biotechnology," described how the various agencies would exercise their respective regulatory oversight for products developed through biotechnology. For example, FDA has authority over the human health and safety (and labeling) of domestic and imported foods in the U.S. market, including genetically modified foods (except meat and poultry, which are regulated by the USDA). USDA, through the Animal and Plant Health Inspection Service (APHIS), regulates field-testing of genetically modified plants to focus on effects on plants and the environment. EPA regulates pesticidal substances, including those produced in plants, also with the focus on environmental issues. The Framework laid the groundwork for a well-coordinated system to ensure that new agricultural biotechnology products receive appropriate oversight. The agencies have worked cooperatively and consulted as necessary to clarify jurisdictional questions for developers of such products.

Does FDA review the food safety impacts of each new product before it comes to market?

FDA has established a consultation process through which developers of genetically modified human foods and animal feeds routinely consult with FDA and provide the Agency with information on the safety and nutritional assessments that they conduct on new varieties before marketing. Bioengineered foods and food ingredients (including food additives) must adhere to the same standards of safety under the FFDCA that apply to their conventional counterparts. This means that these products must be as safe as the traditional foods in the market. FDA has broad authority to initiate regulatory action if a product fails to meet the safety standards of the FFDCA. FDA evaluates the information provided to it during the consultation process to ensure that human food safety issues or other regulatory issues (labeling, for example) have been addressed prior to commercial distribution of the food. Some examples of the information routinely discussed and shared with FDA include: information about the identity and function of any new genetic material and of new substances produced by that genetic material; analysis of composition, including important nutrients and a comparison with traditional varieties; and information on whether the potential for the genetically modified food to induce an allergic response has been altered.

Does USDA have a role? For imported genetically modified products, do importers have to make any declarations prior to shipping the food to the U.S.?

As noted above, APHIS is responsible for protecting American agriculture against pests and diseases. That agency regulates the field testing of genetically modified plants. In regard to importation of genetically modified products, APHIS also authorizes the importation into the U.S. (or movement between States) of any genetically modified organism that is a potential plant pest. (APHIS should be consulted for details of their requirements.) For a food to be imported into the U.S. and marketed, the food must conform to the requirements of the FFDCA: there is no special declaration required for genetically modified foods.

Are labeling requirements under consideration?

FDA requires labeling when it is necessary to alert consumers to a safety concern, for example, if a new allergen were present in the food. A food is also required to be labeled to disclose significant differences in products, such as significant alterations in nutritional content or new requirements for preparation or storage. FDA has not historically required that the methods used to produce new plant varieties be disclosed on the label, however, and the Agency is not aware of any information that the use of modern genetic engineering leads to products that differ, as a class, in safety or quality from products developed through other methods.

4. **How does FDA's seafood HACCP regulation differ from FSIS's meat and poultry HACCP regulation? Is there any scientific basis for the difference? If not, what is the basis for the difference? Why has FDA not adopted pathogen reduction and microbial testing standards in the seafood HACCP rule? How does FDA intend to measure pathogen reduction outcomes of its HACCP program? Would the use of pre-market microbial testing provide the opportunity to prevent illness in cases where the test results indicated presence of pathogens?**

The FDA seafood Hazard Analysis Critical Control Point (HACCP) regulations and the HACCP regulations issued by FSIS for meat and poultry are essentially the same in that they require the application of the seven internationally recognized principles of HACCP. Because the programs are directed toward different industries, there are some slight differences in detail, but

these are not significant. In most respects, the HACCP requirements are interchangeable.

Whether a performance standard or testing requirement for a particular pathogen or pathogens should be mandated along with a HACCP program depends on the circumstances. A major impetus for the HACCP program operated by FSIS for meat and poultry was to reduce the very large number of estimated illnesses from certain pathogens in these products. In the case of commercial seafood, involving literally hundreds of species and a range of habitats from around the world, there is a broad spectrum of potential hazards. These hazards include natural toxins, parasites, chemical contaminants, and pathogens, but (unlike with meat and poultry) none of them stands out as causing a single, overarching problem.

One of the major goals of FDA's seafood HACCP program, as reflected by program design, has been to foster a science-based understanding within the seafood industry of the full spectrum of potential hazards that could affect these products as well as an understanding and application of scientifically established practical controls for them. Until the advent of this program, that kind of knowledge has generally not been a precondition for the commercial processing of seafood in the U.S. Although the program regulations are intentionally brief in order to allow for maximum flexibility in their implementation, they incorporate an expectation that seafood processors must at least consider all potential hazards when determining whether controls are needed in their specific situations.

Another factor affecting program design was the general understanding that the microbial load on raw fish tends to be naturally very low. Many of the pathogens of concern to humans are natural inhabitants of the intestines of beef, swine, and poultry. This is not the case for cold-blooded fish. FDA therefore assumed that reductions in microbial load on fish would not be easily measured, nor would they necessarily be of major public health significance.

To test the validity of these assumptions, FDA conducted a nationwide survey of raw fish products for the presence of *Salmonella*. In addition, FDA contracted with the University of Florida to conduct a study of the effect of normal consumer cooking practices on *Salmonella* counts. It must be remembered that HACCP takes into account how the product will be used by the consumer. Most seafood products are cooked.

The results of the *Salmonella* survey on raw fish products showed both a very low incidence of *Salmonella* (i.e., it normally was not found in the product) and very low counts when it was found. The results of the cooking practices study are still being assessed, but FDA's preliminary review indicates that even if the consumer undercooks the product, the cooking is still likely to be adequate to kill pathogens. These studies indicate that premarket microbial testing would have little impact on actual rates of illness.

Although FDA did not couple seafood HACCP with specific pathogen reduction targets in its regulations, pathogens are a hazard that must be controlled where necessary as part of the FDA program. It is FDA's expectation that processors will, at a minimum, use HACCP as a tool to implement all of FDA's existing and future performance standards relevant to seafood, including those for toxins and chemical contaminants as well as for pathogens. FDA is developing a risk assessment for *Listeria* that may provide insights into better HACCP or sanitation controls for this organism in certain seafood products. Moreover, FDA plans to significantly increase its own sampling regime as part of next year's inspection program. The Agency is especially interested in verifying whether scientifically established HACCP controls are effective when properly applied to cooked, ready-to-eat products. These products are cooked during processing and do not normally receive additional cooking by consumers.

Another consideration in the design of the program was the nature of the seafood industry. While the seafood industry does contain some large, sophisticated processing operations, it is primarily characterized by very small, geographically isolated operations. FDA has long recognized that, for many of these processors, a systematic, daily application of science-based preventive controls as reflected by HACCP would involve a significant cultural and educational change that would take time to develop.

To help prepare the industry for this change, FDA engaged in a five-year program development process that took into account the results of public and private sector HACCP pilots and comments from industry, academia, and consumers. Two significant aspects of this process were the development of low cost, nationally uniform training for industry (especially for small processors) and the creation of a guidelines package for processors (again, especially for small processors) on how to implement practical HACCP systems. The guidelines contain FDA's best advice on

hazards and controls for most commercial species and processing situations. A copy of FDA's "Fish and Fisheries Products Hazards and Controls Guide: Second Edition" is enclosed for your information. Several foreign countries have translated them and incorporated them into their own seafood regulatory programs.

For most firms, the first direct feedback from FDA on the status of their HACCP systems came during the first inspection. The Agency assumed that, in addition to training and guidelines, a certain amount of trial and error by the industry coupled with critique from FDA would be necessary before most firms would be capable of operating HACCP systems that are fully appropriate to their circumstances. FDA was, therefore, gratified to discover that about 1,200 processors had solved all of their significant HACCP issues before the first FDA HACCP-based inspection.

For those who had not fully implemented their HACCP systems, the primary difficulties they were having were associated with just getting started. Currently, our field personnel report that even where firms still have work to do on their HACCP systems, those systems are now in a much more advanced state than they were at this time last year. For example, firms that had no HACCP plans at all now generally have plans, although they may still be having problems implementing them completely. We are also seeing a more positive response to the feedback we are providing during inspections. Firms are grasping that feedback much more readily and assuring us that they will make corrections.

To facilitate that progress, FDA has participated in the development of a new training course for processors on how to solve practical implementation problems and has held implementation workshops in a number of district offices around the country. More interventions of this type are under consideration.

Independent confirmation of that progress occurred last April, when the New York Sea Grant Extension Program published the results of a survey taken of the seafood industry in seven New England and mid-Atlantic States. The purpose of the survey was to obtain information on the effects of the FDA seafood HACCP regulations, both costs and burdens, from the industry perspective. A copy of this report, "Seafood HACCP Implementation Survey Evaluation Report," is enclosed. FDA was extremely interested in the results of the survey, given the Agency's expectation that the seafood HACCP program should serve

as a catalyst for the education of the seafood processing industry as well as for behavioral changes deriving from that education.

Here are some of the survey's more significant findings, as reported by industry participants:

- Industry is making significant upgrades in facilities and equipment, primarily to enhance the ability to maintain proper temperatures. Time and temperature control are keys to seafood safety for many products. Examples include thermometers, coolers, monitoring devices, truck refrigeration units product test kits, laboratory services, etc.

- Major changes are also occurring in daily plant operations, again relating to better temperature control, closer evaluation of the incoming products that arrive at the plant door, the use of test kits, sample analysis, and other activities.

- The industry is also engaged in a significant re-evaluation of cleaning and sanitizing practices in order to improve overall conditions in plants. Poor sanitation has been a chronic problem in the seafood industry.

- Overall, the industry is experiencing better understanding of food safety hazards and how to control them. In addition, the industry is experiencing improved cooperation from the employees controlling food safety hazards, improved efficiency of operation, and fewer customer complaints.

The survey concluded that the behavioral changes being reported by the industry, along with the investment in tools needed to carry them out, "are likely to result in a significant improvement in industry performance in maintaining the safety and quality of seafood products available in the marketplace." FDA anticipates that a similar, follow-on survey of the industry will occur this year on a national scale.

5. In her written testimony, Caroline Smith DeWaal mentioned that in the 1980s, the Centers for Disease Control and Prevention (CDC) discontinued their annual listing of food-borne illness outbreaks. Why has CDC discontinued this annual listing? To

what extent is this data internally available within CDC? What would be necessary to re-initiate this listing?

CDC continues to publish surveillance summaries on annual outbreaks of foodborne diseases. The most recent published data covers the period 1988-1992. In the past, these summaries came out each year and often included a line listing of each outbreak. More recently, the summaries have not come out annually but have been published as several years of outbreak information at one time. These summaries have not always included a line listing of outbreaks. The summaries do include tables with detailed information about the pathogens and food vehicles responsible for outbreaks. The primary reason for these changes has been competing demands on staff time.

The data are available within CDC and are used to write reports, to provide historical data on pathogens and food vehicles to States investigating outbreaks, and to provide data for other purposes. The major limitation is the timeliness and completeness of reporting. These outbreak data are reported voluntarily by State health departments to CDC. Because of competing demands on State epidemiologists' time, the reports are often received by CDC more than a year after the outbreak, and some reports contain limited information. The reports are received on paper and CDC epidemiologists evaluate and code the forms, which is time consuming.

The combined summary report for the period 1993-1997 is nearing completion. A line listing of outbreaks can be obtained upon request now. CDC plans to make annual summary data on foodborne outbreaks, including listings of individual outbreaks, available on the Internet. One possible limitation is that some States may not allow individual outbreak data to be reported on a line list.

We trust this information responds to your concerns. If we may be of any further assistance, please contact us again.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

2 Enclosures*

* The enclosures referred to are retained in the files of the Subcommittee.