April 10, 1997 DRAFT

Commerce Inspectors

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

NATIONAL FOOD SAFETY INITIATIVE

REPORT TO THE PRESIDENT

- Will vs. Shall
- Seafood Inspectors

TABLE OF CONTENTS

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 to 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:

USDA/FDA/CDC — Agencies began putting systems in place in 1995,

Second benefit: Gathering data for HAACP

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: ~~The Federal Administration will~~ In January, 1997 President Clinton announced that he will ask Congress to fund enhancements to our surveillance system.

- Expanding and enhancing the foodborne disease active surveillance network (Foodnet), by adding new "sentinel sites" that collect outbreak data and by 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:~~ We recommend HHS, USDA, EPA

- 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.

better coverage

- 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:~~ To improve risk assessment, HHS ... should

- 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 vubificus*, 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.

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.

DRAFT 4/11 2pm

INTERSTATE OUTBREAK CONTAINMENT AND RESPONSE COORDINATION

Background

Four federal agencies are charged with responding to interstate 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 potential 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 legally 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~~ more than one state.

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.

1) **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 a standing group of federal, state, and local foodborne disease experts. Industry and other outside experts will be consulted as appropriate. This team's primary task will be to review and assess preliminary information from state and local health departments and 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 after appropriate 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.

2) **Enhance state and local 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 Health 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

- 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.

FY99-2001 Activities

- USDA and FDA will undertake research to identify factors that contribute to the spread of bacteria during transportation of live animals and fresh produce, and develop techniques for eliminating cross-contamination.

- FDA and USDA, working with industry and academia, will develop and assess the effectiveness of 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. In addition to inspection of production and processing facilities, and warehouses, ~~with~~ state and local officials also have primary responsibility for inspection of ~~focusing primarily on~~ restaurants, supermarkets and other retail establishments. At the federal level, consistent with legal mandates, FSIS has responsibility for ~~carcass-by-carcass inspection in~~ meat and 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~~ 6,200 domestic plants and for all imported meat, poultry, and egg products. FDA, on the other hand, 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.

Problem

~~At FDA,~~ The number of inspections conducted by FDA 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. States are also faced with declining resources for inspections and cannot meet the need for increased coverage triggered by FDA's decreased resources for inspections without cooperative efforts such as federal/state partnerships. ~~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.~~ Moreover, since the number of imports has doubled in five years, but the number of inspectors has not increased, a smaller percentage of imports are inspected at entry.

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~~ food safety and consumer protection program with limited resources and increasingly complex public health concerns related ~~and growing increasing threats~~ to food safety.

Increasingly, foods prepared in retail food establishments are becoming an integral part of consumers' daily diets. Recognizing that illnesses associated with retail foods may be reported more frequently, these foods accounted for 37% of the foodborne illnesses reported to CDC in 1992.

Recommendations

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. This conclusion has been borne out by industry, academic, and consumer participants in the public meetings on the food safety initiative and in comments received on the initiative. The seafood HACCP regulations go into effect in December 1997, a strong federal inspection capability is necessary to maintain domestic and international credibility for the U.S. food safety system, the safety of U.S. foods, and to ensure that HACCP is implemented properly. FSIS begins to implement HACCP for the meat and poultry industries in 1998 with phase-in completed in 2000. ~~FSIS intends to publish an ANPR requesting comments on HACCP-based 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 in the following areas. These areas are in the order of priority designated by participants in the Inspections session at the March 31-April 2 public meeting on the food safety initiative and also reflect comments received to the discussion draft. Within each prioritized area, are listed specific activities agencies are either doing or planning to do, based on suggestions and comments from participants in the public process.

Enhance development of HACCP procedures

FY97 Activities:

- FDA will publish a proposed regulation for use of HACCP in the manufacture of juice products.

- FSIS will publish a proposed regulation for use of HACCP in the manufacture of egg products.

- FDA will evaluate ~~considering~~ whether and how to implement HACCP ~~throughout the non-meat/poultry food industry~~ for ~~all~~ other appropriate food commodities and animal feeds. ~~It is recognized that staged implementation, by commodity, might be necessary because of resource limitations.~~

- FDA will ~~conduct inspections and~~ provide additional training in seafood HACCP and FSIS will complete HACCP training of inspectors in large plants.

- FSIS and FDA will evaluate expanding existing cooperative agreements ~~under which~~ so that plants producing both meat and non-meat foods are inspected ~~solely~~ by FSIS inspectors~~, who have been~~ trained in FDA inspectional standards. Without these cooperative agreements, both FSIS inspectors and FDA inspectors inspect the plants. With FSIS inspectors ~~are~~ already in these plants ~~on a continual basis~~, their presence could

be better utilized to maximize use of federal resources without loss of inspectional coverage for FSIS-regulated foods.

- FSIS plans to conduct a series of public meetings to discuss:
  - How HACCP requirements will be implemented in slaughter plants consistent with the legal mandate of carcass-by-carcass inspection and how the roles and responsibilities of inspection personnel will change with that implementation, and
  - The design and testing of new concepts consistent with HACCP principles, for achieving food safety and other consumer protection objectives in the inspection of meat and poultry products, during production, and through distribution channels to consumers.
- FSIS and state associations will complete development of HACCP-based control measures for meat and poultry processing at the retail level.

FY98 Activities with Food Safety Initiative Funds

- FDA would implement seafood HACCP and conduct inspections to ensure proper implementation. FDA would acquire approximately 80 new investigators to implement seafood HACCP and expend approximately $ 6.4 million.

~~- FDA will also continue HACCP training for federal, and state regulatory officials and industry.~~

- A Performance-Based Organization (PBO), located at and operating as part of FDA, would be created as the organizational structure for seafood inspectors currently located at the Department of Commerce's National Marine Fisheries Service. These inspectors would be integrated into the seafood HACCP program. This would provide additional resources to implement seafood HACCP and consolidate voluntary and mandatory seafood programs within one agency, assuring consistency and better utilization of resources. ~~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.~~
- FDA and FSIS would cooperate in evaluating the feasibility of HACCP for commodities such as fresh fruits and vegetables.

Longterm Activities

- FDA should implement HACCP procedures, as appropriate, for other foods, using risk assessment techniques where possible.

Enhance safety of foods produced in retail food establishments

More than 3,000 state and local regulatory agencies have primary responsibility for monitoring retail food establishments to assure that the consumer is protected. There are approximately 785,000 commercial and institutional food establishments, 128,000 grocery and convenience stores, and 1.5 million vending operations in the U.S. employing workers with backgrounds as diverse as high school students and non-English speaking individuals, to highly trained food service workers. The nature of the food service industry presents unique challenges to assuring the safety of the food produced.

FY97 Activities

- FDA and FSIS will hold a series of grassroots meetings with state and local regulators in 5 regions to establish retail program standards in accordance with the 1997 Food Code to enhance national uniformity.

FY98 Activities with Food Safety Initiative Funds

- FDA and USDA would enter into public/private partnerships to develop and initiate implementation of a national food safety education program for all segments of the retail food industry using concepts in the 1997 Food Code.

- FDA and USDA would form an alliance, joining expertise of federal, state, and local agencies, industry, and professional and trade associations to promote and implement the Food Code and develop communication techniques targeted to specific groups (e.g., non-English speaking individuals) to overcome barriers to communicating appropriate food safety behaviors to food service workers.

- FSIS would provide HACCP training to state and local inspectors to improve the safety of meat and poultry products processed in retail establishments. This training, at a funding level of $565,000, would augment the training program for federal inspection personnel, more fully covering the farm-to-table continuum.

Longterm Activities

- Achieve adoption of the Food Code, particularly the HACCP provisions, by all 50 states.

Enhance federal/state inspection partnerships

~~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. Maximizing the ~~To maximize~~

the joint federal/state role in inspections through development of new federal/state partnerships would be considered that focussed on coordinating the inspection coverage and preventing duplication of effort, particularly between FDA and the states, is a major step in this direction. FDA would expend approximately $1.25 million of food safety initiative funding in this effort.

FY98 Activities with Food Safety Initiative Funds

- FDA would develop additional federal/state partnerships to 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 applicable at all levels, including retail.

- FDA would expand the number of federal/state partnerships to include more extensive HACCP training of state inspectors, the seafood industry, and the retail food industry.

Longterm Activities

- FDA and USDA should work more closely with industry, professional and trade associations, and academia to assure effective implementation of HACCP, particularly at the production, processing, and retail levels.

- FDA should create a data system to compile inspection data from federal and state inspections, 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.

Enhance inspectional coverage of imported foods regulated by FDA, to address the problem of rising imports and FDA's inability to provide adequate coverage inspections of them

FY98 Activities with Food Safety Initiative Funds

- FDA would expand its program to develop MRAs with trading partners foreign countries under which both countries agree to inspect each other's food exporting firms under equivalent procedures for ensuring safety.

- FDA would also initiate a federal/state communication system through which states can inform federal agencies of problems found with imported products in their jurisdictions.

- FDA would initiate a system for certifying/accrediting private laboratories, including use of a quality assurance procedure, that would be authorized to test samples of food

products for contaminants. ~~This~~The lab certification process 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. FDA anticipates that this effort would require approximately $200,000 to initiate. Such private parties would provide a service to food firms wishing to demonstrate that their products meet applicable federal standards.

Longterm Activities

- FSIS should verify foreign government inspection progress for conformance with the new HACCP and pathogen regulation requirements; this activity will begin in 1997 and should be completed in 2000.

- The laboratory certification process should be extended to include assessing the utility of existing accrediting bodies with FDA providing performance standards and oversight to the process.

- FDA should expand the federal/state communication system states use to inform federal agencies of problems found with imported products in their jurisdictions. As part of this expansion, FDA should evaluate the feasibility of combining this communication system with the federal/state inspection data system discussed above, making the data and information more widely accessible.

Enhance safety of foods during transportation

In considering whether and how to regulate the transportation of meat, poultry, seafood, eggs, and other foods to safeguard the public from pathogenic microorganisms, FSIS and FDA published an ANPR on November 22, 1996. ~~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.~~

FY98 Activities with Food Safety Initiative Funds

- FDA and USDA would establish guidelines for the safe transportation of high-risk food and establish performance standards, including elements such as temperature maintenance, prior cargo and cleaning information for the food shipper's use, to ensure safety of the food at its destination.

Longterm Activities

- FDA and USDA, through the partnerships with states, should provide training and training materials to the transportation industry on safe food transportation.

EDUCATION

Background

An integral part of the overall food safety initiative is providing food safety education to a variety of audiences: consumers -- the general public and specific groups at-risk for foodborne illness; public health professionals and physicians; retail, food service and institutional food preparers; veterinarians, animal and other food producers; food transportation workers and vehicle owners. The challenge is to target educational messages that address the risks relevant to each audience throughout the food chain. Realizing that educational efforts are cost-effective investments, the federal government, state and local governments, private organizations, consumer groups and the industry has been fostering educational programs to address foodborne illness.

The Problem

Despite these educational efforts, foodborne illness is still prevalent throughout the United States. One reason is that food preparers and handlers at each stage of the food chain lack the knowledge of risks involved and the related safe handling practices. Without food safety knowledge and proper food handling procedures practiced by those involved from farm to table, foodborne illness will not be significantly reduced. Individuals at each stage along the farm to table continuum need to be targeted for the appropriate food safety message.

Research to determine the most effective ways to overcome barriers and to insure safe food handling practices is needed for each specific audience. Consumers' food handling practices will either increase or decrease the chances of foodborne illness. Studies show, for example, that 53% of the public eat 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.

Similarly, food preparers in the retail sector must be made aware of how they can prevent food contamination and reduce pathogen growth. For example, during 1988 to 1992, *Salmonella* caused 69% of the 796 bacterial foodborne disease outbreaks; 60% of these *Salmonella* outbreaks were caused by *Salmonella Enteritidis*. *S. Enteritidis* also resulted in more deaths than any other pathogen, with 85% of these deaths occurring among residents of nursing homes.

In addition, health professionals and physicians need knowledge to better detect and treat foodborne illnesses. Producers of animals used in human food production and veterinarians treating such animals must be made aware of food safety implications related to drugs and residues. Finally, those responsible for the transportation of food are often unaware that mishandling of food during shipment can result in contamination.

Recommendations

The goal of this initiative is to target and change unsafe food handling practices by people throughout the food chain, especially those providing food to populations at high risk in hospitals, nursing homes, assisted living facilities, child day care, and senior day care. Objectives include

conducting the appropriate research to identify barriers to safe food handling and the design of persuasive messages to foster behavior change. To address this goal, FDA, USDA, and CDC will develop, through research, effective food safety education materials and services for consumers and for food service operations. Also, the development of a national food safety education program for consumers, retail and other food handlers, will be initiated through new public/private partnerships and existing networks to maximize resources and develop effective, consistent educational messages, campaigns and training programs.

It is anticipated that implementation of the education goals and objectives of the initiative, along with the other elements of the initiative, will result in a significant increase in the number of consumers, and a large portion of the 12 million food service workers, being reached with effective and persuasive food safety messages. Improved safe food handling resulting in a reduction of foodborne illness would be the desired outcome.

Improve education of all target audiences

FY97 Activities

USDA, FDA and CDC will:

- Expand existing information systems such as the Foodborne Illness Education Information Center while laying the groundwork for a national clearinghouse to provide consumers and educators with food safety information.
- Initiate innovative methods for sharing food safety information in order to reach larger audiences, such as the use of electronic communications technology and the consolidation of government food safety internet sites.
- Begin a process to establish a National Food Safety Education Council. The Council, through an independent scientific review board, would establish longterm goals and objectives for food safety education and changing unsafe food handling practices.
- Convene broad alliances that network federal government agencies, industry, consumer, trade, state and local food protection agencies, and academic organizations to share and conduct food safety education activities.

Improve Consumer Education

Consumer education will be conducted in several phases. Phase one, to begin immediately, has the goal of raising awareness of the general public to the need for safe food handling practices. A second phase will build a long-term education program designed to effectively change consumer food handling behavior.

FY97 Activities

USDA, FDA, CDC will:

- Form a partnership with private-sector organizations, through a *Memorandum of*

Understanding, to conduct a public food safety awareness education campaign, with a logo and key basic messages, to emphasize the need for safe food handling. Specific audiences will include high-risk consumers, minorities and non-English speaking populations.

- Conduct a conference on food safety education, "*Changing Strategies; Changing Behaviors*," scheduled for June 12-13, 1997. The conference will be a forum to introduce plans for the national food safety awareness campaign.
- Promote September as National Food Safety Education Month, which was established two years ago by the National Restaurant Association. The kick-off of the national awareness campaign will begin this month.

FY98 Activities with Food Safety Initiative Funds

USDA, FDA and CDC would:

- Develop national "safe food handling" guidelines like the Dietary Guidelines. Under the auspices of the National Council, convene the scientific review board to determine guidelines and review them periodically. The board would also identify at-risk audiences for targeted food safety education programs.
- Conduct research necessary to determine effective methods of fostering behavior change in targeted consumer audiences and methods to evaluate effectiveness of educational methods and programs.
- Consider use of food labels to convey food safety information.
- Expand the capacity of the clearinghouse for food safety information.
- Continue work to promote food safety messages and personal hygiene in schools and to incorporate food safety education into school curricula.
- Sponsor journalists' conferences on food safety issues to inform the media.

Long-term Activities

USDA, FDA and CDC should:

- Conduct research necessary to develop a visual communication tool to convey food safety principles, like the food guide pyramid.
- Implement, through partnerships and alliances, a massive education campaign to encourage the use of the new educational tools developed, especially targeted to school curricula and specific at-risk audiences.
- Continue to promote the National Food Safety Education Council and to expand capacity of the clearinghouse for food safety information.

Improve Retail, Food Service, and Institutional Education

FY 97 Activities

USDA, CDC, and FDA will:

- Form an alliance of federal, state, and local health agencies, as well as private parties, to promote education efforts on retail and food service food safety issues,

using existing networks to strengthen the programs, including a multilingual approach to include safe food handling provisions in the 1997 Food Code and HACCP principles.

FY98 Activities with Food Safety Initiative Funds

USDA, FDA and CDC would:

- Develop and initiate a highly focused program to change food workers' unsafe food preparation behaviors and include a multilingual approach. Programs will address the high turnover in foodservice workers and target teenage workers, small businesses, and new entrepreneurs.
- Develop guidelines for retail and food service processing operations for meat, poultry and seafood to train state and local inspectors to identify hazards at the retail level.
- Provide training to state and local regulators as well as retail, food service and institutional industries to increase the use of HACCP principles and provisions in the 1997 Food Code.

Long-term Activities

USDA, FDA and CDC should:

- Continue to support alliances in the development of a food safety agenda in their respective areas.
- Continue to provide training to state and local regulators and the retail food industry in the 1997 Food Code, as well as implementation of HACCP.

Improve Veterinarian and Producer Education

FY98 Activities with Food Safety Initiative Funds

USDA, FDA and CDC would:

- Use existing mechanisms such as the Cooperative Extension and professional associations to strengthen and implement programs to educate producers, veterinarians, state and local regulators about proper drug use and the incorporation of HACCP principles to reduce foodborne pathogens into industry quality assurance programs.
- Encourage the improvement of veterinary and producer education at veterinary and agriculture colleges to address foodborne pathogens in animals and their manures so produced.

Long-term Activities

USDA, FDA and CDC should:

- Continue to expand educational programs for producers of animals for human food

consumption, veterinarians, state and local regulators about proper drug use and the incorporation of HACCP principles into quality assurance programs.

- Continue to schedule regular training sessions, including satellite teleconferences, educational symposia, and presentations at producer and practitioner meetings. Guidelines and educational materials will be developed and disseminated through existing networks to food producers and the veterinary medical community.

Improve Health Professional Education

Long-term Activities

- CDC, in cooperation with FDA and USDA, should train public health professionals on foodborne disease and clinical microbiology and foodborne illnesses with non-traditional symptoms by using multimedia and distance learning techniques and the National Laboratory Training Network

Improve Industry Education in the Transportation Area

FY97 Activities

- USDA and FDA may establish final regulations for safe transportation and enforcement procedures.

Long-term Activities

- FDA and USDA should form an alliance among government agencies 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.
- FDA and USDA should conduct training and education for state and local health transportation authorities so they can apply HACCP information during inspections of food processing facilities and transportation vehicles in their jurisdiction.

A BLUEPRINT FOR A BETTER FOOD SAFETY SYSTEM

Background

A comprehensive strategic plan for food safety is needed to reduce foodborne illness over the long term. The plan would be used to help set priorities. A strategic planning process would also help to improve coordination and efficiency to make the best use of limited resources.

Elements of the strategic plan might include: Improving coordination among all food safety participants in numerous aspects of prevention and response; improving the infrastructure for rapid identification and response to outbreaks; and developing a strategic, long-range research agenda.

The Challenge

A major challenge will be obtaining consensus on priorities within a food safety system that is extremely complex and for which there are many competing interests. Since authority for regulating food safety is fragmented among several federal agencies and state and local jurisdictions, there are often conflicting priorities and disagreement on priorities. This is compounded by differences between the scientific community and the public regarding the nature and extent of the risks associated with various foods and foodborne pathogens. Such issues include: the structure of a coordinated, strategic plan for food safety research; policy and technical issues associated with agricultural manures; policy and technical issues associated with food irradiation; issues associated with exchange of information about foodborne disease outbreaks; and best approaches to prevention, intervention, and control.

Recommendations

The process for preparing a comprehensive long-term food safety strategic plan should facilitate the participation of all interested parties. Extensive dialogue will be needed to build trust in the process, obtain agreement on the priorities, strategies for achieving change, and a process for measuring progress.

Another mechanism that could be used to facilitate a strategic planning process would be to have the food safety agencies overseeing the process and then incorporating appropriate elements of the strategic planning process into their individual agency strategic plans. As with the other suggested approaches, a process would be developed for selecting a constituent committee which would receive suggestions and recommendations from a series of public meetings, focus groups and a public comment process that would be used to develop the strategic plan.

Identify an appropriate mechanism for developing a strategic planning process

While there is agreement among all sectors that improvements can be made in the food safety

system to enhance its effectiveness, there are various opinions on how to reach this overall goal. Developing a long range strategic planning process which includes maximum participation provides such a mechanism. Various strategic planning models could be used. Whichever model is selected, there are several essential elements that should be considered in designing the optimal mechanism. Because it is critical that the process be perceived as inclusive and equitable, interested parties should be given an opportunity to comment on the recommended approach prior to its implementation. Specific information would be provided regarding the general objective, scope and conduct of the planning process, management of the process, selection criteria for participants, and other relevant factors. It is recognized that it is unlikely that there will be unanimous agreement, therefore, a general consensus will be used as the foundation upon which the planning processes is built.

Identify essential participants and selection criteria for participation

Participation in any strategic planning process can be accomplished in a number of ways. Open sector and regional meetings provide a means of reaching the largest number of people. The process must be open, transparent, and capable of including broad and balanced participation involving all stakeholders in the food safety system.

Prepare a three- to five-year strategic plan

Participants in the planning process would be charged with developing a strategic long-range agenda that could be used to help set priorities, improve coordination and efficiency, identify gaps in the current system, and enhance and strengthen prevention and intervention strategies, and identify measures to show progress.

Measure progress to evaluate the effectiveness of the plan in reducing the annual incidence of foodborne illness

Progress would be reviewed after two years to determine the strategic plan's impact on reducing the annual incidence of foodborne illness. Measurable goals and objectives would provide a basis for establishing progress. Measurements could be based on a decline in the number of outbreaks, more effective prevention and intervention programs, more rapid responses to foodborne illness outbreaks, changes in behavior, and better detection and quantification methodologies.

TO: Sally, Greg, Nancy-Ann, Klein, Jennings, Magaziner

SUBJECT: FDA Reform Provisions Re: Pediatric Studuies for New Drug Applications

This note assesses the Kassebaum bill provision, Sec. , that seeks to provide incentives for drug developers to conduct pediatric studies for new drugs.

Background:

About 80% of drugs are not approved specifically for use in children. That is, companies have not done studies to assess pharmicokinetics/dosing, safety, or efficacy of most drugs when used in children. Yet about 80% of drugs are used in kids. FDA does not require manufacturers to do studies on kids unless they are seeking to put pediatric use on the label.

Provision: ~~Concern~~ ~~lack of studies, children can't~~ ↑ Studies would increase assurance of Safety and efficacy, and ↓ uncertainty about reimbursement.

Extends 6 month period of market exclusivity for a drug if - (1) the Secretary makes a written request for pediatric studies ... (add: based on a finding that such studies will significantly benefit children) and (2) the applicant conducts requested studies.

Required studies can simply be pharmicokinetic studies, but may be clinical trials.

FDA PROPOSAL:

6 mo. may be too long: Year of exclusivity for successful drug estimated by OTA at $100 million; 6 mo. at $50 million. Studies expected to cost 750,000 - 1,000,000.

FDA wants proportionality requirement.

FDA wants Commissioner to ask for studies -- so will only be done where there are significant benefits in children.

DISCUSSION:

FDA requires by regulation that phase 2 and 3 studies address subpopulations (e.g. women) even where label won't make specific claims w.r.t. population.

FDA Pres has authority to require by regulation.

FDA requiring phase 4 (postmarket) pediatric testing of protease inhibitors.

Could do by regulation.

Probably too generous

Industry will push (has been pushing) for longer period of exclusivity, but Kassebaum is holding at 6 months.

VPOTUS said he'd like to do something about ~~the general~~ problem in AIDS ~~industry~~ meeting w/FDA and Industry re: Pediatric ~~wa~~ uses for ~~AIDS~~ drugs.

FLOTUS is interested but hasn't voiced concern.

April 15, 1996 **DRAFT**

FDA REFORM – KASSEBAUM BILL
CONCERNS ABOUT S. 1477

I. MOST SERIOUS CONCERNS

Contracting Out Review If FDA Misses Unrealistic Time Frames. Section 404 requires FDA to contract for outside review if in any fiscal year it fails to meet the statutory time frame for 95% of the applications in a particular category. This provision applies to drug, biologic, device, and food additive reviews.

S. 1477 sets forth unrealistic timeframes for all products. For drugs and biologics, it ignores the negotiated and successful PDUFA timeframes. Moreover, by requiring FDA to meet with sponsors at specified times throughout the review period and to provide a written list of deficiencies and information needed to bring the application into a form that would require approval prior to those meetings (see e.g., sections 404 and 707), the bill is cutting product review times in half. For animal drugs, the bill explicitly cuts the review period in half (see section 806). The overly burdensome, bureaucratic requirements imposed by the bill further ensure that FDA will be unable to meet the deadlines. The Agency has not and can not meet the timeframes set forth in the bill using existing resources.

Failure to meet a deadline for even one application could trigger the contracting out requirement. Alternatively, if the Agency rushes a decision in order to avoid the contracting out hammer, it may have to choose between having more disapprovals or compromising the safety and effectiveness by approving without a thorough review. If contracting out is triggered, then the Agency will have to significantly reduce its work force in order to pay for the third party review. This will create an administrative nightmare. It is the American public that will suffer the consequences of a consumer protection Agency that has been hollowed out by so-called hammer provisions used to enforce compliance with unrealistic and unrealizable performance goals.

Privatization Of All Device Review. The Committee adopted an amendment that would require FDA, within one year, to allow third party review, at the request of applicants for all device applications. It would allow medical device companies to pay private companies to review applications to market devices ranging from heart valves to products used to test the blood supply. FDA would have 15 days to review the third party's decision on a 510(k) submission and 45 days to review the third party's decision on a PMA. It leaves no discretion to the Agency to retain for review even the most complicated or potentially dangerous devices. It allows the party whose product is being reviewed to choose and directly compensate the third party reviewer. This financial arrangement creates a serious conflict of interest potential.

Blocking FDA From Helping Patients Obtain High Quality Information About the Drugs They Take. Section 607 (an amendment adopted by the Committee) precludes FDA from implementing its MedGuide program, which would ensure that patients receive written information when they get a new prescription (including information about how to take the drug, side effects, and dangerous interactions with foods or other drugs). FDA's proposal would have deferred a mandatory program until the year 2000, to give the pharmacy industry time to implement the voluntary program they have promised since 1980. The amendment prohibits FDA from even providing guidance on the development of the voluntary program requirements. Misuse of prescription drugs accounts for many injuries and deaths and for about $20 billion in health care costs per year. Since drug companies are permitted to promote prescription drugs, FDA should be permitted to participate in insuring that consumers receive accurate information.

Product Approval Standards. Section 602, the **drug approval standard**, states that substantial evidence may consist of data from one well-controlled clinical investigation and confirmatory evidence. This may lower the effectiveness requirement from two adequate and well-controlled studies to, at most, one. Although FDA does, when appropriate, accept data from one adequate and well-controlled trial, this should not be the standard.

Section 703, the **device approval standard**, would require the agency to accept retrospective or historical clinical data as a control or for determining the effectiveness of a device if sufficient valid data are available and the effects of the device are clearly defined and well understood. The provision indicates a preference for a lower quality of evidence.

Section 802(a) amends the **animal drug approval standard** to redefine the "substantial evidence" criteria that currently must be met to establish effectiveness. The requirement for adequate and well-controlled studies would be changed to "scientifically sound studies." Section 802 also replaces the requirement that the studies "fairly and reasonably show effectiveness" to a requirement that there is a "reasonable assurance of effectiveness."

Health Claims. The Committee adopted an amendment that would permit companies to include in the labeling of food products, claims that have been recommended by NIH, CDC, or the National Academy of Science. This fundamentally alters the criteria for health claims that were so carefully worked out in the Nutrition Labeling and Education Act of 1990. Under the bill, there would be no single body to make decisions on health claims. The result could be inconsistent decisions by different organizations and companies picking and choosing among government bodies.

Statutory Hammer Giving Preference to Foreign Approvals. Section 404 requires FDA to give special priority to (i.e., make a decision within 30 days on) applications, notifications, or petitions for products that have been approved in the EU or UK if by July 1, 1998, FDA fails to meet a time period for action on an application, notification, or petition for approval or clearance of a new drug, biologic, device, or animal drug that is a significant improvement over existing products or of a food additive that has the potential to make foods

more wholesome and contribute to a healthier diet.

II. SERIOUS CONCERNS THAT THE COMMITTEE AGREED TO ADDRESS

Erosion of Product Quality Standards. Section 604 allows firms to change how they manufacture drugs and biologics and to distribute them to the public without FDA review of the changes. Specifically, it allows changes in product manufacture without FDA review if there is not a resulting change in formulation or release specifications. Changes that do not affect formulations or release specifications, however, can still change the safety and effectiveness of a product. For example, in the infamous "Cutter" incident with the Salk polio vaccine, the company simply changed the type of filter used in manufacturing the vaccine. No change in formulation or release specifications resulted, but the change in filter led to live virus in the product. Eleven people died and about two hundred more got polio. This provision also would allow a company to change the strain of a virus used for a vaccine or to change the detergent used to cleanse a blood derivative of HIV virus, both of which raise serious safety concerns.

These problems can exist even for "well-characterized" drugs. For example, the manufacturer of carbamazapine, a well-characterized product used to treat epilepsy, simply got its bulk drug material from a different supplier. The formulation was unchanged, as were the release specifications. However, the change in bulk substance meant that the product dissolved differently in people's bodies. Because of this change in the effectiveness of the product, people with epilepsy had seizures that would have been prevented without the manufacturing change.

FDA has wide experience with respect to manufacturing changes that can cause safety and effectiveness problems. Manufacturers do not often share with each other manufacturing problems. Manufacturers may well use an approach to "validating" the change that another manufacturer used, and that FDA knows failed to detect an adverse effect on the safety of the product. When FDA reviews the change and validations, it can tell the manufacturer that the approach to validation is inadequate. Under the bill, the manufacturer could unsuspectingly release unsafe products.

Device Modifications. Section 702(d) originally was drafted in a way that would have permitted manufacturers to make significant and potentially dangerous modifications without submitting any data to FDA. Although the provision was improved, it still fails to address the need for manufacturers to submit 510(k)s when they make significant manufacturing changes or modifications. We understand that this will be corrected. If it is not, however, the provision remains problematic.

Promotion of Off-Label Uses. Prior to mark up, S.1477 had a provision that would have permitted companies to distribute journal articles and other types of information (such as textbook chapters, continuing medical education materials, etc.) to promote unapproved uses

Although the provision was stricken from the bill, we understand that an alternative provision is likely to be offered when the bill goes to the floor. There are problems with a provision that would allow manufacturers to promote uses that have not been proven safe and effective. The most serious problem is that it would reduce the incentive for companies to do the scientific research and have the new uses reviewed by FDA (in fact, there would be a disincentive because FDA might determine that the new use is not supported by the evidence). Off-label use promotion must be tied to the submission of an application supporting that use.

- can be worked out
- Gibson & have time

III. OTHER PROBLEMS WITH S. 1477

The Mission Statement. Section 102 suggests that FDA's public health protection activities are limited to protecting the public from unsafe or ineffective products. In fact, FDA's mission is to prohibit the marketing of products that have not been proven to be safe and effective. Because drugs and devices often carry inherent risks, Congress has required that they be proven safe before they can be sold.

Scientific Review Groups. Section 107 would require FDA to provide advisory committee materials to the affected sponsor. Therefore, FDA would no longer be able to give confidential information to an advisory committee. In addition, it requires FDA to make a final determination within 60 days of an advisory committee recommendation. This assumes that all matters presented to advisory committees are susceptible to "final" determination. This is not always true. A better approach would be to require FDA to make a determination within 60 days or to notify the affected persons of the reason why a decision has not been made and the timetable by which a decision will be made.

Appeals within the FDA. Section 108 requires FDA to establish an appeals system. It permits individuals to request scientific review group evaluation of any significant scientific issue pending before or made by the agency. FDA has procedures for appeals. This section would require FDA to develop yet another appeals process that may not fit all issues and may not be necessary. The issues that may be referred to a scientific review group should be limited to decisions that have been made -- not issues that are pending. The 60-day timetable for final determination is problematic.

Access to Unapproved Therapies. Section 202 authorizes sponsors of investigational new drugs and devices to make these products available to individuals with certain serious diseases or conditions. The provision is a codification and expansion of what FDA already does. Expanded access, however, should not be allowed to interfere with trials to establish safety and efficacy. Unlimited access would lead to this. There should be a requirement for active pursuit of testing and FDA should be permitted to terminate expanded access if it finds that expanded access is interfering with clinical trials.

Expanding Humanitarian Use of Devices. Section 203 amends the HUD provision to require a decision on a HUD exemption request within 30 days. It eliminates the current provision that limits the duration of an exemption and eliminates the requirement for regulations prior to implementation. The 30 day time frame in the bill is not realistic. It does not allow enough time to do a credible job of assessing a HUD application.

Clinical Research on Drugs and Biological Products. Section 302 requires written notification of a clinical hold within 30 days – it precludes telephone calls. This would allow less time to review a clinical investigation notification because a letter has to be drafted. A preferable approach would be to require a telephone call within 30 days followed by a letter within an additional 30 days. Section 302 also limits the circumstances under which FDA's could place an ongoing investigations on clinical hold. FDA could not longer issue a clinical hold because the clinical investigators are not qualified, the information provides by the sponsor is misleading, erroneous, or materially incomplete; the IND does not contain sufficient information to assess the risks to subjects; or the plan or protocol for the investigation is clearly deficient.

Clinical Research On Devices. Section 303 would permit developmental changes in devices under investigational device exemptions in response to information collected during an investigation without additional approval if the changes are not a significant change in design or basic principles of operation. This section also would permit changes to clinical protocols that do not affect the validity of the data so long as such changes do not affect any patient protection provisions of the protocol. These give sponsors wide latitude to make changes to an investigational device or study protocol during the course of a clinical trial without prior approval by FDA, a third party, or an IRB. The result may be study data that is a mixture of results from the various mid-study changes. This could complicate or undermine FDA's ability to make rational determinations about the safety and effectiveness of the investigational device.

Effectiveness, Outcome, and Cost-Effectiveness Standards. Section 408 provides that the review of an application cannot include the evaluation of any use that the applicant has not requested be included in the labeling. This appears to prohibit FDA from including, in the labeling, warnings about indications for which a product is dangerous or known not to be effective.

Definition of a Day for Purposes of Product Review. Section 409 defines the term "day" for purposes of reviewing a submission. It is problematic if it would require FDA to complete its review of a submission within a few days of receiving a substantial amount of new information.

Initial Classification of Devices. Section 702(b) would permit a 510(k) submitter to request advisory committee review of classification decisions prior to final classification. This is a workload issue. In addition, many 510(k) submissions do not contain adequate or sufficient information to warrant advisory committee review. The timeframes for panel meetings are

unrealistic.

Device Tracking. Section 704 limits tracking to class II and III devices, changes the criteria for a tracking requirement, and eliminates FDA's discretion to apply the provision to "any other device." The provision eliminates the "discretionary" category, which now includes infusion pumps, breast implants, and other silicone related devices. The provision was made more acceptable by adding "would be reasonably likely to be" before "life threatening." It would be preferable if the "permanently implantable" language was changed to "implanted for more than 30 days."

Combination Animal Drugs. Section 802(b) lists factors to be considered by FDA when approving combination drugs. It does not require sponsors of combination animal drugs to demonstrate effectiveness for their products; they would be permitted to include in a combination animal drug two or more drugs that are targeted to the same indication without having to show that each active ingredient provides some additional benefit. It also does not require the sponsors of animal drug combinations to establish the safety of the combination to the animal targeted to receive the combination.

Minor Species Animal Drugs. Section 802(d) eliminates the requirement that sponsors establish the effectiveness of a drug intended for use in a minor species or intended for a minor use. Elimination of a requirement to show effectiveness takes us back to 1962. There is no point to having available drugs that cannot be shown to be effective.

Indirect Food Additives. Section 902 purports to create a notification system for indirect food additives. The process, however, is not a true notification system. FDA may not simply permit a "notified" substance to go on the market; it is required to act by regulation to "approve" a notification. Because the bill calls for a regulation for each notification, it is not a true notification, but is a petition review process with a 90-day timeframe.

~~Affir~~ ~~Affirm~~

Necessary changes

① prowess

② problem

③ Our proposed solution

Title IV -- Efficient, Accountable, and Fair Product Review

Contracts for Expert Review [§ 403(a)] ok but not great green.
RED Off-Label Promotion [§ 407]
Effectiveness, Outcome, and Cost-Effectiveness Standards [§ 408] Technical change warnings/work out
Alternative Approval of Supplemental New Drug Applications [§ 410] — as is (Remedy amendment)
Red Pediatric Studies Marketing Exclusivity [§ 411]

Title VI -- Drug and Biological Products Regulatory Reform

New Drug Approval Standard [§ 602]
Manufacturing Changes [§ 604] YELLOW
Effective Medication Guides [§ 607] RED

Title VII -- Device Regulatory Reform

technical?
Fixed Automatic Exemption of All Class I Devices [§ 702(a)] — ② GMP ① Performance standards,
Substantial Equivalence Determinations [§ 702(c)]
B Medical Device Modifications [§ 702(d)] Big but agreed to work out
RED Medical Device Approval Standards [§ 703]
Device Performance Standards [§ 708]
Accredited Party Participation [§ 709] -- Medical Device Pilot Program RED

Title VIII -- Animal Drug Regulatory Reform

Evidence of Effectiveness [§ 802(a)] —

Title IX -- Food Regulatory Reform

Health Claims of Food Products [§ 903] RED

Miscellaneous Provisions

Shortened Review Times w/ Statutory Hammers Hammers -- RED
Review Times -- YELLOW

** There are additional technical and substantive changes throughout the bill that are important, but do not make FDA's "serious concerns" document. GREEN

— work out

Bright green

R

FDA probably has the authority to require such studies by regulation. FDA requires by regulation that phase 2 and 3 studies address subpopulations (e.g. women) even where the drug's label won't make specific claims w.r.t. population. FDA is requiring phase 4 (post-market) pediatric testing of protease inhibitors.