



**Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700**

Speeches

Eighteenth Annual USDA Cooperative Food Safety Research Workshop

Remarks prepared for delivery by Thomas J. Billy, Administrator of the Food Safety and Inspection Service, before the Annual Cooperative Food Safety Research Workshop, December 9, 1997, Riverdale, MD.

Good morning. It's a pleasure to be here at the gathering of the Eighteenth Annual USDA Cooperative Food Safety Research Workshop. I cannot overemphasize how important it is that we maintain a dialog on our research needs and accomplishments.

FSIS is very proud of its long-standing research relationship with ARS, which was initially formalized in 1981 with an Memorandum of Understanding between the two agencies. In the ensuing roughly seventeen years, the research relationship has grown and changed, recently becoming a partnership focused on team work, in keeping with the trend throughout government.

Importance of Research

I know it is clear to this audience the importance of research to our Departmental food safety initiatives. There are many data gaps that exist from farm to table that keep us from making further progress in our fight against foodborne illness. We need to know more about the hazards in meat, poultry, and egg products and their relationship to adverse human health outcomes.

Fortunately, we have been able to make significant progress in spite of these data gaps. Next month we begin HACCP implementation in the largest 300 meat and poultry plants, and *Salmonella* performance standards go into effect in concert with HACCP. We are also making progress on our farm-to-table strategy by working with industry, consumers, and the appropriate Federal, State and local government agencies to create a seamless national food safety assurance system.

But enormous challenges remain. We have just touched the surface in terms of doing all that we can to improve food safety. Your work is critical to our ability to progress even further. In fact, often it's a prerequisite to most progress.

We must plan carefully throughout this process to get the most return we can from our research investment. And, we must be sure that we are targeting research on the most critical areas in terms of public health concern.

Food Safety Research Agenda

To that end, in May 1997, FSIS issued its Food Safety Research Agenda as one means of communicating with those outside our Agency about our priorities for food safety research. The document, which was developed with the help of a working group representing a broad base of Federal scientific expertise, outlines the priority pathogenic organisms on which we recommend that research dollars be concentrated. It also establishes risk assessment as an integral feature in determining the public health hazards associated with these and other pathogens.

We encourage the use of this document as a standard against which food safety research projects should be judged. In other words, we expect research conducted to answer the questions outlined in this research agenda.

Presidential Initiatives

We are fortunate that this year the importance of food safety research has been confirmed at the highest levels of the Administration. The President's Food Safety Initiative strongly supports the need for research, as part of a comprehensive approach to reduce foodborne illness.

One challenge for the future will be to integrate the research needs stated in the FSIS Research Agenda, and those contained in the President's Food Safety Initiative, into a comprehensive plan. To assist in this process, the President's Food Safety Initiative calls for the convening of an interagency working group by the White House Office of Science and Technology Policy to coordinate Federal research planning and priority setting. The goal of this working group will be to develop a coordinated Federal food safety research plan, which will extend to our research partners in States, industry, and academia.

This interagency committee will hold its first meeting soon. The first step for the committee will be to develop an organized picture of the existing Federal research portfolio, followed by a determination of what steps need to be taken to design a more coordinated research plan.

Importance of Partnerships

It is clear in examining all of these initiatives that partnerships and teamwork are critical to the future. In the interest of enhancing the partnership between FSIS and ARS, we have developed a new strategy of using Scientific Liaison teams (SLTs) to track, guide, and assist the research that ARS performs on behalf of FSIS. The resulting improved communication between our two agencies will better enable ARS to meet the research needs and objectives of FSIS so that we may, in turn, meet our own food safety regulatory objectives.

The teams will meet periodically to review, evaluate, and guide current ARS research projects and provide feedback both to ARS and to the FSIS Office of Public Health and Science on a regular basis. Because the teams will be expected to evaluate food safety research from all sources for its scientific merit and relevance to FSIS needs, we envision that they will serve as an important link between FSIS research needs and the research community at large.

Closing

In closing, we look forward to hearing the reports from ARS scientists about the important work they have accomplished. Many of these issues are front-burner issues for us, such as the prevalence of premature browning of hamburger, new pathogen inactivation technologies such as steam pasteurization, and methods to detect *Campylobacter*. I appreciate your hard work on our behalf and look forward to continuing our partnership.

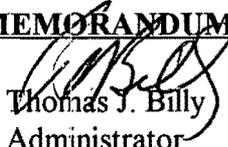
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BRIEFING MEMORANDUM FOR THE UNDER SECRETARY

FROM: 
Thomas J. Billy
Administrator

DEC 10 1997

SUBJECT: Interstate Shipment of State-inspected Meat and Poultry Products

PURPOSE OF BRIEFING:

On December 11, 1997, the Administrator will brief the Under Secretary and the Deputy Under Secretary on the status of FSIS activities regarding Interstate Shipment of State-inspected Meat and Poultry Products.

BACKGROUND:

The Federal Meat Inspection Act and the Poultry Products Inspection Act require that all meat and poultry products sold in interstate commerce be inspected by the Federal Government. Under the State-Federal Cooperative Inspection Program, individual States are authorized to inspect meat and poultry products sold solely within their boundaries, provided their inspection program is "at least equal to" that of the Federal Government. Currently, 25 States have USDA-approved inspection programs for meat and/or poultry.

The argument to change the current prohibition on interstate shipment of State-inspected products is that: State programs are, by definition, equal to the Federal program. Yet, unlike federally-inspected products and imported products inspected under "equivalent" foreign programs, State-inspected products are kept from markets in other states, including sometimes markets literally across the street from the State-inspected establishment. This restriction places the many, mostly small, rural enterprises at an unreasonable competitive disadvantage with the mostly big federally-inspected companies who have no such restriction, and is leading to the demise of these small business.

State officials want to protect if not strengthen their programs in this era of increasingly tight State budgets. They justifiably fear that their programs are vulnerable to elimination in State legislatures because while states pay only 50 percent of the cost of their program, we pay the other 50 percent--about \$40.5 million. State legislative budget cutters know that if they do away with their State meat and poultry inspection program, FSIS must by law provide Federal inspectors to do the job at no cost to the State. When a State-inspected plant becomes federally-inspected so it can ship products outside the State, the viability of the State program is further eroded by loss of that plant and the political support it provides.

On the other hand, managers of State-inspected plants wanting to market outside the State frequently have a comfortable working relationship with the State inspection program. They fear that obtaining a grant of Federal inspection would cost them money to upgrade their operation

and cause other problems which could be avoided if they remained under the State program.

In the face of these fears, many State program officials and owners of State-inspected plants have concluded that the solution is a change in Federal law to permit State-inspected meat and poultry products to be distributed in interstate commerce.

Chronology of Earlier Events:

- The 1996 Farm Bill directed USDA to report to Congress on “steps to achieve interstate shipment of products inspected under State programs that are “at least equal to” the Federal inspection program.”
- USDA provided a report to Congress in July 1996, recommending that before state-inspected establishments are authorized to ship products in interstate commerce, the following conditions should be met:
 - States should implement FSIS’ Pathogen Reduction/HACCP regulations;
 - FSIS resources need to be adequate to accommodate any additional oversight needed to substantiate “at least equal to” status;
 - Legislation should clarify that the Secretary retains ultimate authority over products prepared for interstate commerce;
 - A number of additional issues, mostly dealing with potential conflicts of Federal and State laws, would have to be resolved.
- On February 19, 1997, the Ohio Department of Agriculture, joined by some State-inspected plants, filed a lawsuit against the USDA seeking to have current law be declared unconstitutional on the basis that it violates plaintiffs’ right to due process of law under the 5th Amendment and right to equal protection under the 14th Amendment. (Ohio Department of Agriculture v. USDA, C2-97-215, S.D.Ohio.). Other states have now joined the suit.
- The Secretary has expressed support for removing barriers for small plants that want to make interstate meat and poultry shipments, but has also stated that there are a number of issues that must be addressed first, and that more effort is required to “involve all the stakeholders in a deliberative process to resolve these issues.”
- FSIS published a Federal Register Notice on June 10, 1997, announcing public meetings and requesting comments on interstate shipment. The comment period ended on August 22, 1997.

- FSIS held public meetings on interstate shipment on June 16-17, 1997, in Sioux Fall, SD, and on July 22-23, 1997, in Washington, DC. These public meetings grew out of the Department's commitment to the National Association of State Departments of Agriculture, during the pathogen reduction and HACCP public meetings, to address the interstate issue.

Current Status and Next Steps:

- FSIS has developed a concept for a legislative proposal based on the findings of the Secretary of Agriculture's report, the comments in response to the June 10 Federal Register Notice, and the public hearings' comments.
- FSIS submitted the legislative proposal concept paper to the Meat and Poultry Advisory Committee for consideration at its September 10, 1997, meeting.
- The concept paper, as revised based on comments of the Advisory Committee and the Under Secretary's office, suggests that specific provisions of a legislative proposal on interstate shipment of State inspected meat and poultry products should include:
 - 1) New provisions to the Federal Meat Inspection Act and the Poultry Products Inspection Act would redefine the relationship between Federal and State programs. The provisions would authorize the Secretary of Agriculture to enter into State-Federal cooperative agreements that provide for State meat and poultry inspection programs to enforce Federal meat and poultry inspection laws and regulations within their State as part of a seamless national inspection program.
 - 2) A one year transition period (January 26, 2000 to January 26, 2001) will exist during which States will transition from State programs enforcing "at least equal to" requirements to programs enforcing Federal meat and poultry laws and regulations.
 - 3) Prior to January 25, 2000, comprehensive reviews, designed in consultation with stakeholders, of all State meat and poultry programs will be conducted.
 - 4) Prior to entering into the new agreements to participate in the national inspection program, States will have to be certified as having implemented all recommendations from a comprehensive review and be certified as fully implementing HACCP.
 - 5) In addition to assisting the Secretary in the administration and enforcement of Federal meat and poultry inspection laws and regulations, State programs may impose additional inspection requirements on establishments.

6) An annual review process to certify that State inspection programs meet the terms of State-Federal cooperative agreements will be designed in consultation with stakeholders.

7) USDA will collect samples and test for *Salmonella* in State inspected meat and poultry establishments to determine compliance with pathogen reduction performance standards. The Secretary shall collect samples and conduct other tests in State plants to determine compliance, such as for residues, chemicals, and other microbial agents as deemed necessary.

8) USDA will conduct sampling of State inspected products in the commercial distribution chain to ensure that food safety and economic adulteration requirements are being enforced.

9) The Secretary may contribute Federal funds in excess of 50 percent of the total cost of a State meat or poultry inspection program as an incentive for States to maintain their inspection programs. (A separate economic analysis will identify the appropriate share.)

10) In States operating State meat and poultry inspection programs, establishments will have the option of applying for either a Federal or State grant of inspection. Limitations will be set on switching between Federal and State grants; perhaps once per year. Under a State grant of inspection, inspected and passed product will be eligible for both Federal and State inspection seals.

11) Technical statutory changes may need to be made to ensure the Secretary's authority in jurisdictional issues. The Secretary shall retain primary jurisdiction in matters such as labeling and seizure and detention.

- FSIS is currently obtaining comments on the concept paper from the Deputy Administrators.
- FSIS will have legislative language on interstate shipment of State-inspected meat and poultry products prepared by the first week of January 1998 for consideration by the Meat and Poultry Advisory Committee at its January 13 -14 meeting.
- The Meat and Poultry Advisory Committee will finish its consideration of the concept paper in January 1998.

Release No. 0041.98

Remarks

OF
SECRETARY DAN GLICKMAN
UNIVERSITY OF WASHINGTON PUBLIC HEALTH SCHOOL
SEATTLE, WASHINGTON -- JANUARY 28, 1998

Thank you, Provost Huntsman. I want to thank State Secretary of Health Bruce Miyahara for joining us. And, I should recognize the woman who brought me to Seattle, Suzanne Kiner. I met Suzanne in Chicago at the memorial service marking the 5th anniversary of the Pacific Northwest outbreak. This morning, I met with Suzanne, her daughter Brianne, Nancy Donley, the president of a wonderful organization -- Safe Tables Our Priority -- and other families who were victims of that terrible, I hope, unrepeatable tragedy. This afternoon, I'll go to the state public health lab and meet some of the heroes -- the epidemiologists who helped bring the outbreak under control.

Washington needs no lecture on the importance of safe food. Long before the tragedy of 1993, this state and this university have been on the cutting-edge in fighting food-borne illness. Washington was the first state -- back in 1987 -- to make E. coli 0157:H7 a reportable disease. Today, some 40 states have followed suit. I'm proud to have in the audience today Dr. Phillip Tarr, a world expert on Hemolytic Uremic Syndrome, along with Dr. John Kobayashi, one of our nation's finest epidemiologists. These are true pioneers in the safety of America's food.

I also want to introduce someone on my team. Just a few years ago, the words 'public health' were rarely uttered at the Department of Agriculture. Today, we have an Office of Public Health and Science which is headed by Dr. Kay Wachsmuth who used to be a researcher here at the University of Washington. We're very lucky to have her. She's one of the world's leading experts in microbiology and infectious diseases.

You know, I talk a lot to folks in the meat and poultry industry and to consumers, but I rarely talk to scientists. That's because when I talk to all of you about the CDC, or epidemiology or the finer points of microbial testing and DNA fingerprinting, and I get something wrong, you can call me on it. So I stand here not without trepidation. On the other hand, I never confuse myself with a scientist. My domain is public policy, and I'm here because our arenas -- science and government -- are making a dramatic difference -- and can do more to improve the public health.

You know, we hear people grouse all the time about how much better things would be if government just got out of the way. But ask those same people: who should make sure the planes they fly run safely? Who should ensure the solvency of the banks that hold their life savings? Who should be in charge of the nation's defense? The unanimous answer is government. Food safety falls into this same category, and people don't just want government involved in food safety. They want government to do more.

Why? Because people look to government to protect them in ways that they cannot fully protect themselves. People want government to be actively involved in protecting the public health and safety. They know, in the same way that the fox can't guard the chicken coop, that it is sound public policy for the government to be the chief overseer of public health and safety functions.

There is no responsibility that I take more seriously as Agriculture Secretary quality of every American life, every day, which is why USDA's work is very much a p effort to improve public health by supporting cutting-edge science.

In his State of the Union, the President talked in detail about the stunning ad technology, particularly in the field of biomedicine. In the 1980s, it took nine yea that causes cystic fibrosis. Last year, scientists located the gene that causes Park

Scientists stand on the cusp of dramatic breakthroughs that could revolutionize understand, treat and prevent some of our most devastating diseases. We know our sci these advances. The real question is: will they have the resources? Last night, Pres resounding 'yes,' proposing an historic increase -- a boost of \$1.15 billion to be biomedical research. And, that's just in his 1999 budget. He intends to increase by Institutes of Health over the next five years -- bringing the total federal investme \$20 billion.

Clearly, advances in food safety are closely linked to the forward march of sci another family to go through what the families I met with this morning have been through. Ask them. Ask Doctor Tarr. It's not something you would wish on your worst enemy. We don't have a silver bullet, at least not yet. But we do have the power to take dramatic steps toward safer food.

From new science-based meat and poultry inspections to historic investments in everything from cutting-edge research and surveillance to consumer education, I am proud of what this Administration has done for food safety in America. Alongside a balanced budget and a formidable U.S. economy, I believe that a science-based revolution in the safety of our food will be one of our lasting legacies.

The same month this Administration took office -- along with Senator Patty Murray, who has been a great champion of our food safety efforts -- tragedy struck here, galvanizing the nation behind a morally unstoppable mandate for dramatic change. At the time, that meant modernizing our systems -- taking what science had learned and raising the bar on food safety.

The best example is USDA's new meat and poultry inspection system which went on-line at the bigger plants this Monday. For close to a century, our inspectors had to rely solely on their human senses -- sight, touch and smell -- to spot contamination. We now know that the biggest dangers in our food are invisible pathogens that cannot be detected without the help of science. The old ways -- which date back to the turn of the century when Upton Sinclair wrote *The Jungle* and sparked the passage of the Federal Meat Inspection Act, one of America's first consumer protection laws -- were no longer adequate.

Our new inspection system recognizes what science has discovered. For the first time, there will be regular tests for generic *E. coli* and salmonella. For the first time, plants and processors will be required to not just catch contamination, but close the safety gaps that invite it. For the first time, the focus is on prevention, and America's public policy makes it crystal clear that industry is responsible for producing safe food.

We call the new system Hazard Analysis and Critical Control Points -- HACCP, for short. It requires plants to come up with a tailored prevention plan that targets key points in their operation where contamination might occur and outlines specific steps to ensure safety. USDA's job is to make sure the plans work through testing, inspections, and reviews of company records.

This is a major cultural change. I've talked to industry and consumer

groups over the past few weeks to make it clear that USDA will be fair but firm in its enforcement. HACCP's goal is to use modern science to significantly improve food safety, and we will not back away from that goal. In 1996, we shut down six plants for inadequate sanitation. In 1997, as companies phased in their HACCP sanitation plans that number rose to 20. So companies need to take their new responsibilities very seriously, every day.

When there are problems, our goal is to step in early enough that failures can be addressed without any major disruptions and certainly before illnesses occur. Many companies are good about fixing problems quickly. Unfortunately, others let the complaints pile up, engaging in a game of regulatory chicken, knowing that USDA's only formal recourse is to shut them down. Some offenses are so egregious that severe action is warranted. But many times it's not, and a lesser punishment, such as a fine, would do. Unfortunately, while the Consumer Product Safety Commission and the FAA can issue fines, USDA cannot. It is an unjustifiable anomaly. After all, USDA can fine you for abusing a circus elephant, for failing to report to the watermelon committee, or selling a cat without a license. Yet when it comes to unsafe food -- the only one of these actions that puts people's lives at stake -- our hands are tied. It's wrong. We should not treat unsafe food differently than any other threat to the public health.

I want to thank Senator Murray for her effort on behalf of the Food Safety Enforcement Enhancement Act which would give USDA the authority to fine companies that violate food safety standards. This would give them a strong incentive to fix problems quickly so things don't escalate to the point where a plant's very existence is on the line. No one wants that. But as USDA has demonstrated, to protect the public health, we will take whatever action is necessary.

I'll never forget during the Hudson recall when I stopped in at a fast-food restaurant for lunch. I asked the guy at the register, 'how do you know when your burgers are cooked.' He said, 'we use a meat thermometer.' Then, I asked, 'how do you use it?' He looked at me and said, 'we stick it in our customers ears.' In a roundabout way, that was an encouraging answer. Evidently, he'd been asked that question one too many times .. consumers wanted to know.

Do you know what NPR's top 3 stories of 1997 were? One: Princess Diana. Two: Iraq's chemical weapons. Three: the Hudson Beef recall. Consumers are interested and increasingly educated. Meat thermometer sales this past Thanksgiving were at record highs. These trends reflect a basic truth in today's world: 'the health interests of consumers and the economic interests of the food industry are coming together. Why? Because safe food sells.

Look at the global scares of 1997: During the avian flu epidemic in Hong Kong -- where they killed all the chickens -- Hong Kong consumers cut their poultry purchases in half. With the mad cow problem in Europe, beef sales there dropped 40%. Here at home, what was the market impact of the Hudson beef recall? Nearly zero. People trusted that government and the public health community were putting their safety first. That trust is rare around the world. All of us must constantly challenge ourselves to earn it.

I mentioned that with the early food safety advances of this Administration, the focus was more on adjusting our standards to reflect modern science. Our challenge now is to push the frontiers of our knowledge, seeking new ways to improve food safety and better understand our enemy.

Why are we seeing new, more virulent, resistant strains of E. coli and

other pathogens? As our surveillance has increased, we've found that campylobacter is the number one cause of food-borne illness. Why? There are also on-farm questions: What causes E. coli to show up in some animals and not others? Are there ways to prevent it from appearing or multiplying? This would be the ultimate in prevention: Can we stop pathogens from showing up in the first place? Dr. Dale Hancock is doing some very interesting work at Washington State on these issues.

Some of the new technologies we're developing are equally fascinating. I understand that there is work underway to adapt Gulf War technology that identifies nerve gas in the air for use in detecting pathogens on food. It would work sort of like night-vision goggles that arm our eyes with the ability to quickly and easily spot microbial threats.

There are also existing technologies, like irradiation. FDA recently cleared the practice for use on meat. USDA's now working on a regulation, but the jury of public opinion is still out. Of course, increased public concern over food safety might make it more popular today than it has been over the years for poultry.

But clearly, as we look ahead to the next generation of food safety challenges, increasingly we look to science and technology for answers. This Administration recognized this in our White House Food Safety Initiative, investing in cutting-edge research; enhanced inspections; a catchy, easy-to-understand all of you -- a national high-tech early warning system to prevent food-borne illnesses.

The early warning system helps us dramatically cut down the time it takes to identify and get to the source of an outbreak. We can now do in 24 hours what -- just a few years ago -- would have taken two weeks. Just a few years ago, to try and link a person's illness to an outbreak or get at the source of the problem would have required mailing samples around the country and conducting hundreds of hours of lab work. Now, folks can enter the genetic fingerprint of a particular pathogen into a national database, and the computer quickly sorts through all the entries for a match -- saving time, saving money, saving lives.

This system is not unlike what law enforcement uses to track criminals. A police officer plugs in a suspect's fingerprints and instantly gets any criminal record or outstanding warrants. Our scientists can get a similar 'rap sheet' on a pathogen -- everything from its link to an outbreak, to its known sources, to the toxins it produces. I want to commend the work done at the Washington state public health lab which is among a handful of state labs around the country that have joined with CDC in doing DNA fingerprinting. In early February, this database will be available nationwide, marking a world of difference in fighting outbreaks. Anyone who's been involved in these efforts knows what a difference every day, hour and minute makes in tracking the culprit.

DNA fingerprinting enabled Dr. Kobayashi and his team to quickly pinpoint the Odwalla outbreak involving unpasteurized apple juice. It also enabled us to identify the Hudson outbreak. The state lab in Colorado plugged their strains into the national database, spotted the outbreak, and e-mailed the information to the CDC. CDC was then able to link the illnesses to hamburger thanks to DNA data on the food side of the equation that was provided by USDA's lab in Athens, Georgia. In the Pacific Northwest outbreak, which was before we had this rapid response capability, 732 people became ill before we could identify the problem. In the Hudson case, we stopped the outbreak at 16 illnesses. Our goal is to keep bringing that number down, but we have made dramatic progress.

I say we' for a reason. Our ability to work across federal, state, university and private lines will be critical to our efforts. Food is now produced, processed and moved quickly around the country -- in massive quantities. The days where the norm is food-borne illness linked to local church picnics are likely to be subsumed by outbreaks with a far greater geographic reach, requiring a national community of scientists to work together. We are building that community today.

In looking ahead, the increasingly central role of science and public health experts in fighting the next generation of food safety battles is obvious to me. But it would be far too easy to put everything on your shoulders. You must give us the scientific answers and technological breakthroughs. But government must ensure that you get the resources you need to get the job done right.

Before I proceed, I should have you know that this Administration is under strict orders not to reveal what's in President Clinton's 1999 budget. But I made a special phone call, and got permission to share some good news with all of you. We know from the State of the Union Address that this will be the first balanced budget in a generation which means that we're going to see some tough decisions on funding priorities.

I know that has some concerned about the future of our food safety efforts. Don't be. As the federal budget comes down, the federal food safety budget will go up -- way, way up. In 1998, we increased food safety investments by \$43.5 million. For 1999, President Clinton will propose an increase of \$101 million, over and above the 1998 levels, to continue high-priority research and surveillance.

This is a show of faith in the work of many of the people in this room. It is a reflection of the strong desire of the American people for a food safety revolution. And, it is a sign of respect for the many families who have worked through their own tragedies to push government, industry, consumers, and the scientific community to rise to one of the greatest public health challenges of our time. I want to thank the scientific community here in Washington for the pioneering role you have played on food safety. I am grateful for all that you have done. But with this new, invigorated commitment, it is my hope that your greatest achievements are yet ahead. This Administration will support you every step of the way. Thank you.

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**Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700**

Backgrounders

February 1998

Foodborne Diseases Active Surveillance Network (FoodNet)

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC) are collaborating with state health departments and local investigators at seven locations across the country to identify more accurately the incidence of foodborne illness in the United States. Through the Foodborne Diseases Active Surveillance Network (FoodNet), the agencies involved will be better able to track the incidence of foodborne illness and monitor the effectiveness of food safety programs in reducing foodborne illness.

Background

FSIS ensures the safety, wholesomeness, and accurate labeling of meat, poultry, and egg products. FDA ensures the safety and wholesomeness of foods other than meat and poultry. CDC monitors the rates of foodborne diseases in the United States, investigates outbreaks of foodborne illnesses, and facilitates efforts to prevent foodborne disease.

Traditionally, foodborne diseases are reported to local and state health departments and to CDC through passive surveillance systems or laboratory-based reporting systems. Current data from these systems are used to estimate that there are 6 million to 33 million cases of bacterial foodborne diseases in the United States each year. However, these systems do not provide precise estimates to evaluate food safety reforms and program changes, nor how they will affect the incidence of foodborne disease.

These existing "passive" systems rely on a number of events. First, an individual with foodborne illness must choose to seek medical care. Then, the patient's physician must decide to collect cultures and request laboratory analysis. And finally, results must be reported to state health departments and then to the CDC. If any step in the process is missed, the case goes unreported. CDC estimates that only one to five percent of foodborne disease cases are reported.

To overcome the difficulties caused by such a large number of unreported cases, the collaborating FoodNet sites have set up a system to actively identify laboratory-confirmed cases of foodborne illness and to perform surveys to more accurately estimate the actual number of people who become sick with diarrhea each year.

FoodNet is in keeping with the National Academy of Sciences' recommendation for more community-based surveillance of pathogens and of foodborne disease incidence in humans. The project measures the impact of programs aimed at reducing the pathogens on meat and poultry.

The program, originally known as the Sentinel Site Survey, began with a 3-month trial in 1995, and has been actively collecting data since January 1996. Coordinated by CDC, data is collected at sites in Atlanta, GA, at Emory University and the Veteran's Affairs Medical Center; in northern California at the

California Department of Health Services and the University of California at Berkeley; in Connecticut at the Connecticut Department of Public Health and Addiction Services, and Yale University; in Minnesota at the Minnesota Department of Health; and in Oregon at the Oregon State Health Division. And, beginning in January 1997, an additional county in Connecticut and 12 counties in Georgia were added to FoodNet. This increased the population under surveillance by an additional 1.5 million to now include 14.7 million people. Also, investigators in New York and Maryland joined the program and now conduct active surveillance in several counties within their states.

Data is collected through: population-based surveys; laboratory surveys; physician surveys; and case-control studies.

Laboratory Survey

Laboratories that conduct microbiological testing of stool samples were surveyed to determine their practices for processing and culturing samples. They are reporting results from cultures so that FoodNet can determine the number of culture-confirmed cases of foodborne bacterial illnesses.

Population Survey

The population-based surveys are intended to develop estimates of the numbers of diarrheal cases that occur in the study population each year, the proportion of persons with diarrhea who seek health care, and their food handling behaviors and practices. Data is being gathered through random telephone surveys with individuals who reside within the sites.

Physician Survey

The primary purpose of the initial physician survey is to determine how often and under what circumstances physicians order tests. As changes occur in the way health care is provided over time, FoodNet will monitor how those changes affect stool culturing practices.

Case-control Studies

Case-control studies are used to statistically determine risks associated with different foods and to obtain information on potential exposure. Case-control studies consist of interviews with selected persons who had laboratory-confirmed cases of *Salmonella* or *E. coli* O157:H7, and a random selected control group of people in the community who were not ill.

The FoodNet program specifically targets seven bacterial pathogens--*Campylobacter*, *E. coli* O157:H7, *Listeria*, *Salmonella*, *Shigella*, *Vibrio*, and *Yersinia*. In addition, the case-control studies seek to develop a better understanding of two of those pathogens, *Salmonella* and *E. coli* O157:H7.

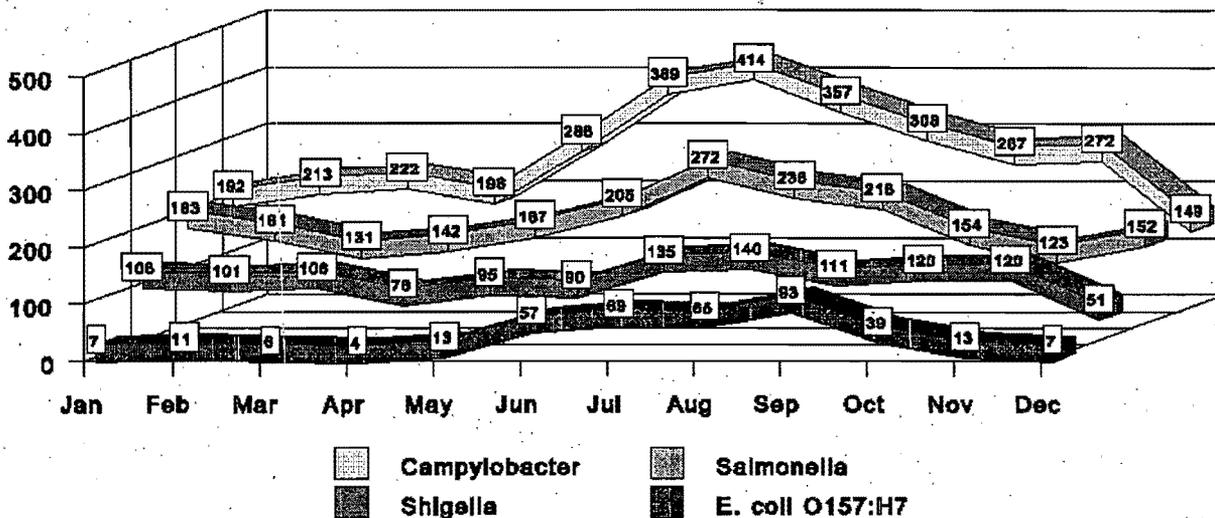
In 1997, FoodNet began active surveillance for hemolytic uremic syndrome (HUS), a serious potential outcome of infections caused by *E. coli* O157:H7 and other *Shiga* toxin producing *E. coli* infections. In addition, FoodNet initiated active surveillance for *Cryptosporidia* and *Cyclospora* at three of the survey sites.

First Year's Results

FoodNet completed its first year of gathering data on December 31, 1996. Results from the first year of the study were published by CDC in the March 28, 1997, issue of the *Morbidity and Mortality Monthly Report (MMWR)* (copies of the *MMWR* are available through the Internet at <http://www.cdc.gov/epo/mmwr/mmwr.html>).

FoodNet found 7,259 laboratory-confirmed diarrheal cases attributable to the 7 bacterial pathogens targeted. Of those cases, 45 percent--or 3,267 cases--were attributed to *Campylobacter*. *Salmonella* was identified in 29.5 percent (2,142 cases), *Shigella* in 17.2 percent (1,251 cases), *E. coli* O157:H7 in 5.3 percent (384 cases), *Yersinia* in 1.9 percent (135 cases), *Listeria* in 0.9 percent (63 cases), and *Vibrio* in 0.2 percent (17 cases).

FoodNet: Cases, by month of collection, all sites 1996



An important benefit of the data collection is the identification of outbreaks which might previously have gone undetected or

treated as isolated cases.

How Data Will Be Used

FSIS, FDA, CDC, and the project sites will use FoodNet information to monitor the incidence of foodborne diseases in the United States. Outbreaks identified during this surveillance project will be investigated and appropriate control measures taken. This system will help identify new and emerging foodborne pathogens.

FSIS will use the pathogen data to evaluate the effectiveness of new food safety programs and regulations in reducing foodborne pathogens on meat and poultry. In July 1996, the Agency published a final rule requiring meat and poultry plants to begin implementing pathogen reduction and hazard analysis and critical control point (HACCP) systems to reduce microbial contamination. The rule mandates microbial testing for *Salmonella* to verify the effectiveness of HACCP procedures in reducing pathogenic organisms in meat and poultry.

FDA published a final rule implementing HACCP principles for seafood in December 1995. The provisions of that rule took effect on December 18, 1997. FDA will include data from FoodNet in its evaluation of the effectiveness of HACCP systems as well as other food safety interventions in reducing foodborne pathogens in seafood, dairy products, fruits and vegetables, and to develop future food safety programs.

The Future of FoodNet

For the project to be successful, data must be collected over a number of years to chart national trends and consider the effectiveness of control strategies. The data at this point are very preliminary and cannot be relied upon as an accurate indicator of either the prevalence of foodborne illness or its causes.

Beginning in fiscal year 1998, all sites will participate in a case-control study for *Campylobacter* infections. Previously, the case-control studies were limited to laboratory-confirmed cases of *Salmonella* or *E. coli* O157:H7.

For More Information...

Technical Inquiries:	Peggy Nunnery (202) 501-7515
Media Inquiries:	Jacque Knight (202) 720-9113
Food and Drug Administration:	Judith Foulke (202) 205-4144
Centers for Disease Control and Prevention:	Tom Skinner (404) 639-3286
Consumer Inquiries:	USDA's Meat and Poultry Hotline: 1-800-535-4555, or in Washington, DC: (202) 720-3333
FSIS Web site:	http://www.fsis.usda.gov/

This backgrounder is also available at the FSIS Web site at:
<http://www.fsis.usda.gov/background/bfoodnet.htm>

Additional information about the Foodborne Disease Active Surveillance Network is available at:
<http://www.fsis.usda.gov/OPHS/fsisrep1.htm>

[Backgrounders Menu](#) | [FSIS Home Page](#) | [USDA Home Page](#)

Release No. 0123.98

Remarks

OF
SECRETARY DAN GLICKMAN
'TURNING THE TABLES ON FOOD-BORNE ILLNESS'
NATIONAL PRESS CLUB -- MARCH 19, 1998

Good afternoon. Not too long ago, I was at an event where Cokie Roberts was the emcee. When she introduced me, it was after a dinner, and she got up and said she watched me eat the whole time, and everything I ate, she ate, because she knew it would be safe.

That's a risky strategy. You could gain a few pounds. I've always said that even though I wasn't a farmer (I just represented them as a Congressman from Kansas for 18 years), my training for this job started at an early age ... sitting at my mother's table with her saying, eat, eat, eat.'

I enjoy a good meal, and even as a person who works constantly on food safety issues, I can honestly say that I enjoy my meals with the confidence and peace of mind that comes with knowing that America does indeed have the safest food in the world. Yes, it's true, more and more today we eat the world's food. But we do a good job of making sure it's safe, and thanks to President Clinton, we are taking our food safety efforts to a whole new level.

You know, when I was up for this job, my confirmation hearings focused on things like wheat and cattle prices, dairy and crop insurance reform. But when I took this job, my mother gave me one piece of advice: Dan, she said, just make sure the food is safe.'

Everywhere I go, food safety is what's on people's minds. Folks literally walk up to me on the street and ask, 'how do I cook a hamburger right?' You know, a research group asked folks what stories they followed most closely last year: 1) Princess Diana. 2) Iraq's chemical weapons. 3) the Hudson Beef recall.

Consumers understand how important this is; they want government to do more; but they also have confidence in their food supply, and that is rare around the world. When they killed all the chickens due to the bird flu epidemic in Hong Kong, consumers there cut poultry purchases in half. With the mad cow problem in Europe, beef sales there dropped by 40%. What was the market impact here during last year's hamburger recall? Nearly zero.

Folks today have their qualms with government, but not when it comes to food safety. In this arena, people unanimously want a strong government. It may get smaller overall, it may do less, but people always will look to government to protect them in ways they cannot protect themselves: making sure the airplanes we fly in are safe, making sure our nation is secure, making sure the banks that hold our life savings are solvent, making sure the food we feed our families is safe.

You know, tomorrow is National Agriculture Day which is news to most folks. As we've moved from an agricultural to an industrial service economy where only 2 percent of our people work directly on the farm, our public perception of agriculture has come to border on science fiction. It's sort of like Star Trek where a computer magically produces whatever food you

desire.

Our lives in Washington don't seem so far off from that futuristic scenario. Here in our nation's capital, it's the dead of winter. But if you step into a Safeway or Giant or Fresh Fields, you'll find a tropical paradise of fresh fruits and vegetables -- along with abundance of every kind -- meat, poultry, seafood -- whatever you want, whenever you want it.

Americans also spend less of their income on food than any other people in the world -- about 11%. In China, it's 50%. This abundance and affordability -- along with a strong U.S. economy -- affects everything from our waistlines to our health. We're a heftier people today. We're also healthier. Last week the National Cancer Institute announced the first decline in cancer rates in 60 years. One reason cited was improved diets, including more fresh fruits and vegetables.

Yet today, we also know that more than 9,000 Americans die every year from foodborne illness. Turning the tables on foodborne illness requires responding to a complex web of trends: new, more virulent, more drug-resistant pathogens; how we process and distribute food; we're eating more outside the home -- 40% of the American food dollar today is spent in restaurants, paying others to prepare our meals; we eat food from around the world; and, we have a growing senior population whose immune systems are more vulnerable.

We face a far more complex food safety challenge today. It is one that requires everyone -- farmer, rancher, scientist, public policy maker, processor, shipper, grocer, cook -- to do their part.

We've made progress. This time last century, more U.S. troops died in the Spanish-American War from eating contaminated food than from battle wounds. A few years later, Upton Sinclair wrote 'The Jungle,' which pushed America to enact its first meat and poultry safety laws -- really our first consumer protection laws. This book also launched the progressive movement here.

When Sinclair published his book, then-Agriculture Secretary James Wilson wrote to the Postmaster General saying it was the most scurrilous slander he'd seen, and could the Postmaster instruct his delivery folks to prevent its distribution? ... We have come a long way.

Like that first consumer groundswell, what President Clinton -- with the strong support of consumers and by and large the food industry -- is doing I believe will go down in history as one of the most significant consumer and public health victories of this decade.

Like Sinclair's book affected the people of his time, we had our own shocking, unifying catalyst for change. President Clinton took office the same month the Pacific Northwest E. coli outbreak began, when hundreds were sickened and four young children died. That tragedy united government, consumers, industry and the public health community behind a food safety revolution.

USDA now has an independent, arms-length Food Safety and Inspection Service -- the largest food safety agency in the world -- staffed with some of the best public health scientists in the world. Their core mission is preventing foodborne disease. Just a few years ago, these folks worked in the same agency that markets U.S. agriculture. Now, they are totally separate.

We banned the sale of hamburger contaminated with harmful E. coli. This decision has kept millions of pounds of unsafe food off the market, but it was highly controversial at the time.

President Clinton has invested heavily in a state-of-the-art surveillance system that allows doctors and scientists to do in 24 hours what just a few years ago took two weeks. Instead of conducting hundreds of hours of tedious lab work, doctors now can enter the DNA fingerprint of a pathogen into a national database and quickly search for vital, life-saving information. It's like the system law enforcement uses where they scan suspects' fingerprints into a computer to get their criminal records. On our system, scientists can get a similar 'rap sheet' on a pathogen -- everything from its link to an outbreak, to known sources, to the toxins it produces.

In the Pacific Northwest, before we had this rapid response, 732 people became ill before we zeroed in on the cause. Last year, we stopped the Hudson outbreak at 16 illnesses.

This Administration also put the safe-food-handling instruction stickers on the meat and poultry you buy at the grocery store, and we have education campaigns that promote basic in-kitchen safety practices -- like washing your hands, and storing foods at proper temperatures.

In fact, President Clinton's Food Safety Initiative works at every point from farm to table to secure food safety. And, he's asking for an extra \$101 million to advance inspections, fruit and vegetable safety, cutting-edge research, consumer education and national surveillance.

This year, we also started a new approach to meat and poultry inspections. For nearly a century, inspectors had to look for contamination, even though many dangerous threats in our food supply are invisible. Now, we use technology to go after these hidden dangers. There are regular tests for E. coli and salmonella, and we require plants not just to catch contamination, but to close safety gaps.

This is a major cultural change. Our public policy now makes it crystal clear that industry is responsible for producing safe food. In fact, they have primary responsibility. It's not just up to inspectors to catch unsafe food. It's not just up to consumers to cook their meat thoroughly, and wash their fruits and vegetables well. Industry, also, is responsible for producing safe food.

This is a profound and positive step, but it must be taken firmly. Most in the industry are eager to rise to the new safety standards. They know safe food sells. They are 100% committed, and they are the first to tell me that some in the industry do not meet their safety responsibilities.

The experts agree. They'll tell you it's the few folks who drag their feet on the little things that time and again wind up causing the major public health incidents. I've asked Congress for the authority to fine them for putting the public's health at risk. Right now, all USDA can do is drop what I call the 'atomic bomb' -- shut a plant down. That's an action that affects people's livelihoods, and it is only taken in extreme cases. But I don't think our food safety efforts should solely focus on the lowest common denominator. Fines tailored to the seriousness of the offense would allow us to get folks' attention, and fix minor flaws before they become major problems.

Most folks are surprised when I tell them USDA does not have this authority, and they are shocked when I tell them that no one in government

can order a recall of unsafe food ... It's true. While industry by and large acts in good faith, what concerns me is the changing nature of the food business. Take hamburger plants. The big guys can now produce upwards of a million pounds of product a day, and ship most of it virtually overnight across the country.

When we ask for a recall. We have no assurance that every corner store, every retail outlet, every distributor will act and act quickly. We don't even have mandatory notification. Days can go by before USDA is even informed that the public may be at risk. This is a terrible situation to be in during an outbreak when every day, every hour that goes by without action someone could get sick or worse.

This is way out of step with America's strong consumer protection laws. After all, if I sold an unsafe toy or car, other government agencies could order a recall, and fine me for putting people at risk. USDA can fine people under various statutes: sell a cat without a license, abuse a circus elephant fine, fine. Yet, if you produce unsafe food -- the only one of these items that puts financial penalty.

I'll let you draw your own conclusions why. I'll just say that not once has a c said, don't let government protect me from unsafe food.' There's a bill before Cong Food Safety Enforcement Enhancement Act -- that would give USDA these powers -- fines, mandatory notification, and the power to order a recall if a voluntary recall fails.

We're also in a new fiscal environment today. The American people want government to do more on food safety -- more inspections, more research, more consumer education -- and the American people want a balanced budget. Given these conflicting demands, we have to find new ways to appropriately fund the most critical functions of government. How can we do this?

Well, the entire Nuclear Regulatory Commission is funded through fees for services rendered to the industry. The Food and Drug Administration has fees for safety evaluations of pharmaceuticals; there are safety fees on the railroad and airline industries. The Administration wants the entire Federal Aviation Administration funded through user fees. And, when chemical companies register new pesticides with the Environmental Protection Agency, they are charged for the work EPA has to do to ensure their product can safely be used on our food.

In each of these cases, safety is a company's most valuable asset. Industry should not look entirely to taxpayers to safeguard it. And, relative to these other proposals, USDA is asking for a mere pittance: less than one penny a pound. How much are you willing to pay for safe food?

We also need to challenge more state and local governments to adopt the food code -- which is a uniform set of food safety guidelines for the links in our commercial food chain that are primarily overseen by state and local jurisdictions -- that is, the 1 million restaurants, grocery stores and cafeterias in this country. The food code is our top scientists best recommendations for one high standard of safety. I'd like to see it in action across the country.

We must keep challenging industry to step up to the plate. I give them a lot of credit. I see the cattlemen here today. They've invested millions of dollars in food safety research. Some in the fast-food industry have set their own standards over and above government's. If you compare today's food safety revolution to Sinclair's, the biggest difference is industry. This time around, they are providing real leadership, and taking their

responsibilities seriously.

When you look back on what this Administration has done to date, you see government catching up with science -- using what science knew to raise the bar of food safety. When we look ahead, the next great frontier is pushing the boundaries of what science knows and can do for us.

I sat on the front row at the President's State of the Union speech. The biggest applause he got was when he announced that he would seek the largest funding increases in history for the National Science Foundation and the National Institutes of Health. He got this applause because every Member of Congress understood the importance of this work to people's lives. The same is true for food safety research and President Clinton has been generous in his funding.

Science is the next great food safety frontier, and without question, our greatest weapon in the battle for food safety is new technology. Earlier this decade, scientific advances enabled us to beat back Listeria. Now, scientists see glimmers of hope that we may be at a turning point on E. coli. Today, I have an exciting breakthrough to announce on the salmonella front -- one we hope may prove just the tip of the iceberg in a new food safety revolution.

This week, USDA received FDA approval for a new anti-salmonella spray that has proven up to 99.9% effective in eliminating salmonella in poultry. Scientists know that naturally occurring organisms in adult chickens are highly successful in warding off salmonella. This means the bacteria's usual window of opportunity is when the chicks are young. This new product allows poultry producers to mist young chicks with these good organisms. The chicks then do their preening, which gets the good guys into their system and keeps the salmonella out. And, as long as the spray gets on the chicks before the salmonella, they will be salmonella free.

We tested 80,000 chicks. The presence of salmonella was reduced to zero with just one spray right as they hatched. I have also directed that we proceed with the next stage of our research which will focus on breeder hens to see if we can prevent salmonella from passing from a hen to her eggs. We are very optimistic about this, and it will bring us even closer to a 100% solution.

We are also now seeking to apply the same principle in cattle and hogs -- which holds the promise of opening up a whole new world for prevention of foodborne illness.

This is a major milestone for food safety. But I do want to make clear that proper processing and safe in-kitchen preparation remain essential. I also want to give a world of credit to Donald Corrier and David Nisbet of USDA's Agricultural Research Service lab in College Station, Texas, along with all of their partners in this pioneering effort.

Our scientists stand on the verge of many more breakthroughs. They are looking into the origins of campylobacter -- which is the leading cause of food-borne illness in our nation. I should point out that preliminary data on our salmonella spray indicates that it fights campylobacter, too.

There are a number of folks converting Gulf War technology to food-safety uses. pregnancy tests -- that would go on your juice cap or other food packaging and give you a clear sign if your food has been contaminated.

We need to encourage these advances. That means more funding for food

safety research, and it means a more strategic, coordinated use of these funds -- making sure that every project fits into a national food safety strategy driven by the public health experts.

I wish I could stand here today with a simple solution to the food safety challenge -- you know, some magical 5-point government plan that would make foodborne illness go away. But that's not something government alone can do. This President and this Administration have done more than any before us to improve the safety of America's food. Together with farmers and ranchers, with the food industry, with the public health community and the research community and the consumer community, I believe we are turning the tables on foodborne illness -- setting the nation on an irreversible path toward a safer food supply and a healthier American people.

Thank you.

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

MEMORANDUM FROM THE SECRETARY

TO: FSIS EMPLOYEES

SUBJECT: HACCP IMPLEMENTATION

Paul Johnston
3-24-98

A year and a half ago, I congratulated the employees of the Food Safety and Inspection Service for a landmark accomplishment—the issuance of a new rule on pathogen reduction and HACCP systems for meat and poultry production to greatly enhance food safety. The new rule revolutionized the manner in which meat and poultry production is regulated and requires industry to take greater responsibility for the safety of its products.

Now, after 18 months of intensive preparation on your part, SSOP's are in place and you have begun implementing and enforcing HACCP in large livestock and poultry slaughter and processing plants across the country. On behalf of President Clinton and myself, I would like to congratulate you and your colleagues for the months of meticulous groundwork that have led up to this historic enhancement in the safety of our meat and poultry.

I want to single out the continuing importance FSIS inspectors have in the smooth implementation of the new rule, and to continued progress in improving food safety. For almost 100 years, Federal inspectors have played an essential role in protecting American consumers and will continue to do so. HACCP is not about decreasing the numbers of inspectors nor about diminishing the role of the Federal inspector. Many of you will play an expanding role in evaluating industry's ability to maintain effective SSOP and HACCP systems. Others will continue to directly inspect product, including performing valuable organoleptic examinations. Still others may be redeployed to carry out other important food safety and consumer protection activities outside plants.

Whatever the case, under the Administration's budget, every inspector who wants one will continue to have a job with FSIS. Some jobs may be in different locations, may require new training, and may even support a higher grade, but every position will play a vital role in our food safety mission. FSIS inspectors can continue to take advantage of agency-funded educational opportunities to enhance their skills for their future roles with FSIS. Regardless of the location or specific set of duties assigned, the role of the Federal inspector remains critical to ensuring that the regulated industry implements effective HACCP and pathogen reduction programs to protect the public from food-borne illness. Food safety is one of President Clinton's

highest priorities, and it is clearly one of the critical functions of USDA as we enter the 21st century. As I travel around the country, I sense more public interest in our food safety agenda and accomplishments than any time in the history of our Department. It is a real credit to our FSIS team that public confidence in our food safety system remains so high.

All FSIS employees--veterinarians, laboratory personnel, support staff, and compliance officers--join inspectors in helping to protect the public health. I commend the employees of FSIS for being outstanding examples of the very best the Federal Government has to offer. The important mission of FSIS to ensure food safety is in good hands. Thank you for your continuing dedication.



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

TO: (See Distribution List)

FROM: Catherine E. Woteki *C EWoteki*
Under Secretary
Food Safety

APR 30 1998

SUBJECT: USDA Food Emergency Rapid Response & Evaluation Team

As you know, the Secretary of Agriculture has made improving food safety a high personal priority. As part of his commitment, on April 22 he issued a directive (attached) charging me with the responsibility for organizing and coordinating the work of an intra-departmental Food Emergency Rapid Response & Evaluation Team (FERRET). The Team will be responsible for recommending to the Secretary and Deputy Secretary of Agriculture (1) a plan that would enhance USDA's capacity to respond rapidly to food safety emergencies, as they might arise, and (2) a long-term strategy for preventing food safety emergencies.

The Secretary has asked me to chair a Team whose membership also would include the Under Secretaries for Food, Nutrition, and Consumer Services; Farm and Foreign Agricultural Services; and Research, Education, and Economics; the Assistant Secretary for Marketing and Regulatory Programs; and General Counsel.

Additionally, he has asked that – as appropriate – the Team involve in its work the Under Secretaries for Environment and Natural Resources and Rural Development, the Press Secretary's Office, Office of Legislative Affairs, Office of Budget and Policy Analysis, Office of the Chief Economist and Office of Intergovernmental Affairs, as well as appropriate representatives from FDA, EPA, and CDC.

The Secretary and I need and value your active participation in the Team's work. My office will be calling you shortly to notify you of our first meeting.

Attachment

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

APR 22 1998

MEMORANDUM FOR: Catherine E. Woteki
Under Secretary
Food Safety

FROM: Dan Glickman
Secretary Of Agriculture

SUBJECT: USDA Food Emergency Rapid Response & Evaluation Team

Through this memorandum, I am charging you, as USDA's senior food safety official, with the responsibility of organizing and coordinating the work of an intra-departmental Food Emergency Rapid Response & Evaluation Team. I am directing you and the Team to develop a plan which the Department can use (1) in responding quickly and appropriately to food safety emergencies as they arise, especially those which cross agency jurisdictions, and (2) to evaluate our emergency episodes and use what is learned to improve our long-term strategy for preventing food safety emergencies, particularly by returning that information to the appropriate mission areas for evaluation and action.

The Team will be our coordinating mechanism for developing departmental responses to food safety emergencies, and will advise on food safety issues that might arise from emergencies. Such timely, accurate information, developed from an objective, well-coordinated response team will enhance the public health, protect consumers, while at the same time informing the marketplace of problems which need to be addressed for the benefit of all. The Team will make recommendations in these areas to the Secretary and Deputy Secretary of Agriculture.

Team membership should include, but not be limited to:

Under Secretary for Food Safety (Chair)
Under Secretary for Food, Nutrition, and Consumer Services
Under Secretary for Farm and Foreign Agricultural Services
Under Secretary for Research, Education, and Economics
Assistant Secretary for Marketing and Regulatory Programs
General Counsel

As appropriate, I also would anticipate your including the Under Secretaries for Environment and Natural Resources and Rural Development, the Press Secretary's Office, Office of Legislative Affairs, Office of Budget and Policy Analysis, Office of the Chief Economist and Office of Intergovernmental Affairs. The members of the team will utilize staff from their own mission areas as necessary and appropriate to provide information, advice and counsel to themselves and the team as a whole.

The USDA Food Emergency Rapid Response & Evaluation Team is charged with:

- Addressing quickly and appropriately emergency food safety issues that cross agency jurisdictions, for example USDA commodity purchases, assigning the highest priority to responding to issues or incidents that have the potential of putting families' and school children's health at risk – a priority that is consistent with the President's April 21, 1997 "Protection of Children From Environmental Health Risks and Safety Risks" executive order, or issues which may arise in other areas of the department, for instance, grain storage and inspection, or other commodity programs;
- Establishing goals for communicating internally and externally the outcomes of food safety issues addressed by the Team, including communication with other government offices, agencies, and departments; the Congress; school administrators, school food preparers, and school children's parents, industry groups and trade associations, members of the scientific community, and state and county officials, as well as other consumers, as appropriate; and, the news media.
- Lending support to the Federal Outbreak Response Coordination Group (FORCG) initiated by President Clinton in May, 1997, as part of his Food Safety Initiative. FORCG will function as the primary mechanism to improve communications between Federal food safety agencies and state agencies with food safety responsibilities.
- Producing guidelines and procedures for responding to emergency situations.

In addition to working with USDA Sub-cabinet, I expect you to collaborate with your counterparts at FDA, EPA, and CDC to ensure this department's timely response to emerging issues and USDA's active role in interdepartmental activities.

This charge to you is effective immediately. Please prepare a response to me by May 1, 1998 and include an anticipated time line for establishing the Team and producing a document that responds to the items listed in the directive.

Release No. 0295.98

Statement

of
Agriculture Secretary Dan Glickman
on House Introduction of the
Food Safety Enforcement Enhancement Act
July 21, 1998

"I want to thank Congressmen Baldacci for introducing HR 4266, USDA's "Food Safety Enforcement Enhancement Act."

"This legislation is an important part of the Clinton Administration's comprehensive effort to improve food safety. Our broad-based strategy includes cutting-edge research into the root causes of foodborne illness, expanded consumer education, and more nationwide monitoring to control outbreaks more quickly. Most importantly, we have fundamentally improved our meat and poultry inspection system by focusing on prevention and by incorporating scientific testing directly targeted at harmful bacteria like E. coli 0157:H7 and salmonella.

"But we need additional enforcement tools to ensure that this new system is as effective as possible. As the law stands today, USDA cannot fine a company for lax safety standards. We can assess fines for all kinds of other things: selling a cat without a license, abusing a circus elephant, selling a potato that's too small. Yet if you produce unsafe food -- the only one of these actions that puts people's lives at risk -- USDA cannot impose any financial penalty. This legislation grants USDA the authority to fine companies that violate food safety laws.

"It is time to treat food safety as seriously as we do any other threat to human health. Right now, when a car kills due to faulty manufacturing, a plane engine fails revealing critical safety gaps, or a toy harms the children it was meant to please -- the federal government can act quickly to remove them from the marketplace. Food safety is just as important. That's why this legislation requires prompt government notification when contaminated meat or poultry may have entered the market, and it allows for mandatory recalls when voluntary means fail to remove all potentially unsafe product from the market.

"Again, I thank Congressman Baldacci and his 15 co-sponsors for their leadership on this vital issue. I look forward to working with them on what I hope will be a successful attempt to turn this bill into law."

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Note to reporters: The other House sponsors are Congressmen LaTourette, Klink, Doyle, Pomeroy, Farr, DeLauro, Ackerman, Allen, Sanders, Hinchey, Gejdenson, Coburn, Fazio, Kaptur, and Blumenauer. The companion Senate bill, S. 1264, was introduced by Senator Harkin on October 7, 1997. Its other sponsors are Senators Daschle, Leahy, Johnson, Durbin, Murray, Moseley-Braun, Boxer, Mikulski, Torricelli, Dodd, and Kennedy.

by
Secretary of Agriculture Dan Glickman
Regarding the WTO's Decision on the EU Beef Hormone Ban
May 28, 1998

"We are pleased with the WTO's final decision that the European Union must bring its ban on meat from animals treated with growth-promoting hormones into compliance with the WTO Dispute Settlement Panel and Appellate Body rulings by May 13, 1999.

"This decision shows that the WTO dispute-settlement process works, even in the case of sensitive, long-running disputes. The disciplines of the WTO Sanitary-Phytosanitary Agreement, for which the United States fought long and hard in the Uruguay Round, have been preserved. Countries have been put on notice that they can no longer hide behind measures that have no scientific basis and are inconsistent with obligations to which they have agreed.

"U.S. beef producers have waited a decade for this day to come. We trust that the EU will now do the right thing and implement market opening measures by the WTO-mandated deadline. The United States, and now the WTO, expect nothing less."

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**MEMORANDUM OF UNDERSTANDING
AMONG
THE UNITED STATES DEPARTMENT OF AGRICULTURE
AND
THE UNITED STATES DEPARTMENT OF HEALTH AND
HUMAN SERVICES
AND
THE ENVIRONMENTAL PROTECTION AGENCY**

I. INTRODUCTION

A. PARTIES

The parties to this agreement are the United States Department of Agriculture (USDA), the United States Department of Health and Human Services (HHS) and the Environmental Protection Agency (EPA).

B. BACKGROUND

While the American food supply is among the safest in the world, there are still millions of Americans stricken by illness every year caused by the food they consume, and some 9,000 a year -- mostly the very young and elderly -- die as a result. The threats are numerous and varied, ranging from *Escherichia coli* 0157:H7 in meat and apple juice, to *Salmonella* in eggs and on vegetables, to *Cyclospora* on fruit, to *Cryptosporidium* in public drinking water supplies -- and most recently, to hepatitis A virus in frozen, sliced and sugared strawberries.

In his January 25, 1997 radio address, President Clinton directed three Cabinet members -- the Secretary of Agriculture, the Secretary of HHS, and the Administrator of the EPA -- to identify specific steps to improve the safety of the food supply. Their May, 1997, report to the President identified several issues and outlined a comprehensive new initiative to address those issues and improve the safety of the Nation's food supply.

One issue addressed in the report to the President was the coordination among federal, state and local agencies in responding to interstate outbreaks of foodborne illnesses. This MOU builds on previous Administration steps to modernize our food safety system and respond to emerging challenges as well as creating partnerships and leveraging the resources of federal, state and local agencies as part of the Vice President's National Partnership for Reinventing Government.

Four federal entities are charged with responding to outbreaks of foodborne illness (for the purpose of this MOU, foodborne illness also includes waterborne illness): USDA, EPA, and the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) at HHS. Each of the four federal agencies has a critical role when a outbreaks occur. CDC's primary responsibility is to assist state and local health departments in investigating outbreaks of illness and in identifying the cause of the outbreak. FDA, the Food Safety and Inspection Service (FSIS) at USDA, and EPA also have responsibility for determining whether a product they regulate may be causing illness, and for halting the spread of illness by taking regulatory action against the suspect products, or wastes (other than animal

manures) that have the potential to contaminate the air, land, or waters used to produce the food product. The food product implicated in a foodborne outbreak determines which regulatory agency has primary jurisdiction: FSIS regulates meat, poultry, and egg products; FDA regulates all other foods including game meats, bottled drinking water and shell eggs; and EPA regulates water, drinking water from public systems and pesticides, and manages organic and inorganic wastes used or disposed of on agricultural land. While each entity has clearly defined areas of responsibility, the successful containment of many outbreaks of foodborne illness involves more than one federal entity.

All states and many local governments with varying expertise and resources share responsibility with the federal agencies for response to such outbreaks and, also, have a critical role. Identification and investigations of foodborne illness often begin at the community or state level. States and local governments share with the federal government the legal responsibility for protecting the health of their residents. The majority of foodborne outbreaks occur at the local or state level, however, many outbreaks involve federal agency jurisdiction. Illnesses cross state borders, and most foods or food ingredients are processed or produced in another state or by international trading partners. Federal involvement is also necessary when contaminated food from a common source has been distributed to grocery stores, restaurants, and homes in more than one state.

When outbreaks of foodborne illness occur, federal agencies work with state and local health and agricultural authorities in their investigation and in implementation of control measures through consultation, diagnostic assistance, and by regulatory action against the products. In some instances, on-site assistance is requested by local and state authorities from the CDC to establish the cause of an outbreak, and from other agencies to help find the source of the problem. For large or multistate outbreaks, federal agencies play a critical coordination role to ensure consistency of approach and implementation of needed control measures.

C. RECOGNITION OF NEED

Although significant communication already occurs among the federal agencies; among federal, state and local agencies; among the various state agencies; and between state and local agencies, better coordination is needed to meet new and growing threats to the nation's food supply, enhance the level of public health protection, provide standards for prevention of future foodborne illness outbreaks, leverage agency resources and experience, and avoid duplication of effort and move more quickly since products can be widely distributed.

Further, a critical element of an effective, rapid response to a foodborne illness outbreak is ready communication by all the involved parties. Although there are communication systems in place, the systems need to be expanded and coordinated to achieve rapid exchange of information and data between key outbreak response personnel in each agency at the federal, state and local levels and the affected food industry.

The report to the President recommended the establishment of an intergovernmental group, to be known as the Foodborne Outbreak Response Coordinating Group, to improve the approach to interstate outbreaks of foodborne illness and develop a national, coordinated outbreak response system.

II. PURPOSE

A. This memorandum of understanding ("Memorandum") among the parties is entered into in order to form the Foodborne Outbreak Response Coordinating Group ("FORCG").

B. The purpose of the FORCG is defined by the following goal, mission and objectives:

1. It is the goal of FORCG to improve the approach to interstate outbreaks of foodborne illness by federal, state and local agencies charged with responding to such outbreaks.
2. Toward this goal, it is the mission of FORCG to include federal, state and local agencies with outbreak response duties in the development of a national comprehensive and coordinated foodborne illness outbreak response system.
3. This mission will be accomplished by subscribing to the following management objectives which will, in turn, guide FORCG:
 - a. FORCG will review and evaluate outbreak response at the federal agency level (among agencies), including cooperation among federal agencies and between state and local agencies and affected industries. FORCG will identify areas where efficiency can be gained and make specific recommendations for improvement. FORCG will work with federal, state, and local governments, the food industry, health professionals, and consumer advocates to implement beneficial changes.
 - b. Standard operating procedures will be developed for the rapid exchange of data and information associated with foodborne illness outbreaks between involved agencies and for dissemination to the public. The procedures will cover the exchange of data and information associated with an outbreak and will complement systems established for exchange of information about day-to-day occurrences of foodborne illness.
 - c. A nationwide survey will be conducted to catalogue existing state and local food safety program infrastructures.
 - d. Working groups will be established to develop recommended procedures for outbreak response coordination between federal and state agencies, and between state and local agencies levels to improve the coordinated response to interstate outbreaks.

III. ORGANIZATION AND MEMBERSHIP

A. Under Title II, Section 204, Subpart (a) of the Unfunded Mandate Reform Act of 1995, Pub. L. 104-4, elected state officers, or their designated representatives with authority to act on their behalf, may meet with federal officers to exchange views, information, or advice relating to the management or implementation of federal programs established pursuant to public law that explicitly or inherently share intergovernmental responsibilities or administration. The parties, therefore, agree that all members of FORCG will be federal officials or state employees with the requisite authority.

B. FORCG will have the following members:

1. Two representatives from USDA: The Under Secretary for Food Safety and the Administrator for FSIS, or their designees.
2. Four representatives from HHS: The Assistant Secretary for Health, the Commissioner of the FDA, the Director of CFSAN and the Director of CDC, or their designees.
3. Two representatives from EPA: The Assistant Administrator for the Office of Prevention, Pesticides and Toxic Substances and the Assistant Administrator for Water, or their designees.

4. One state employee who is a representative of the Association of Food and Drug Officials.
5. One state employee who is a representative of National Association of City and County Health Officials.
6. One state employee who is a representative of the Association of State and Territorial Public Health Laboratory Directors.
7. One state employee who is a representative of the Council of State and Territorial Epidemiologists.
8. One state employee who is a representative of the National Association of State Departments of Agriculture.

IV. RESPONSIBILITIES AND SCOPE OF WORK

A. FORCG will be co-chaired by the Under Secretary for Food Safety (USDA) and the Assistant Secretary for Health (HHS). His or her designee will facilitate each meeting.

B. One member will be designated as the outbreak response coordinator for each department or agency that has a role in an outbreak response. The duties of each outbreak response coordinator will be identified as FORCG develops the overall outbreak response system. HHS will designate the Assistant Secretary for Health as the primary person in charge of coordination for HHS. USDA will designate the Under Secretary for Food Safety as the primary person in charge of coordination for USDA. EPA will designate the Assistant Administrator for Water as the primary person in charge of coordination for EPA when drinking water is involved, and the Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances will be the primary person when Pesticides and Toxic Substances are involved.

V. GENERAL PROVISIONS

A. FORCG will meet Bi-monthly.

B. This Memorandum may be modified with supplemental written agreements signed by the parties and can be terminated in writing, in whole or in part, by consensus of the parties.

C. This Memorandum will become effective on the date the final signature is affixed hereto.

D. This Memorandum is entered into within the limits of the statutory authority of the parties to the Memorandum.

SIGNATURES

Catherine E. Woteki, Ph.D., R.D.
Under Secretary
Food Safety
U.S. Department of Agriculture

David M. Satcher, M.D., Ph.D.
Assistant Secretary for Health and
Surgeon General
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Services

Lynn R. Goldman, M.D.

Robert Perciasepe

Assistant Administrator for Prevention, Pesticides, and
Toxic Substances
Environmental Protection Agency

Assistant Administrator for Water
Environmental Protection Agency

[Return to May 22, 1998 Talk Paper](#)

Home

Hypertext updated by ear 1998-MAY-29



**Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700**

Speeches

Office of the Under Secretary for Food Safety
U.S. Department of Agriculture

The Importance of Sound Science

Remarks prepared for delivery by Dr. Catherine Woteki, Under Secretary for Food Safety, before a public meeting on the President's National Food Safety Initiative, October 2, 1998, Arlington, VA.

It's a pleasure to join my colleagues from the Office of Science Technology Policy, the Department of Health and Human Services, the Environmental Protection Agency, and the Department of Agriculture at this very important meeting to begin the development of a comprehensive, strategic Federal food safety plan.

One of my tasks here today is to talk just a few minutes about the part of the vision statement that addresses the importance of science. As Neal Lane said in his opening remarks, "sound science must underpin all of our food safety efforts."

This is important for two major reasons. First, science must guide our program and policy decisions. And second, the application of science holds real promise for major improvements in food safety. Continued investment in food safety research will provide the information we need to make better decisions, and it will provide the technologies to prevent—or at least to reduce—foodborne diseases.

The vision statement says, "We work within a seamless food safety system that uses farm-to-table preventive strategies and integrated research, surveillance, inspection, and enforcement. We are vigilant to new and emergent threats and consider the needs of vulnerable populations. We use science- and risk-based approaches along with public/private partnerships."

It is clear that within such a seamless system, science must guide our food safety priorities—whether we are talking about research, regulation, or surveillance. With scarce resources, we must set our priorities in all three areas wisely based on the best science available. What are the most critical food safety threats? What methods will work best to attack them? These are the types of questions we must answer through science.

We also must use science to set good food safety policies. For example, science-based HACCP systems are being widely adopted as a means of preventing contamination from pathogens and other hazards in meat, poultry, seafood, and fruit juices.

Unfortunately, we don't always have all of the information we need to make every food safety decision. The best we can do is make decisions based on the information we have available today, and invest in research that will fill the information gaps.

If we are to achieve the seamless, prevention-based, integrated food safety system in the vision statement, we will need a better understanding of pathogens in food and what interventions can be implemented farm-to-table to help control them.

By the same token, we need to push forward the scientific frontiers in our understanding of the risks posed by chemical residues in food and water. We need better methods to estimate exposure and risks to special groups—such as children and the elderly—that may be more sensitive to the effects of pathogens, pesticides and other hazardous contaminants. We also need to better understand the potential for chemicals to affect the endocrine, immune, and nervous systems.

At the same time, new food safety challenges continue to emerge as a result of factors such as changing food habits, a global food supply, and a changing population. Emerging pathogens are testing our ability to respond quickly and effectively. Just think about the impact of *E. coli* O15:H7-- a pathogen that was virtually unknown 15 years ago but is now a household name.

A critical review of the federally-supported portfolio of food safety research has already begun through the National Science and Technology Council and will continue as a result of the new Joint Institute for Food Safety Research. But we have a lot of work to do before we can honestly say we have a coordinated and cooperative food safety research strategy and that we are making the best use of public-private partnerships to further that strategy.

Under the President's National Food Safety Initiative, I can speak for all the participating agencies when I say that we are committed to using science and risk-based approaches to assure the public of the highest level of safety we can attain. I was also pleased that the recently published report from the National Academy of Sciences, *Ensuring Safe Food From Production to Consumption*, further supports the science-based directions we are taking.

***Salmonella* Enteritidis**

In closing, I would like to offer a specific example—perhaps a prototype—of this seamless food safety system that uses science- and risk-based approaches. It is our strategy to address the public health problem associated with *Salmonella* Enteritidis in eggs and egg products.

Epidemiological data from the Centers for Disease Control and Prevention showed there was an increasing problem with infections of *Salmonella* Enteritidis associated with these products.

A multi-disciplinary team from government and academia conducted a quantitative microbial risk assessment to characterize the adverse health effects associated with consuming eggs and egg products contaminated with the pathogen and to help us identify interventions that could lead to public health improvements. Through public meetings, the industry, consumers, and the scientific community offered data and advice. FSIS and FDA then published, jointly, an advance notice of proposed rulemaking to initiate a comprehensive and coordinated process to address this public health problem.

Cooperative endeavors with industry and other regulatory agencies sharing the responsibility for food safety will characterize our approach, now and in the future. But this approach will only work if we have good scientific information to work with.

Public Discussion Format

Now that we have described the three themes contained in the vision statement, we will begin, following the break, a facilitated discussion of the draft vision statement. We see the vision statement as a starting point, and thus a good place to begin the strategic planning process.

We are here today to listen to you. We want to receive as much input as possible from all of our

constituencies. This public process is absolutely necessary to ensure that we arrive at a strategic plan that has a broad base of support.

We have developed six questions to help facilitate and provide a framework for the discussion and have allocated a certain amount of time for each question. We recognize that many people have requested time to present their views, and we will be as flexible as we can to honor these requests within the time constraints. We hope you will try, as much as possible, to speak to the six questions.

I will ask the first question now so that you can begin thinking about the answer during the break.

Question #1: Does the vision statement accurately depict an achievable food safety system vision? What modifications, if any, would you make?

With that question in mind, we will take a 15-minute break.

For

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President's Council on Food Safety



U.S. Department
of Agriculture



Department of Health
and Human Services



Environmental
Protection Agency



Department
of Commerce

Charter

December 16, 1998

Article I: Purpose.

On August 25, 1998, the President, by Executive Order 13100, established the President's Council on Food Safety ("Council") to improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs. The purpose of the Council is to protect the health of the American people by preventing foodborne illness through improving the safety of the food supply by means of science-based regulation and well-coordinated surveillance and investigation, inspection, enforcement, research, and educational programs. The Council is to: develop and update periodically a comprehensive strategic plan for Federal food safety activities; make recommendations to the President on how to implement the comprehensive strategy and enhance coordination among Federal agencies, State, local and tribal governments, and the private sector; advise Federal agencies in setting priority areas for investment in food safety and developing a coordinated food safety budget for the Administration; and to oversee research efforts of the Joint Institute for Food Safety Research. The President also directed the Council to evaluate and report back to him on the proposals contained in the National Academy of Sciences (NAS) report on food safety.

This Charter provides the basis for collaboration among the members of the Council in carrying out its responsibilities as set forth in the Executive Order.

Article II: Membership

The following individuals shall be members of the Council:

1. Secretary of Agriculture,
2. Secretary of Commerce,
3. Secretary of Health and Human Services,
4. Administrator of the Environmental Protection Agency,
5. Director of the Office of Management and Budget,
6. Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy,
7. Assistant to the President for Domestic Policy, and
8. Director of the National Partnership for Reinventing Government.

Each member may designate a senior Federal employee to serve as an alternate representative to perform the duties of the Council member.

Article III: Co-Chairs

The Secretaries of Agriculture and of Health and Human Services and the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy, or their designated alternates, shall serve as co-chairs of the Council.

The co-chairs shall provide leadership and direction to the Council, and coordinate the formation and schedule of standing committees. Each meeting will be led by one co-chair, and this responsibility shall rotate quarterly among the co-chairs.

Article IV: Staff Support Services

Staff support services for the activities of the Council will be provided by the Co-Chairs through a Secretariat, which will consist of a senior Federal employee from the Department of Agriculture and one from the Department of Health and Human Services. Other members may provide additional staff support services, as necessary. The Secretariat will facilitate planning, coordination, and communication among Council members.

Article V: Meetings

The Council shall meet on a quarterly basis at a time and location chosen by the co-chairs. Additional meetings may be held at the call of the co-chairs or at the request of a majority of the members.

A majority of the Council membership shall constitute a quorum for the transaction of business. All decisions made by the Council at the meetings shall be by consensus defined as substantial agreement as determined by the chair.

The Secretariat will prepare updates of the Council's activities and make the information available for public inspection and copying and on the Council Internet web site.

The Council will prepare a report for submission to the President on March 1 of each year. The report will contain, at a minimum, a description of the Council's activities and accomplishments during the preceding fiscal year, a description of the planned activities for the coming year, a review of strategic planning objectives, and progress made toward accomplishing those objectives.

Article VI: Duties and Responsibilities

The specific responsibilities of the Council are to:

1. Develop and update periodically a comprehensive strategic Federal food safety plan ("plan") to reduce the incidence of foodborne illness and its chronic sequelae by further enhancing the safety of the nation's food supply and monitoring the impact of these enhancements. The plan will address public health, resource, and management questions facing Federal food safety agencies and will focus on the full range of food safety issues, including the needs of regulatory agencies and the actions necessary to ensure the safety of the food Americans consume. The planning process will consider both short-term and long-term issues including new and emerging threats to the nation's food supply and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council will take into consideration the findings and recommendations of the NAS report "Ensuring Safe Food from Production to Consumption" and the review of Federal food safety research by the interagency working group under the auspices of the National Science and Technology Council.

The strategic 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.

The Council will conduct public meetings to engage consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process.

2. Consistent with the strategic plan, advise Federal agencies of priority areas for investment in food safety and work with member agencies in developing annual food safety budgets for submission to the Office of Management and Budget (OMB) to sustain and strengthen priority activities on food safety, eliminate duplication, and ensure the most effective use of resources for achieving the goals of the plan.
3. Oversee the Joint Institute for Food Safety Research (JIFSR). The Council will evaluate the reports from JIFSR on food safety research activities and give direction to JIFSR on research needed to establish the most effective possible food safety system.
4. Evaluate and report to the President on the NAS report, "Ensuring Safe Food from Production to Consumption". After providing opportunity for public comment, including public meetings, the Council will, by February 21, 1999, report to the President on the Council's response to and recommendations concerning the NAS report and appropriate additional actions to improve food safety.

Article VII: Committees

The co-chairs, after consultation with Council members, shall establish committees of Council members, their alternates, or other Federal employees, as they deem necessary, to facilitate and carry out effectively the responsibilities of the Council. Such committees shall report to the Council.

The following committee shall be established by the co-chairs:

JIFSR Executive Research Committee

This committee will evaluate the reports from the JIFSR on its efforts to coordinate food safety research and make recommendations to the Council regarding research needed to establish the most effective possible food safety system.

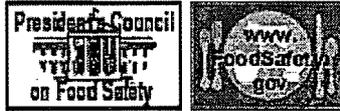
Article VIII: Web Site

The Council shall establish an Internet web site. The Department of Agriculture shall be the system owner of the web site and shall be responsible for maintaining it. The Council website will provide links to websites of all federal agencies having food safety responsibilities.

Article IX: Effective Date

This Charter shall become effective on the latest date affixed below and may be modified with supplemental agreements signed by all the members of the Council.

December 16, 1998



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**Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700**

Speeches

Office of the Under Secretary for Food Safety
U.S. Department of Agriculture

A Farm-To-Table Food Safety Strategy

Remarks prepared for delivery by Dr. Catherine Woteki, Under Secretary for Food Safety, before the American Farm Bureau Federation, Albuquerque, New Mexico, January 10, 1999.

Thank you for the opportunity to join you today to talk about food safety. January is always a good time to reflect on our accomplishments and focus on priorities for the new year. It's also a good time to be in New Mexico!

Over the past several years, food safety has received attention at the highest levels of government and by the public. I don't have a crystal ball, but I believe that food safety will continue to receive much attention in 1999.

I also believe that the long-term effect of this attention will be to strengthen consumers' confidence in the safety of our food supply. News about recalls or the identification of a new food safety problem can have some short-lived negative effects, such as reducing consumer purchases of specific products. But the attention has some positive effects as well, because everyone—government, industry, and the public—is coming together to make our good food safety system even better. And in surveys, consumers continue to believe that government food safety agencies are protecting them.

Foodborne illnesses are not new, of course. But many factors have forced us to pay closer attention to foodborne pathogens as a health risk.

First, is the growing knowledge about pathogens, how they are transmitted through food, and their role in causing disease.

Second, new pathogens are emerging. Pick up a microbiology textbook from 20 years ago and you won't even find mention of *E. coli* O157:H7. Shigatoxin is another pathogen of concern.

Third, our population is aging, and the elderly and immune-compromised are two groups that are growing in numbers and are more susceptible to foodborne diseases.

Lastly, several factors are creating opportunities for bigger outbreaks, including concentration in the food industry, increases in imported foods, more convenience foods that are prepared in advance, and a population that is not as savvy as our grandparents when it comes to food preparation. Calls to our toll-free Meat and Poultry Hotline show that consumers still need the basics on what temperatures to cook their turkeys and how to safely store leftovers.

One thing is clear—foodborne illness *is* a problem we need to be concerned about. And by "we," I mean everyone involved in food production, processing, distribution, and preparation. We all have a role to

play in preventing foodborne illness. You may have heard the statistics about foodborne illness. The Council for Agricultural Science and Technology (CAST), based on data from the Centers for Disease Control and Prevention, estimates that annually, 6 to 33 million Americans become ill, and that foodborne illness contributes to the deaths of perhaps 9,000 persons each year. The economic impact of foodborne illness, in terms of medical care, lost wages and associated costs, is \$5.6 to \$9.4 billion per year.

And we must remember that foodborne illness is not just a minor digestive upset. It can result in very serious, life-threatening health problems such as Guillain-Barré Syndrome, which is paralysis associated with *Campylobacter*, and Hemolytic Uremic Syndrome—life-threatening kidney damage associated with *E. coli* O157:H7.

There have been some recent concerns about the statistics on foodborne illness and their accuracy. The Centers for Disease Control and Prevention in Atlanta is now conducting a review and will come up with a revised estimate in the near future. Although it is important to have accurate estimates of the burden of foodborne illness, we don't need exact figures in order to take action. The fact is, a large percentage of foodborne illnesses are preventable, and there is a lot we can do to reduce the numbers. Recognition of the preventable nature of foodborne illness is a major motivation for the President's Food Safety Initiative.

Food Safety Strategy

Fortunately, we have a food safety strategy in place that is leading to concrete improvements in food safety. Our strategy is based on two very important points. First, we know that partnerships are critical to our success. All of us—government, industry, academia, and consumers—are in this fight against foodborne illness together, and none of us can do the job alone.

And second, we must keep a broad, farm-to-table focus when finding solutions to our food safety problems. It will require multiple steps, all along the farm-to-table chain, for real progress to occur. There is no one quick food safety fix.

Farm-to-Table Strategy

Let me talk about our farm-to-table strategy in a little more detail. We believe that each sector in the food system is responsible for doing whatever it can to improve food safety. We know there are many data gaps when it comes to knowing *how* to reduce pathogens. This is particularly true on the farm. But as science and technology improve, scientific principles for reducing pathogens and other hazards will emerge. We expect each sector to take full advantage of these developments to improve food safety. This is already happening. We are seeing many instances of new technology being used to make food safer. For example, slaughter plants are using antimicrobial rinses and steam vacuum technology to reduce pathogens on carcasses. And competitive exclusion products are now commercially available to poultry producers to prevent *Salmonella* from becoming established in chickens.

Our involvement in farm-to-table food safety does not mean we believe that Federal regulation is needed to solve all problems. For example, in plants, where animals are slaughtered and meat and poultry processed, the Federal government clearly has the authority and the responsibility to take regulatory action.

But the animal production level—that is, on the farm and during intermediate stages before animals reach the slaughter plant—is an example of where we do not envision a direct regulatory role. Rather,

we are working with producer groups toward the voluntary application of food safety assurance programs, based on HACCP principles. At the same time, we are guiding and supporting research that will tell us what really works and what is practical in real-life situations to make food safer.

We have seen a lot of interest among producers in doing their part. Of course, because women are key managers on farms, you have a large role in implementing many of these initiatives. I'll cite some examples, but there are many more.

For example, producers have joined forces with government agencies in South Dakota to develop a quality assurance beef safety plan. Feedlots in that state are participating in a pilot project to identify and manage the critical control points affecting beef safety in feedlots. The goal is to develop an overall set of guidelines and a protocol for each feedlot to assure buyers that food safety is a priority.

The National Pork Producers Council, in cooperation with government, is implementing a nationwide, multi-step quality assurance program, which includes 10 basic production practices to improve food safety, herd health and the environment. It has been shown that producers implementing this program not only produce a safer product, but a more profitable and higher quality product.

And the Beef Industry Food Safety Council has developed a research agenda to reduce, or possibly eliminate, *E. coli* O157:H7.

President's Food Safety Initiative

Food safety received a major boost in 1997, when President Clinton announced his major Food Safety Initiative. In fact, this month is the 2-year anniversary of the President's radio address. The initiative continues to provide new funds for needed improvements in areas such as foodborne diseases surveillance, research, inspections, and consumer education. It also unifies the various food safety initiatives being carried out by Federal agencies with responsibility for food safety. Twelve agencies in four Federal departments have a role in food safety, and seven of these are in USDA. We have been able to make much progress through this initiative. I will highlight just a few areas.

For instance, the FoodNet surveillance network has been expanded under the President's initiative. FoodNet tracks foodborne diseases in the United States and helps public health officials better understand the sources of these illnesses. We are learning some important information from FoodNet. Second-year data indicate that *Campylobacter* is the most frequently isolated pathogen in cases of diarrheal disease, which has led us to take a number of steps to address the problem.

Under the President's initiative, we also have made progress in responding to outbreaks of foodborne illness. Last year, Vice President Gore announced the new Foodborne Outbreak Response Coordinating Group, a partnership of Federal and State agencies established to better respond to foodborne illness outbreaks. We are sharing more information now about outbreaks, coordinating responses with State departments of health and agriculture, and we are trying to standardize our procedures as much as possible.

We also are improving inspections for meat and poultry products by requiring the implementation of HACCP—Hazard Analysis and Critical Control Points—Systems in all plants. Under HACCP, plants identify critical control points during their processes where hazards such as microbial contamination can occur, establish controls to prevent or reduce those hazards, and maintain records documenting that the controls are working as intended. HACCP has already been implemented in all large plants—those with 500 or more employees. This month, small plants will be required to have HACCP in place, and next

January, very small plants must meet the requirements.

We also are doing more under the President's initiative to educate everyone involved in the farm-to-table chain about what they can do to improve food safety. Our Fight BAC! food safety campaign for consumers features "BAC," a green, slime-oozing bacterium. The campaign emphasizes four basic safety food handling messages—Clean, Separate, Chill, and Cook. Activities also are being carried out to educate food handlers at other points in the farm-to-table chain.

NAS Report

As we continue our progress in these and other areas, we also are having to respond to major concerns on the part of Congress about whether we are organized at the Federal level in a manner to best protect the public from foodborne illness. In 1997, a bill was introduced by Senator Durbin and Representative Fazio to create a single food safety agency. And the House Appropriations committee last year asked the National Academy of Sciences to conduct a study to determine the scientific and organizational needs of an effective food safety system. The Academy released its report in August, and the President's Food Safety Council, which I will mention in just a moment, is in the process of responding to the recommendations contained in the report. Specifically, the Academy had three major recommendations.

First, the Academy concluded that an effective and efficient food safety system must be based in science. It noted that while many rational, science-based regulatory philosophies have been adopted, this adoption has been uneven.

Second, the committee said that Federal statute changes are needed to enable the U.S. food safety system to be based in science. The committee recommended statute changes that would allow inspection, enforcement, and research efforts to be based on scientific risk assessments. It also recommended that Congress and the Administration require development of a comprehensive, national food safety plan.

Third, the Academy said that Congress should establish--by statute--a unified and central framework for managing Federal food safety programs. Under this structure, one official should be responsible for Federal efforts in food safety and have control of resources allocated to food safety.

President's Food Safety Council

A public dialogue about what is the best system for ensuring food safety will continue as we—both Congress and the Administration—review the recommendations. In August, President Clinton signed the order creating the President's Food Safety Council, which he charged with developing a comprehensive strategic plan for Federal food safety activities and ensuring that Federal agencies develop coordinated food safety budgets each year. One of the Council's first jobs will be to review the Academy's study, solicit public input, and report back to the President with recommendations on appropriate actions to improve food safety. Of course, Congress, which funded the study, also is expected to weigh in on the recommendations. The Council also will be preparing a long-range strategic plan and preparing a unified, coordinated food safety budget.

Closing

Clearly, we have an ambitious agenda ahead, and there will be many upcoming discussions about how best to improve the national food safety system. Fortunately, there are many points of agreement on where we should be headed, and they are reflected in the vision statement developed by the President's

Food Safety Council:

"We work within a seamless food safety system that uses farm-to-table preventive strategies and integrated research, surveillance, inspection, and enforcement. We are vigilant to new and emergent threats and consider the needs of vulnerable populations. We use science- and risk-based approaches along with public/private partnerships."

This vision statement will guide us as we work to meet our goal of reducing the incidence of foodborne illness to the extent possible.

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[Speeches Menu](#) | [FSIS Home Page](#) | [USDA Home Page](#)

Department of Health and Human Services
U.S. Department of Agriculture
February 25, 1999

Background

2000 President's Food Safety Initiative

For the third consecutive year, the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) have 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, agencies can maximize the use of their resources and achieve the greatest improvements in food safety. This process began with the May 1997 report to the President, entitled, Food Safety from Farm-to-Table: A National Food Safety Initiative. The report 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.

1998 and 1999 Activities

The 1998 budget initiative brought much-needed new resources to enhance surveillance of foodborne disease and outbreaks and better coordinate our response to outbreaks, improve inspections and compliance—particularly seafood HACCP inspections, target important new research and risk assessment to critical scientific gaps, and strengthen education and training especially of those who handle food at critical points from the retail setting to the home. The 1999 initiative built on science-based gains made in these areas, and placed increased emphasis on ensuring the safety of domestic and imported fresh produce and imported foods; targeted retail food safety education; transformed traditional meat and poultry inspection systems to science-based HACCP systems; and developed scientific information and tools to control a greater range of food safety hazards.

2000 Budget Request

For 2000, the Administration is proposing an increase of \$74.8 million for the President's Food Safety Initiative. Of this amount, \$40 million is allocated to HHS and \$34.8 million to USDA. The 2000 President's Food Safety Initiative builds on the foundation established in 1998 and 1999. Additional resources will be targeted to: (1) further develop a nationally integrated, seamless, and science-based food safety system, (2) enhance public health surveillance and increase the speed and efficiency of responses to outbreaks of foodborne illness, and (3) place greater emphasis on the control of foodborne hazards in the pre-harvest phase of the farm-to-table continuum. Funding is requested for the following activities:

Enhance Surveillance and Investigation to Improve Outbreak Response (+\$16.4 million):

HHS (+\$16.4 million): The Food and Drug Administration (FDA), working through the Centers for Disease Control and Prevention (CDC) will expand its access to PulseNet and increase outbreak response and associated traceback activities. FDA will begin initial development of electronic

communication and data sharing systems for use in Federal-State monitoring and traceback activities. FDA, working with CDC, will also expand and increase the overall capacity of the National Antimicrobial Resistance Monitoring System (NARMS) and the number of States covered to assure a higher probability of detecting emerging resistant pathogens capable of animal to human transmission and to minimize the occurrence of foodborne outbreaks including those from outside of the United States. CDC will identify foodborne hazards and characterize the risk posed by those hazards, increase the speed with which the presence of hazards in foods can be determined and controlled, and improve the accuracy and timeliness of public health data that justify food safety control programs and evaluate their effectiveness. CDC will also work with the States to improve diagnostic capacity for viruses and parasites, and expand the network of States with capacity to interact electronically with CDC to evaluate and improve diagnostic practices.

Strengthen Coordination and Improve Efficiency (+\$0.5 million):

USDA (+\$0.5 million): The Food Safety and Inspection Service (FSIS) will assign district epidemiologists to work with State Departments of Agriculture and Public Health to better coordinate responses to foodborne disease outbreaks and recalls. Efforts will be directed at increasing the speed and efficiency of responding to outbreaks of foodborne illness and to prevent further outbreaks. Funds will provide the specialized training, supplies, technology, and equipment for district epidemiology officers. This effort will further assist Federal, State, and Local integration in support of a seamless national food safety program.

Expand Inspection and Compliance Efforts with Additional Emphasis on High Risk Foods, Imported Produce, and Enhancing Federal-State Partnerships (+\$19.3 million):

HHS (+\$16.9 million): FDA will increase inspection coverage and frequency of coverage of domestic firms, with the highest risk firms being inspected once per year beginning in FY 2001. FDA will increase the number of inspections of foreign processors and will conduct evaluations of foreign food production systems. FDA will continue to provide training to State and local food safety officials and industry in the effective use of preventive control systems, such as hazard analysis and critical control point (HACCP) systems-especially seafood HACCP systems, and to perform inspections of HACCP systems. FDA will provide States resources and "hands-on" training to promote the adoption of the Food Code by retail establishments.

USDA (+\$2.4 million): In 2000, all State meat and poultry establishments will be required to have implemented hazard analysis and critical control point (HACCP) systems. By that time, the 26 State meat and poultry inspection programs will be required to amend their regulations to make them equal to Federal regulations. To facilitate this transition, FSIS will conduct the pathogen testing required by the HACCP rule of State inspected meat and poultry products in FSIS laboratories. In addition, FSIS will conduct comprehensive reviews of State laboratories to validate the ability of these laboratories to meet HACCP testing requirements. Demonstrating compliance with pathogen testing requirements of the HACCP rule will be a major prerequisite for permitting interstate shipment of State inspected product. Assisting States will integrate and unify efforts to create a seamless national inspection program.

Improve Capability to Estimate Risks Associated with Foodborne Hazards (+\$7.9 million):

HHS (+\$1.5 million): FDA will develop methods for predicting the risk associated with foodborne pathogens and will develop partnerships with government, industry, and academic scientists to conduct studies that demonstrate comparability of disease across species. FDA will continue a program of research in quantitative risk assessment (particularly for microbial hazards) that is targeted to address the

limitations in risk assessment methodologies. FDA will continue to build the activities of the interagency Risk Assessment Consortium that provides a forum for coordination of Federal microbial risk assessment research. FDA through the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) will continue development of a risk assessment clearinghouse to better establish government, industry, and academic partnerships.

USDA (+\$6.4 million): The Agricultural Research Service (ARS), the Cooperative State Research, Education, and Extension Service (CSREES), the Economic Research Service (ERS), and the National Agricultural Statistics Service (NASS) will extend risk assessment modeling and data collection to include the pre-harvest phase for all foods. Previous risk assessment activities have focused on post-harvest operations. This pre-harvest modeling is necessary to determine the effects of various production practices, processing, and transportation systems on the behavior and subsequent contamination of poultry, beef, and swine as they are presented for slaughter. A Nationwide survey of fruit and vegetable producers and packinghouses will be conducted to establish a baseline of agricultural handling practices related to food safety. Data from the survey would be used to target food safety education materials and to conduct economic analyses concerning food safety related agricultural practices.

Continue to Develop and Disseminate Targeted Food Safety Education Materials (+\$2.4 million):

HHS (+\$1.5 million): FDA, in cooperation with USDA and other Federal, State, and local agencies, will develop multi-lingual education programs for food service workers and will implement a National education and training program to ensure greater safety in retail food preparation practices, including the use of HACCP principles in retail establishments. Efforts will focus on the development of education materials for educating and training relating to proper storage, handling, and transportation practices identified in the Food Code. In addition, FDA will develop educational messages for using antimicrobial drugs for use in animal foods.

USDA (+\$0.9 million): CSREES, will develop educational programs that target high-risk, under-served populations who are at increased risk from developing foodborne illnesses, such as the elderly, children, and immuno-compromised individuals. Food safety education materials will also be provided to very small retailers and distributors to increase their awareness of their food safety responsibilities as part of a Nationwide education and training program. In addition CSREES will develop and implement training programs for producers, veterinarians, and crop consultants on good manufacturing and agricultural practices that can minimize microbial contamination of their products.

Accelerate Food Safety Research (+\$28.2 million):

USDA (+\$24.5 million): ARS and CSREES will support research projects that will contribute to the development of effective methods of handling and treating agricultural products to minimize microbiological contamination. Control of animal production practices, including manure management, will prevent possible distribution of pathogens to crops or other animals from surface runoff and irrigation waters. In addition, improved detection methodologies will be developed to enable producers to monitor their production processes for contamination. Research will also be supported to develop the knowledge necessary to prevent the development of antibiotic drug resistance. Research results will be used to develop strategies to prevent both the emergence and the maintenance in food producing animals of pathogenic and non-pathogenic antibiotic resistant bacteria. The Agricultural Marketing Service (AMS) will establish microbiological baselines for pathogens on fruits and vegetables. This information will contribute to the identification of microbiological hazards and the development of intervention strategies to reduce the food safety risks posed by these products.

HHS (+\$3.7 million): FDA will expand research on methods development and prevention technologies. FDA will collaborate with other Federal agencies and the private sector at the National Center for Food Safety and Technology (NCFST) and with academia to translate preventive technologies and techniques into appropriate versions for use by small firms and consumers. FDA and USDA will expand mechanisms to transfer technologies to States, small and large firms, foreign governments, consumers, and others. FDA will expand its ongoing research on the development of methods for detecting foodborne pathogens in animal feeds.

PRESIDENT'S FOOD SAFETY INITIATIVE FY 2000 BUDGET					
ACTIVITY	1997	1998	1999	2000 Budget	Increase Over 1999
Dollars in Thousands					
<u>SURVEILLANCE:</u>					
USDA:					
Food Safety and Inspection Service	\$1,000	\$1,500	\$1,500	\$1,500	\$0
Economic Research Service	32	32	282	285	3
Subtotal, USDA	1,032	1,532	1,782	1,785	3
HHS:					
Food and Drug Administration	737	3,897	3,897	10,297	6,400
Centers for Disease Control and Prevention	4,500	14,500	19,000	29,000	10,000
Subtotal, HHS	5,237	18,397	22,897	39,297	16,400
Subtotal, Surveillance	6,269	19,929	24,679	41,082	16,403
<u>COORDINATION:</u>					
USDA:					
Food Safety and Inspection Service	0	0	0	500	500
HHS:					
Food and Drug Administration	7,173	7,723	7,723	7,723	0

Subtotal, Coordination	7,173	7,723	7,723	8,223	500
INSPECTIONS:					
USDA:					
Food Safety and Inspection Service	0	565	10,113	12,513	2,400
HHS:					
Food and Drug Administration	<u>73,244</u>	<u>81,114</u>	<u>105,614</u>	<u>122,514</u>	<u>16,900</u>
Subtotal, Inspections	73,244	81,679	115,727	135,027	19,300
RISK ASSESSMENT:					
USDA:					
Agricultural Research Service	5,461	4,498	4,909	7,309	2,400
Cooperative State Research, Education, and Extension Service	145	150	2,612	3,702	1,090
Food Safety and Inspection Service	0	0	3,260	3,260	0
Economic Research Service	33	33	236	686	450
National Agricultural Statistics Service	0	0	0	2,500	2,500
Office of the Chief Economist	<u>62</u>	<u>60</u>	<u>158</u>	<u>158</u>	<u>0</u>
Subtotal, USDA	5,701	4,741	11,175	17,615	6,440
HHS:					
Food and Drug Administration	<u>2,589</u>	<u>6,539</u>	<u>6,539</u>	<u>8,039</u>	<u>1,500</u>
Subtotal, Risk Assessment	8,290	11,280	17,714	25,654	7,940
EDUCATION:					
USDA:					
Cooperative State Research, Education, and Extension Service	2,365	2,365	7,365	8,287	922

Food Safety and Inspection Service	0	0	3,659	3,659	0
Food And Nutrition Service	0	0	2,000	2,000	0
Office of the Chief Economist	27	38	38	38	0
Economic Research Service	420	420	420	420	0
Subtotal, USDA	2,812	2,823	13,482	14,404	922
HHS:					
Food and Drug Administration	4,800	6,870	6,870	8,370	1,500
Centers for Disease Control and Prevention	0	0	476	476	0
Subtotal, HHS	4,800	6,870	7,346	8,846	1,500
Subtotal, Education	7,612	9,693	20,828	23,250	2,422
RESEARCH:					
USDA:					
Agricultural Research Service	44,186	50,351	64,959	74,279	9,320
Cooperative State Research, Education, and Extension Service	3,724	6,250	14,788	23,799	9,011
Agricultural Marketing Service	0	0	112	6,297	6,185
Subtotal, USDA	47,910	56,601	79,859	104,375	24,516
HHS:					
Food and Drug Administration	20,793	27,193	27,693	31,393	3,700
Subtotal, Research	68,703	83,794	107,552	135,768	28,216
TOTAL, INITIATIVE	171,291	214,098	294,223	369,004	74,781

PRESIDENT'S FOOD SAFETY INITIATIVE

FY 2000 PROPOSAL					
TOTAL INITIATIVE	1997	1998	1999	2000 Budget	Increase Over 1999
	Dollars in Thousands				
USDA:					
Agricultural Research Service	\$49,647	\$54,849	\$69,868	\$81,588	\$11,720
Cooperative State Research, Education, and Extension Service	6,234	8,765	24,765	35,788	11,023
Agricultural Marketing Service	0	0	112	6,297	6,185
Food Safety and Inspection Service	1,000	2,065	18,532	21,432	2,900
Economic Research Service	485	485	938	1,391	453
Office of the Chief Economist	89	98	196	196	0
National Agricultural Statistics Service	0	0	0	2,500	2,500
Food and Consumer Service	0	0	2,000	2,000	0
Subtotal, USDA	57,455	66,262	116,411	151,192	34,781
HHS:					
Food and Drug Administration	109,336	133,336	158,336	188,336	30,000
Centers for Disease Control and Prevention	4,500	14,500	19,476	29,476	10,000
Subtotal, HHS	113,836	147,836	177,812	217,812	40,000
TOTAL, INITIATIVE	171,291	214,098	294,223	369,004	74,781

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USDA RESPONSE

to the

NATIONAL ACADEMY OF SCIENCES REPORT

“Ensuring Safe Food from Production to Consumption”

FINAL



United States Department of Agriculture

RESPONSE TO THE NATIONAL ACADEMY OF SCIENCES REPORT, "ENSURING SAFE FOOD FROM PRODUCTION TO CONSUMPTION"

NAS REPORT OVERVIEW

Introduction. USDA believes that the National Academy of Sciences (NAS) report, "Ensuring Safe Food from Production to Consumption," is a valuable contribution to the ongoing and necessary dialogue on the future direction of the national food safety system. The report, initiated in 1997 at the request of Congress, provides an examination of the scientific and organizational needs of an effective food safety system and gives us the opportunity to expand the food safety and public health dialogue.

NAS Attributes of the Effective Food Safety System. The NAS Report defines 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." Further, the report outlines the five major components or attributes of a model food safety system:

1. Science-based, with a strong emphasis on risk analysis or risks deemed to have the greatest potential impact and including comprehensive surveillance and monitoring as the basis for risk analysis;
2. A national food law that is clear, rational, and comprehensive, as well as scientifically based on risk;
3. A unified mission and single food safety entity at the Federal level with authority and resources to implement a science-based policy in all Federal activities related to food safety;
4. A responsive organization partnering with non-Federal partners; and
5. An adequately funded organization able to promote the public's health and safety.

In considering our present complex, multi-faceted food safety system—characterized as having evolved "piecemeal over a century"—the report claims that it "is not the product of planning, and it is often not equipped to anticipate changes. But the situation is not just haphazard; changes in risks have made the system outmoded. The role and organization of government entities have remained largely unchanged, and the food safety system has fallen behind today's needs."

NAS Recommendations. To transform our present system, the Academy proposed three major recommendations:

First, the report concluded that an effective and efficient food safety system must be based on science. It noted that while many rational, science-based regulatory philosophies have been adopted, progress has been uneven.

Second, the NAS committee said that changes to Federal statutes might well be needed to enable the U.S. food safety regulatory system to adopt and use the best science available. The committee suggested that the statutory changes would allow inspection, enforcement, and research efforts to be based on scientifically supportable risk assessments. It also recommended that Congress and the Administration require development of a comprehensive food safety plan.

Third, the authors urged Congress to establish a unified and central structure for managing Federal food safety programs. It offered four possible structures under which one official would be responsible for Federal efforts in food safety. Further, the NAS recommended that Congress should provide the Agency responsible for food safety at the Federal level with sufficient resources and the tools necessary to integrate and unify the efforts of authorities at the state and local levels to enhance food safety.

While the NAS report's analysis and recommendations offer much for USDA to consider, the Department believes, based on its first-hand experience, that while some further changes in authority and a rationalization of resources are desirable, major reinvention or major restructuring of Federal food safety activities may not be needed to raise the level of food safety. Existing statutory authorities, which were reviewed and significantly amended in 1994, are not major impediments to improvement. USDA's current authority provides the flexibility needed to implement substantial change and improvement. We have most of the necessary tools; improvements are already emerging.

A SCIENCE-BASED USDA REORGANIZATION

A Farm-to-Table Strategy

The committee report defines safe food as "food that is wholesome, that does not exceed acceptable levels of risk associated with pathogenic organisms or chemical and physical hazards, and whose supply is the result of the combined activities of Congress, regulatory agencies, multiple industries, universities, private organizations, and consumers." Clearly this definition implies that the safety of our food supply requires that everyone, at every step of the production process, make a serious commitment to food safety. We are all responsible.

Recognizing its responsibility, USDA has adopted a farm-to-table approach that looks at food safety as an integrated and interdependent system. Actions and programs within USDA are directed across this food production continuum rather than focused on any individual component. However, our farm-to-table strategy recognizes that our statutory authorities

limit regulatory oversight and enforcement to prescribed areas. Therefore our strategy relies upon voluntary adoption of quality control programs at the production level, and partnership with states, the private sector, and research and education agencies to strengthen the base for such voluntary programs.

Discussed below are a number of the more important aspects of the dynamic system that USDA is in the process of implementing that we feel will more fully explain our position.

Reorganization

Much has been said about the need for organizational and structural change in the intergovernmental system as well as the need for more coordination within an improved food safety system. The Administration has been actively engaged in organizational and program changes to eliminate conflicts, enhance coordination of responses to public health issues and emergencies, and coordinate research planning and prioritization.

Office of the Under Secretary for Food Safety. In 1994, the Congress and Administration cooperated in enacting a major reorganization of food safety within USDA, creating the new mission area and Office of the Under Secretary for Food Safety, which oversees the Food Safety and Inspection Service (FSIS) and the U.S. Manager of Codex Alimentarius. Under that legislation, a mission area dedicated to public health was created within USDA, and the legislation mandated that this office be occupied by an individual with a proven background in public health and safety.

This action also effectively eliminated what had appeared to some as a conflict of interest by separating the food safety and regulatory function from marketing functions related to agricultural products, two mission areas that had previously been housed together within the Department.

The Food Safety and Inspection Service. FSIS, the USDA regulatory agency under the Under Secretary for Food Safety that is responsible for the safety of meat, poultry, and egg products, also underwent a major reorganization. Among its most significant features were the establishment of a more efficient field organizational structure and the establishment of a new Office of Public Health and Science to provide scientific focus, leadership, and expertise to address the most important public health risks related to meat, poultry, and egg products. Within this new office, the Agency established the following divisions:

Emergency Response, which coordinates all Agency recall activities associated with outbreaks of foodborne illness;

Emergency Pathogens and Zoonotic Diseases, which monitors emerging human pathogens in the food supply and animal populations and studies farm-to-table control and prevention strategies;

Food Hazard Surveillance, which maintains both active and passive surveillance systems for foodborne illness; and

Epidemiology and Risk Assessment, which leads and coordinates all agency investigation and traceback activities associated with outbreaks of foodborne illness and conducts quantitative microbial risk assessments.

Research

Research is a key component of the President's Food Safety Initiative. There have been a number of actions taken by the Administration and the Department in the past few years that have provided an expanded role for research in the U.S. food safety system.

Office of the Under Secretary for Research, Education and Economics. The 1994 reorganization of USDA centralized research activities in the newly created mission area of Research, Education and Economics (REE). Food safety research is largely funded through two USDA agencies—the Agricultural Research Service (ARS) and the Cooperative State Research, Education and Extension Service (CSREES). Together in FY 1998 these agencies conducted and funded in excess of \$56 million in food safety research. The centralized research focus enables the Department to better leverage existing funds.

The REE research activities, both intramural and extramural, are intended to meet the need of the regulatory agencies to achieve improved food safety via HACCP implementation and other initiatives. To that end, ARS, the intramural research arm of USDA, and FSIS have yearly food safety and research budget and planning sessions. These sessions provide one mechanism to ensure that proposed research initiatives address the specific priorities of FSIS. In addition, FSIS consults closely with other USDA agencies to ensure that its critical research and information needs are being met.

CSREES supports food safety research via several funding mechanisms—formula funds, National Research Initiative competitive grants, special research grants awarded by a competitive process, and special site-specific grants that are appropriated by Congress. The priorities for competitive grants are based on stakeholder input, including government agencies in support of their public health mission.

Interagency Working Group on Food Safety Research. The Administration has also been actively engaged in other coordinated research planning and prioritization. In 1998, an Interagency Working Group (IWG) on Food Safety Research was created. The IWG, co-chaired by USDA and the Department of Health and Human Services (HHS), develops a government-wide coordinated strategy for food safety research, including the identification of information gaps and priorities for future research. The IWG provides a forum for coordination, collaboration, and communication in setting and reviewing the Federal research agenda.

Joint Institute on Food Safety Research. In July 1998, the President directed the Secretary of Agriculture and Secretary of Health and Human Services to develop a Joint Institute on

Food Safety Research (JIFSR). The JIFSR concept provides a mechanism for coordinated planning of food safety research among the various parts of government and the private sector, as well as fostering effective translation of research results into practice. The JIFSR, operationally located in REE at USDA, 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. The JIFSR is currently being developed jointly by USDA, HHS, and Office of Science and Technology Policy. The program is expected to be fully developed by late 1999.

New Technology Development. One of USDA's goals is to encourage the application of new technology by industry to improve food safety. Some new technology approved for industry use includes steam pasteurization, antimicrobial rinses to reduce pathogen loads on raw products, and competitive exclusion to reduce *Salmonella* levels in poultry on farms. In addition, the Food and Drug Administration (FDA) has approved irradiation for meat products. Research could also clarify how to increase economic incentives for industry to develop and adopt new technologies to reduce foodborne hazards.

National Database for Food Safety Research. USDA, through the direction of ARS and its National Agricultural Library, is developing a national database on food safety research. 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.

National Food Safety Research Conference. The recently signed Agricultural Research Bill mandates that USDA sponsor a national food safety research conference. This conference was held in November 1998. The conference provided a valuable means of disseminating research results and a forum for discussing stakeholder priorities for future food safety research. The Bill also mandated four workshops to follow the conference.

Risk Assessment

The NAS report's focus on the use of scientific risk assessment and cost benefit analysis in order to develop rules that will have the most positive influence on public health is appropriate and is mandated by Congress for most USDA regulatory actions that impact public health and have an annual impact on the economy of \$100 million or more. The analysis of risk and benefits should begin at the start of any regulatory development progress. Because scientific certainty is not realistically attainable, these analyses can guide the process and help decision makers make the tough decisions a science-based food safety system will require.

USDA has a strong lead agency involved in risk assessment activities, the Office of Risk Assessment and Cost-Benefit Analysis within the Office of the Chief Economist. In addition, the Economic Research Service (ERS), the Animal and Plant Health Inspection Service (APHIS), FSIS, CSREES, and ARS conduct research used in risk assessment or use risk assessment in managing their programs. USDA is conducting quantitative microbial risk

assessments to focus food safety resources on reducing those risks that have the greatest consequences for human health. These risk assessments draw on the technical expertise residing in these six agencies. Risk assessment is also being used to identify data gaps and target research that should have the greatest value in terms of impact on public health.

USDA has completed a farm-to-table quantitative risk assessment for *Salmonella enteritidis* in eggs and egg products and has initiated a risk assessment for *E. coli* O157:H7 in ground beef. It has also entered into a cooperative agreement with Harvard University's School of Public Health and Tuskegee University's School of Veterinary Medicine for a risk analysis of bovine spongiform encephalopathy (BSE).

USDA also plays an important role by supplying data on pesticide residues in food through its Pesticide Data Program. These data are used by the Environmental Protection Agency to conduct realistic dietary risk assessments and to address pesticide registrations issues. The PDP is a critical component of the Food Quality Protection Act of 1996, which directs the Secretary of Agriculture to collect, in a uniform manner, pesticide residue data on foods most likely consumed by infants and children. PDP operates in partnership with cooperating state agencies, which are responsible for sample collection and analysis using statistically reliable protocols. Following the PDP model, USDA has begun development of a Microbiological Data Program that will yield statistically reliable data on the level of microbiological organisms found in the U.S. food supply.

FLEXIBILITY AND COORDINATION IN THE PRESENT SYSTEM.

Inspection

The NAS Report identifies a desire for a "national food law that is clear, rational, and comprehensive, as well as scientifically based on risk" as a major component of a model food safety system. Further, the document notes that the continuous inspection system of meat and poultry through sight, smell, and touch ("organoleptic" inspection) creates inefficiencies, and should be replaced by a science-based approach that is capable of detecting hazards of concern.

USDA already has substantial flexibility under its current meat and poultry inspection authority to create a more risk-based regulatory system similar to the one recommended by the report. In fact, major steps have already been taken to achieve that objective. It is important to note that current law requires continuous antemortem and postmortem inspection at all official slaughter and processing facilities. These laws do not specify how this inspection mandate is to be implemented. This continuous inspection requirement for animals ensures use of the best sanitary dressing processes, prevents fecal contamination, reduces the incidence of disease-causing pathogens, and prevents the meat from diseased animals from entering the food supply. Wholesale elimination of inspection of all animals and carcasses is therefore not the most prudent course of action.

Statutory Differences. It should be noted that there is a fundamental difference between the statutes that govern the inspection and oversight of meat and poultry, implemented by FSIS, and the statutes for other foods, enforced by HHS via the Food and Drug Administration.

It is FSIS' statutory responsibility to ensure that no meat and poultry that may be adulterated receives the mark of inspection and enters the marketplace. Companies slaughtering or processing meat and poultry have a legal obligation to report such activity to FSIS and FSIS is obligated to provide appropriate inspection to the plant. FSIS also has the responsibility to ensure that other countries maintain equivalent inspection and oversight of meat and poultry products intended to be exported to the United States from those countries.

FDA's statutory responsibility is much different. FDA is obligated to remove adulterated foods from the marketplace. It has the authority to inspect establishments producing food but cannot provide daily inspection of even high-risk food products at this time.

Pathogen Reduction and HACCP. In July 1996, USDA published its landmark rule on Pathogen Reduction and HACCP. The rule requires all 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. To make sure HACCP systems are working as intended, the rule also sets in-plant performance standards for *Salmonella*, the first-ever pathogen reduction performance standards for a broad range of products and a major shift from the Agency's traditional reliance on "command and control" regulations.

Performance standards provide companies with the flexibility they need to innovate and efficiently meet their food safety responsibilities. Standards also provide FSIS with measurable points to ensure that the food plants they oversee are in compliance and successfully producing meat and poultry products deserving of the USDA inspection mark. The largest meat and poultry plants were required to have HACCP systems in place and to meet the performance standards for *Salmonella* by January 26, 1998. Small plants were required to meet those requirements by January 25, 1999, and very small plants by January 25, 2000.

New Inspection Models. As USDA focuses on HACCP implementation throughout the industry, it has begun development of a project to design new inspection models that better address current public health risks in the meat and poultry supply. These changes will improve the efficiency and effectiveness of inspection oversight and permit better use of Department resources.

State Cooperative Meat and Poultry Inspection Programs. FSIS oversees and supports (with more than \$40 million annually) 25 state inspection programs for meat and poultry. An additional state (Minnesota) is presently initiating a meat inspection program. These cooperative programs permit states to inspect product for distribution within their own boundaries. The State inspection programs must be equivalent to the Federal program conducted by FSIS.

Voluntary Services. To promote and facilitate the adoption of HACCP-based auditing programs, USDA offers voluntary, HACCP-based auditing and verification services to fresh-cut produce processing facilities.

Information Sharing. FSIS has a trained inspection force in every Federally inspected meat and poultry slaughter and processing plant in the United States. In some cases, products are being processed in the same plants that fall under the jurisdiction of FDA because they are food products that do not contain meat or poultry. FSIS and FDA are in the process of establishing and implementing a Memorandum of Understanding (MOU) to facilitate appropriate sharing of information among senior agency field personnel regarding safe food production in these plants.

Modernizing Information Technology. As one step in the adoption of new information technologies in inspection programs, FSIS has developed an interactive computer system – the Field Automation and Information Management (FAIM) – for its own use, and is encouraging states to adopt it by sharing the costs of implementation. The system permits the field inspection force to have in their possession regulations, scheduling information, and appropriate information regarding enforcement. It can also be used for training. FSIS has conducted discussion with FDA regarding FAIM's applicability to its inspection system.

Food Code and International Standards. USDA is also working more closely with its counterparts at the Federal, State, and local level to encourage national uniformity in food safety standards through support and endorsement of the Food Code.

Because world trade in agricultural commodities continues to grow, USDA is working through the Codex Alimentarius Commission to encourage international uniformity in food safety standards. Responsibility for oversight of the U.S. manager of Codex is in the Office of Food Safety.

The NAS reports having 12 primary Federal agencies (seven of which are housed within USDA) involved in key food safety issues fragments the current system and implies that the system suffers from a crippling lack of coordination. In fact, in recent years tremendous progress has been made in strengthening ties among food safety agencies at all levels of government, industry, academia, and the public—sharing a common public health mission and fulfilling that mission more effectively by continuing to build partnerships in so many food safety areas.

Production

Voluntary Quality Control Programs. The Animal Production Food Safety Staff in FSIS is an excellent example of developing partnership with states to encourage the voluntary implementation of quality control programs at the animal production level. The education of small producers is of particular concern as we move forward with HACCP implementation in small plants. We believe that changes in the marketing of animals will be expected by plants operating under HACCP, and we want to help producers be ready for these changes.

Surveillance

FoodNet Surveillance Network. In July 1995, USDA began a collaborative project with HHS, through its Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), to collect more precise information on the incidence of foodborne disease in the United States. The FoodNet surveillance network has been expanded under the President's Food Safety Initiative, and it is providing valuable information on trends in foodborne illness and on the association between cases of illness and the types of foods consumed.

Monitoring for Adulteration. USDA also conducts a number of monitoring programs to ensure that FSIS-regulated meat and poultry products are free of microbial, chemical, and animal species adulterants. When adulterated products are found, they are removed from commerce to protect the health of consumers.

Farm-Level Surveillance and Education. USDA also conducts farm-level surveillance through the Animal and Plant Health Inspection Service (APHIS). APHIS has a field force of veterinarians who work cooperatively at the state and local level to ensure the health of poultry and livestock populations. APHIS' National Animal Health Monitoring System has conducted nine science-based studies addressing information gaps in the areas of animal health, welfare, and production; product wholesomeness; and the environment in the cattle, swine, and layer industries.

Antibiotic Resistance. The National Antibiotic Resistance Monitoring System was established in 1996 as an interagency cooperative activity to monitor emerging resistance in foodborne pathogens, beginning with Salmonella. The effort is coordinated and directed through HHS by the Food and Drug Administration's Center for Veterinary Medicine (CVM) and includes CDC and three USDA agencies (ARS, APHIS, FSIS). Both APHIS and FSIS play an integral role in system design and the acquisition of isolates.

BSE Study. In 1998, FSIS, APHIS, and the Office of Risk Assessment and Cost-Benefit Analysis (ORACBA) cooperated to develop a contract for the Harvard School of Public Health to examine any unrecognized pathways of possible BSE entry into the United States. USDA has been working successfully since 1989 to prevent its entry, and this cooperative effort is regarded as one more safeguard for the American people.

Pesticide Data Program. In the area of pesticide residue data for dietary risk assessment, USDA's Pesticide Data Program is being focused to address national priorities involving at-risk populations. Examples include data for acute dietary studies, aggregate risk associated with drinking water, and cumulative exposure assessments. Also being compiled are data for fresh versus processed as well as imported versus domestic agricultural products.

Outbreak Response

FORC G. In 1998, Vice-President Gore announced the formation of the Foodborne Outbreak Response Coordinating Group (FORC G), a partnership of Federal and State agencies established to better respond to foodborne illness outbreaks. The role of this interagency group, co-chaired by the Under Secretary for Food Safety and the Assistant Secretary for Health, 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.

FERRET. Within USDA, the Secretary asked the Under Secretary for Food Safety to form and chair an internal Food Emergency Rapid Response and Evaluation Team (FERRET), designed to enable USDA to be prepared to respond to such emergencies as outbreaks involving foods purchased by USDA feeding programs, and formulate plans across mission areas to diminish those possibilities in the future.

Field Epidemiology. USDA has stationed field epidemiology officers in a number of FSIS district offices to provide more rapid response. USDA also is exploring changes in its recall policies and procedures in light of a number of large recalls that strained the system currently in place.

PulseNet, the national database of molecular fingerprints of pathogens, developed through partnerships involving CDC, FSIS, FDA, and State governments, allows a comparison of strains of bacteria to determine whether or not there is a single source for outbreaks or sporadic cases.

Education

Improving research, inspection, and surveillance alone will not ensure safe food. Education and training for all those involved in producing, processing, and distributing food are essential to the goal of providing the public with safe food products. The budget for food safety education has increased from a modest \$2.8 million in FY 1997 to \$13.5 million in FY 1999. Although it is still in the concept stage, the Joint Institute on Food Research will also provide a mechanism for joint planning and prioritization of food safety education activities.

Consumer Education. The President's Food Safety Initiative has spurred new consumer education programs within USDA 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 and HHS. In addition, USDA is working

through organizations such as the Association of Food and Drug Officials (AFDO) to provide education to those who handle food at the retail level and is carrying out extensive HACCP education for its own and State employees involved in inspection. USDA is also working with industry to develop science-based food safety assurance programs for fresh-cut fruit and vegetable processing facilities.

Epidemiology Applications. USDA is basing its safe food handling education on science. Epidemiology information from FoodNet and other sources is helping to identify types of foods associated with illness, behaviors that can contribute to disease, and populations who are more vulnerable. In addition, USDA is increasingly using risk assessments and research data to develop accurate and high-priority consumer messages. An example is an ARS/FSIS study on the premature browning of ground beef, which led to a nationwide education campaign to promote the use of food thermometers when cooking hamburger.

Animal and Food Handler Education. CSREES administers a food safety education program (the National Food Safety and Quality Initiative) in partnership with land-grant institutions across the United States. This program supports food safety education initiatives at all land-grant institutions as well as specific education initiatives that reach animal and food handlers along the entire farm-to-table chain. In addition, science-based programs in HACCP training for the meat and poultry industry are funded by CSREES through Fund for Rural America grants and special research grants. The scope and focus of these educational programs are developed in consultation with stakeholders, including other Federal agencies involved in food safety education.

Summary

The NAS report and its recommendations open important areas of dialogue on the direction of food safety into the 21st century. We can never get away from the fact that at any point in the farm-to-table continuum, harmful bacteria or chemicals can contaminate food. Therefore, at every point along the way, everyone must be proactive in keeping food safe. That is exactly what we are doing at USDA—being proactive, not reactive, to the challenges presented by an increasingly sophisticated food production system.

We wish to utilize all the effective tools available in the current food safety system as well as increasing the science-based nature of that program. We feel strongly that we must be single-minded about our commitment to improving the nation's food safety system. Clearly, we in USDA and the authors of the NAS report are in agreement on this point.

Where we differ—and we believe this is healthy disagreement—is in the details of how best to accomplish these improvements. We have tried to demonstrate in the preceding section that much has already been done. These accomplishments, however, came within the existing laws, structure, and system. Achieving consensus on a new comprehensive national food safety law or major organizational changes will bring about worthwhile deliberations, but it will also not be easy. USDA focusing its energy on the foundation we have already established and building from there will best serve the American public.

A DISCUSSION OF THE NAS REPORT RECOMMENDATIONS

RECOMMENDATION I: AN EFFECTIVE AND EFFICIENT FOOD SAFETY SYSTEM MUST BE BASED IN SCIENCE

Background

The report notes that the United States has enjoyed notable successes in improving food safety and that with increasing knowledge, many rational, science-based regulatory philosophies have been adopted. The reports adds, however, that adoption of these regulatory philosophies has been uneven and difficult to ensure given the fragmentation of food safety activities, and the differing missions of the various agencies responsible for specific components of food safety. The greatest strides in ensuring food safety from production to consumption, the Academy noted, can be made through a scientific, risk-based system that ensures that surveillance, regulatory, and research resources are allocated to maximize effectiveness.

Strengths of the Recommendation

USDA agrees that a food safety system that is based on science is important in ensuring that surveillance, regulatory, and research activities provide the greatest public health benefits. This involves identifying the foremost public health needs, discovering the most cost-effective opportunities for improvement, and setting priorities. As knowledge increases, new technologies become available. The nature of food hazards changes and the food safety system must be flexible enough to identify, adapt to, and take advantage of these changes. The system should provide economic incentives to develop new inventions, commercial scale-up, and industry adoption.

A research effort with industry, consumer, academic, and government participation could develop options and evaluate them. The benefits and costs of each option should be considered, the impact on public and private economic incentives for food safety at each of the three stages of innovation (invention, commercial scale-up, and industry adoption) appraised, and the short-run versus the long-run impact on economic incentives estimated.

Weaknesses of the Recommendation

USDA's progress thus far in implementing a science-based strategy, and its commitment to further this progress, supports the underlying philosophy that food safety measures must be based in science. However, it is also true that the science underlying these

measures is subject to large uncertainties. A joint Food and Agricultural Organization/World Health Organization consultation¹ in risk management and food safety notes that, “in many cases, there is insufficient quantitative information to translate requirements for ‘safety and wholesomeness’ into a definitive quantitative assessment of the risks to human health.” By default, most food safety risk assessments are not quantitative predictions of the expected level of damaging effects but rather qualitative assessments of whether a hazard at a particular level is safe or unsafe.

In addition, the Committee failed to consider that it is neither feasible, nor good public policy, to perform detailed, quantitative risk assessments for every problem. The level of detail in a risk analysis should be commensurate with the problem’s importance; expected health, economic, or social impact; and the expected impact and cost of control measures². It is important to adopt a tiered approach to food safety risk analyses and to avoid paralysis by analysis. For decisions with insignificant regulatory or economic impacts, simplistic, routine analyses are often appropriate. And in emergency situations, rapid public health and scientific assessments are needed. In many cases, relative risk rankings are sufficient, and precise predictions of actual public health risk unnecessary and even counterproductive, if they result in ineffective allocation of resources. For the purposes of promulgating a major rulemaking, more elaborate analyses with independent review are warranted. So long as USDA continues to develop measures of benefits and costs of health-promoting interventions, it will be better able to choose among interventions in emergency situations and to decide whether risks and intervention costs entail significant impacts.

Science must also be tempered with other considerations, such as technical feasibility, statutory mandates, policy considerations, budget constraints, and consumer preferences. As the Committee itself acknowledged, the determination of what constitutes a safe food involves a subjective evaluation of social issues and values, as well as a scientific assessment of risk. For example, public health benefits should be balanced with associated costs. Executive Order 12866³ and USDA administrative guidance require agencies to consider economic factors in decision making. The Reorganization Act of 1994 established the USDA Office of Risk Assessment and Cost Benefit Analysis, which is charged with ensuring that major regulations proposed by USDA are based on sound scientific and economic analysis.

Barriers to Implementing the Recommendation

There are many barriers, or challenges, to improving the scientific basis of food safety programs. First, public health needs change. New food safety challenges continue to emerge as a result of changing food habits, a global food supply, and a changing population. An example is the impact of *E. coli* O157:H7—a pathogen that possibly did not exist 20

¹ FAO and WHO. 1997. Risk Management and Food Safety. Report of a Joint FAO/WHO consultation, Rome, Italy, January 27-31. FAO Food and Nutrition Paper No. 65.

² Presidential/Congressional Commission on Risk Assessment and Risk Management. 1997. Framework for Environmental Assessment and Risk Management. www.riskworld.com/Nreports/1997/risk-rpt/pdf/EPAJAN.PDF.

³ 58 FR 51735; October 4, 1993.

years ago but has been responsible for major outbreaks of foodborne illness in recent years. Second, the scientific understanding of risk changes as well. There remains a steep learning curve when it comes to understanding the hazards in food and how to minimize resulting risks. Third, there is a fragmentation of research and regulatory efforts, although cooperation and coordination among public health agencies at the Federal, State, and local level, and with the private sector, is improving. Fourth, limited resources exist to conduct surveillance, monitoring, and risk assessments to identify the most salient public health needs. And fifth, inconsistent food safety standards exist at the Federal, State, local, and international levels. Mechanisms are in place to reduce this inconsistency, but it is a long-range project.

Conclusion

USDA's food safety programs are already science-based and the Department is striving to make them more so. Considerable improvements have been made over the past several years as a result of the President's Food Safety Initiative and individual agency activities. Elements important to a science-based program—surveillance, outbreak response, risk assessment, research, inspection, and education of stakeholders—exist and are continually being strengthened.

However, the scientific information produced from research and risk assessment efforts will not result in improved food safety unless there is a strong educational component in the system. This means there must be education for all those involved in producing and handling food as well as for those persons involved in government food safety activities. Strengthening also involves improving coordination among the various public-private entities involved in these activities. Under any organizational structure, coordination among agencies and between the public-private sector is critical.

In addition, science must be tempered with other considerations, such as technical feasibility, statutory mandates, policy considerations, budget constraints, practicality, and consumer preferences. A new rapid test that works in the laboratory may not work in real-life plant environments. In some circumstances, it may be more appropriate to focus resources on a lesser risk, if that risk can be addressed relatively easily and quickly.

Additionally, emphasis should be placed on better evaluating science-based programs. Initial efforts have been made in this area. For example, *Salmonella* data from the first year of HACCP implementation show a trend toward fewer contaminated products. And FoodNet data provide a picture of the incidence of foodborne illness, and whether it has changed for specific pathogens. But much more needs to be done to ensure that the programs in place are doing what they are designed to do.

USDA believes that the necessary elements of a science-based program are in place, and that improvements planned for the next 5-10 years will enhance food safety. Specifically, USDA recommends that the President's Council on Food Safety consider in its strategic planning process how to accomplish the following enhancements:

Organizational Improvements A new organizational structure is in place in FSIS, and the Agency will be doing much more to improve its infrastructure for recruiting and retaining scientists. In particular, USDA could take more advantage of visiting scientist programs, term appointments, and senior level biomedical research scientists. More training is needed to prepare a new cadre of risk analysts. The degree to which a food safety program is science-based is directly related to staff expertise.

Surveillance As USDA approaches the new millennium, it will be looking for new ways to achieve surveillance goals and to monitor the food supply. Although the FoodNet has provided information never before available in the United States about the prevalence of foodborne illness, it remains an incomplete picture of national prevalence.

In addition, new and improved ways are needed to monitor the food supply. For example, new detection methods for *Campylobacter* will allow USDA to better estimate the prevalence of this pathogen. In the future, it may even become possible for the consumer to judge the presence of pathogens on foods in the grocery store or refrigerator by looking at a simple colorimetric marker on the product packaging.

USDA also conducts farm-level surveillance through the Animal and Plant Health Inspection Service, which, although only indirectly involved in the area of food safety, has a field force of veterinarians who work cooperatively at the State and local level to ensure the health of poultry and livestock populations. APHIS' National Animal Health Monitoring System has conducted nine science-based studies addressing information gaps in the areas of animal health, welfare, and production, product wholesomeness, and the environment in industries including the cattle, swine, and layer industries. Further use of these resources to enhance food safety should be considered.

Outbreak response A tremendous amount of time and expense is currently being expended on recalling products that are found to contain certain pathogens such as *E. coli O157:H7*. USDA needs to systematically evaluate the effectiveness of these recalls. In the future, USDA should be able to determine how much product was returned and make an effort to estimate, when appropriate data are available, how many illnesses may have been averted by the recall. USDA also needs emergency response funding to enable it to respond to epidemics and possible bioterrorism incidents.

Risk assessment The Federal government needs to create and use a national microbial risk assessment capability as a means of identifying hazards and quantifying risk and assist in creating similar capacities internationally. This will enable limited resources to be used more effectively to conduct risk assessments, and will enable resources to be used more effectively to address food safety problems according to the relative risks they pose.

Finally, there is an acute need to develop new methods and data for microbial risk analysis. In the area of dose-response assessment, because clinical trials with human subjects are not feasible for the virulent pathogens of greatest concern, animal and *in vitro* models are needed to fully integrate dose-response information into the risk assessments. Investigation of outbreaks, however, could provide more information on the exposed population and the

pathogen levels in foods capable of causing illness. It is equally important to develop methods and conduct monitoring that will enable an efficient assessment of the occurrence and level of microbial pathogens at different points along the farm-to-table pathway. In this area, methods and models are especially needed to predict the growth and decline of pathogens under a variety of environmental conditions and under a variety of interventions. When developing databases on pathogen occurrence and levels from farm to table, cooperative efforts among industry, academia, and government should be fostered.

Research. Through the Joint Institute for Food Safety Research, a research infrastructure has been established to ensure scientific support for a risk-based, farm-to-table food safety program. The Institute will continue a critical review of the federally supported portfolio of food safety research that was begun through the National Science and Technology Council. Future goals in the area of research will be to establish a coordinated scientific research agenda, integrate research efforts through an increased use of partnerships and other means, increase resources to support science-based decision making, encourage the application of new technologies to improve food safety, and conduct research on the costs and benefits of interventions.

Inspection. USDA will further improve the inspection of meat, poultry, and egg products through the continued implementation of HACCP and HACCP-based inspection models. It will also continue to promulgate more science-based regulatory requirements. An example is additional performance standards for pathogen reduction, which can be developed as more monitoring and surveillance data become available.

USDA also will work with FDA and others toward consistent food safety standards nationally and internationally. The Conference for Food Protection and the Codex Alimentarius Commission are the primary mechanisms through which these activities will take place. However, the CAC is only a body for the international harmonization of science-based food safety standards. It has neither the resources nor the mandate to assist its members—in particular, developing countries—to strengthen their capability to meet internationally agreed-upon standards. USDA should become more active in this area of technical cooperation with developing countries.

Education. USDA will continue science-based education and training programs for producers, processors, distributors, food handlers, and consumers, as well as those involved in regulatory activities. It is essential to include in these programs new scientific information on foodborne pathogens and their control and effective food safety management strategies. An increased effort will be made to provide education to the growers and producers of food products to reduce pathogen occurrence in the production setting, thus reducing the need for remedial action later in the food production chain. There also will be a focus on “at-risk” populations to provide the most vulnerable segments of the population with increased knowledge of how to avoid the risk of foodborne illness. This will be accomplished through enhanced cooperative programs with stakeholders from all segments of the food system. In

addition, USDA will continue to encourage voluntary use of science-based food safety techniques, such as HACCP, in the food industry.

RECOMMENDATION IIA: CONGRESS SHOULD CHANGE FEDERAL STATUTES SO THAT INSPECTION, ENFORCEMENT, AND RESEARCH EFFORTS CAN BE BASED ON SCIENTIFICALLY SUPPORTABLE ASSESSMENTS OF RISKS TO PUBLIC HEALTH.

Background

The report contains several criticisms of the current food safety laws. It states that the laws—particularly what the report characterizes as the requirement that there be continuous inspection of meat and poultry production through sight, smell, and touch (“organoleptic” inspection)—create inefficiencies, do not allow resource use to reflect the risks involved, and inhibit the use of scientific decision-making in activities related to food safety, including the monitoring of imported food.

The report recommends revision of the current statutes on food safety to create a comprehensive national food law under which:

1. Inspection, enforcement, and research efforts can be based on a scientifically supportable assessment of risks to public health. This means eliminating the continuous inspection system for meat and poultry and replacing it with a science-based approach that is capable of detecting hazards of concern.
2. There is a single set of flexible science-based regulations for all foods that allows resources to be assigned based on risk, that permits coordination of Federal and state resources, and that makes it possible to address all risks from farm to table.
3. All imported foods come only from countries with food safety standards equivalent to U.S. standards.

Strengths of the Recommendation

The report’s recommendations that Federal statutes should provide agencies with authority to make decisions based on risks to the public health and on scientific considerations make perfect sense. USDA has no disagreement with these recommendations. In fact, the Clinton Administration’s Pathogen Reduction Act of 1994, which was not passed by Congress, would have made more explicit the mandate that the Secretary of Agriculture is to use the best available scientific and technological data in prescribing regulations. USDA supports increased coordination among Federal agencies, and between the Federal government and the states, in pursuit of food safety goals.

In fact, imported meat, poultry, and egg products *now* come only from countries with food safety standards that are equivalent to U.S. standards. In fact, the statutes administered by FSIS prohibit the importation of meat, poultry, and egg products from countries not identified by the Secretary of Agriculture as having inspection systems equivalent to that of the United States. FSIS has a monitoring system in place with these exporting countries.

Weaknesses of the Recommendation

The report overstates the problems with the current statutory requirements. The statutory requirement for inspection of all poultry and meat carcasses and products is misunderstood by the authors of the report. For instance, the report reflects the mistaken belief that the statutes require the current method of organoleptic inspection of all carcasses. In fact, the statutes do not prescribe how inspection is to be carried out. USDA has the flexibility to create, and is in fact has begun to develop, the more risk-based regulatory system recommended by the Academy. The Department has adopted regulations requiring that HACCP be implemented in all slaughter and processing plants and is studying how best to effect further inspection improvements in slaughtering plants. It has also adopted pathogen reduction measures. Clearly, the Agency is pursuing a science-based approach to reducing the risks to the American public from meat and poultry.

While the current law does not “require” organoleptic inspection as it has been accomplished by FSIS historically, it does require antemortem and postmortem inspection of all official slaughter and processing facilities. The report fails to note that this inspection requirement has served American consumers well. Postmortem inspection is the key to ensuring that plants are employing the best sanitary dressing processes and that they are effectively preventing fecal contamination, which harbors the pathogens that cause disease. Inspection of all animals and carcasses also serves to protect the public from diseases and other hazards to human health. Europe’s experience with BSE should serve as a reminder that wholesale elimination of inspection of all animals and carcasses is not the most prudent course of action.

The inspection of all animals and carcasses does not necessarily lead to inefficiencies, as the report seems to suggest. FSIS has instituted a study of new inspection models for carrying out its antemortem and postmortem inspection mandates. This study is designed to test whether the public will be adequately protected with plants doing the sorting and government inspectors providing oversight inspection and verification inspection of the slaughter process.

Consumers expect safe food, but they also expect food to be wholesome and not to be economically adulterated. Consumers also want assurance that animals used for food are healthy and well cared for, and are slaughtered humanely. There are several methods of ensuring safety, and continuous inspection is one of many options.

However, given the prominence of meat and poultry products in the American diet, a comprehensive continuous inspection program is necessary if consumer expectations are to be fulfilled.

The report also fails to recognize the efforts at resource coordination that Federal agencies are making under their current authorities. First, as part of the President's Food Safety Initiative, agencies have formed FORC-G to coordinate outbreak response and to develop appropriate procedures for emergency responses. In addition, FSIS and FDA will soon enter into a Memorandum of Understanding under which each agency will share selected inspection results of interest with the other agency, which should minimize duplication. Also, FSIS and FDA are working together on final rules and a MOU that will minimize duplication in reviews of the safety of new substances for use in food (see Page 45 of the report). These efforts should increase the efficiency of the Federal government's food safety program. More importantly, they represent only a beginning effort at coordination.

Finally, the report fails to acknowledge the difficulties in obtaining passage of the sweeping new law that it recommends. The report cites the absence of a food safety counterpart to the Clean Air Act and the Occupational Safety and Health Act (Page 85). In fact, legislative proposals to do many of the things that the report finds to be necessary (e.g., enhance FDA's authority over imports) have been introduced in Congress in recent years but have not received necessary support in the legislative process. Given this history, the President's Food Safety Council will need to consider the political feasibility of major statutory changes.

Conclusion

USDA believes that the President's Council on Food Safety should not recommend a major overhaul of the food safety laws without first conducting a full assessment of these statutes and recognizing the significant regulatory changes, both current and planned, allowed by them.

The 1994 Reorganization of USDA accomplished the creation of the Office of Under Secretary for Food Safety, separate and apart from its previous position with Marketing in the Department. In addition, the research functions were centralized in the Office of the Under Secretary for Research, Education and Economics, enabling food safety research to be coordinated and enhanced.

USDA also believes that it has achieved, and can continue to accomplish, significant scientifically based improvements in its food safety programs under current authorities. The report's failure to recognize this fact, and its reliance on an incomplete and inaccurate understanding of current laws and the inspection program, has led the authors of the NAS report to recommend sweeping legislative changes that are not supported by facts in the report. This is particularly true given the report's failure to assess the significant difficulties in obtaining the type of broad legislative change that it recommends. USDA, in conjunction with the other federal food safety agencies and the states, has made substantive progress, and will continue to strive, for an ever more effective and efficient food safety system that is based on the best available science and appropriate analysis and assessment of risk. While we do not agree that *major* statutory reforms are needed, we do recommend that some

changes be made. For example, the following legislative changes will, we believe, enhance the Department's ongoing efforts to improve food safety:

1. USDA has sought, and would benefit from, enhancements to its enforcement authority. The Food Safety Enforcement Enhancement Act, forwarded by the Clinton Administration and introduced during the last Congress, included new tools needed to support the new science-based inspection system. Specific examples of proposed legislation that are highly desirable include authority to mandate recalls and the authority to assess civil penalties in administrative proceedings for violations of inspection laws and regulations.
2. USDA is exploring statutory changes that would allow meat and poultry products produced under state inspection to be distributed in interstate commerce while ensuring a seamless Federal-State food safety system.
3. USDA supports legislative clarification of the current system for the regulation of eggs and egg products.
4. USDA supports statutory changes to the FDA statutes that would permit FSIS inspectors not only to report their findings to FDA but also to actually perform inspections for that agency to increase interagency efficiencies.
5. FSIS should be given explicit authority to enter into cooperative agreements for food safety risk assessment. Under the current statutes, FSIS has to go through other USDA agencies that have that authority.

RECOMMENDATION IIB: CONGRESS AND THE ADMINISTRATION SHOULD REQUIRE DEVELOPMENT OF A COMPREHENSIVE NATIONAL FOOD SAFETY PLAN. FUNDS APPROPRIATED FOR FOOD SAFETY PROGRAMS (INCLUDING RESEARCH AND EDUCATION PROGRAMS) SHOULD BE ALLOCATED IN ACCORDANCE WITH SCIENCE-BASED ASSESSMENTS OF RISK AND POTENTIAL BENEFITS.

Background

The NAS report's recommendation Iib contains two parts. The first part recommends that Congress and the Administration require preparation of a comprehensive, national food safety plan. The report's Executive Summary lists several essential features of such a plan, including a unified food safety mission; integrated Federal, State, and local activities; adequate support for research and surveillance; and increased efforts to ensure the safety of imported foods. The second part of the recommendation suggests that resources be allocated on the basis of science-based assessments of risk and potential benefits.

Since publication of the NAS report, much has been done to initiate a comprehensive national food safety plan. On August 25, 1998, President Clinton issued Executive Order 13100 establishing the President's Council on Food Safety. One of the Council's primary purposes is to develop a comprehensive strategic plan for Federal food safety activities that contains specific recommendations on needed changes, including goals with measurable outcomes. The plan's principal goal is to establish a seamless science-based food safety system. The plan will set priorities, improve coordination and efficiency, identify gaps in the current system and mechanisms to fill those gaps, continue to enhance and strengthen prevention strategies, and develop performance measures to show progress.

The Council will consult with all interested parties in preparing the plan and consider both long-term and short-term issues, including new and emerging threats and the special needs of vulnerable populations such as children and the elderly. The Council will advise agencies of priorities for investing in food safety and ensure that Federal agencies annually submit coordinated food safety budgets to OMB. In short, the President's Food Safety Council will develop a national food safety plan and the budget to accomplish what the Committee recommends.

Food safety agencies have already taken the first steps to develop the national plan by holding interagency strategic planning sessions, developing a draft vision statement for the U.S. food safety system, and establishing the roles of all those involved in food safety. In addition, during 1997 and 1998, the Federal food safety agencies involved a wide range of stakeholders in public meetings and written comments to public dockets.

At its first formal meeting, on December 16, 1998, the Council approved the process to develop a national food safety plan and a unified budget to support the plan. These decisions clear the way for meeting the Committee recommendation for a comprehensive national food safety plan.

However, the NAS report recommendation goes a step further than a national plan by urging that resources be allocated according to science-based assessments of risk and potential benefits. While this seems like a very good idea, early attempts by Federal agencies to carry out risk-based allocation of resources have not been successful.

The Federal experience with comparative risk assessment to allocate resources dates to 1986, when the U.S. Environmental Protection Agency (EPA) assessed the risks posed by various environmental problems. In 1988, the agency released its findings in a report entitled, "Unfinished Business." This project did not enjoy broad credibility because 1) it was so broad and 2) critics within the agency suggested that programs with sufficient staff to devote to the inter-office working group were able to generate the most favorable analysis.

EPA asked the Science Advisory Board (SAB) to review the validity of "Unfinished Business." The expert panel declined to provide a consensus ranking of human health risks, citing scientific uncertainties and the subjective nature of such comparisons. In 1996, EPA requested that the SAB revisit comparative risk assessment and the Board established an Integrated Risk Project (IRP). As of December 1998, the final report was still undergoing

peer review and did not prioritize specific pollution problems. Ultimately, none of the national environmental risk ranking exercises has significantly impacted EPA's budget allocations.

Since 1987, more than 24 states and localities have completed risk ranking exercises. Usually, priority-setting was an initial, primary objective. However, as the projects evolved, other objectives such as "enhancing stakeholder involvement" generally eclipsed priority-setting. In state projects, contentious issues with potentially large economic repercussions were omitted from the comparative risk discussions. Commonly, the final risk rankings were used to initiate new programs or to increase the budget of existing programs that addressed highly ranked risks.

Strengths of the Recommendation

Proponents of risk-based allocation of resources see comparative risk analysis as objective, rational, and based on sound science. They believe that it should be an integral part of food safety strategic plans because it provides an efficient method of applying limited Federal resources to public health priorities. It is argued that comparative risk analysis would increase the predictability, transparency, and overall credibility of the process of allocating funds to food safety programs. USDA believes that the analysis of risks and benefits should be an integral part of the regulatory development process. In fact, the output from these analyses can truly serve as a guide to the process and help decision makers choose an appropriate course of action.

Weaknesses of the Recommendation

The limitations of comparative risk analysis are the time and resources required to conduct them. As more risk assessments are conducted, the techniques and databases will be developed and they will be more timely and more precise. Policy makers will have the risk assessments as valuable scientific inputs to their decision-making processes.

Barriers to Implementing the Recommendation

The President's Council on Food Safety has made significant progress in developing a process for a national food safety plan and unified budget. However, developing and successfully implementing a national plan will require strong cooperation, coordination, and communication. Each Federal, State, and local agency has unique mandates, authorities, history, culture, and operating procedures. These differences make the planning and implementation process extremely complex. While the food safety agencies may agree on goals and outcomes, it will be more difficult to ensure accountability for performance. The discipline necessary to achieve all that the NAS report has recommended will come only with a strong central authority that has the ability to direct food safety resources. Science-based risk assessments can be conducted on a variety of levels. If time is short, screening-level risk

assessments should be used to provide information to decision makers. In other cases, more detailed risk assessments of a broader scope are preferred to identify and evaluate a wide range of policy options."

Conclusion

Science-based risk assessment does not seek absolute certainty. Rather, it endeavors to bring the best existing science to the problem at hand. Risk assessment and cost benefit analysis should be built into the regulatory management and decision process so that these valuable tools can inform decision makers in an appropriate way. Though risk assessment and cost-benefit analysis are an important part of the information provided to a decision maker, it must be remembered that there are legal, political, and other economic concerns that must also be considered. Only with the best analysis possible can the limited food safety and public health resources be appropriately allocated.

USDA believes that the President's Council has already set in motion activities that meet the NAS report's recommendation and supports continuation of this process. In response to the NAS report, the President's Council requested the Food Safety Risk Assessment Consortium to consider how to develop a comparative risk analysis for food safety strategic planning. The Consortium developed three options.

Under Option 1, USDA's Economic Research Service (ERS) would lead an analysis using cost-of-illness methodology to rank foodborne pathogen risks, based on CDC surveillance data. This option does not require any additional funds, and could be accomplished during CY1999.

Option 2 would expand Option 1 by considering a broad range of food safety hazards, including pesticides and chemicals. The analysis would rank hazards on several criteria, such as cost of illness, chronic and acute illness, and environmental effects. This option would cost approximately \$823,000 and would take 24 months to complete.

Under Option 3, scientists would select highly ranked hazards and evaluate control measures and net benefits. They would determine which actions or interventions yielded the best return in terms of reducing illness. Intervention options might include education; better surveillance; more inspection; or formal, quantitative risk assessments and focused research. This option would cost approximately \$2,143,000 and would accomplish the objectives described in options 1 and 2. However, it would require 51 months to complete.

These options could provide helpful input to a national food safety plan. USDA cautions, however, that the Council avoid repeating mistakes of the past in applying risk assessment that is too strict, rigorous, or inflexible. Instead, the Department recommends that priorities be established on the known greatest risks at the current time, with the understanding that scientific risk estimates can change frequently over time and are likely to do so. How economic incentives for new food safety innovations could be increased should also be investigated.

RECOMMENDATION IIIA: TO IMPLEMENT A SCIENCE-BASED SYSTEM, CONGRESS SHOULD ESTABLISH, BY STATUTE, A UNIFIED CENTRAL FRAMEWORK FOR MANAGING FEDERAL FOOD SAFETY PROGRAMS, ONE WHICH 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.

Background

The NAS report finds that the current regulatory structure for food safety in the United States is not well-equipped to meet current challenges. Specifically, it notes: The system is facing tremendous pressures with regard to:

- emerging pathogens and ability to detect them;
- maintaining adequate inspection and monitoring of the increasing volume of imported foods, especially fruits and vegetables;
- maintaining adequate inspection of commercial food services and the increasing number of larger food processing plants; and
- the growing number of people at high risk for foodborne illnesses.

The report cites the strengths of the current food safety system, including the advent of FoodNet and PulseNet, HACCP implementation, and the Partnership for Food Safety Education. It also identifies deficiencies, which it attributes partly to “the fragmented nature of the system.” The Committee attributes the fragmentation largely to a lack of adequate integration among the various Federal agencies involved in the implementation of the primary statutes that regulate food safety, and observes that this lack of adequate integration occurs also with state and local activities.

The report goes on to note that 12 primary federal agencies are involved in key food safety functions. The Committee also references more than 50 memoranda of agreement between various agencies related to food safety. The agencies to which the Committee refers are listed below, within their four cabinet-level agencies.

U.S. DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

Agricultural Research Service

Agricultural Marketing Service

Animal and Plant Health Inspection Service

Economic Research Service

Grain Inspection, Packers and Stockyards Administration

Cooperative State Research, Education and Extension Service

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Centers for Disease Control and Prevention

National Institutes of Health

U.S. DEPARTMENT OF COMMERCE

National Marine Fisheries Service

U.S. ENVIRONMENTAL PROTECTION AGENCY

A Single Voice for Food Safety. USDA agrees that communication, coordination, and cooperation between federal agencies can and should be improved. The Department also points to specific examples of effective coordination between USDA agencies and other federal agencies. For example, the Joint Institute for Food Safety Research (JIFSR) is expected to provide an even more effective forum for discussion and coordination of research plans and allocation of resources.

The report attributes the lack of adequate integration among Federal, State, and local food safety authorities in part to the absence of “focused leadership” that has the responsibility, the authority, and the resources to address key food safety problems. The

report presents several examples of possible organizational structures to create a single federal voice for food safety. These include:

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

Although the report indicates many of the authoring committee's members believe that a single, unified agency headed by a single administrator is the most viable structure for implementing the "single voice" concept, the report recognizes that there may be many other models that would be workable.

Council on Food Safety. In August 1998, the President established by Executive Order the Council on Food Safety. The Secretary of Agriculture, the Secretary of Health and Human Services, and the head of the White House Office of Science and Technology Policy are the co-chairs of the Council. The Executive Order assigned three key responsibilities to the Council:

1. Develop a comprehensive strategic federal food safety plan.
2. Develop a coordinated federal food safety budget.
3. Oversee federal food safety research efforts.

Strengths and Weaknesses of the Four Options

In this context, USDA agencies make the following observations about the four options presented by the Committee in recommendation IIIA.

Options 1 and 2. Council on Food Safety; designating one current agency as lead agency.

Strengths: USDA believes Option 1, the Food Safety Council, could foster interagency cooperation, permit appropriate allocation of resources to most urgent questions, and allow synergy among research, education, and regulatory functions. In addition, a Food Safety Council with specific responsibilities has already been appointed (as described above).

Some USDA agencies believe that Option 2, the Lead Agency concept with other agencies reporting to that Agency Administrator, could be workable, but do not cite any specific supporting points (and favor it second to the Council on Food Safety).

Weaknesses: USDA agencies agree that some parts of the Federal government's food safety activities may be appropriate for consolidation within a single agency. They regret that the Committee report did not focus more carefully on specific food safety issues for which interagency efforts need improvement and on specific methods for achieving that improvement, beyond what is already underway or planned. USDA agencies suggest that the Food Safety Council's strategic plan, which will be based on input from the agencies, provide more attention to this topic.

Options 3 and 4: Single agency reporting to one current cabinet-level Secretary; or Independent single agency at cabinet level.

Strengths: One strength of consolidating food safety within the USDA is that most of the Federal Government's food safety resources (7 of the 12 agencies) currently report to the Secretary of Agriculture.

Weaknesses: In addition to the weaknesses noted with Options 1 & 2, USDA agencies point out that massive reorganizations require broad legislative support as well as additional funding and are very time-consuming. They also have the potential to damage customer service and even public health protection if not managed very carefully. Finally, some USDA agencies are particularly concerned that options 3 and 4 would be particularly detrimental to research and educational activities. They do not believe that a clear need has been demonstrated for a single independent food safety agency.

Other Models

The Committee has recommended that other models be examined. USDA proposes one for consideration.

Structural model—Joint Chiefs of Staff: An analogous situation existed some years ago in the military, where uniformed services operated independently if not at odds with one another, despite a shared goal: National Defense. Inter-service relations were characterized by competition, noncommunication, and waste. After the Goldwater-Nichols Bill was passed into law, however, the Joint Chiefs of Staff was given command authority over the individual services, with a rotating Chair.

The result was that the services retained their core missions, but are now obliged to coordinate in many areas where their missions coincide. Logistics, research and development, information technology and communications, and emergency response are among the many functions now served by joint commands.

Service in "joint" billets, once to be avoided, has become desirable if not mandatory career steps for senior military personnel. There is near universal agreement that the changes

have enabled the services to become more effective and efficient, to the benefit of the taxpayers and national defense. This model could be instructive as we look for ways to make the federal government's food safety activities more effective and efficient.

Challenges

In general, USDA agencies do not believe that a major reorganization of responsibility, authority, and budget-making is timely, necessary, or desirable in order to achieve the model food safety system.

USDA agencies are concerned about a number of specific issues. These issues are surfaced because USDA believes they warrant closer attention by the Food Safety Council in its analysis and report to the President.

- *Food safety issues cross jurisdictional lines.* Many food safety issues simply cannot be dealt with by a single agency. For example, BSE is an animal health issue and a human health issue. The foodborne disease problem is also a waterborne disease problem. *Salmonella enteritidis* in shell eggs is not only a food safety issue but also an animal health and a marketing issue; support for the scientific investigation to unravel the secret of ovarian transmission came from both the public health and agricultural communities. And, of course, food safety is also a nutritional issue. In this country and around the world, people do not gain the nutritional benefits of the food available to them if they suffer foodborne illness, particularly when accompanied by dehydration due to prolonged diarrhea. That makes foodborne illness also an international issue of concern to susceptible populations such as children, the elderly, and persons with immune-compromised conditions.
- *Not all food safety problems are amenable to regulatory solutions.* All food safety problems or concerns cannot be resolved by legislation or regulation. For example, irradiation of pork for trichina control was approved more than a decade ago; approval of irradiation of raw beef for microbial control is waiting in the wings. Despite the scientific and regulatory view that irradiation is an effective technology for minimizing food pathogens, public perceptions about irradiation—anxieties not even related to food safety—have prevented its widespread use. In our pluralistic system, the marketplace and other forces will influence, sometimes drive, our regulatory agenda.

In addition, all of the options the Committee has listed involve transfer of “command and control” functions from numerous agencies to a single Federal entity. It is noteworthy that USDA, among other federal agencies, is engaged in a politically popular regulatory reform effort to replace “command and control” regulations with science-based “performance standards” whenever possible.

- *Most food safety problems have multiple “solutions.”* A regulatory solution, i.e., standard setting and enforcement, is not always the best solution to a food safety problem. Research, education, and voluntary compliance can reduce the need for regulation.

- *New partnerships are silver, old ones are gold.* We should build upon, not discard, existing successful partnerships. For example, CSREES, FSIS, FDA, CDC, and other private and governmental organizations now participate in the Partnership for Food Safety Education. This group serves to coordinate all food safety educational programs among private and governmental agencies, and is a key element of the Food Safety Initiative. Within that partnership, the RFP for projects on food safety education from CSREES was shared with other Federal agencies to gain input and improve coordination of these efforts.

Yet that partnership would not have been possible without relying on the many effective working relationships developed among the participants over the years, including joint projects on residue control and nutrition labeling. Moving food safety education programs into a single food safety agency would be of concern because of the potential loss of the very important partnership that CSREES has with its partners in the Land-Grant system and the Cooperative Extension Service. This partnership is critical to the easy and rapid transfer of research results from CSREES-funded programs directly into the Extension System and on to the end users.

By the same token, the Joint Institute for Food Safety Research builds on long-term research coordination among food safety agencies. ARS and CSREES continue to work closely on planning of research agendas and allocation of funds for research projects. In the writing of the two current new Requests for Proposals (RFPs) by CSREES, the general outline of the RFP was discussed in detail with other Federal agencies, including FDA, FSIS, and ORACBA, to ensure that we were meeting their needs as much as possible within the confines of the authorizing language for the programs.

- *There is strength in diversity.* Public partnerships are strengthened by having diverse views and expertise among the members, to better anticipate all factors that will affect resolution of any food safety issue. For example, any attempt to place "pure" food safety research and education in one agency could actually jeopardize our ability to deliver improved food safety to consumers. Research and education programs for food safety do not operate as separate activities within the agencies but rather draw significant strength from one another. While some projects are entirely focused only on food safety, the food safety research portfolio actually includes many other projects in such areas as animal health and animal genetics, which provide major contributions to the total set of information that supports the national food safety effort.

Conversely, scientific expertise and endeavors should always inform regulatory activities. Each regulatory agency must have a cadre of trained and involved scientists to facilitate communications and cooperation with the research/education agencies. [Applied research, especially focused on adaptation and adoption of new diagnostic methodologies and development of risk assessment models, remains a crucial element of the action agency.]

Conclusion

The President has directed the Council, as one of its first activities, to review the NAS report and, after providing opportunity for public comment, including public meetings, report back to the President within 180 days with its response. The Council was asked to consider appropriate additional actions to improve food safety, including proposals for legislative reform and reorganization of the food safety system.

However, any reorganization of food safety activities must recognize agency activities that are not related to food safety and how they relate to the food safety responsibilities. Reorganization must not be done at the expense of these responsibilities and activities. Congress had valid reasons for creating a single agency, ARS, to conduct agricultural research, a single agency, EPA, to regulate pesticides, a single agency, APHIS, to regulate animal and plant health. Those reasons still exist. USDA is concerned that separating

- agricultural research related to food safety from agricultural research that is not could weaken both;
- regulation of foodborne animal diseases from the regulation of other animal diseases could weaken both; and
- regulation of pesticides for food crops from the regulation of pesticides for nonfood crops could weaken both.

USDA recognizes that some reorganization and consolidation of activities may be desirable but is concerned that a massive reorganization of the federal government's food safety activities may create as many problems and inefficiencies as it solves.

USDA believes that before the Council considers reorganization, it should do what the Committee has suggested: identify and analyze other existing models in government for achieving mutual and truly national food safety goals. Some of these models might address structure, and some might address facilitating mechanisms.

RECOMMENDATION IIIB: CONGRESS SHOULD PROVIDE THE AGENCY RESPONSIBLE FOR FOOD SAFETY AT THE FEDERAL LEVEL WITH THE TOOLS NECESSARY TO INTEGRATE AND UNIFY THE EFFORTS OF AUTHORITIES AT THE STATE AND LOCAL LEVELS TO ENHANCE FOOD SAFETY.

Background

The authors of the NAS report concluded that reorganization of federal food safety responsibilities is necessary to implement a science-based food safety system. Recommendation IIIB addresses the issue of integrating and unifying the efforts of authorities at the state and local levels to enhance food safety.

The report identified five statutory tools required to integrate local and state food safety activities into an effective national system:

1. Authority to mandate adherence to minimal federal standards for products or processes.
2. Continued authority to deputize state and local officials to serve as enforcers of federal law.
3. Funding to support, in whole or in part, activities of state and local officials that are judged necessary or appropriate to enhance the safety of food.
4. Authority given to the Federal official responsible for food safety to direct action by other agencies with assessment and monitoring capabilities.
5. Authority to convene working groups, create partnerships, and direct other forms and means of collaboration to achieve integrated protection of the food supply.

This recommendation acknowledges the “equally critical roles” of state and local government entities with those of the federal sector in ensuring food safety, and suggests changes in federal authorizing and appropriating legislation may be necessary to achieve better integration of federal, state, and local activities.

The report also notes: “The work of the states and localities in support of the federal mission deserves improved formal recognition and support.” We believe that the report is highlighting this critical point at a serendipitous time.

Strengths of the Recommendation

USDA recognizes, and agrees with the report's conclusion, that the divisions among federal, state, and local authority often complicate the administration of regulatory programs.

Weaknesses of the Recommendation

USDA believes that most of the statutory tools suggested by NAS already exist for USDA, as noted below.

- *Authority to mandate adherence to minimal federal standards for products or processes.*

The Federal meat and poultry inspection laws already provide USDA with the clear authority to set minimum federal standards and require adherence to those standards. Both the states and other governments must satisfy the "equal to" provisions of those key laws. USDA has preemption authority if it becomes necessary. Twenty-five states operate state inspection programs inspecting product for in-state sale, and one additional program is in development.

In practice, however, USDA has rarely had to call upon this authority to achieve food safety goals. For example, it is generally for budgetary reasons rather than program inadequacies that states give up their inspection programs for products produced and sold within the state. USDA in practice often defers to State Attorneys General where state laws are equivalent in addressing particular compliance matters.

- *Continued authority to deputize state and local officials to serve as enforcers of federal law.*

Under Federal-State Cooperative Inspection Program Agreements (formerly Talmadge-Aiken), State employees carry out inspection in federally inspected plants. Approximately 250 plants now operate under such agreements. We are also exploring new approaches, under current law, to extend this concept into other areas of food safety.

- *Funding to support, in whole or in part, activities of state and local officials that are judged necessary or appropriate to enhance the safety of food.*

Under current law, USDA provides up to 50 percent of the costs of state inspection programs (for 25, and soon to be 26, states with inspection programs for meat and poultry products produced and sold within the state). This support adds up to more than \$40.5 million dollars per year.

Under current law, USDA (through FDA due to lack of FSIS cooperative agreement authority) has funded animal production food safety outreach projects involving 11 states. These projects bring together at the state level all of those involved in food animal production, veterinary practice, animal health, public health, and related areas to assess the

current level of food safety awareness among food animal producers; promote increased awareness of needs for food safety at the animal production level; identify production practices that enhance food safety and articulate them to producers, transporters, and marketers; provide a continuing forum for addressing food safety issues as they arise; and support education and information activity that results in food animals being presented for slaughter that will yield safe, wholesome food products. The projects vary according to regional and food animal species differences, but all seek the same result—safe food. (\$405,000.) Contract states are Louisiana, Oregon, Michigan, South Dakota, Nebraska, Texas, New York, Wisconsin, Ohio, and Vermont.

An essentially identical contract was developed with the state of Colorado, and will be funded through APHIS (\$45,000.)

Under current law, USDA (CSREES) transferred an employee to Iowa State to develop an educational program to train veterinarians as auditors for on-farm food safety and quality assurance processes. Under current law, USDA funded animal production food safety workshops in Colorado, Nebraska, and Ohio (\$25,000 through the Livestock Conservation Institute). These workshops provided extensive information to the state-based information multipliers on food safety, consumer concerns, HACCP, packers and retailers' needs, and what producers can do to best address these issues.

Under current law and the President's Food Safety Initiative, USDA is enhancing state labs and computer capabilities. Under current law, FSIS is supporting the State training initiative for HACCP.

- *Authority to convene working groups, create partnerships, and direct other forms and means of collaboration to achieve integrated protection of the food supply.*

USDA believes it does have the authority under current law to convene working groups and to create partnerships. The federal-state initiative to encourage adoption of the Food Code does not require statutory authority. What FSIS lacks is cooperative agreement authority, which it is pursuing already in the legislative venue.

USDA also believes that any formal comment from the Council to the President on this recommendation should fold in and be responsive to the views of the states. The Department believes the strategic plan described under Recommendation IIB above is the vehicle for obtaining that input. It is doubtful that any changes in the federal-state-local relationship on food safety will be effective if they are not mutually agreeable.

Barriers to Implementing the Recommendation

The discussion under Recommendation IIA is also relevant here in that the President's Council on Food Safety should not undertake overhaul of the food safety laws without first conducting a full assessment of these statutes.

Conclusion

USDA recommends that the President's Council on Food Safety incorporate the ongoing dialogue with the states into its strategic planning process.

At a September 1998 "50-state" meeting, participants (largely state regulatory officials) developed a vision statement for an ideal national integrated food safety system and a list of issues that would need to be addressed to reach the ideal system. Since that time, six key operational "intersections" have been identified for integrating federal, state, and local government activities:

1. Roles and responsibilities; capacities and resources.
2. Coordinating outbreak responses and investigations.
3. Data collection and sharing.
4. Communication.
5. Minimum uniform standards.
6. Laboratory operations and coordination.

Action plans for these six areas need to be considered by the Council as well as the participating agencies at federal, state, and local levels. It is also important to emphasize that current work on a national integrated system has been built on successful federal/state/local food safety initiatives over the past several years, within existing frameworks.

In some cases, the activities were generated by the States and in other cases by the federal agencies. In some instances, specific issues have served as the trigger (promoting adoption of the Food Code, *E. coli* O157:H7 in ground beef, HACCP implementation in small and very small plants, interstate shipment, Salmonella in eggs). In other cases, agencies such as FSIS and FDA, which have themselves established new, cooperative modus operandi (dating back, perhaps, to nutrition labeling), have drawn state and local agencies into addressing emerging issues such as food safety in transportation and food safety in animal production.

USDA believes that some of the landmark food safety improvements from 1992 to 1998 could not have occurred without the active participation of state and local agencies. One case in point is safe-handling labels for raw meat and poultry. Another is the "sentinel site project," precursor to FoodNet and PulseNet.

USDA believes that the Council's planning process provides the opportunity to draw the States into the process as primary and equal partners in the development of the food

safety system of the future. We believe that the national integration project described above is one of the appropriate vehicles for doing so.