



United States
Department of
Agriculture



Department of
Health and Human
Services



United States
Environmental
Protection Agency

February 21, 1997

Dear Stakeholder:

On January 25, 1997, President Clinton announced a new initiative to improve the safety of the Nation's food supply. Recognizing that food safety is not simply a responsibility of the Federal Government and that an effective, comprehensive food safety strategy must involve partners outside the Federal Government, the President directed us to work with consumers, producers, industry, States, tribes, universities, and the public to identify additional ways to improve food safety through Government and private sector action, including public-private partnerships. The President asked us to report back with our recommendations within 90 days.

We are strongly committed to an open process that includes a full discussion of the wide range of issues that may be raised by our various constituencies. Our experience has shown that we are most successful in solving problems when we proceed in this manner. In short, we need your participation and your advice to develop the best possible recommendations for the President.

To begin this dialogue, we are inviting you to attend a public meeting on March 5, 1997, in Washington, D.C., to discuss the initiative. Our staffs have been meeting for several months to identify major issues in a number of key areas, including surveillance, research, risk assessment, inspections, coordination, and education. A document which outlines those issues and identifies possible ways in which they could be addressed is enclosed with this letter.

We want to emphasize two things. First, this document reflects the current thinking of our food safety experts. But we recognize that you and other constituencies may identify other issues or approaches that should be included in the initiative. We encourage you, then, not only to think critically about the enclosed document, but to bring other issues that you may have to the meeting on March 5.

Second, this is only the beginning of the process. We are planning a longer meeting in late March or early April in which all interests would work through the issues we have collectively identified. While the President directed us to complete our report within 90 days, we want to assure you that we are committed to continuing a dialogue and partnerships that will generate great benefits for all Americans throughout the next 4 years of this Administration.

We have made substantial improvements in food safety over the past 4 years, and we once again thank you for your efforts. We look forward to working with you as we pursue this initiative and build upon the progress we have made to date.

Sincerely,

DAN GLICKMAN
Secretary of
Agriculture

DONNA E. SHALALA
Secretary of
Health and Human Services

CAROL M. BROWNER
Administrator
Environmental Protection Agency

Enclosure



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**FOOD SAFETY FROM FARM TO TABLE:
A NEW STRATEGY FOR THE 21st CENTURY**

**DISCUSSION DRAFT AND CURRENT THINKING
A NATIONAL FOOD SAFETY INITIATIVE**

A NEW INTERAGENCY STRATEGY TO PREVENT FOODBORNE DISEASE

In his radio message on January 25, 1997, President Clinton announced a new initiative to improve the safety of the nation's food supply. The President announced he will request \$43 million in his 1998 budget to fund a nationwide early warning system for foodborne illness, enhance seafood safety inspections, and expand food safety research, risk assessment, training, and education. President Clinton also directed the Secretary of Health and Human Services and of Agriculture, and the Administrator of the Environmental Protection Agency to work with consumers, producers, industry, states, universities, and the public to identify additional ways to reduce the incidence of foodborne illness and to ensure our food supply is the safest in the world.

The President directed Secretaries Shalala and Glickman, and Administrator Browner to report back to him with recommendations in 90 days. He instructed them to explore opportunities for public/private partnerships to improve food safety. And he asked that their recommendations include ways to improve surveillance, inspections, research, risk assessment, education, and coordination among local, state, and federal health authorities.

We need your advice. Your perspective is essential in providing the President with a report that identifies current needs in food safety, as well as assuring the future safety of our food supply and the health of consumers. We need the perspective and suggestions of all groups who are concerned about food safety and public health to make this a successful endeavor.

The goal of this initiative is to reduce, to the greatest extent possible, the incidence of foodborne illness. The thoughts in this draft focus on the public health principle that society should identify and take preventive measures to reduce the risk of illness, and that it should focus its efforts on those hazards that present the greatest risks.

The ideas in this draft represent our preliminary thoughts on this subject. A comprehensive food safety plan, describing actions and resources necessary to achieve the goals of reduced foodborne illness, will require extensive deliberation and in-depth discussion with all stakeholders in food safety, including consumers, state, tribal, and local public health officials, industry, and members of the scientific community. This draft is intended not as a prelude to government action, but an exploration of what might result from the upcoming seminars and conferences. While this initiative focusses on reducing the incidence of microbial foodborne illnesses, we recognize that chemical contaminants are also a cause of foodborne illness, but with chronic long term effects.

BACKGROUND

The American food system provides consumers with an abundant supply of convenient, economical, high-quality, and safe food products. This system is built on the enterprise and innovative capacities of those who produce and market food in the United States, and it is driven

by the high expectations of American consumers for the foods they purchase for their families. Foodborne illness, however, still occurs in the United States. Over the last four years the Clinton Administration has developed and implemented major steps towards reinventing food regulation:

- In 1993, the Vice President's National Performance Review issued a blueprint for reinventing our nation's food safety system.
- The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) issued regulations that will require the meat, poultry, and seafood industries to follow Hazard Analysis and Critical Control Points (HACCP) procedures. HACCP, which calls for food industries to implement preventive measures of their own design, will streamline regulation of these foods, increase the industries' responsibility for and control of their own safety-assurance actions, and generally bring regulation of meat, poultry, and seafood in line with state-of-the-art scientific procedures.
- Beginning in 1994, the Centers for Disease Control and Prevention (CDC) embarked upon a strategic program to detect, prevent, and control emerging infectious disease threats, some of which are foodborne, and has made significant progress toward this goal in each successive year.
- The Safe Drinking Water Act of 1996 includes responsible regulatory improvements to help states and water systems prevent drinking water contamination problems. Resources are provided for the first time for drinking water infrastructure that will help hundreds of communities protect their residents from harmful contaminants.

While these advances are significant, they may not be enough. New pathogens, new food products, huge increases in imported foods, the growing importance of food exports, and increasing antimicrobial resistance among foodborne pathogens present new challenges to the nation's food safety programs. The food safety system is in need of reform, especially reform that builds on the preventive principles embodied in HACCP.

HISTORY OF THE FOOD SAFETY INITIATIVE

Achieving a significant reduction in the incidence of foodborne illnesses requires the cooperative efforts of public health and regulatory agencies at the federal, state, tribal and local levels, as well as all other parties responsible for and concerned about food safety and reducing the incidence of foodborne illness (i.e., consumers, industry, and academia). Partnerships - between public agencies and industry, federal agencies and state, tribal or local agencies, public agencies and academia, to name a few possibilities - will be invaluable in leveraging the resources focused on reducing the incidence of foodborne illness and enhancing communication.

Representatives of various government agencies have drafted a structure for the food safety initiative for your further deliberations. Ad hoc working groups, representing the varied perspectives of the FDA, CDC, the Department of Agriculture's Research, Education and Extension agencies, as well as the FSIS and Animal and Plant Health Inspection Service (APHIS), and the Environmental Protection Agency (EPA), have been meeting for several months to identify major food safety concerns and propose recommendations on what resources and activities are needed to have a significant impact on reducing the incidence of foodborne illness both in the short term and over the long term. The working groups worked from the premise that an effective food safety initiative must have several, interrelated components which, together, have far greater impact on reducing the incidence of foodborne illness than is possible to attain with any single component. Moreover, these elements must form the groundwork for the design and implementation of strategies to meet current needs, for continually evaluating the effectiveness of ongoing activities, and for identifying and implementing strategies to meet future needs. These elements include surveillance, coordination, risk assessment, research, inspections, and education.

This draft, which primarily defines short-term activities, describes the elements of a food safety initiative and tentatively identifies critical issues and the working groups' current thinking on preliminary recommendations. In some cases these recommendations have been included as part of the President's FY98 budget. However, no specific decision as to what will constitute the final food safety initiative, including how the strategic planning process is structured, have been made. Input from groups and individuals such as yourself, state, tribal and local agencies, consumers, industry, academia, and other stakeholders will be incorporated into the food safety initiative.

Two open public meetings of all parties interested in food safety are planned to take place in Washington, DC. The first, scheduled for March 5, 1997, is an information meeting to familiarize interested parties with the President's initiative and introduce the draft discussion document. A second meeting is tentatively scheduled for late March-early April to discuss the food safety initiative. The purpose of the second meeting is to present the key issues and solicit both comment on the preliminary recommendations and additional suggestions for inclusion in the report to President Clinton.

Using this draft as a starting point, we are asking for your perspective on how best to enhance the safety of the food supply and reduce foodborne illness. Please consider the following questions in guiding your response, considering both the immediate future and the long term:

Questions:

1. Have the critical elements of an effective food safety initiative been identified? Are there others? What are they?

2. Have the appropriate issues within each element been identified? If not, what additional issues should be included?
3. What are the priorities among the issues identified or added to each element of the initiative?
4. What steps should be taken to begin to resolve issues within each element of the initiative?
5. What are the responsibilities of various stakeholders in working toward resolution of the issues?
6. How can we better utilize public/private partnerships to reduce foodborne illness?
7. How should food safety activities be better coordinated across the federal agencies, accommodating the needs and perspectives of state and local agencies, consumers, industry, and academia, to maximize the effect of available resources?
8. How do we ensure and measure the effectiveness of the food safety initiative?
9. How should the evaluation be structured so that the results of the early evaluation can be factored into the strategic planning process?
10. What recommendations do you have for the structure of the strategic planning process?

The comments, suggestions, and information from these meetings will be used in preparing the report to the President.

FOODBORNE ILLNESS: A SIGNIFICANT PUBLIC HEALTH PROBLEM

Foodborne infections remain a major public health problem. The Council for Agricultural Science and Technology, a private non-profit organization, estimated in its 1994 report, *Foodborne Pathogens: Risks and Consequences*, that as many as 9,000 deaths and 6.5 to 33 million illnesses in the United States each year are food-related. Hospitalization costs alone for these illnesses are estimated at over \$3 billion a year. Costs for lost productivity for 7 specific pathogens have been estimated to range between \$6 billion and \$9 billion. Total costs for all foodborne illnesses are likely to be much higher. These estimates do not take into account the total burden placed on society by the chronic, often life-long consequences caused by some foodborne pathogens.

Additional, important safety concerns are associated with the greater susceptibility to foodborne infections of several population groups. These include persons with lowered immunity due to HIV/AIDS, those on medications for cancer treatment or for organ transplantation, as well as pregnant women (and their fetuses), young children, and elderly persons. Patients taking antibiotics, or antacids, are also at greater risk of infection from some pathogens. Other groups who may be disproportionately affected include persons living in institutional settings, such as hospitals and nursing homes, and those with inadequate access to health care, such as homeless persons, migrant farm workers, and others of low socioeconomic status.

Sources of Foodborne Contamination

Sources of food contamination are almost as numerous and varied as the contaminants themselves. Bacteria and other infectious organisms are pervasive in the environment. *Salmonella enteritidis* enters eggs directly from the hen. Bacteria (occasionally pathogenic) inhabit the surfaces of fruits and vegetables in the field. Molds and their toxic byproducts can develop in grains during unusually wet or dry growing seasons, damage and stress during harvesting, or during improper storage. Seafood may become contaminated from agricultural and other runoff, as well as by sewage, microorganisms, and toxins present in marine environments. Many organisms that cause foodborne illness in humans can be part of the normal flora of the gastrointestinal tract of food-producing animals without any adverse effects to the animal. Milk, eggs, seafood, poultry, and meat from food-producing animals may become contaminated due to contaminated feed, misuse of veterinary drugs, or poor farming practices, including production and harvesting activities, or disposal of solid waste on land. Foods may become contaminated during processing due to malfunctioning or improperly sanitized equipment; misuse of cleaning materials; rodent and insect infestations; and improper storage. Foods may become contaminated in retail facilities and in the home through use of poor food handling practices.

Although many hazards threaten the safety of our food, certain foodborne hazards are of particular public health concern, and would be targeted for immediate attention by this initiative. Studies have shown that the following microbial pathogens are the predominant foodborne pathogens. They are: *Salmonella* species, *Campylobacter jejuni/coli*, *Escherichia coli* O157:H7 and other related strains; the parasites *Toxoplasma gondii* and *Cryptosporidium parvum*; and the Norwalk virus.

The microbial pathogens listed above, and discussed in greater detail below, may give rise to diseases that are far more serious than the uncomfortable but relatively temporary inconvenience of diarrhea and vomiting, which are the most common symptoms of so-called "food poisoning." Foodborne infections can result in very serious immediate consequences, such as spontaneous abortion, as well as long-lasting conditions such as reactive arthritis, Guillain-Barré syndrome (the most common cause of acute paralysis in adults and children), and hemolytic uremic syndrome (HUS), which can lead to kidney failure and death, particularly in young children. The microbial pathogens described below are not listed in order of importance or severity.

Salmonella

Salmonella species cause diarrhea and systemic infections, which can be fatal in particularly susceptible persons, such as the immuno-compromised, the very young, and the elderly. An estimated 800,000 to 4 million infections occur each year in the United States, most of them as individual cases apparently unrelated to outbreaks. Animals used for food production are common carriers of salmonellae, which may subsequently contaminate foods such as meat, dairy products, and eggs. Foods often implicated in outbreaks include poultry and poultry products, meat and meat products, dairy products, egg products, seafood, and fresh produce. Between 128,000 and 640,000 of these infections are associated with *Salmonella enteritidis* (SE) in eggs. Over the past decade, more than 500 outbreaks have been attributed to SE with over 70 deaths. In 1994, an estimated 224,000 people became ill from consuming ice cream in one outbreak alone.

Campylobacter

The bacterium, *Campylobacter*, is the most frequently identified cause of acute infectious diarrhea in developed countries and is the most commonly isolated bacterial intestinal pathogen in the United States. It has been estimated that between 170,000 and 2.1 million cases of campylobacteriosis occur each year with an associated 120-360 deaths. *Campylobacter jejuni* and *Campylobacter coli* (2 closely related species) are commonly foodborne, and are the infectious agents most frequently described in association with Guillain-Barré syndrome, perhaps as frequently as 1 in 1000 cases. Several prospective studies have implicated raw or undercooked chicken as major sources of *C. jejuni/coli* infections. Unpasteurized milk and untreated water have also caused outbreaks of disease.

***Escherichia coli* O157:H7**

Several strains of the bacterium *E. coli* cause a variety of diseases in humans and animals. *E. coli* O157:H7 is a type associated with a particularly severe form of human disease. *E. coli* O157:H7 causes hemorrhagic colitis, which begins with watery diarrhea and severe abdominal pain and rapidly progresses to passage of bloody stools, and has been associated with HUS. HUS is a life-threatening complication of hemorrhagic colitis characterized by acute kidney failure, and is particularly serious in young children. *E. coli* O157:H7 has its reservoir in cattle, but the dynamics of *E. coli* O157:H7 in food-producing animals are not well understood. It has been estimated that approximately 25,000 cases of foodborne illness can be attributed to *E. coli* O157:H7 each year with an estimated 6 deaths. *E. coli* O157:H7 outbreaks have recently been associated with ground beef, raw milk, lettuce, and minimally processed and fresh fruit juices. The most recent outbreak, in the Fall of 1996 in 3 western states and British Columbia, was associated with unpasteurized apple juice and sickened 66 people and caused the death of one child.

Toxoplasma gondii

T. gondii is a parasitic protozoan. It has been estimated that 1.4 million cases of toxoplasmosis occur annually with an associated 310 deaths. Otherwise healthy adults who become infected usually have no symptoms, but may get diarrhea. Pregnant women who become infected during pregnancy may pass the disease to their fetuses. In infants infected before birth, fatal results are common. Should the infant survive, the effects of infection are typically severe. The disease can also be serious in persons with weakened immune systems and often is fatal to people with HIV/AIDS. *T. gondii* has been found in virtually all food animals. The two primary ways that humans become infected are consumption of raw or undercooked meat containing *T. gondii* or contact with cats that shed cysts in their feces during acute infection. Under some conditions, the consumption of unwashed fruits and vegetables may contribute to these infections.

Cryptosporidium parvum

C. parvum is a parasitic protozoan. The most common consequence of infection in otherwise healthy people is profuse watery diarrhea lasting up to several weeks. Children are particularly susceptible. Cryptosporidiosis can be life-threatening among persons with weakened immune systems. The largest recorded outbreak of cryptosporidiosis was a waterborne outbreak that occurred in Milwaukee, Wisconsin in 1993, affecting over 400,000 people. More recently, a waterborne outbreak in Las Vegas resulted in at least 20 deaths attributed to *Cryptosporidium*. The first large outbreak of cryptosporidiosis from a contaminated food occurred in 1993. This outbreak was attributed to fresh-pressed apple cider. *Cryptosporidium* is found in feces of infected mammals and has been transmitted through contaminated water and food.

Norwalk virus

Norwalk viruses are important causes of sporadic and epidemic gastrointestinal disease, that involve overwhelming, dehydrating diarrhea. An estimated 181,000 cases occur annually with no known associated deaths. In January 1995, a multi-state outbreak of viral gastroenteritis due to Norwalk virus was associated with the consumption of oysters. A 1993 Louisiana outbreak of Norwalk virus gastroenteritis, involved seventy ill people and was associated with the consumption of raw oysters. In 1992, another outbreak occurred which included 250 cases. Outbreaks of Norwalk virus intestinal disease have been linked to contaminated water and ice, salads, frosting, shellfish and person-to-person contact, although the most common food source is shellfish. Several such outbreaks are believed to have been caused by oysters contaminated by sewage dumped overboard by oyster harvesters and recreational boaters.

THE CURRENT SYSTEM FOR PROTECTING FOOD

Ensuring the safety of food is one of the core functions of government. It is carried out by a system that, while generally successful in protecting the public, can be confusing for its complexity and diversity. Authority is divided among federal, state, and local governments; and the private sector also plays an important role. From the farm to the consumer's dinner table, the responsibilities can be summarized as:

- On the farm, food is regulated by state agencies supported principally by the EPA, which acts to ensure that pesticides are approved for safe use, by the FDA, which oversees use of drugs and feed in milk- and food-producing animals, and by APHIS, which is concerned with food-animal disease control. Federal responsibility also covers production and harvesting activities that discharge wastewater to surface and ground waters, and solid waste to land, all of which could contaminate growing and process waters or grazing land.
- Food processing for foods other than meat, poultry, and egg products (except shell eggs) is regulated by the FDA, whose inspectors are responsible for visiting about 53,000 plants periodically, with emphasis on the highest risk foods or processing techniques. FDA has fewer than 700 inspectors and analysts devoted to this activity. Meat, poultry, and all other egg products are regulated by FSIS, whose 8,000 inspectors are present in 6,500 slaughter and processing establishments to ensure that these products are safe, wholesome, and properly labeled. State and local governments also inspect food processors, with varying frequencies and under varying standards.
- Food being transported in interstate commerce is subject to federal and state regulation, although that area has received little attention in the past. USDA's FSIS and HHS's FDA have jointly published an Advanced Notice of Proposed Rulemaking (ANPR) on whether

regulations are needed to govern the handling of meat, poultry, seafood, eggs, and other foods susceptible to harmful bacteria during transportation.

- The importation of food from foreign countries is overseen by FSIS for meat, poultry, and most egg products and FDA for all other foods. If an imported food is suspect, it can be tested for contamination and its entry into the United States denied.
- Restaurants, supermarkets, and institutional food services (such as schools and hospitals) are generally regulated by states and local health authorities, and FDA publishes the *Food Code*, which consists of model recommendations for safeguarding public health when food is offered to the consumer. Recommendations are developed by consensus of state government representatives at the Conference for Food Protection. FSIS and FDA are working with states to update the *Food Code* in light of the changing retail and food service environment and emerging food safety issues, especially with regard to meat, poultry, egg products, and seafood. The Conference for Food Protection serves as one forum for fostering cooperation among federal, state and local governments in the oversight of food products and the conditions under which they are produced, processed, transported, stored, and handled through retail sale or food service to the consumer.
- National standards for drinking water are set by EPA, and enforced generally by local public water authorities; FDA establishes complementary standards for bottled water.
- Surveillance of foodborne illness is primarily the responsibility of state and local health departments and the CDC, which seek to identify cases of illness, determine their source, and control outbreaks. FDA or FSIS are called in when a link to a regulated food is suspected.
- In the home, consumers also have a responsibility for proper handling and storage of food, as consumer mishandling contributes to many cases of foodborne illness. As a result of this knowledge, FSIS promulgated safe handling labels for raw meat and poultry products.
- Other responsibilities related to food safety include research into the cause and transmission of foodborne illness, and education on treatment and prevention of foodborne illness. These responsibilities are carried out by the USDA, FDA, CDC, EPA, the National Institutes of Health, other federal components, and the states. Basic biomedical research on pathogenic organisms is conducted at the National Institutes of Health. The federal government also supports related research in universities. The private sector supports research within its own laboratories and in universities.

THE FOOD SAFETY SYSTEM MUST BE PREPARED FOR THE 21ST CENTURY

The system for identifying and preventing foodborne illnesses described above was largely created in the early years of this century. It must be modernized. The current system is inadequate to properly identify, track, and prevent food-related illness and to prevent future cases from occurring. State and federal resources are not closely coordinated and duplication of effort is not uncommon. In 1981, FDA inspected food firms every 2-3 years, but can now visit those plants, on average, only once every 10 years. Our understanding of some disease causing organisms is so limited that our ability to protect the public health is seriously constrained. Food processors, restaurateurs, supermarket managers, and consumers often don't understand the threat from foodborne pathogens and the methods available to prevent and control them.

IMMEDIATE ACTIONS TO IMPROVE FOOD SAFETY

There are many causes of foodborne illness, many points at which foods can become contaminated, and numerous factors that make some groups of people more susceptible than others. Needless to say, no single preventive measure will ensure the safety of all foods. However, a number of practical preventive steps can be taken immediately to reduce the incidence of many foodborne infections.

Any initiative designed to improve the safety of the food supply should focus on the hazards and foods that present the greatest risks to public health, should emphasize development and implementation of preventive controls of those risks, and should seek opportunities for such controls through a collaborative process with the responsible sectors of the food industry and all other stakeholders. This prevention-control concept is HACCP, a science-based, state-of-the-art process for building safety into the production, handling and storage of food. HACCP is being implemented by the meat, poultry, and seafood industries with FSIS and FDA regulatory oversight. The application of such preventive controls to other types of food may be important to protecting food in the years to come.

Under this initiative, the federal government, in concert with state and local governments would conduct research and risk assessments to determine how foodborne illnesses occur and can be prevented or controlled; improve surveillance and investigative efforts to locate and monitor illnesses caused by food; achieve more effective and efficient monitoring of the safety of the food supply through inspections of food processors; and reinvigorate education of all those involved in food preparation focussing on the use of safe practices. These issues, and our current thinking about them, are described below.

A NEW “EARLY WARNING SYSTEM” FOR PUBLIC HEALTH SURVEILLANCE

Background

The primary goal of the American system of public health is to prevent disease before it occurs. While prevention of all disease may not be possible, stopping outbreaks of foodborne illness before they affect large numbers of people is a major goal. America needs a more effective early warning system that can catch outbreaks early, preventing illness and death. Such a system will also advance our understanding of foodborne illness and further our prevention efforts. In his January 25 radio address, the President announced a new national early warning system for foodborne illness that he is funding in his FY98 budget.

Preliminary Problem Identification

Surveillance and investigation of foodborne disease are powerful tools to detect new foodborne disease challenges, to determine what the specific food sources are, and to learn how best to keep the foods from becoming contaminated in the first place. Rapid detection of outbreaks is critical to stopping them before they affect many people. A key element in an early warning system is the ability to detect, compare, and communicate unusual patterns of illness and laboratory findings within and among states and among federal partners. Enhancing the capacity of states to monitor foodborne disease and to investigate and control outbreaks will lead to better general control measures and fewer illnesses. One way to achieve this is to expand the existing Active Foodborne Disease Surveillance Network (sentinel sites) to identify, investigate and control a broad spectrum of foodborne diseases. A second important way to enhance early warning is to increase the capacity of many states to deal with new foodborne challenges. These enhancements will help us identify outbreaks and other foodborne disease challenges early, and prevent illness and deaths.

Current Thinking

The federal government in cooperation with state and local health departments is proposing to take the following steps to establish a new national early warning system for, and enhance surveillance of, foodborne disease. These changes will result in an improved system for detecting and reporting foodborne illnesses and outbreaks that will enable public health agencies to rapidly put into place measures to control the spread of foodborne disease. This system will also collect critical data to recognize trends and target prevention strategies, including HACCP systems, and to evaluate the effectiveness and efficiency of prevention strategies already in place.

1) Enhance and expand the Active Foodborne Disease Surveillance Program

CDC, FDA, and USDA currently support five food sentinel sites at state health departments to

track cases of foodborne infections and to determine the sources of the most common ones. The existing sites should be strengthened, and the number of "enhanced" sites should be increased to 7 in FY 97, and to at least 8 in the following year. The sites and federal food safety agencies should be electronically linked together to create a powerful new network to detect, respond to, and prevent outbreaks of foodborne illness. Adding additional states will improve geographic and demographic representation, making this network more likely to detect diseases and outbreaks that are regional rather than national in distribution.

2) Enhance early detection of foodborne disease nationwide

In addition to establishing enhanced food sentinel sites, an early warning system would require improved early detection of foodborne disease in additional states in FY 98 by providing resources for improved surveillance, investigation, control, and prevention of foodborne disease outbreaks. While sophisticated laboratory studies can identify causes of illness and show relationships among bacteria, laboratory methods are insufficient without investigators who can collect samples, interview people, and trace the source of contamination to find out why the illness occurred. New electronic tools need to be developed to enable rapid detection of outbreaks, and to enhance communication about outbreaks to appropriate agencies. CDC also should provide additional resources to states to increase their surveillance and response capacity for the serious long-term consequences of foodborne disease, such as hemolytic uremic syndrome.

3) Modernize public health laboratories

CDC should provide resources and training to upgrade public health laboratory capabilities in the Active Surveillance sites and in other states so that they can rapidly identify a broad range of foodborne infections including new parasitic and viral pathogens, and can use new techniques of DNA "fingerprinting." CDC would work with states to develop, standardize, and transfer those methods. These new capacities would allow rapid identification of the cause of some outbreaks that currently go undiagnosed.

4) Create a national electronic network for "fingerprint" comparison

CDC should fund a new computer network and database system that would capture bacterial "fingerprints" in a national database, linking CDC, FDA, USDA, and states that have this new capacity as well as the federal laboratories into a new national network. This technology would, for example, permit rapid recognition that an *E. coli* O157:H7 bacterium cultured from a patient in Washington was indistinguishable from one isolated from another patient in California, which would suggest to public health investigators that a product distributed in both California and Washington may be contaminated with the organism.

In addition to identifying, investigating, and reporting cases of foodborne disease in humans, surveillance of contamination levels in foods, in animals used for food, and in their feed is important to control and prevent foodborne diseases, and to monitor the measures that reduce the risk of exposure. Therefore, to make the "early warning system" fully operational, and to translate its findings into long-term improvements in the safety of the food supply, additional surveillance activities would be required.

5) **Increase national surveillance for antimicrobial resistance of foodborne pathogens**

CDC should expand surveillance for antimicrobial resistance in *Campylobacter*, *Salmonella*, and *E. coli* O157:H7 isolated in humans, and FDA and USDA should take similar steps for bacterial samples from food-producing animals and food products, in a way that permits these data to be compared. CDC, FDA and USDA should develop standard procedures for sharing necessary information, and for responding to increases in resistance, or other "red flag events" such as the discovery of an important new resistant bacterium.

6) **Enhance oversight of animal feeds and feedstuffs for the impact of drugs and other therapies in food animal populations and pathogens**

FDA may consider increasing monitoring of animal feed processing to determine the nature and extent of pathogen contamination and the impact of control strategies on pathogen reduction in animals.

COORDINATION

Background

At the federal level, there are four agencies charged with responding to outbreaks of foodborne illness (including waterborne illness): FDA and CDC at HHS, FSIS at USDA, and EPA. While CDC's primary responsibility is to work with state and local health departments to identify and investigate sporadic cases and outbreaks of illness, FDA, FSIS, and EPA have the additional responsibility of taking regulatory action against the suspect products, or those who contaminate the air, land, or waters used to produce the food product. Which regulatory agency gets involved depends on the type of food involved, with FSIS having primary jurisdiction over meat, poultry, and egg products, FDA over all other foods including shell eggs and EPA over water and pesticides. While each agency has clearly defined areas of responsibility, most outbreaks of foodborne illness involve more than one agency.

In addition, investigations of foodborne illness usually begin at the community or state level. These illnesses may cross jurisdictional boundaries and may be linked to foods or food ingredients that were processed or produced in another state or by international trading partners, necessitating the involvement of federal agencies. Federal involvement is also necessary when contaminated foods from the same sources may be in grocery stores, restaurants, and homes in other parts of the country. Companies responsible for affected products also have a critical role to play as many product recalls are voluntary.

In most outbreaks of foodborne illness, federal agencies work with state and local health authorities in their investigations and implementation of control measures through consultation, diagnostic assistance, and recommendations for control measures. In some instances on-site assistance is requested by the local and state authorities. For large or multi-state outbreaks, federal agencies play a critical coordination role to assure consistency of approach and implementation of needed control measures.

Preliminary Problem Identification

Although significant coordination already occurs among the federal and state agencies, the mere fact that more than one agency is involved in any one outbreak of foodborne illness can cause some confusion. Many times a joint effort is hindered by a lack of communication or a misunderstanding of each agency's role in a particular situation.

Current Thinking

Improved coordination among the federal agencies, between federal and state agencies, and

among the various state agencies would enhance the level of public health protection, make the best use of interagency collaboration, and avoid duplication of effort.

1) Improve federal/state coordination in the management of response to foodborne illness

A Foodborne Outbreak Response Coordinating Group made up of representatives of the federal and state agencies charged with responding to outbreaks of foodborne illness should be created to coordinate the investigation and response to significant outbreaks of foodborne illness. The overall goal of this group should be to ensure that a coordinated and professional response, with all governmental resources pulling together, is undertaken to effectively investigate and respond to foodborne illness. The group should determine jointly each agency's responsibilities during the various phases of outbreak investigations, and who would play the role of spokesperson for each phase or component of an outbreak. In addition, the group should coordinate communications and decisions about appropriate actions during outbreaks and appropriate follow-up to prevent similar outbreaks. The coordinating group should also meet several times a year to review its work and the response to outbreaks.

Each participating agency could fund and enhance programs that provide opportunities to exchange employees, on a temporary basis, among federal agencies and between federal and state agencies. Such an exchange would facilitate coordination by sharing expertise and providing an opportunity to better understand the various roles each agency plays in an investigation of a foodborne illness.

2) Improve federal/state coordination in the management and response to foodborne illness

Better coordination between federal and state agencies and among the various state agencies would speed the identification and subsequent control of foodborne illness and the removal of the contaminated foods from the distribution chain.

In order to improve coordination, the federal agencies can sponsor a national meeting with state and local officials to develop recommendations on how to better coordinate the overall government response to foodborne illness.

For example, one specific issue that is discussed in FDA's FY98 budget is the occurrence of *Salmonella enteritidis* in layer hens and improved monitoring of the hens and liquid bulk egg products (before pasteurization) for contamination. The federal agencies should work to establish a federal/state cooperative program to solve this problem.

3) **Enhance the basic infrastructure for foodborne illness surveillance and coordination at state health departments**

The epidemiology offices and laboratories within state health departments are charged with the surveillance of infectious and non-infectious conditions, and, along with other state officials, with the investigation of outbreaks. They collect surveillance data from physicians, laboratories, local health departments and other sources. Yet, the resources available in many states for the surveillance and investigation of foodborne diseases are limited and decreasing, thereby limiting the states' effectiveness. As a result, outbreaks may go undetected or are never investigated.

This problem could be rectified by making sure that, given an assessment and cataloguing of available state resources, states are provided support for foodborne disease surveillance programs and assistance to better investigate outbreaks of foodborne illness.

RISK ASSESSMENT

Background

It is a basic public health tenet that public resources devoted to reducing risks should be in proportion to the toll they take on human health. Risk assessment is the tool best suited to set priorities among public health risks. Furthermore, risk assessment is a requirement for any science-based system of preventive controls. Indeed, risk assessments and evaluations of alternative risk management strategies are often carried out for major federal regulations. Pursuant to the USDA's Reorganization Act of 1994, USDA is required to conduct risk analyses for all major regulations. Such evaluations ensure that risk reduction strategies are cost effective and promote the maximum net benefit to society of efforts to reduce foodborne illness. Sound risk assessments, including bacterial, parasitic, and viral food contaminants, are also critical to World Trade Organization treaty negotiations, which require that U.S. food safety standards be based on scientifically valid measures derived through risk assessment.

Preliminary Problem Identification

Risk assessment's objective is to characterize the nature and size of the risk to human health associated with hazards, and to make clear the degree of scientific certainty of the data and the assumptions used to develop the estimates. Risk assessments require a substantial amount of specific information on the hazard and on the exposed population to provide meaningful information for those making risk management decisions. Even for chemical hazards, for which risk assessment methods have been most thoroughly developed, data gaps force the use of assumptions about exposure, hazard potency, and characteristics of the population at risk, and mathematical "models" of chemical action or of the way that the body deals with a chemical.

Risk assessment is far less developed for foodborne pathogens. Intensive commitment is necessary to develop critically needed data such as pathogen behavior in numerous foods under hundreds of conditions, and information about especially sensitive populations, such as children.

Current Thinking

This initiative's risk assessment activities would focus on developing better use of data and better models to inform surveillance plans, HACCP-based prevention strategies for process control systems and for food inspections, and research programs to fill critical food safety information gaps.

1) Establish a risk assessment consortium

All federal agencies with risk management responsibilities should establish jointly a new

consortium at which federal agencies can set collective priorities for risk assessment research and collective priorities and strategies for the further development and implementation of risk assessment and risk management. The consortium should be established at the Joint Institute for Food Safety and Applied Nutrition, a collaborative activity of FDA's Center for Food Safety and Applied Nutrition and the University of Maryland.

The consortium should focus federal research on developing data for risk assessments, focused and applied specifically to address the scientific, risk-based goal of preventive control that is the central principle of this food safety initiative.

Research supported and conducted through this initiative should cover several areas critical to developing our ability to conduct risk assessments for foodborne disease-causing organisms and to assess the effectiveness of control measures. Data and methods developed in response to the Safe Drinking Water Act Amendments of 1996, for example, will be relevant to food safety evaluations.

2) Develop better data and modeling techniques to assess exposure to microbial and chemical contaminants, including animal drug residues, through the food supply

Risk assessment of foodborne illness is dependent on accurately estimating the quantity of a toxin or pathogen ingested by the consumer (i.e., exposure assessment). This initiative would address the numerous data and modeling deficiencies in estimating exposure to microbial and chemical contaminants. Specifically, research should be conducted in: incidence and prevalence of microbial pathogens and chemical hazards in food; typical behaviors of commercial and home preparation operations; validation of dynamic exposure assessment models; intake data regarding food consumption patterns of the general population and sensitive subpopulations; and specific data on food vehicles of sporadic and epidemic disease. Research using biomarkers should be pursued. Biomarkers are surrogates that indicate that exposure has occurred or that some effect has occurred, particularly when actual evidence of exposure and effect are difficult or impossible to obtain.

3) Develop dose-response assessment models for use in risk assessment

Research is needed to estimate the relationship between the quantity of a biological agent and the frequency and magnitude of adverse human health effects in a population. Dose-response assessments typically include estimates of the rates of infection, morbidity, and mortality. For bacterial hazards, the World Health Organization's Expert Consultation on the Application of Risk Analysis to Food Standards Issues (FAO/WHO, March 1995) refers to these steps as "hazard characterization."

BIOSCIENCE RESEARCH

Background

Currently, one of the most critical needs in food safety research is for techniques to more rapidly and accurately identify and characterize foodborne hazards. FDA, CDC, EPA, and the USDA's Research, Education, and Economics agencies (the Agricultural Research Service, the Cooperative State Research, Education, and Extension Service) conduct research related to pathogenic microorganisms and other contaminants that threaten the safety of food.

Preliminary Problem Identification

New pathogens, some of them foodborne, have emerged over the last 10 years. Many of these organisms can not be easily detected, or detected at all in foods. Other microorganisms, previously thought to be innocuous, have emerged as more virulent. Just because organisms are present at levels that can not be easily detected, however, does not mean that the organisms can not cause human illness. Newly recognized pathogens are causing serious disease outbreaks. Foodborne pathogens are increasingly overcoming time-tested controls, such as heating and refrigeration, and are developing new virulence and new ways to evade our immune defenses.

Current Thinking

Effective control of foodborne pathogens requires that prevention be targeted at high-risk foods and at high-risk points in their production and distribution. These interventions ideally are guided by risk assessment, for which all too often we have insufficient data. Research is needed to support HACCP implementation, to enable verification that critical control points in HACCP systems are working, and to target the data gaps that hamper risk assessment. Among the data gaps and information needs identified here are numerous opportunities for collaboration and resource leveraging among federal agencies, the private sector, and universities.

1) Improved detection methods

As stated above, many foodborne pathogens cannot be easily detected, or detected at all in foods. Methods need to be developed, validated, and implemented for rapid testing of very low levels of *Campylobacter*, *Salmonella*, *Toxoplasma*, *Vibrio*, *E. coli* O157:H7, *Cyclospora*, *Cryptosporidium*, Norwalk virus and naturally occurring toxins in food animals, in agricultural and aquaculture products, animal feeds, and processed food products. Some research efforts may initially focus on *Campylobacter*, because those foodborne infections are so prevalent and may lead to chronic diseases (Guillain-Barré syndrome); also methods to isolate and identify this pathogen are time-consuming and expensive. Research could be coordinated with EPA's efforts to develop better test methods and assessments of health effects from *Cryptosporidium* and other

contaminants in drinking water. Improved methods are needed for identifying foodborne pathogens, including emerging pathogens, in clinical specimens and to subtype known foodborne pathogens.

2) Understanding antimicrobial resistance

Microorganisms can become resistant to antimicrobial agents and conditions that have been traditionally relied on to eliminate or prevent the growth of foodborne pathogens, but have become insufficient to prevent breakthrough of newly emerging pathogens. Research is needed to determine how microorganisms associated with foodborne disease become tolerant to various types of antimicrobials and to traditional food safety safeguards such as heat or cold, low pH, high salt, and disinfectants and to elucidate factors in animal and plant production systems and processing environments that influence the development of resistance. This research will lead to the identification of food production and processing practices that are likely to permit pathogen contamination or proliferation and will provide guidance in the modification of traditional techniques or the development of new techniques to prevent or control pathogen growth.

3) Understanding antibiotic drug resistance

Pathogens in food-producing animals may become resistant to drugs partially due to improper use of the drugs, particularly antibiotic drugs, in those animals. One possible way to deal with this problem might be to adjust the required period of drug withdrawal prior to slaughter. For example, studies should be conducted to explore possible changes to "withdrawal time" requirements that could reduce transfer of resistant pathogens with minimal disruption to industry production practices. In addition, industry in collaboration with federal agencies could determine the basis for the ability of microorganisms to rapidly adapt to changing environments and, together, develop animal production and treatment mechanisms to minimize this adaptive ability.

4) Prevention techniques: Pathogen control, reduction, and elimination

Contaminants are introduced into the food supply at numerous points along the way from farm to store. Food animals may carry pathogens, but remain healthy themselves, complicating controls at the point of slaughter. Animal feed and drinking water can be "hidden" but significant sources of contamination. Possible research recommendations to address these problems for *Salmonella*, *Campylobacter*, *Toxoplasma*, *Vibrio*, *E. coli* O157:H7, *Cyclospora*, *Cryptosporidium*, and Norwalk virus in all food products are the following (to be carried out in conjunction with universities and the private sector):

- Develop drugs and other therapies to prevent initial colonization.

- Develop new methods to reduce or eliminate contaminants from animals and plants before slaughter or harvest.
- Develop new disinfection methods and equipment and systems modifications for processing and production plants, and wholesale and retail outlets.
- Develop new methods of surface decontamination of fresh fruits, vegetables, meat, poultry.
- Develop heat-based and/or other disinfection methods for seafood, meat, eggs, produce, and animal feeds.

5) **Food handling, distribution, and storage**

Food production and processing often occur thousands of miles apart. Transportation systems for live animals, fresh produce, and packaged foods offer many opportunities for contamination, such as heat, cold, and other stresses that make animals and plants more susceptible to infection, and cross-contamination from the vehicle itself. Possible research recommendations include the following:

- Investigate immune system "biomarkers" of stress that might indicate predisposition to infection during transport.
- Develop in- or on-package sensors of storage conditions to alert consumers of products not stored safely.

INSPECTIONS

Background

Inspection of commercial food processors is an integral part of the food safety assurance system. Inspections are carried out by federal, state and local authorities, with state and local officials focusing primarily on restaurants, supermarkets and other retail establishments. At the federal level, consistent with legal mandates, FSIS has carcass-by-carcass inspection in meat, poultry, and slaughter plants while they are operating, and continuous inspection in meat, poultry, and egg-product processing plants--in all, about 8,000 inspectors for 6,500 domestic plants and for all imported meat, poultry, and egg products. FDA does periodic, random inspections of all other food processing plants--less than 700 inspectors and analysts for 53,000 U.S. plants and for all other imported foods.

Preliminary Problem Identification

At FDA, the number of inspections has decreased steadily since 1981, when 21,000 inspections were conducted, so that today resources exist to carry out only about 5,000 inspections per year. The result is that an FDA-regulated plant gets inspected by FDA, on the average, only once every 10 years. FDA also relies upon the states to conduct some inspections under contract, but that number has dropped from 12,000 in 1985 to 5,000 now. Moreover, the inspectional coverage of imported foods has dropped as well, as the same number of import inspectors are now inspecting almost twice as many imports as just five years ago. Certainly FDA is finding greater problems, e.g., the number of products recalled for life-threatening microbial contamination has increased almost 5-fold since 1988 and inspectors are finding more hazardous conditions in the plants they inspect. FSIS is faced with a similar challenge of continually providing the most effective inspection program with limited resources and growing threats to food safety.

Current Thinking

Scientists and other food safety experts have concluded that the most effective and efficient mechanism for assuring that food processors identify and control hazards that could threaten food is the application of the HACCP concept of built-in preventive controls. FDA has begun to implement HACCP for the seafood industry, and FSIS for the meat and poultry industries; FSIS intends to publish an ANPR requesting comments on HACCP systems for egg processing plants, and FDA plans to work with the food industry, as it has in a pilot program over the last 2 years. To ensure that HACCP is properly implemented, and to ensure more efficient and effective monitoring of the safety of the food supply, the following preliminary recommendations are being made.

1) Enhance development of HACCP procedures

FDA is considering whether and how to implement HACCP throughout the non-meat/poultry food industry for all appropriate food commodities. It is recognized that staged implementation, by commodity, might be necessary because of resource limitations. To ensure that HACCP is being properly implemented, FDA should conduct inspections and provide necessary training and outreach activities. FSIS will continue development of a HACCP-based inspection system. FSIS plans to conduct a public meeting and then subsequent field trials to gather data to support future decisions on designing new inspection procedures in a HACCP environment.

2) Upgrade FDA's food inspection program

FDA has included implementation of seafood HACCP in its FY98 budget request. If HACCP is to be an effective program for ensuring that food processors have modern, state-of-the-art food safety procedures in effect, FDA must improve its inspection capabilities, so that the highest risk food plants (such as seafood) are inspected at least once per year. To maximize the joint federal/state role in inspections, development of new partnerships with the states may be considered, that focus on coordinating the inspection coverage and preventing duplication of effort.

FSIS and FDA may consider expanding and re-focussing existing cooperative agreements under which plants producing both meat and non-meat foods are inspected solely by FSIS inspectors, who have been trained in FDA inspectional standards. FSIS inspectors are already in these plants; their presence could be better utilized to maximize use of federal resources.

FSIS and FDA are considering whether and how to regulate the transportation of meat, poultry, seafood, eggs and other foods in order to safeguard the public from pathogenic microorganisms, as reflected in the ANPR published on November 22, 1996.

3) Enhance federal/state inspection partnerships

Additional federal/state partnerships can ensure improved coordination between the federal food safety agencies and state regulators for the training of state inspectors in federal food safety standards, as well as provide the states with equipment and technology for the rapid sharing of inspection results and for a national database for the monitoring of all food inspections. This information sharing would help both federal and state regulators make inspections more effective and efficient.

FDA may consider establishing a process for certifying private laboratories that would be authorized to test samples of food products for contaminants. This may embody a similar process currently being discussed by a coalition of industry, private laboratories, professional

associations, and accrediting bodies with input from federal agencies. Such private parties would provide a service to food firms wishing to demonstrate that their products meet applicable federal standards.

4) **Enhance inspectional coverage of imported food, to address the problem of rising imports and FDA's inability to provide adequate inspections of them**

FDA should develop more Mutual Recognition Agreements (MRAs) with foreign countries, under which both countries agree to inspect each other's food exporting firms under equivalent procedures for ensuring safety. Once such MRAs are in place, FDA could better focus its import inspections on foods coming from countries with the least reliable safety standards.

EDUCATION

Background

Educating people about steps they must take to prevent and control foodborne illness is a vital link in the food preparation chain. Educational efforts have already been made at the federal level. For example, FDA has a website which offers information on many food safety issues, has established a 24-hour seafood hotline, and has published brochures on such topics as food safety advice for persons with AIDS and posters on such topics as listeria in soft cheese. USDA has taken similar steps through its Cooperative Extension network, its Meat and Poultry Hotline, and by requiring safe handling instruction labels for meat and poultry products.

Preliminary Problem Identification

Despite these efforts, and the work that states, consumer groups and the food industry have done in this area, foodborne illness still occurs from a lack of knowledge of the risks involved at all stages of food preparation. For instance, choices consumers make about how they handle food prepared at home and whether they eat food that increases the risk of foodborne illness can have a significant impact on the incidence of foodborne illness. Studies show, for example, that 53% of the public eat food with raw eggs, 23% eat undercooked hamburger, 17% eat raw clams and oysters, and 26% do not wash their cutting boards after using them for raw meat or poultry.

Foodborne illnesses have also been traced to commercial food establishments. For example, many food establishments do not know that the pooling and undercooking of eggs can increase the risk of *Salmonella enteritidis*. Currently, a much higher percentage of those who receive their food in an institutional environment are victimized by the more serious consequences of foodborne illness. For example, during 1988 to 1992, *Salmonella* caused 69% of the 796 bacterial foodborne disease outbreaks; 60% of these *Salmonella* outbreaks were caused by *S. enteritidis*. *S. enteritidis* also resulted in more deaths than any other pathogen with 85% of these deaths occurring among residents of nursing homes.

Producers of animals used in human foods production and veterinarians treating such animals also need education in food safety practice. Drugs used to treat these animals are not always used appropriately, and can be purchased over the counter by non-veterinarians and mis-used, resulting in harmful residues in meat and milk, decreased effectiveness of these drugs, and increased antimicrobial resistance.

Finally, those responsible for the transportation of food are often unaware of unsafe practices that result in the contamination and mishandling of food during shipment.

Current Thinking

Understanding and practicing proper food handling procedures from farm to table would significantly reduce foodborne illness.

1) Improve consumer education

An alliance including industry and consumer groups should mount a comprehensive food safety awareness campaign for consumers, highly focused on messages and tactics targeted to the general public and to special populations such as high-risk consumers. The campaign should be centered around an easily recognized symbol or catch phrase and should include a national print and broadcast media campaign and incorporate food safety messages into school curricula. An emphasis should be placed on multilingual activities to ensure the widest coverage.

Innovative methods for sharing information related to food handling behaviors should be developed in order to reach larger audiences. As part of this effort, a National Food Safety Education Alliance of industry, consumer, trade, state and local food protection agencies, and academic organizations focused on changing unsafe food handling practices should be convened. Research should be conducted to determine effective methods of providing information and evaluation of educational programs. A national clearinghouse should be established to provide consumers and food safety educators with food safety information.

2) Improve retail, food service, and institutional education

A highly focused campaign should be developed to change food workers' unsafe food preparation behaviors. A multilingual approach should be developed. An alliance of federal, state, and local health agencies, as well as private parties, should be formed to develop education efforts on food safety issues. Activities of the alliance should include educating retail food service workers about the safe handling perishable food product provisions in the 1997 *Food Code*.

In addition, guidelines should be developed by USDA and the states for retail and food service operations which process meat and poultry products to train state level inspectors to identify hazards at the retail level. Efforts should also be undertaken to educate the retail, food service and institutional industries in order to increase the use of HACCP principles.

3) Improve veterinary and producer education

Development and implementation of a program could be considered to educate producers of animals for human food consumption, veterinarians, state and local regulators about proper drug use and the incorporation of HACCP principles into industry quality assurance programs. The

program could entail regularly scheduled training sessions, including satellite teleconferences, educational symposia, and presentations at producer and practitioner meetings. Guidelines and educational materials could also be developed and disseminated through a national clearinghouse to food producers and the veterinary medical community.

4) Improve industry education in the transportation area

Government agencies could form an alliance to develop educational materials and train food transportation vehicle owners and operators and food processing establishments on hazards associated with the transportation of food products, particularly hazards associated with temperature controls, prior cargoes, and sanitation methods. Training and education for state and local health and transportation authorities could also be conducted so they can apply this information during inspections of food processing facilities and transportation vehicles in their jurisdiction.

A STRATEGIC PLAN FOR REDUCING FOODBORNE ILLNESS OVER THE LONG TERM

Background

The broad issues of a sustainable safe food system include, among other issues, improving the infrastructure for rapid identification and response to outbreaks, improving coordination among all food safety participants in numerous aspects of prevention and response, and developing a strategic, long-range research agenda. Stakeholders include food producers and manufacturers, consumers, academic institutions, representatives from the food service sector, including retail, restaurant, and institutional food service settings, veterinary and medical professionals, and federal, state, and local public health and agricultural officials.

Preliminary Problem Identification

Making the necessary improvements in the food safety system will not be easy. Because so many lines of authority must be crossed, so many new working relationships established, and so many fundamental changes in infrastructure made, the current system must be “reinvented.” For example, the federal government needs to develop a long-term, coordinated research agenda to truly address research needs to support a fundamentally improved food safety system, and strategies for developing such an agenda would need to be developed through such a planning process. Extensive dialogue will be required among the many stakeholders in various regions of the country to agree upon priorities, strategies for achieving change, and a process for achieving change.

Current Thinking

A significant activity proposed as part of this food safety initiative is the creation of a process that facilitates the participation of all stakeholders in discussing the issues and setting an agenda for consideration of fundamental change in the food safety system.

A contract could be established with an independent organization to bring together all major stakeholders for discussion of fundamental changes to the present food safety system. A major purpose of this strategic planning exercise would be to identify changes that should be made to the present organizational and procedural structure that would bring about permanent improvements in efficiency and coordination. Dialogue groups could be established to develop a strategic plan. Opportunities for input could include symposia held in geographically dispersed sites to encourage stakeholder participation.

Documents developed from the deliberations and recommendations of these symposia could be the focus of further discussion during a series of open meetings. The product of this series of

dialogues, symposia, and hearings could form a report, which would provide the outline necessary for targeting needed structural changes in the federal/state food safety system.

April 10, 1997 DRAFT

**FOOD SAFETY FROM FARM TO TABLE:
A NEW STRATEGY FOR THE 21st CENTURY**

NATIONAL FOOD SAFETY INITIATIVE

REPORT TO THE PRESIDENT

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EXECUTIVE SUMMARY

Ensuring the safety of the food supply is one of government's most enduring and important functions. However, the Federal, state and local governments face many challenges in maintaining and improving food safety. Indeed, disease-causing microorganisms (pathogens) threaten the public health, and in some cases the threat is growing and becoming more deadly. To address this concern, President Clinton asked the Secretaries of Agriculture and Health and Human Services and the Administrator of the Environmental Protection Agency to prepare a comprehensive report on the food safety and to make recommendations for improving the safety of the American food supply. To prepare this report, the three departments carried out an intensive dialogue with the many stakeholders in food safety, including food producers and processors, consumers, states, and academia.

This report outlines new, and in some cases innovative, ways of doing things, to get the diverse talents and resources in the Federal government pulling together--in partnership with State and local health officials, the food industry, academic scientists, and consumer groups--to identify and act against

threats to the safety of the food supply. The report identifies specific steps that should be taken that will begin to reduce food-related disease in the coming months, as well as build a foundation for improved food safety for years to come.

The problem is evident. Every day, thousands of Americans are stricken by illness caused by the food they consume, and up to 9,000 a year--mostly the very young and elderly--die as a result. The threats from food are numerous and varied, ranging from *Escherichia coli* (*E. coli*) 0157:H7 in meat and apple juice, to *Salmonella* in eggs, to *Cyclospora* on fruit, to *Cryptosporidium* in drinking water. Our understanding of many of these pathogens is limited; for some, we do not even know how much must be present in food for there to be a risk of illness. The public health system in this country has limited means to identify and track the causes of foodborne illness; and Federal, State and local food safety agencies need to improve coordination for more efficient and effective response to outbreaks of illness. Meat and poultry plants are inspected every minute they're operated, yet years can go by before other food plants receive a Federal inspection. Increasing quantities of imported foods flow into this country daily with little scrutiny. Some food processors, restaurateurs, food service workers, supermarket managers, and consumers are ignorant of the threat of foodborne contaminants and how to protect food.

The problems identified above do not mean that the U.S. food supply is unsafe; it is one of the world's safest and most wholesome. However, more can be done, and there is enormous medical and scientific talent in the public agencies responsible for food safety. Working with the food industry, the Clinton Administration has devised a safety assurance system for the harvesting, processing, transportation, handling, and storage of food. That system, which relies upon preventing the contamination of food, must be put into place at every step of the food delivery process--from the farm to the consumer's dinner table. Known as HACCP, it represents a new paradigm that allocates responsibility between government and the private sector.

This report contains recommendations in seven areas, which are summarized below:

1) **Surveillance/ Early Warning -- Prevent occurrence or mitigate extent and severity of foodborne illness outbreaks.**

American needs a more effective early warning system that can catch outbreaks early, preventing illness and death. A key element in such a system is an ability to detect, compare and communicate unusual patterns of illness and laboratory findings within and among states and their Federal partners. Improvements to accomplish that goal include:

- Expanding and enhancing the foodborne disease active surveillance network (Foodnet), by adding new sentinel sites that collect outbreak data and strengthening

existing sites.

- Improving early detection of foodborne disease nationwide by funding state efforts to gather epidemiologic data, developing electronic capability to collect and share data on outbreaks, and creating a national electronic network for bacterial fingerprints to help identify the source and cause of outbreaks.
- 2) **Interstate Outbreak Containment and Response Coordination -- Improve overall efficiency and emergency response coordination for outbreaks.** At the Federal level, there are four agencies charged with responding to outbreaks of food- and waterborne illness: HHS's Centers for Disease Control and Food and Drug Administration, USDA's Food Safety and Inspection Service, and EPA. But the current system is characterized by lack of communication, poor data sharing, and a misunderstanding of each others' roles. Recommendations for improvement are to:
- Establish an intergovernmental group to coordinate investigations and responses to outbreaks that would ensure that outbreaks causes are identified quickly and accurately, to coordinate decisions about government response to outbreaks, and to ensure that one person speaks for all during each phase of the outbreak.
 - Enhance the basic infrastructure for foodborne illness and surveillance and coordination at State health departments.
- 3) **Risk Assessment -- Improve risk assessment tools and interagency coordination in risk assessment.** Risk assessment's objective is to characterize the nature and size of the risk to human health associated with hazards, which in turn can lead regulators to the correct decisions about controlling those hazards. Risk assessment activities should be improved by:
- Establishing a risk assessment consortium of the various agencies, to set priorities and guide Federal risk research.
 - Develop better data and modeling techniques to assess exposure to microbial contaminants in the food supply.
 - Develop ecology studies for microbes in food (rates of growth under specific conditions in food, etc.).
- 4) **Bioscience Research -- Expand research to develop new methods for identifying and controlling foodborne pathogens.** This is one of the most critical needs in food safety, as many pathogens cannot even be identified in food, and others

have developed resistance to time-tested controls such as heating and refrigeration. Research should:

- Develop rapid, cost-effective tests for the presence of pathogens such as *Salmonella*, *Cryptosporidium*, *E. Coli* 0157:H7, and Hepatitis A.
- Understand how pathogens become resistant to food preservation and antibiotics
- Develop technologies for prevention and control of pathogens.

5) **Inspections -- Improve FDA's inspectional process with more resources, expanded use of HACCP, and increased coverage of imported foods.** Although meat and poultry are inspected continuously by FSIS, and HACCP rules for those foods are being implemented, other foods, which are subject to FDA inspection, are much less frequently inspected--and inspectors are finding more problems when they do enter those facilities. For example, the number of products recalled for life-threatening contamination has increased 5-fold since 1988. The most efficient mechanism for insuring that inspections are effective is by having food processors use HACCP procedures of preventive controls. Thus, recommendations are to :

- Implement the HACCP requirements already in place for seafood by adding new seafood inspectors, and transfer the Commerce Department's seafood inspection program to FDA as a Performance Based Organization empowered to certify seafood firms as meeting HACCP requirements as part of their fee-for-service inspection and grading program.
- Expand HACCP to other foods.
- Improve coverage of imported foods via agreements with foreign countries to ensure that such foods are inspected at their source.

6) **Education -- Expand and improve food safety education for food processors, retailers, restaurateurs, food service workers, and consumers.** Everyone handling food needs to be better educated about how to safely do so, and health professionals need better training in their knowledge of foodborne disease detection and treatment. Understanding and practicing proper food handling techniques from farm to table would significantly reduce foodborne illness, and the food industry is anxious to collaborate with government on such efforts as:

- Designing food handling guidelines similar to U.S.

Dietary Guidelines.

- Developing information systems about safe food handling practices.
- Using technology to spread information, such as consolidating various governmental Internet sites.
- Training health professionals in detection and treatment.

- 7) **Strategic Planning -- Develop a strategic plan and a shared long-term agenda for an improved food safety system.** Many of above recommendations are focused on immediate actions to improve food safety. However, a long-term planning exercise is necessary to develop the knowledge base necessary to identify and attack foodborne illness over the coming decades and to identify systemic changes (including organizational, procedural, and structural changes) that would lead to lasting improvements.

A NEW INTERAGENCY STRATEGY TO PREVENT FOODBORNE DISEASE

In his radio message on January 25, 1997, President Clinton announced a new initiative to improve the safety of the nation's food supply. The President announced he will request \$43 million in his 1998 budget to fund a nationwide early warning system for foodborne illness, enhance seafood safety inspections, and expand food safety research, risk assessment, training, and education. President Clinton also directed the Secretary of Health and Human Services and of Agriculture, and the Administrator of the Environmental Protection Agency to work with consumers, producers, industry, states, universities, and the public to identify additional ways to reduce the incidence of foodborne illness and to ensure our food supply is the safest in the world. The President directed Secretaries Shalala and Glickman, and Administrator Browner to report back to him with recommendations in 90 days. He instructed them to explore opportunities for public/private partnerships to improve food safety. And he asked that their recommendations include ways to improve surveillance, inspections, research, risk assessment, education, and coordination among local, state, and federal health authorities. This report is the result of that 90-day process of deliberation and discussion among all stakeholders in the nation's food safety system, including federal, state, and local agencies, consumer groups, universities, food producers, manufacturers, distributors, representatives of the retail and restaurant sectors, and many others.

The goal of this initiative is to reduce, to the greatest extent possible, the incidence of foodborne illness. The recommendations presented in this report are based on the public health principle that society should identify and take preventive measures to reduce the risk of illness, and that it should focus its efforts on those hazards that present the greatest risks.

BACKGROUND

The American food system provides consumers with an abundant supply of convenient, economical, high-quality, and safe food products. This system is built on the enterprise and innovative capacities of those who produce and market food in the United States, and it is driven by the high expectations of American consumers for the foods they purchase for their families. Foodborne illness, however, still occurs in the United States. Over the last four years the Clinton Administration has developed and implemented major steps towards reinventing food regulation:

- In 1993, the Vice President's National Performance Review issued a blueprint for reinventing our nation's food safety system.

- The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) issued regulations that will require the meat, poultry, and seafood industries to follow Hazard Analysis and Critical Control Points (HACCP) procedures. HACCP, which calls for food industries to implement preventive measures of their own design, will streamline regulation of these foods, increase the industries' responsibility for and control of their own safety-assurance actions, and generally bring regulation of meat, poultry, and seafood in line with state-of-the-art scientific procedures.
- Beginning in 1996, the Centers for Disease Control and Prevention (CDC) embarked upon a strategic program to detect, prevent, and control emerging infectious disease threats, some of which are foodborne, and has made significant progress toward this goal in each successive year.
- The Safe Drinking Water Act of 1996 includes responsible regulatory improvements to help states and water systems prevent drinking water contamination problems. Resources are provided for the first time for drinking water infrastructure that will help hundreds of communities protect their residents from harmful contaminants.

While these advances are significant, they may not be enough. New pathogens, new food products, huge increases in imported foods, the growing importance of food exports, and increasing antimicrobial resistance among foodborne pathogens present new challenges to the nation's food safety programs. The food safety system is in need of reform, especially reform that builds on the preventive principles embodied in HACCP.

HOW THIS REPORT WAS PRODUCED

Achieving a significant reduction in the incidence of foodborne illnesses requires the cooperative efforts of public health and regulatory agencies at the federal, state, tribal and local levels, as well as all other parties responsible for and concerned about food safety and reducing the incidence of foodborne illness (i.e., consumers, industry, and academia). Partnerships -- between public agencies and industry, federal agencies and state, tribal or local agencies, public agencies and academia, to name a few possibilities -- will be invaluable in leveraging the resources focused on reducing the incidence of foodborne illness and enhancing communication.

As noted above, this report is the final product of the 90-day process of deliberation and discussion among all stakeholders that President Clinton called for in his January 25 radio address. The basis for discussion was a discussion draft that summarized the thinking of the relevant Federal agencies about a

possible structure for the food safety initiative. This draft presented the agencies' current thinking about the resources and activities needed to have a significant impact on reducing the incidence of foodborne illness. The current thinking draft was based on premise that an effective food safety initiative must have several, interrelated components which, together, have far greater impact on reducing the incidence of foodborne illness than is possible to attain with any single component. Moreover, these elements must form the groundwork for the design and implementation of strategies to meet current needs, for continually evaluating the effectiveness of ongoing activities, and for identifying and implementing strategies to meet future needs. These elements include surveillance, coordination, risk assessment, research, inspections, and education.

In order to maximize opportunities for dialogue and feed-back during the 90-day period, a number of meetings were held and written comments were received into public dockets. Several meetings of major stakeholders were held with Executive Office staff, and two major public meetings were held. The first took place on March 5, and the second on March 31 through April 2. These meetings presented opportunities for all stakeholders to comment on the preliminary recommendations as they were presented in the current thinking draft and to present additional suggestions for inclusion in the final report to President Clinton.

FOODBORNE ILLNESS: A SIGNIFICANT PUBLIC HEALTH PROBLEM

Foodborne infections remain a major public health problem. The Council for Agricultural Science and Technology, a private non-profit organization, estimated in its 1994 report, *Foodborne Pathogens: Risks and Consequences*, that as many as 9,000 deaths and 6.5 to 33 million illnesses in the United States each year are food-related. Hospitalization costs alone for these illnesses are estimated at over \$3 billion a year. Costs for lost productivity for 7 specific pathogens have been estimated to range between \$6 billion and \$9 billion. Total costs for all foodborne illnesses are likely to be much higher. These estimates do not take into account the total burden placed on society by the chronic, often life-long consequences caused by some foodborne pathogens.

Additional, important safety concerns are associated with the greater susceptibility to foodborne infections of several population groups. These include persons with lowered immunity due to HIV/AIDS, those on medications for cancer treatment or for organ transplantation, as well as pregnant women (and their fetuses), young children, and elderly persons. Patients taking antibiotics, or antacids, are also at greater risk of infection from some pathogens. Other groups who may be disproportionately affected include persons living in institutional settings, such as hospitals and nursing homes, and those with inadequate access to health care, such as homeless persons, migrant farm workers, and others of low socioeconomic status.

Sources of Foodborne Contamination

Sources of food contamination are almost as numerous and varied as the contaminants themselves. Bacteria and other infectious organisms are pervasive in the environment. *Salmonella* serotype Enteritidis enters eggs directly from the hen. Bacteria (occasionally pathogenic) inhabit the surfaces of fruits and vegetables in the field. Molds and their toxic byproducts can develop in grains during unusually wet or dry growing seasons, damage and stress during harvesting, or during improper storage. Seafood may become contaminated from agricultural and other runoff, as well as by sewage, microorganisms, and toxins present in marine environments. Many organisms that cause foodborne illness in humans can be part of the normal flora of the gastrointestinal tract of food-producing animals without any adverse effects to the animal. Milk, eggs, seafood, poultry, and meat from food-producing animals may become contaminated due to contaminated feed, misuse of veterinary drugs, or poor farming practices, including production and harvesting activities, or disposal of solid waste on land. Foods may become contaminated during processing due to malfunctioning or improperly sanitized equipment; misuse of cleaning materials; rodent and insect infestations; and improper storage. Foods may become

contaminated in retail facilities and in the home through use of poor food handling practices.

Although many hazards threaten the safety of our food, certain foodborne hazards are of particular public health concern, and would be targeted for immediate attention by this initiative. Studies have shown that the following microbial pathogens are the predominant foodborne pathogens. They are: *Salmonella* species, *Campylobacter jejuni/coli*, toxin-producing strains of *Escherichia coli*, including O157:H7; the parasites *Toxoplasma gondii* and *Cryptosporidium parvum*; and the Norwalk virus.

The microbial pathogens listed above, and discussed in greater detail below, may give rise to diseases that are far more serious than the uncomfortable but relatively temporary inconvenience of diarrhea and vomiting, which are the most common symptoms of so-called "food poisoning." Foodborne infections can result in very serious immediate consequences, such as spontaneous abortion, as well as long-lasting conditions such as reactive arthritis, Guillain-Barré syndrome (the most common cause of acute paralysis in adults and children), and hemolytic uremic syndrome (HUS), which can lead to kidney failure and death, particularly in young children. The microbial pathogens described below are not listed in order of importance or severity.

Salmonella

Salmonella species cause diarrhea and systemic infections, which can be fatal in particularly susceptible persons, such as the immuno-compromised, the very young, and the elderly. An estimated 800,000 to 4 million infections occur each year in the United States, most of them as individual cases apparently unrelated to outbreaks. Animals used for food production are common carriers of salmonellae, which may subsequently contaminate foods such as meat, dairy products, and eggs. Foods often implicated in outbreaks include poultry and poultry products, meat and meat products, dairy products, egg products, seafood, and fresh produce. Between 128,000 and 640,000 of these infections are associated with *Salmonella enteritidis* (SE) in eggs. Over the past decade, more than 500 outbreaks have been attributed to SE with over 70 deaths. In 1994, an estimated 224,000 people became ill from consuming ice cream in one outbreak alone.

Campylobacter

The bacterium, *Campylobacter*, is the most frequently identified cause of acute infectious diarrhea in developed countries and is the most commonly isolated bacterial intestinal pathogen in the United States. It has been estimated that between ~~170,000 and 2.1~~ and 4 million cases of campylobacteriosis occur each year with an associated 120-360 deaths. *Campylobacter jejuni* and *Campylobacter coli*

(2 closely related species) are commonly foodborne, and are the infectious agents most frequently described in association with Guillain-Barré syndrome, perhaps as frequently as 1 in 1000 cases. Several prospective studies have implicated raw or undercooked chicken as major sources of *C. jejuni/coli* infections. Unpasteurized milk and untreated water have also caused outbreaks of disease.

Toxin-producing Escherichia coli

Several strains of the bacterium *E. coli* cause a variety of diseases in humans and animals. *E. coli* O157:H7 is a type associated with a particularly severe form of human disease. *E. coli* O157:H7 causes hemorrhagic colitis, which begins with watery diarrhea and severe abdominal pain and rapidly progresses to passage of bloody stools, and has been associated with HUS. HUS is a life-threatening complication of hemorrhagic colitis characterized by acute kidney failure, and is particularly serious in young children. *E. coli* O157:H7 has its reservoir in cattle, but the dynamics of *E. coli* O157:H7 in food-producing animals are not well understood. It has been estimated that approximately 25,000 cases of foodborne illness can be attributed to *E. coli* O157:H7 each year with ~~an estimated 6 deaths~~ as many as 100 deaths. *E. coli* O157:H7 outbreaks have recently been associated with ground beef, raw milk, lettuce, and minimally processed and fresh fruit juices. The most recent outbreak, in the Fall of 1996 in 3 western states and British Columbia, was associated with unpasteurized apple juice and sickened 66 people and caused the death of one child.

Toxoplasma gondii

T. gondii is a parasitic protozoan. It has been estimated that 1.4 million cases of toxoplasmosis occur annually with an associated 310 deaths. Otherwise healthy adults who become infected usually have no symptoms, but may get diarrhea. Pregnant women who become infected during pregnancy may pass the disease to their fetuses. In infants infected before birth, fatal results are common. Should the infant survive, the effects of infection are typically severe. The disease can also be serious in persons with weakened immune systems and often is fatal to people with HIV/AIDS. *T. gondii* has been found in virtually all food animals. The two primary ways that humans become infected are consumption of raw or undercooked meat containing *T. gondii* or contact with cats that shed cysts in their feces during acute infection. Under some conditions, the consumption of unwashed fruits and vegetables may contribute to these infections.

Cryptosporidium parvum

C. parvum is a parasitic protozoan. The most common

consequence of infection in otherwise healthy people is profuse watery diarrhea lasting up to several weeks. Children are particularly susceptible. Cryptosporidiosis can be life-threatening among persons with weakened immune systems. The largest recorded outbreak of cryptosporidiosis was a waterborne outbreak that occurred in Milwaukee, Wisconsin in 1993, affecting over 400,000 people. More recently, a waterborne outbreak in Las Vegas resulted in at least 20 deaths attributed to *Cryptosporidium*. The first large outbreak of cryptosporidiosis from a contaminated food occurred in 1993. This outbreak was attributed to fresh-pressed apple cider. *Cryptosporidium* is found in feces of infected mammals and has been transmitted through contaminated water and food.

Norwalk virus

Norwalk viruses are important causes of sporadic and epidemic gastrointestinal disease, that involve overwhelming, dehydrating diarrhea. An estimated 181,000 cases occur annually with no known associated deaths. In January 1995, a multi-state outbreak of viral gastroenteritis due to Norwalk virus was associated with the consumption of oysters. A 1993 Louisiana outbreak of Norwalk virus gastroenteritis, involved seventy ill people and was associated with the consumption of raw oysters. In 1992, another outbreak occurred which included 250 cases. Outbreaks of Norwalk virus intestinal disease have been linked to contaminated water and ice, salads, frosting, shellfish and person-to-person contact, although the most common food source is shellfish. Several such outbreaks are believed to have been caused by oysters contaminated by sewage dumped overboard by oyster harvesters and recreational boaters.

Other pathogens

Many other food borne pathogens also cause morbidity and mortality in the United States. These include *Listeria*, *Vibrio* species, especially *Vibrio vulnificus*, Shiga toxin-producing *E. coli* other than serotype O157:H7, other *E. coli* groups, *Shigella*, Hepatitis A, *Bacillus cereus*, *Clostridium botulinum*, *Clostridium perfringens*, *Staphylococcus aureus*, the agents of ciguatera and scombroid poisoning, and others known and yet to be identified.

THE CURRENT SYSTEM FOR PROTECTING FOOD

Ensuring the safety of food is one of the core functions of government. It is carried out by a system that, while generally successful in protecting the public, can be confusing for its complexity and diversity. Authority is divided among federal, state, and local governments; and the private sector also plays an important role. From the farm to the consumer's dinner table,

the responsibilities can be summarized as:

- On the farm, food is regulated by state agencies supported principally by the EPA, which acts to ensure that pesticides are approved for safe use, by the FDA, which oversees use of drugs and feed in milk- and food-producing animals, and by APHIS, which is concerned with food-animal disease control. Federal responsibility also covers production and harvesting activities that discharge wastewater to surface and ground waters, and solid waste to land, all of which could contaminate growing and process waters or grazing land. The ecology of human pathogens in food animals on farms and ranches, in wild animals, in slaughter operations, and in processing facilities has received little attention in the past.
- Food processing for foods other than meat, poultry, and egg products (except shell eggs) is regulated by the FDA, whose inspectors are responsible for visiting about 53,000 plants periodically, with emphasis on the highest risk foods or processing techniques. FDA has fewer than 700 inspectors and analysts devoted to this activity. Meat, poultry, and all other egg products are regulated by FSIS, whose 8,000 inspectors are present in 6,500 slaughter and processing establishments to ensure that these products are safe, wholesome, and properly labeled. State and local governments also inspect food processors, with varying frequencies and under varying standards.
- Food being transported in interstate commerce is subject to federal and state regulation, although that area has received little attention in the past. USDA's FSIS and HHS's FDA have jointly published an Advanced Notice of Proposed Rulemaking (ANPR) on whether regulations are needed to govern the handling of meat, poultry, seafood, eggs, and other foods susceptible to harmful bacteria during transportation.
- The importation of food from foreign countries is overseen by FSIS for meat, poultry, and most egg products and FDA for all other foods. If an imported food is suspect, it can be tested for contamination and its entry into the United States denied.
- Restaurants, supermarkets, and institutional food services (such as schools and hospitals) are generally regulated by states and local health authorities, and FDA publishes the Food Code, which consists of model recommendations for safeguarding public health when food is offered to the consumer. Recommendations are developed by consensus of state government representatives at the Conference for Food Protection. FSIS and FDA are working with states to update the Food Code in light of the changing retail and food service environment and emerging food safety issues, especially with regard to meat, poultry, egg products, and seafood. The

Conference for Food Protection serves as one forum for fostering cooperation among federal, state and local governments in the oversight of food products and the conditions under which they are produced, processed, transported, stored, and handled through retail sale or food service to the consumer.

- National standards for drinking water are set by EPA, and enforced generally by local public water authorities; FDA establishes complementary standards for bottled water.
- Surveillance of foodborne illness is primarily the responsibility of state and local health departments and the CDC, which seek to identify cases of illness, determine their source, and control outbreaks. FDA or FSIS are called in when a link to a regulated food is suspected.
- In the home, consumers also have a responsibility for proper handling and storage of food, as consumer mishandling contributes to many cases of foodborne illness. As a result of this knowledge, FSIS promulgated safe handling labels for raw meat and poultry products.
- Other responsibilities related to food safety include research into the cause and transmission of foodborne illness, and education on treatment and prevention of foodborne illness. These responsibilities are carried out by the USDA, FDA, CDC, EPA, the National Institutes of Health (NIH), other federal components, and the states. ~~Basic biomedical research on pathogenic organisms is conducted at the National Institutes of Health~~ research on the biology, genetics, pathogenesis, natural history, and epidemiology of bacteria implicated in foodborne diseases is actively supported by the NIH, and in particular, by the National Institute of allergy and Infectious Diseases. Research efforts are focuses on understanding the disease process and using the information to design effective prevention and treatment strategies aimed at reducing human disease. The federal government also supports related research in universities. The private sector supports research within its own laboratories and in universities.

THE FOOD SAFETY SYSTEM MUST BE PREPARED FOR THE 21ST CENTURY

The system for identifying and preventing foodborne illnesses described above was largely created in the early years of this century. It must be modernized. The current system is inadequate to properly identify, track, and prevent food-related illness and to prevent future cases from occurring. State and federal resources are not closely coordinated and duplication of effort is not uncommon. In 1981, FDA inspected food firms every 2-3 years, but can now visit those plants, on average, only once every 10 years. Our understanding of some disease causing

organisms is so limited that our ability to protect the public health is seriously constrained. Food processors, restauranteurs, supermarket managers, and consumers often don't understand the threat from foodborne pathogens and the methods available to prevent and control them.

IMMEDIATE ACTIONS TO IMPROVE FOOD SAFETY

There are many causes of foodborne illness, many points at which foods can become contaminated, and numerous factors that make some groups of people more susceptible than others. Needless to say, no single preventive measure will ensure the safety of all foods. However, a number of practical preventive steps can be taken immediately to reduce the incidence of many foodborne infections.

Any initiative designed to improve the safety of the food supply should focus on the hazards and foods that present the greatest risks to public health, should emphasize development and implementation of preventive controls of those risks, and should seek opportunities for such controls through a collaborative process with the responsible sectors of the food industry and all other stakeholders. This prevention-control concept is HACCP, a science-based, state-of-the-art process for building safety into the production, handling and storage of food. HACCP is being implemented by the meat, poultry, and seafood industries with FSIS and FDA regulatory oversight. The application of such preventive controls to other types of food may be important to protecting food in the years to come.

Under this initiative, the federal government, in concert with state and local governments would conduct research and risk assessments to determine how foodborne illnesses occur and can be prevented or controlled; improve surveillance and investigative efforts to locate and monitor illnesses caused by food; achieve more effective and efficient monitoring of the safety of the food supply through inspections of food processors; and reinvigorate education of all those involved in food preparation focussing on the use of safe practices. These issues, ~~and our current thinking about them,~~ and our recommendations for addressing them, are described below.

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A NEW EARLY WARNING SYSTEM FOR FOODBORNE DISEASE SURVEILLANCE

Background

The primary objective of the American system of public health is to prevent disease before it occurs. While prevention of all disease may not be possible, stopping outbreaks of foodborne illness before they affect large numbers of people is a major goal. America needs a more effective early warning system that can catch outbreaks early, preventing illness and death. Such a system will also advance our understanding of foodborne illness and further our prevention efforts. In his January 25 radio address, the President announced a new national early warning system for foodborne illness that he is funding in his FY98 budget.

Problem

Surveillance and investigation are powerful tools to detect new foodborne disease challenges, to determine what the specific food sources are, and to learn how best to keep the foods from becoming contaminated in the first place. Rapid detection of outbreaks is critical to stopping them before they affect many people. A key element in an early warning system is the ability to detect, compare, and communicate unusual patterns of illness and laboratory findings within and among states and among federal partners. Enhancing the capacity of states to monitor foodborne disease and to investigate and control outbreaks will lead to better general control measures and fewer illnesses. One way to achieve this is to expand the existing Foodborne Disease Active Surveillance Network (FoodNet) to identify, investigate and control a broad spectrum of foodborne diseases. A second important way to enhance early warning is to increase the capacity of many states to deal with new foodborne challenges. These enhancements will help us identify outbreaks and other foodborne disease challenges early, and coupled with the other elements of this initiative, prevent illness and premature deaths related to foodborne diseases.

Recommendations

The federal government, in cooperation with state and local health departments, is proposing to take the following steps to establish a new national early warning system for, and enhance surveillance of, foodborne disease. These changes will result in an improved system for promptly and accurately detecting and reporting foodborne illnesses and outbreaks so public health agencies can rapidly institute appropriate and correctly focused measures to control the spread of foodborne disease. This system will also collect critical data to recognize trends and target prevention strategies, including Hazard Analysis and Critical Control Point (HACCP) systems, and to evaluate the effectiveness and efficiency of prevention strategies already in place.

Enhance and Expand Foodborne Diseases Active Surveillance

CDC, FDA, and USDA currently support five FoodNet sites at state health departments to track cases of foodborne infections and to determine the sources of the most common ones. The existing sites should be strengthened, and their number should be increased to 7 in FY97, and to at least 8 in the following year. The sites and federal food safety agencies should be electronically linked to create a powerful new network to detect, respond to, and prevent outbreaks of foodborne illness. Adding additional sites will improve geographic and demographic representation, making this network more likely to detect diseases and outbreaks that are regional rather than national in distribution.

FY97 Activities

- Two new FoodNet sites, encompassing several counties in New York State and Maryland, will begin FoodNet activities.

FY98 Activities with Food Safety Initiative Funds

- CDC, FDA, USDA, and the Council of State and Territorial Epidemiologists (CSTE) would add at least one other site to FoodNet, and enhance personnel resources at all sites to improve surveillance, analysis of data, and timely and appropriate release of information.
- CDC and the FoodNet sites would develop and conduct case-control studies of *Campylobacter* and *Cryptosporidium* infections to guide control efforts.

Enhance early detection of foodborne disease nationwide

In addition to establishing enhanced sentinel sites, an early warning system would require improved early detection of foodborne disease in additional States in FY98 by providing resources for improved surveillance, investigation, control, and prevention of foodborne disease outbreaks. While sophisticated laboratory studies can identify causes of illness and show relationships among pathogens, laboratory methods are insufficient without investigators who can collect samples, interview people, and trace the source of contamination to find out why the illness occurred. New electronic tools need to be developed to enable rapid detection of outbreaks, and to enhance communication about outbreaks to appropriate agencies. CDC also should provide additional resources to States to increase their surveillance and response capacity for the serious long-term consequences of foodborne disease, such as hemolytic uremic syndrome.

FY97 Activities

- FoodNet sites to gather epidemiologic data on cases of hemolytic uremic syndrome.

FY98 Activities with Food Safety Initiative Funds

- CSTE and CDC, in conjunction with FDA and USDA, would define critical capacity elements that State and local health departments require to conduct surveillance, investigation, control, and prevention of foodborne illnesses; CDC should help States improve identified deficiencies.
- CDC and CSTE would develop an electronic module for collecting and transmitting to CDC, USDA, and FDA data on outbreaks of foodborne illness.
- CDC would begin a case-control study of hepatitis A to determine the proportion of cases due to contamination of food so optimal control strategies can be determined.
- Scope of epidemic assistance for outbreaks of foodborne disease would be expanded when States request direct CDC or FDA and USDA participation in investigations.
- CDC and, where appropriate FDA and USDA, would collaborate with State health departments to improve diagnostics, outbreak detection, and electronic communications.
- Gulf Coast *Vibrio* surveillance would be strengthened by CDC, FDA, and states.

Longterm Activities

- Continue to enhance surveillance and investigative systems to improve the ability of State and local health departments to promptly and accurately identify foods that are the source of foodborne illness.

Modernize Public Health Laboratories

CDC should provide resources and training to upgrade public health laboratory capabilities in FoodNet sites, and in other States so they can rapidly identify a broad range of foodborne infections, including those caused by parasitic and viral pathogens, and can use new techniques of DNA fingerprinting. These new capacities would allow rapid identification of the cause of some outbreaks that currently go undiagnosed.

FY97 Activities

- CDC will collaborate with FoodNet sites to determine serotypes of *E. coli* other than O157 that cause hemolytic uremic syndrome in children in the United States.

FY98 Activities with Food Safety Initiative Funds

- The Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) and CDC would improve diagnostic assays and provide additional resources to

improve the capacity of State laboratories to detect foodborne pathogens, including selected viruses and parasites.

- CDC would provide sufficient funds to States to support the production of serotyping reagents for *Salmonella* because they are critical for outbreak identification.
- CDC would develop DNA amplification-based tests for foodborne pathogenic bacteria that are difficult to detect by culture (e.g., Shiga toxin-producing *E. coli* other than *E. coli* O157:H7 and other disease-causing *E. coli*) and would provide resources and technical assistance to States to improve their capacity in diagnosing these pathogens.

Longterm Activities

- CDC should begin developing molecular alternatives to serotyping for *Salmonella*.

Create a National Electronic Network for Fingerprint Comparison

CDC should fund a new computer network and database system that would capture fingerprints of pathogens in a national database, linking CDC, FDA, USDA, and States that have this new capacity into a new national network. This technology would, for example, permit rapid recognition that an *E. coli* O157:H7 bacterium cultured from a patient in Washington was indistinguishable from one isolated from another patient in California, which would suggest to public health investigators that a product distributed in both California and Washington may be contaminated with the organism.

In addition to identifying, investigating, and reporting cases of foodborne disease in humans, microbiological surveillance of pathogens in foods, in food animals and their manures so produced, and in animal feed is important to control and prevent foodborne diseases, and to evaluate the measures that reduce the risk of exposure. Therefore, to make the "early warning system" fully operational, and to translate its findings into long-term improvements in the safety of the food supply, additional surveillance activities would be required.

FY97 Activities

- CDC will provide resources and technical assistance to State health departments for DNA fingerprinting of *E. coli* O157, and begin to establish a centralized national electronic database of DNA fingerprint patterns.

FY98 Activities with Food Safety Initiative Funds

- Continue to expand the national electronic database of DNA fingerprint patterns.
- CDC, in collaboration with participating State health

department laboratories, and FDA and USDA ~~federal food regulatory agencies~~, would develop standardized methods for DNA fingerprinting of *Salmonella* serotypes Typhimurium and Enteritidis and would transfer the techniques to selected State health departments.

- CDC, ASTPHLD, and CSTE would develop guidelines for maximizing the utility of DNA fingerprinting at State health departments in foodborne disease surveillance and outbreak investigations.
- CDC, FDA, and USDA would set up centralized national electronic databases of DNA fingerprint patterns of *Salmonella* serotypes Typhimurium and Enteritidis.

Longterm Activities

- CDC should continue to develop standardized DNA fingerprinting methods for other foodborne disease-causing bacteria as appropriate and will transfer the standardized methods to State health department and appropriate federal laboratories.
- CDC should begin implementing automated foodborne disease outbreak detection algorithms based on the DNA fingerprint patterns submitted by State health department laboratories.

Increase National Surveillance for Antimicrobial Resistance of Foodborne Pathogens

CDC should expand surveillance for antimicrobial resistance in *Campylobacter*, *Salmonella*, and *E. coli* O157:H7 isolated in humans, and FDA and USDA should take similar steps for these bacteria isolated from food-producing animals and their manures, and from food products, in a way that permits these data to be compared. CDC, FDA and USDA should develop standard procedures for sharing necessary information, and for responding to increases in resistance, or other red flag events such as the discovery of an important new resistant bacterium.

FY97 Activities

- CDC, FDA, and USDA will conduct surveillance of antimicrobially resistant *Salmonella* and *E. coli* O157:H7 isolates.

FY98 Activities with Food Safety Initiative Funds

- CDC, FDA, and USDA would initiate surveillance of antimicrobial resistance in isolates of *Campylobacter* from humans and animals, including poultry.
- FDA and CDC would conduct surveillance and epidemiologic studies to monitor and reduce the incidence of foodborne disease associated with emerging and drug resistant pathogens.

Longterm Activities

- CDC, FDA, and USDA should continue monitoring and comparing the antimicrobial resistance of *E. coli* O157:H7, *Salmonella*, and *Campylobacter* strains in humans and animals.
- FDA and CDC should conduct physician and veterinary drug prescribing surveys to assess the impact of antimicrobial drug use on resistance patterns and prevalence to guide regulatory policy and educational campaigns.
- FDA should assist WHO in the development of a veterinary database within the WHONET system.

Conduct Surveillance of Human Pathogens in Food Animal Populations, and Enhance Oversight of Animal Feedstuffs, Feeds, and Manures for the Impact of Drugs and Other Therapies

FY98 Activities with Food Safety Initiative Funds

- FDA would increase the monitoring of animal feed processing to determine the nature and extent of pathogen contamination and the impact of control strategies on pathogen reduction in animals.
- USDA, CDC, FDA, and EPA would convene a working group to discuss how to conduct surveillance of human pathogens in food animals and their manures, and should target one pathogen on which to begin surveillance in FY99.

INTERSTATE OUTBREAK CONTAINMENT AND RESPONSE COORDINATION

Background

Four federal agencies are charged with responding to outbreaks of foodborne illness (including waterborne illness): FDA and CDC (at HHS), FSIS (at USDA), and EPA. All states, and many local governments, with widely varying expertise and resources, share responsibility with the federal government for response to interstate outbreaks. When an interstate outbreak occurs, all of the affected entities must work together to prevent deaths and minimize illnesses. The better coordinated the response, the more quickly the outbreak will be contained.

Each of the four federal agencies has a critical role when an outbreak occurs. CDC's primary responsibility is to assist state and local health departments in identifying and investigating sporadic cases and outbreaks of illness and to prevent additional cases from occurring. FDA, FSIS, and EPA have the additional responsibility of taking regulatory action against the suspect products, or wastes such as animal manures which have the potential to contaminate the air, land, or waters used to produce the food product. The type of food affected determines which regulatory agency has jurisdiction: FSIS regulates meat, poultry, and egg products; FDA regulates all other foods including shell eggs; and EPA regulates water and pesticides and manages organic and inorganic wastes used or disposed of on agricultural land. While each agency has clearly defined areas of responsibility, the successful containment of most outbreaks of foodborne illness involves more than one agency.

The states and many local governments also have a primary role. Identification and investigations of foodborne illness usually begin at the community or state level. States are responsible for protecting the health of their residents. Federal agencies become involved when illnesses cross state borders or when foods or food ingredients that were processed or produced in another state or by international trading partners. Federal involvement is also necessary when contaminated foods from the same sources have been distributed to grocery stores, restaurants, and homes in other parts of the country.

In many outbreaks of foodborne illness, federal agencies work with state and local health authorities in their investigations and implementation of control measures through consultation,

diagnostic assistance, and recommendations for control measures. In some instances on-site assistance is requested by the local and state authorities. For large or multi-state outbreaks, federal agencies play a critical coordination role to assure consistency of approach and implementation of needed control measures.

Companies responsible for affected products also have a critical role to play. Most food product recalls are voluntary. Federal and state agencies can benefit from industry's expertise about contaminated products and their distribution patterns.

Problem

Changes in how food is produced and distributed has led to a growing number of regional and national foodborne outbreaks. Although significant coordination already occurs among the federal, state, and local agencies, better coordination is needed to meet these new and growing threats to the nation's food supply. More than one agency is involved in virtually every large foodborne outbreak. Breakdowns in communication can cause confusion that can lead to public harm. Joint efforts are often hindered by a lack of communication or a misunderstanding of each agency's role in a particular situation, putting the public health at risk.

Recommendations

While state and local health departments will remain the primary organizations responsible for the detection and the conduct of investigations of outbreaks confined within their borders, federal, state, and local governments should improve coordination of interstate outbreaks. Improved coordination among the federal agencies, among federal, state, and local agencies, among the various state agencies, and between state and local agencies would enhance the level of public health protection, leverage agency resources and experience, and avoid duplication of effort.

Improve outbreak containment through better federal/state/local coordination of the evaluation of and response to foodborne illness

CDC, EPA, FDA, and USDA will establish an intergovernmental group to coordinate the investigation and response to interstate outbreaks of foodborne illness. In addition to the four federal agencies, the Foodborne Outbreak Response Coordinating Group (FORCG) will include representatives of state and local agencies charged with responding to outbreaks of foodborne illness. The group will serve four purposes.

First, FORCG will oversee the federal response to an outbreak of foodborne illness.

Second, FORCG will establish an early outbreak detection and evaluation team consisting of federal, state, and local foodborne disease experts. This team's primary task will be to ensure that the cause of an outbreak is established quickly and accurately. It will use information generated by the new national early warning system to identify potential problems and real outbreaks. The team will also develop algorithms and protocols for evaluating the evidence about the cause of an outbreak.

Third, FORCG will establish an outbreak response coordinating

team for each outbreak that requires a federal response. During an outbreak, this team will ensure a coordinated and rapid response to contain the outbreak. The team will be modeled on the Incident Command System that is used by other federal emergency responders such as the Forest Service and the Department of the Interior to manage forest fires and the Federal Emergency Management Administration. The team will determine jointly each agency's responsibilities during the various phases of outbreak investigations, and will designate a single spokesperson for each phase or component of an outbreak. In addition, this team will coordinate communications and decisions about appropriate actions during outbreaks and appropriate follow-up to prevent similar outbreaks.

Fourth, FORCG will review and evaluate outbreak response and the work of the two outbreak teams. FORCG will undertake these reviews in consultation with industry and consumer representatives. Based on these deliberations, FORCG will assess the infrastructure for outbreak response, make recommendations for improving the current system, and work with federal, state, and local governments, the food industry, health professionals, and consumer advocates to implement beneficial changes. FORCG will meet several times a year for this purpose.

FY97 Activities

CDC, EPA, FDA, and USDA, in consultation with representatives of state and local governments, will establish the Foodborne Outbreak Response Coordinating Group.

The Foodborne Outbreak Response Coordinating Group will establish the Early Outbreak Detection and Evaluation Team and the Outbreak Response Coordinating Team.

Enhance state infrastructure for foodborne outbreak detection, evaluation, and response coordination

The epidemiology offices and laboratories within state and local health departments are charged with the surveillance of infectious and non-infectious conditions, and, along with other state and local officials, with the investigation of outbreaks. They collect surveillance data from physicians, laboratories, local health departments, and other sources. Yet, the resources available in many states and communities for the surveillance and investigation of foodborne diseases are limited and decreasing, thereby limiting the effectiveness of their response. As a result, outbreaks may go undetected or are never investigated.

CDC, EPA, FDA, and USDA will address the problem first by assessing and cataloguing available state resources, and then by working with states and providing support for foodborne disease surveillance programs and assistance to better investigate outbreaks of foodborne illness.

FY97 Activities

FORCG, with assistance from the Association of Food and Drug Officials, the Association of State and Territorial Public Health Laboratory Directors, the Council of State and Territorial Epidemiologists, and the National Association of State Department's of Agriculture, will begin a nationwide audit to catalogue the existing state and local food safety program infrastructure.

FORCG, in consultation with the appropriate outside organizations, will establish working groups consisting of federal, state, and local officials to develop recommended procedures for outbreak response coordination at the state and local level.

FY98 Activities with Food Safety Initiative Funds

CDC, EPA, FDA, and USDA should assist states and local governments in developing the infrastructure necessary to ensure proper detection, evaluation, and coordinated response to foodborne outbreaks.

CDC, EPA, FDA, and USDA should establish a program to improve outbreak coordination through the exchange of employees among federal, state, and local food safety programs and within state and local programs.

RISK ASSESSMENT

Background

The impact of increased funding for research directed at improving risk assessments will be to focus public resources on reducing those risks that pose the greatest hazard to human health. The president's budget includes \$3.95 million for this activity, which will be spent on research in the areas that offer the greatest potential to fill critical food safety data gaps. While obvious severe hazards in the food supply will be addressed under the overall food safety initiative, risk assessment provides an objective foundation upon which efficient allocation of scarce food safety resources can be established. ~~It is a basic public health tenet that public resources devoted to reducing risks should be in proportion to the toll the take on human health. Risk assessment is the tool best suited to set priorities among public health risks.~~ Furthermore, risk assessment is a requirement for any science-based system of preventive controls. Indeed, risk assessments and evaluations of alternative risk management strategies are often carried out for major federal regulations. Pursuant to the USDA's Reorganization Act of 1994, USDA is required to conduct risk analyses for all major regulations. ~~Such evaluations ensure that risk reduction strategies are cost effective and promote the maximum net benefit to society of efforts to reduce foodborne illness.~~ Sound risk assessments, including bacterial, parasitic, and viral food contaminants, are also critical to trade issues that go before the World Trade Organization ~~treaty negotiations~~, which require that U.S. food safety standards be based on scientifically valid measures derived through risk assessment.

Risk assessment plays a fundamental role in the risk analysis triad of risk assessment, risk management, and risk communication, and is therefore critical to the food safety initiative. The reliability of preventive measures and the level of public health protection sought by risk managers through this initiative are dependent upon the quality of the data and the quality of the risk assessment. Simply put, more accurate risk assessments lead to more informed risk management and better risk analysis.

Preliminary Problem Identification

Risk assessment's objective is to characterize the nature and size of the risk to human health associated with hazards, and to make clear the degree of scientific certainty of the data and the assumptions used to develop the estimates. Risk assessments require ~~a substantial amount of~~ specific information on the hazard and on the exposed population to provide meaningful information for those making risk management decisions. Even for chemical hazards, for which risk assessment methods have been most thoroughly developed, data gaps force the use of assumptions

about exposure, hazard potency, and characteristics of the population at risk. ~~and mathematical "models" of chemical action or of the way that the body deals with a chemical.~~

Risk assessment is far less developed for food borne pathogens. Intensive commitment is necessary to develop critically needed data such as pathogen behavior in numerous foods under hundreds of conditions, and information about especially sensitive populations, such as children.

Current Thinking Recommendations

This initiative's ~~risk assessment~~ activities would focus on developing ~~better use of data and better~~ to improve models for risk assessment; thereby, preventing ~~to prevent~~ foodborne disease by informing ~~inform~~ surveillance plans, HACCP-based prevention strategies for process control systems and for food inspections, and research programs to fill critical food safety information gaps. Recommendations are being made in three areas. Within these three areas recommendations are separated into what will be done now, what would be done with the FY '98 budget, and what should be done in the future.

Establish a risk assessment consortium

All federal agencies with risk management responsibilities for food safety should establish jointly a consortium at which federal agencies can set collective priorities for risk assessment research and collective priorities and strategies for the further development and implementation of risk assessment and risk management, to assist agencies in fulfilling their specific food safety regulatory mandates.

FY97 Activities

- ❖ The consortium should be established in 1997 as part of ~~at~~ the Joint Institute for Food Safety and Applied Nutrition, a collaborative activity of FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine and the University of Maryland. The consortium should ~~focus~~ guide federal food safety research on developing data for risk assessments, focused and applied specifically to address the scientific, risk-based goal of preventive control that is the central principle of this food safety initiative.
- ❖ The consortium should be inclusive and seek out risk assessment and communication professionals and potential contributors from agencies as well as other public and private sources. Because the focus of the initiative will be on pathogenic microorganisms, a definitive list of current ongoing microbial risk assessment research either ongoing in government agencies or funded by government grants will be collected to provide the basis for developing initial strategies. Also in 1997, the

consortium would begin the process of establishing a clearing house that will collect and catalog data offered by the private sector, trade associations, federal and state agencies, and international sources.

FY98 Activities with Food Safety Initiative Funds

- ❖ A series of interagency meetings will be scheduled in 1997 to develop a strategy to address long-term needs for exposure data in areas such as farm commodity inputs; processing ; transportation; home/restaurant/retail food handling; food consumption data and computer modeling. A strategic plan will be developed for research into dose-response; chronic sequelae; biomarkers; and adapting surveillance data as well. This process will include a broad spectrum of academic, industry and government expertise that will be obtained through an acceptable process such as an advisory committee.

Long-term Activities

- ❖ The consortium will continue to identify critical research needs, propose effective research, and reach consensus on the priority of these needs based on their potential to reduce the uncertainty of risk management decisions in food safety and provide the greatest positive impact. Research supported and conducted through this initiative would cover several areas critical to developing our ability to conduct risk assessments for foodborne disease-causing organisms and to assess the effectiveness of control measures. Data and methods developed in response to the Safe Drinking Water Act Amendments of 1996, for example, will be relevant to food safety evaluations.

Develop better data and modeling techniques to assess exposure to microbial and chemical contaminants, including animal drug residues, through the food supply

Risk assessment of food borne illness is dependent on accurately estimating the quantity of a toxin or pathogen ingested by the consumer (i.e., exposure assessment). This initiative ~~would~~ addresses ~~the~~ numerous data and modeling deficiencies in estimating exposure to microbial and chemical contaminants. Specifically, research should be conducted into the incidence and prevalence of microbial pathogens and chemical hazards in food at all stages of the food chain; typical behaviors of commercial and home preparation operations; validation of dynamic exposure assessment models; intake data regarding food consumption patterns of the general population and sensitive subpopulations; and specific data on food vehicles of sporadic and epidemic disease. Research using biomarkers should be pursued. Biomarkers are surrogates that indicate that exposure has occurred or that some effect has occurred, particularly when

actual evidence of exposure and effect are difficult or impossible to obtain.

FY98 Activities with Food Safety Initiative Funds

- ❖ Research projects to be considered and prioritized by the consortium in 1998 include:

- Microbial ecology studies for foodborne pathogens in agricultural environments (e.g. feed, animal manure)

- Quantify effects of key processing steps on levels of pathogens

- Quantify effects of key commercial food service preparation procedures, marketing facilities, and home food handling practices

- Design and test the utility of integrating the collection of exposure and dose response data into outbreak investigation

Long-term Activities

- ❖ Future initiatives will be fluid to adjust to results of short term research and emerging food safety needs. Additional research includes the development of modeling techniques to assess human exposure resulting from the subtherapeutic use of veterinary antibiotics in food-producing animals are needed. In order to reduce uncertainties in exposure estimates, focused food consumption surveys that target food consumed by a variety of subpopulations (e.g., children) are needed as well.

Develop dose-response assessment models for use in risk assessment

Research is needed to estimate the relationship between the quantity of a biological agent and the frequency and magnitude of adverse human health effects in a population. Dose-response assessments typically include estimates of the rates of infection, morbidity, and mortality. ~~For bacterial hazards, the World Health Organization's Expert Consultation on the Application of Risk Analysis to Food Standards Issues (FAO/WHO, March 1995) refers to these steps as hazard characterization.~~

FY98 Activities with Food Safety Initiative Funds

- ❖ Research projects to be considered and prioritized by the consortium in 1998 include:

- Methodology to detect the presence of biomarkers in exposed populations.

- Identification and development of criteria for objective models that permit high to low-dose extrapolation.

- Development of criteria that will be used to select or weight alternative models (theories) for extrapolating from empirical data to quantitative descriptions of risk.

Long-term Activities

- ❖ As stated previously, research priorities will be collectively established by the consortium. Additional research includes the development of an appropriate animal model for determination of whether the threshold or non-threshold models for infectivity are more appropriate for describing low dose infectivity rates for infectious and toxicoinfectious microorganisms. Further research is also needed into the identification of biomarkers of susceptibility, chronic sequelae, microbiological toxicokinetics, and infectious dose.

BIOSCIENCE RESEARCH

Background

Food safety research is critically needed to develop the means to more rapidly and accurately identify and characterize foodborne hazards, to provide the tools for regulatory enforcement, and to develop effective interventions that can be used as appropriate to prevent hazards at each step in the continuum from production to consumption. FDA, CDC, EPA, NIH, and the USDA's Research, Education, and Economics agencies (i.e., Agricultural Research Service and Cooperative State Research, Education, and Extension Service) conduct research related to pathogenic microorganisms and other contaminants that threaten the safety of food. This research supports the needs of both the action agencies and the many food industries.

The Problem

New foodborne pathogens have emerged over the last 10 years. Other microorganisms, previously thought to be innocuous, have been linked to life-threatening diseases after acquiring new virulence genes. Many of these organisms cannot be detected readily due to either a lack of suitable methods or their sporadic occurrence in foods, however, this does not mean that the organisms cannot cause human illness. Certain foodborne pathogens are increasingly being associated with resistance to time-tested controls, such as heating and refrigeration and acid. In some cases, this ability appears to be linked with increased virulence or new ways to evade our immune defenses. Food safety research covering the production to consumption continuum is needed to provide solutions.

Recommendations

Prevention of foodborne pathogens in high risk foods requires an understanding of how foods become contaminated during their production, processing and distribution, and the availability of practical interventions to control or eliminate the biological agent. Selection of target pathogens and foods ideally are guided by risk assessment. Research is also needed to support HACCP implementation, to enable verification that critical control points in HACCP systems are working, and to target the data gaps that hamper both HACCP and risk assessment. Among the information needs and data gaps identified, there are numerous opportunities for collaboration and the development of research partnerships among federal and state agencies, the private sector, and academia. Among these recognized data gaps, the following areas were all identified as priority research needs.

Improved detection methods

Many pathogens cannot be easily detected in foods, e.g., Hepatitis virus in strawberries. Among the needs for improved diagnostics, methods are needed for the rapid, cost-effective testing for a number of pathogens in food animals and their manures, in agricultural and aquaculture products, animal feeds, and processed food products. For these pathogens in particular, methods development must address their low level, sporadic incidence in foods. Research will be coordinated with EPA's efforts to develop better test methods for *Cryptosporidium* and other pathogens in drinking water. Improved methods are needed for the identification and subtyping of foodborne pathogens in human and animal clinical specimens. The development of effective sampling plans and enrichment techniques are vital parts of detection methodology.

FY98 Activities

- USDA, FDA, and EPA would enhance on-going research to develop test methods for *Campylobacter*, *Salmonella*, *Toxoplasma*, *E. coli* O157:H7 and other shiga toxin-producing *E. coli*, *Cryptosporidium*, Hepatitis A, and naturally-occurring mycotoxins and marine toxins.
- FDA would expand its on-going research on the development of methods for detecting foodborne pathogens in animal feeds.

FY99-2001 Activities

Å

- FDA, USDA, and EPA should undertake research to develop test methods for *Vibrio*, *Cyclospora*, and Norwalk virus.

Understanding resistance to traditional preservation technologies

Microorganisms that are resistant to antimicrobial agents and conditions that have been traditionally relied on to eliminate or prevent the growth of foodborne pathogens have become increasingly important as causes of serious foodborne disease. Research is needed to determine how microorganisms associated with foodborne disease become tolerant to various types of antimicrobials and to traditional food safety safeguards such as heat or cold, low pH, high salt, and disinfectants and to elucidate factors in animal and plant production systems and processing environments that influence the development of resistance. There is insufficient understanding of the physiological and genetic basis of resistance to prevent breakthrough of newly emerging pathogens. This research will help identify food production, processing, and handling practices that are likely to contribute to pathogen contamination or proliferation. It is also needed to guide improvement of traditional techniques and the development of new interventions.

FY99-2001 Activities

- USDA and FDA will undertake research into physiological, genetic, and other factors that cause foodborne disease-causing microorganisms to develop resistance to preservation technologies.

Understanding antibiotic drug resistance

Pathogens in food-producing animals and their manures may become resistant to antibiotics and drugs, particularly when used improperly. One possible solution may be to modify drug withdrawal periods. Such an approach requires the development of scientific data on how the animals' microbial populations resistance profile changes in response to the elimination of the drug. Work in this and the preceding section must be based on a sound understanding of microbial physiological and genetic adaptive mechanisms.

FY98 - FY2001 Activities

- FDA and USDA will conduct research to identify and characterize the factors that lead to the development of multiple drug (antibiotic) resistance in foodborne pathogens in farm and aquaculture animals, including establishing the gene transfer mechanisms and selective pressures.
- USDA and FDA will investigate techniques for manipulating the microbial ecology of the intestinal tract of agricultural and aquaculture animals to prevent the development of antibiotic resistance or select for non-resistance. Research will emphasize competitive exclusion techniques (probiotics) and the use of extended drug withdraw periods.

Prevention Techniques: Pathogen avoidance, reduction, and elimination

Contaminants are introduced into the food supply at numerous points along the way from farm to table. Food animals and their manures may carry human pathogens, without any clinical manifestations. Likewise, fresh fruits, fresh vegetables, and grains may harbor pathogens or mycotoxins without any discernable loss of quality. In such cases traditional approaches of segregating contaminated foods are ineffective and active interventions are needed. In particular, new interventions are needed for the prevention or control of the pathogens listed below in raw agricultural commodities and seafood. It is anticipated that developments in this area will also provide new approaches for controlling a variety of other foodborne contaminants.

FY98 Activities

For *Campylobacter*, *Salmonella*, *Toxoplasma*, *E. coli* 0157:H7 and other shiga toxin-producing *E. coli*, and *Cryptosporidium*, FDA and USDA, often in partnership with universities and industry, will:

- Expand research into the microbial ecology of foodborne pathogens and how initial colonization of plants and animals can be prevented.
- Expand research on new methods to reduce or eliminate pathogenic microorganisms from agricultural and aquaculture animals before slaughter/harvest, including the use of probiotics.
- Develop new methods to reduce or eliminate pathogenic microorganisms from plants before harvest.
- Develop new disinfection methods and systems for improved sanitation of processing and marketing equipment and facilities.
- Expand research on new methods of surface decontamination of meat, poultry, seafood, fresh produce, and eggs.
- FDA would initiate research to develop new techniques for eliminating animal feeds as a source of foodborne pathogens.

FY99-2001 Activities

- USDA and FDA will undertake research to develop new ~~surface~~ decontamination methods for *Vibrio* and Norwalk virus on/in marine-harvested and aquaculture-reared seafood, and for *Cyclospora* and Hepatitis A on fresh produce.
- USDA (ARS, CREES) and FDA, working with industry and academia, should develop new techniques for eliminating pathogens that provide alternatives to traditional thermal processing.
- FDA and USDA(FSIS) should work with industry to develop criteria for evaluating the efficacy and safety of the new intervention technologies.

Food handling, distribution, and storage

Food production, processing and consumption often occur thousands of miles apart. Stresses associated with the transportation of live animals and fresh produce may contribute to the dissemination of foodborne pathogens. Effective packaging and proper food storage conditions are critical to maintaining the level of safety achieved by processing.