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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	re: Clearance (1 page)	10/15/1996	b(6)
002. list	re: Clearance (1 page)	10/15/1996	b(6)
003. note	re: Food Safety [partial] (1 page)	n.d.	b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10451

FOLDER TITLE:
Food Safety Background
Food Safety - Background

2014-0046-S
rc1408

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
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PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
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b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

- Expanding amt. of birds ~~inspecting~~
- zero-tolerance

532-9110- ——
Ext 366

Poultry inspectn.

Bruce Ingersoll —

— Wanted to run a story about Tyson – White House connectn — early on poultry

— Went to OMB — Held up — Glickman called Sally). —

— Ingersoll — called at 8:00
— ~~reached~~ press secty reached him at 9:00 – said he was ~~not~~ on deadline on hung up.

— Reuters — de Wall quoted. —
in Reuters story

—

Codify
— Zero tolerance on visible fecal matter
— ↑ The amt of inspectn

Aug '94 proposed rule
Enhanced poultry inspectn program
Most superceded by HAACP. —
in July — we said we would codify zero tolerance on visible fecal matter.

Phone
x66742

Fax
x553249

Goals of "Initiative"

Defining our next steps in food safety, including those in budget initiative

Focus on 90 Days

Identify issues for lengthier discussion, process for on-going dialogue (strategic plan?)

What WH meetings are for:

hear concerns -- substantive process
Working draft -- Have we identified the right issues? Missed some? What might we reach consensus on in next two months?
Is the process workable?

Who will be there

USDA:	Cathie Woteki, Tom Billy
FDA:	Jerry Mande + 1
CDC:	Donald Shriber
EPA:	Jim Aidala

WH	
DPC	Elizabeth Drye
OMB/OIRA:	Sally Katzen or staff
OMB/Ag:	TJ Glauthier (Adrienne Erbach)
OMB/Health:	Nancy-Ann Min (Richard Turman)
VP:	Jean Logan
OSTP:	Carolyn Huntoon

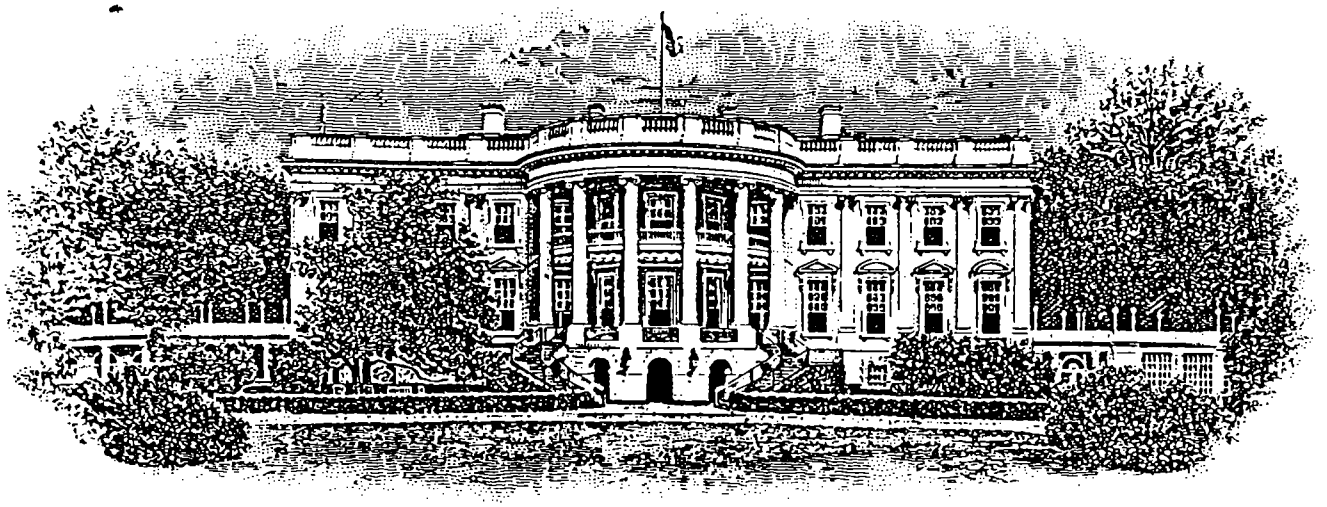
- education conference beyond the 90-day period.
- better ways to

Still waiting

Thursday — 4:30 — to early on Thursday

- Oysters

The White House



DOMESTIC POLICY

5-4304

FACSIMILE TRANSMISSION COVER SHEET

TO: WAVES

FAX NUMBER: 5 5349

TELEPHONE NUMBER: 6-6742

FROM: Elizabeth Drye

TELEPHONE NUMBER: 6-5573

PAGES (INCLUDING COVER): 2

COMMENTS: Please wave in the list of people, attached, for today, Oct. 15, 4:00 pm; Room 472 OEOB. Thank you.

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STATE-OF-THE-ART CLINICAL ARTICLE

Changing Epidemiology of Food-Borne Disease: A Minnesota Perspective

Craig W. Hedberg, Kristine L. MacDonald, and Michael T. Osterholm

From the Acute Disease Epidemiology Section, Minnesota Department of Health, Minneapolis, Minnesota

Food, like water and air, is a basic human need. Furthermore, an abundant and varied supply of food can greatly enhance the quality of life. However, beyond providing energy, nutrients, and gastronomic delight, food is a potential vehicle for pathogenic microorganisms and their toxic products. To many, the concept of food-borne disease is primarily that of the classical picture of staphylococcal intoxication, the sudden onset of severe nausea, cramps, vomiting, and diarrhea that occurs 2 to 4 hours after eating food that has been left too long at room temperature. During the first half of this century, staphylococcal intoxication was the main type of food-borne disease recognized. Over the past 15 years, the epidemiology of food-borne disease has shifted. Increasingly, food-borne disease is being attributed to a wide variety of bacteria, parasites, and viruses. Today the risk of food-borne disease depends on the type of food, its production source, how it is prepared and handled, and the consuming host's resistance to the infectious agent. As these factors change, the epidemiology of food-borne diseases also necessarily changes.

The relationship between cardiovascular disease and consumption of saturated fat has led many Americans to abandon the traditional meat-and-potatoes diet that accompanied the postwar boom of the 1950s. The new American diet emphasizes fruits, vegetables, and grains and deemphasizes meats and foods with a high content of fat. The concept of a diet balanced between the four basic food groups has been replaced by a diet built on a food pyramid. Public information campaigns, such as Five-a-Day for Better Health from the National Cancer Institute, promote increased consumption of fresh fruits and vegetables. Progress has been made in promoting the heart-healthy diet during the past 30 years. However, these dietary changes have also altered the epidemiology of food-borne diseases in the United States.

In this review we discuss results of national surveillance of food-borne disease, the importance of national changes in the factors that contribute to the epidemiology of food-borne disease (as illustrated by the results of food-borne disease surveillance at the Minnesota Department of Health), and issues of food safety for the 1990s and beyond. We focus primarily on investigations conducted in Minnesota because our recent experiences have demonstrated the importance of many of these factors. In addition, the fact that these outbreaks were recognized in Minnesota, a state with only 2% of the population of the United States, suggests that problems of food-borne disease are actually much more widespread.

Food-Borne Disease Surveillance

Estimates of the number of cases of food-borne disease in the United States range from 6.5 to 81 million cases per year, with from 525 to >7,000 food-borne-disease-associated deaths per year. Economic losses to ill persons, food producers, and the national economy have been estimated to be more than $8 billion to $23 billion annually. Better estimates are lacking, in part, because food-borne disease surveillance typically involves a series of events, only some of which are controlled by public health officials. First, an ill individual must seek and have access to medical care. Second, a clinician must obtain stool (or other appropriate clinical specimens) from the patient for microbial analysis. Third, the clinical laboratory must have the technical capability to evaluate the stool for the likely causative agent. Fourth, results of the stool culture and clinical information must be reported in a timely manner to state or local health departments. Finally, public health officials must have the resources to investigate the occurrence of the illness(es). A break at any step in this process will likely result in a failure to recognize the occurrence of food-borne disease.

The purpose of food-borne disease surveillance is to better understand the causes of food-borne disease, to develop and provide for implementation of appropriate control measures, and to detect trends in the epidemiology of food-borne disease. Outbreaks of food-borne disease are typically investigated by state or local health agencies and reported to the national food-borne disease surveillance system of the Centers for Disease Control and Prevention (CDC). From 1973 to 1987, 7,458 outbreaks involving 237,545 cases of food-borne disease in the United States were reported to the CDC. During this period, there was a decline in the proportion of outbreaks due to staphylococcal toxin and *Clostridium perfringens* and an increase in the proportion of out-

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breaks caused by *Salmonella* species. In addition, Norwalk virus, *Campylobacter jejuni*, *Escherichia coli* O157:H7, and *Listeria monocytogenes* emerged as important food-borne pathogens.

The number of outbreaks reported to the CDC peaked during 1982 and declined through 1987. It is unlikely that this decrease is due to an actual decrease in the incidence of food-borne disease in the community. The probable cause is related in part to the increased burdens placed by the epidemic of AIDS on the resources of state and local public health agencies and to the lack of support for the public health infrastructure.

Although national food-borne disease surveillance can be a powerful public health tool, the current system has limitations. Resource constraints affect the abilities of public health officials to adequately investigate small or even large outbreaks of food-borne disease, thus compounding the variability in reporting by type of pathogen. For example, during the 1980s, outbreaks due to *Clostridium botulinum* were reported more commonly to the CDC than were those due to *Campylobacter* species. In addition, the ability of laboratories to isolate and identify organisms in clinical specimens from patients and in implicated foods limits our awareness of the diversity of food-borne pathogens and the relative contribution of organisms that may not routinely be identified by clinical laboratories.

To illustrate recent trends in the occurrence of food-borne disease, we focused primarily on investigations conducted in Minnesota from 1978 through 1993. During this period, ~200 confirmed outbreaks of food-borne disease were investigated by local health departments and the Minnesota Department of Health. In ~10% of these investigations, the public health implications of our findings, with respect to the transmission, detection, and control of food-borne diseases, led to publication of the investigation report (table 1). The Minnesota Department of Health has attempted to aggressively identify and investigate the occurrence of food-borne disease during the past 15 years. Because of this aggressive approach, we believe that the trends evident from our statewide surveillance may be more representative of the true national picture than are data from many other states where resources for conducting such investigations are more limited.

Table 1. Outbreaks of food-borne disease: selected investigations conducted by the Minnesota Department of Health, 1978–1993.

Disease/agent	Vehicle	[Reference]
Brainerd diarrhea	Raw milk	[1]
Campylobacteriosis	Raw milk	[2]
Campylobacteriosis	Raw milk	[3]
Eosinophilia-myalgia syndrome	L-Tryptophan	[4]
Escherichia coli O157:H7 infection	Precooked ground beef patties	[5]
Giardiasis	Home-canned salmon	[6]
Giardiasis	Sandwiches	[7]
Hepatitis A	Relish	[8]
Norwalk gastroenteritis	Frosted bakery products	[9]
Norwalk gastroenteritis	Multiple cold food items	[10]
Norwalk-like gastroenteritis	Nonfrosted bakery products	[11]
Salmonellosis		
S. newport	Ground beef	[12]
S. enteritidis	Fast food	[13]
S. poona	Cantaloupes	[14]
S. javiana	Tomatoes	[15]
S. javiana and S. orantienburg	Cheese	[16]
S. montevideo	Tomatoes	Unpublished observations*
Shigellosis	Cold airline food	[17]
Thyrotoxicosis	Ground beef	[18]

NOTE. The outbreak investigations summarized in this table represent the work of many individuals and agencies in collaboration with the Minnesota Department of Health.

* J. W. McFarland, C. Hedberg, J. Besser-Wiek, et al. (Minnesota Department of Health).

Changes in the Factors That Contribute to the Epidemiology of Food-Borne Disease

Changes in several factors on a national level have contributed to changing the epidemiology of food-borne disease in the 1990s. First, changes in diet have resulted in changes in both the type and source of foods consumed. Increased consumption of food in commercial food service establishments has resulted in greater potential exposure to illnesses transmitted by food handlers. In addition, new methods of food production have been developed along with large and complex networks of distribution. Within the context of these changes in society and industry, new infectious agents continue to emerge and new trends for known agents transmitted through food are recognized.

Changes in Diet

The changes in the American diet that have resulted in part from public health efforts to prevent cardiovascular disease (and more recently cancer) can be demonstrated by changes in the consumption of selected foods in the United States from 1970 to 1990 (table 2). During this period, average per capita consumption of whole milk declined 59% from 219 to 90 lb annually, and per capita consumption of red meat declined 15% from 132 to 112 lb. At the same time, per capita consumption of low fat milk, cheese, poultry, fresh vegetables, and fresh fruits increased 163% (50 to 131 lb), 117% (11 to 25 lb), 87% (34 to 64 lb), 29% (88 to 113 lb) and 16% (101 to 117 lb), respectively. Although these are national summary data based on the availability of foods in the marketplace, the decrease in saturated fat consumption

Table 2. Changes in per capita consumption of selected food items in the United States from 1970 through 1990.

Food item	Pounds of food		Change (%)
	1970	1990	
Whole milk	219	90	−59
Red meat	132	112	−15
Low fat milk	50	131	+163
Cheese	11	25	+117
Poultry	34	64	+87
Fresh vegetables	88	113	+29
Fresh fruit	101	117	+16

NOTE. Data provided by the Economic Research Service, United States Department of Agriculture

predicted by these data is consistent with observed declines in levels of serum cholesterol in the community.

These dietary changes have coincided with dramatic increases in product availability in the United States. During the 1950s, the average grocery store in the United States stocked 300 food items on its shelves. By 1990, this number had increased 80-fold to 25,000 different food items. Currently, it is not uncommon to find grocery stores stocking over 50,000 different food items on their shelves, including hundreds of varieties of fresh fruits and vegetables, exotic seafood, grains, or food supplements.

The increased demand for fresh fruits and vegetables has also produced changes in the operation of food service establishments. Surveys conducted by the National Restaurant Association found that salad bars and separate sections for smokers and nonsmokers have become two of the most frequently sought features in a restaurant. By 1988, 71% of fast-food and family restaurant chains offered salads or salad bars. Meeting the increased demand for fresh fruits and vegetables in the United States has required the seasonal importation of produce from Mexico, Central America, and other tropical areas. Seasonally, >75% of fresh fruits and vegetables are harvested outside the United States and delivered within days to grocery stores and restaurants (table 3). During the winter months from 1989 through 1992, 33% to 70% of cantaloupes, 57% to 72% of green onions, 69% to 79% of cucumbers, and 20% to 64% of tomatoes purchased by consumers in the United States were harvested in Mexico. With the pending formation of a free trade zone between Mexico, the United States, and Canada, it is likely that produce imports from Mexico into the United States will increase substantially in the future. Competition between producers in the United States and in foreign countries may also result in cost-cutting measures in agricultural areas in the United States that already rely on low-paid migrant workers. These factors increase the potential for produce to become contaminated in the field, during packing, or during distribution to retail markets.

The other side of Five-a-Day for Better Health. One result of the increased consumption of fresh fruits and vegetables has been the recent occurrence of large outbreaks of hepatitis A, shigellosis, and salmonellosis due to the widespread distribution of fresh produce items. Although outbreaks of salmonellosis associated with fresh fruits and vegetables traditionally have been rare, four multistate outbreaks of salmonellosis, each involving 100 to 400 confirmed cases, have been attributed to fresh fruit or vegetable sources since 1990; three outbreaks occurred in Minnesota. Two outbreaks (one of *Salmonella chester* in 1990 and one of *Salmonella poona* in 1991) involved consumption of cantaloupes, and two outbreaks (one of *Salmonella javiana* in 1990 and one of *Salmonella montevideo* in 1993) involved consumption of tomatoes.

All of these outbreaks were recognized through statewide surveillance by public health laboratories of *Salmonella* serotypes isolated from humans. The unusual occurrence of an uncommon serotype prompted state health officials to investigate the source of the infections. In each outbreak, results of extensive epidemiologic studies implicated the food item and indicated its probable source of origin. In none of these outbreaks were the outbreak-associated organisms isolated from the implicated fruit or vegetable; most of the implicated food products had been consumed or discarded before investigation. However, following the identification of cantaloupes from Mexico as the source for the *S. chester* outbreak, investigators from the United States Food and Drug Administration (FDA) conducted bacteriologic sampling of imported cantaloupes and watermelons entering at the Mexico-United States border. The FDA isolated numerous serotypes of *Salmonella* from ~1% of the rinds.

Investigation of the *S. poona* outbreak in Minnesota implicated cantaloupes shipped from an agricultural area in the lower Rio Grande area of Texas as the source. Illness was associated with cantaloupe in salad bars or in fruit salads but not with fresh sliced cantaloupe. This fact suggests that temperature abuse of the contaminated fruit may have resulted in increased pathogen load after the fruit was at room temperature for several hours. Since no common restaurants were

Table 3. Percent of selected produce items from Mexico sold in the United States by quarter, 1989–1992.

Quarter	Cantaloupe	Green onion	Cucumber	Tomato
January–March	33–70	57–72	69–79	20–64
April–June	23–40	33–51	15–17	10–30
July–September	0–1	4–20	1	4–8
October–December	9–28	30–45	23–26	5–13
Total	14–20	30–47	27–28	10–20

NOTE. Data are from the Agricultural Marketing Service, United States Department of Agriculture.

identified by patients with *S. poona* infection and because of the widespread distribution of cases, we believe that autologous cross-contamination of the fruit from the rind occurred. The extra handling required to prepare fruit salads and salad bars may have increased the potential for contaminating the fruit from the rind.

These outbreaks demonstrate the emerging potential for food-borne disease associated with fresh fruits and vegetables. Important epidemiologic features of these outbreaks included the absence of recognized clusters of cases associated with households or food service establishments despite the distribution of the implicated food items through both sources, the widespread geographic distribution of outbreak-associated cases, and the apparent sporadic or low-level contamination of the implicated food items. Only the temporal clustering of these unusual *Salmonella* serotypes made it possible to detect the occurrence of these outbreaks.

Delay in the recognition of these outbreaks made it difficult to trace the source of the implicated produce, thus precluding us from determining how the produce was contaminated or what corrective measures were needed to prevent the recurrence of similar outbreaks. Tomatoes are transported and stored at temperatures of 55°F to 60°F and are frequently eaten raw. Cantaloupes are grown on the ground and may be contaminated on their surface with dirt, chemicals, animal excreta, and pathogenic bacteria. The FDA developed specific recommendations for handling melons following these outbreaks after they sampled imported melons. One of these recommendations, thoroughly cleaning the surface of melons and all fruits and vegetables before they are handled and consumed, appears to be prudent. However, the potential efficacy of this recommendation is unknown. Given national trends toward consumption of fresh fruits and vegetables, these outbreaks are likely to occur more frequently in the future.

Increased Consumption of Food in Commercial Food Service Establishments

Along with changing diets, Americans have increased their consumption of food from commercial food service establishments. From 1972 to 1989, the number of restaurants in the United States with table service increased from 112,000 to 161,000. In addition, the number of fast-food restaurants doubled from 73,000 in 1972 to >146,000 in 1989. Of $564 billion spent for food in the United States in 1990, 37% was spent away from home in a commercial food establishment. Coupled with the increased consumption of fresh fruits and vegetables, the growth in the number of food service establishments has resulted in even greater consumption of cold food items prepared by hand by workers in commercial kitchens.

In 1990, ~10 million persons were employed in the food service industry. Typically, wages for food service workers are low, and benefits and advancement opportunities are lacking. In most situations, these workers receive no additional benefit package (no insurance, no sick leave, and no paid vacation). Because nationwide many employers in the food service business experience labor shortages, food handlers are often hired without regard for training in proper sanitation and hygiene. In addition, 38% of individuals employed in food service occupations in 1988 had not completed high school, compared with 14% of all employed individuals. Finally, the turnover rate in food service occupations is high: 42% of all food service employees in 1990 had worked for their current employer for <1 year, thus making it difficult to provide on-the-job training regarding hygiene and sanitation.

Several outbreaks of food-borne disease in Minnesota demonstrate the importance of contamination of food items by food handlers in a variety of food service settings. These outbreaks include viral gastroenteritis associated with bakery products, giardiasis associated with home-canned salmon, salmonellosis associated with a fast-food restaurant, and shigellosis associated with cold food items served on a commercial airline.

The potential for efficient transmission of a pathogen with a low infective dose in cold food items was demonstrated by two outbreaks of Norwalk or Norwalk-like gastroenteritis: in these outbreaks, bakery employees vomited at work and subsequently contaminated 76 L of butter cream frosting in one outbreak and several hundred hamburger buns and oatmeal cookies in another. Attack rates of at least 60% were observed among persons who ate the frosted bakery products, of which 10,000 were sold to the public. In the other outbreak, the observed attack rates were <30% among persons who ate contaminated bakery products that were not frosted. The transmission of Norwalk-like viruses among food service workers can lead to outbreaks of viral gastroenteritis that can persist at an establishment for >1 week. In fact, such transmission appears to be common in outbreaks of viral gastroenteritis. More than one ill food handler was identified in 14 (78%) of 18 restaurant-based food-borne outbreaks of viral gastroenteritis in Minnesota from 1984 to 1991. In six (43%) of these 14 outbreaks, the restaurant voluntarily closed for 72 hours because of the evidence of ongoing transmission to patrons.

Another outbreak that demonstrated efficient transmission and a low infective dose was an outbreak of giardiasis associated with home-canned salmon. Twenty-nine (48%) of 60 employees of a high school developed giardiasis between 2 and 23 November 1979. Epidemiologic investigation implicated consumption of home-canned salmon that was served in employees' lounges on 29 October. The wife of an employee had handled the salmon briefly while transferring it from the canning jars to plastic containers. She became ill with giardiasis 19 days after the salmon was served at the school. However, before transferring the salmon she had dia-

pered her 12-month-old grandson. He was subsequently shown to be an asymptomatic carrier of *Giardia lamblia*. Although she reported washing her hands after diapering her grandson, she was observed to have good hygiene, and the typical amount of salmon consumed by employees was only about one tablespoon, a large proportion of employees who ate the salmon became ill. Reported outbreaks of food-borne giardiasis are uncommon. However, the uncommoness may be due more to the long and variable incubation period, which makes recognition of an outbreak difficult, than to the actual frequency of their occurrence.

The transmission of salmonellosis by food handlers has not been recognized as being important. However, in September 1989, an outbreak of infection with *Salmonella enteritidis* occurred in patrons and employees of a fast-food restaurant in which growth of *Salmonella* on implicated food items was unlikely. Transmission took place over a 9-day period. A single employee who had onset of gastrointestinal illness 1 day before the first reported patron exposures was identified. A case-control study demonstrated that food items handled by this employee were associated with illness. Rates of illness ranged from 0.6% to 2.9% among patrons who ate during hours that the employee worked. Other employees also became ill after eating food handled by the implicated employee. Transmission of illness to patrons continued after the employee stopped working, apparently as a result of additional infected food handlers contaminating sandwiches.

Food handlers with asymptomatic or mild infections with *Shigella sonnei* may have contributed to transmission over a 1-month period in an outbreak of shigellosis associated with consumption of food on a Minnesota-based commercial airline. In October 1988, a local newspaper reported the occurrence of diarrheal illness among members of a Minnesota-based professional football team. Results of a cohort study of team members implicated cold sandwiches prepared in the Twin Cities at the airline's flight kitchen. Temperature abuse of the sandwiches between their preparation on Friday and consumption on Sunday probably allowed growth of *Shigella* and resulted in the relatively high attack rate among football players.

Subsequently, confirmed or probable shigellosis was identified among 240 passengers on 219 flights to 24 states, the District of Columbia, and four countries between 14 September and 13 October. An outbreak-associated strain of *S. sonnei* was isolated from football players and accompanying staff, airline passengers, and flight attendants. Thirty (4.1%) of 725 passengers on 13 flights with confirmed cases had confirmed or probable shigellosis. We estimated that at least 1,900 cases of shigellosis occurred among airline passengers during this outbreak. Illness was associated with consumption of cold food items served on the flights and prepared by hand at the airline's flight kitchen. Food items were likely contaminated during processing by one or more food handlers who acquired *S. sonnei* infection in the community. The larger outbreak was recognized only because of the outbreak among the professional football team members. Given the relatively low attack rate among passengers on scheduled flights, long incubation periods, and dispersion of ill individuals, recognition of this outbreak (or similar outbreaks) by routine surveillance methods such as reporting of cases of shigella infection to the CDC would have been virtually impossible.

New Methods of Food Production

Fresh fruits, vegetables, and other cold food items are now being mass produced and distributed through large and complex networks of distribution. The size and complexity of these operations can greatly magnify the public health significance of food-borne contamination.

The airline-associated outbreak of shigellosis is a case in point. The flight kitchen prepared 100,000 meals per week in an assembly-line fashion in a modern physical plant. Recipes and practices of food preparation had been analyzed for identification of potential hazards. Critical points to control these hazards were identified and monitored. This use of hazard analysis and critical control point evaluations represented the state of the art in food safety. However, the facility received an unsatisfactory sanitation rating, and major deficiencies in hand washing and food handling practices were noted.

The preparation cycle for meals, from initial preparation of ingredients to service on the airplane, frequently encompassed 2 to 3 days. The distribution of job responsibilities allowed individual food handlers to handle cold food items eaten by thousands of airline passengers and airline flight personnel. Although the flight kitchen provided a sick leave benefit, employees were required to have worked 90 days before becoming eligible for this benefit. The median duration of employment for 81 food handlers who were interviewed was 10 months (range, 1 week to 6 years). Several food handlers admitted to working while they were ill with diarrhea. However, due in part to the delay in recognition of the outbreak, none of the food handlers were shown to be infected with *S. sonnei*. The flight kitchen was designed to be a state-of-the-art facility. However, an apparent failure to adequately train and supervise food handlers on the production lines led to the occurrence of this outbreak.

In the modern world of food production and distribution, even relatively small producers become part of large and complex networks of food distribution. This type of distribution network can magnify the outbreak potential of events that may appear to be highly localized. An example of this is a multistate outbreak of infections with *S. javiana* and *Salmonella oranienburg* that occurred due to consumption of contaminated mozzarella cheese and shredded cheese products. As with the fruit- and vegetable-associated outbreaks of salmonellosis, this outbreak was only identified due to an in-

creased incidence of human infection with an unusual *Salmonella* serotype in Minnesota. After an initial case-control study implicated cheese as the source of the outbreak, a second case-control study confirmed that cases were more likely than controls to have consumed mozzarella cheese manufactured at a single cheese plant in Wisconsin or cheese that had been shredded at processing plants that also shredded cheese manufactured at the implicated mozzarella cheese plant. The outbreak-associated strains of both serotypes were isolated from two unopened 16-oz blocks of mozzarella cheese produced at the implicated plant. The most probable numbers of *Salmonella* organisms in these samples were 0.36/100 g (1.6/lb) and 4.3/100 g (19.5/lb). These low levels of contamination made the microbiological assessment of cheese samples very difficult. The implicated mozzarella cheese plant produced and distributed ~5.25 million lb of cheese between March and May 1989. It went bankrupt in May 1989. Although this plant was relatively small by industry standards, the distribution of its cheese to four large processors who subsequently shred it and thereby contaminated cheeses from other sources led to a widespread outbreak of salmonellosis.

Implications for sporadic or low-level contamination. During the 1950s, food-borne outbreaks were recognized because of high attack rates, short incubation periods, and their occurrence in defined groups. In contrast, mass-produced food items with sporadic or low-level contamination may be distributed to thousands of people living hundreds of miles from the source. These outbreaks typically involve low attack rates, often <5% among those consuming the implicated product. However, they assume major importance due to the very large numbers of persons exposed to the bulk product produced. The human consumer appears to have become the ultimate bioassay for low-level or sporadic contamination of our food supply. Today, contaminated food products with a level of contamination capable of infecting only one in 10,000 exposed persons (infective dose [ID], 0.01) take on as much public health importance as those with an ID_{50} of yesteryear.

New food technologies. In attempts to improve the convenience and quality of foods served in a variety of settings, cook-freeze, cook-chill, and minimally processed chilled foods are being developed and distributed. The potential for these foods to serve as vehicles for food-borne disease depends on the source and handling of the product as well as the consumer. In October 1988, 32 cases of bloody diarrhea or culture-confirmed infection with *E. coli* O157:H7 were identified among 1,562 students at a junior high school. A case-control study revealed that cases were more likely than controls to have eaten precooked hamburger patties in the school cafeteria on a specific day. The estimated attack rate among students who ate these hamburgers was 8%. The patties should have been sufficiently cooked by the manufacturer so that enteric pathogens were destroyed before they were frozen and distributed. Consumers do not typically consider these products uncooked since they appear to be similar to other precooked deli meats. However, *E. coli* organisms were cultured from frozen patties that were manufactured at the same plant on the same dates as the implicated patties, but serotype O157:H7 was not isolated. The reason for lack of cooking, or the frequency with which it occurred, was unclear. This outbreak demonstrated that precooked hamburger patties may serve as vehicles for *E. coli* O157:H7 infection. During a 12-month period in 1986 and 1987, more than 2 million of the 3.8 billion lb of raw hamburger produced in the United States were heat processed before distribution. Despite the findings of our investigation of this outbreak, there are currently no federal or state regulatory standards that ensure the safety of heat-processed uncured hamburger patties.

Products of microbial fermentation have been consumed by humans for thousands of years. Increasingly, highly selected and genetically engineered bacteria and fungi are being used in the development of new products and manufacturing processes. In 1989, we documented an outbreak of eosinophilia-myalgia syndrome (EMS), a recently described disease that was associated with such a product. EMS is characterized by marked peripheral eosinophilia with scleroderma-like features. Cases had occurred and patients had sought medical attention for several years before physicians in New Mexico and Minnesota reported that three patients with EMS had all consumed products containing tryptophan before the onset of their illnesses. Within several days of recognizing the occurrence of a cluster of such cases in Minnesota, we completed a case-control study that demonstrated an association between consumption of products with tryptophan and EMS. Following a similar study in New Mexico and a reported death of a patient with EMS in New York, the FDA ordered a recall of these products. Clinical features of the illness did not suggest a food-borne etiology, cases were geographically widespread, the outbreak had been occurring for >6 months before it was recognized, epidemiologic investigation identified the source of the outbreak, and the outbreak was controlled by the removal of tryptophan from the marketplace.

Epidemiologic investigations implicated consumption of tryptophan manufactured by a single Japanese company as the source of the outbreak. This company used a fermentation process involving *Bacillus amyloliquefaciens* to manufacture tryptophan. Analysis of the manufacturing conditions according to the retail lot demonstrated an association between lots consumed by individual cases and the use of reduced quantities of powdered carbon in a purification step as well as the use of a new strain of *B. amyloliquefaciens* (strain V). There was a significant correlation between the reduced amount of powdered carbon used during manufacturing and the use of the new bacterial strain. High-performance liquid chromatography of this company's tryptophan

demonstrated one absorbance peak that was present in nine of 12 retail lots used by cases and three of 11 lots used by controls. It was later determined that the structure of this peak was 1,1'-ethylidenebis(tryptophan).

Our data suggest that the outbreak in 1989 was caused by tryptophan-containing 1,1'-ethylidenebis(tryptophan) or another unidentified contaminant. Furthermore, the implicated tryptophan was manufactured by a single company under specific operating conditions that had changed shortly before the occurrence of the outbreak. Reduction in the use of powdered carbon may have allowed more of the etiologic agent to remain in the final product. The use of *B. amyloliquefaciens* strain V may have produced larger quantities of the etiologic agent than did the use of earlier strains. However, studies conducted by the company suggested that strain V differed from previous strains only in its genetically enhanced ability to synthesize serine and 5-phosphoribosyl-1-pyrophosphate. The role of genetically altered bacteria in this outbreak is not presently known but cannot be discounted.

New Infectious Agents

With each decade since the development of national food-borne disease surveillance, the list of recognized food-borne enteropathogens has expanded. During the 1960s, *C. perfringens* was identified as a food-borne pathogen of major significance. During the 1970s, Norwalk virus was identified as the primary cause of outbreaks of acute infectious nonbacterial gastroenteritis in the United States. During the 1980s, *Campylobacter* was recognized as an important cause of outbreaks associated with the consumption of raw milk and poultry, and *L. monocytogenes* and *E. coli* O157:H7 were reported as food-borne pathogens.

E. coli O157:H7. The emergence of a new pathogen may have regional, national, or global significance depending on the nature of the agent and how and where it enters the food supply. Some organisms emerge into the awareness of the medical and public health communities because investigators begin to conduct surveillance and laboratory studies to identify them (e.g., *Campylobacter, Listeria*). *E. coli* O157:H7 and other verotoxin-producing *E. coli* appear to be relatively new food-borne pathogens that are emerging as major public health problems. Nationally, the first outbreaks of hemorrhagic colitis due to *E. coli* O157:H7 were reported in 1983. These and several subsequently reported outbreaks were associated with the consumption of inadequately cooked ground beef. In addition to increasingly frequent reports of food-borne outbreaks due to *E. coli* O157:H7 infection, evidence of the emerging nature of this pathogen is demonstrated by surveillance for hemolytic-uremic syndrome (HUS).

From 1979 through 1988, 117 patients with HUS were identified through review of medical records from all hospitals in Minnesota. Four children died and 27 suffered serious complications. *E. coli* O157:H7 was isolated from 13 (46%) of 28 patients whose stool was submitted for examination for this pathogen. The incidence of HUS increased from 0.5 cases per 100,000 child-years among children <18 years of age in 1979 (six cases) to 2.0 cases per 100,000 child-years in 1988 (28 cases). The dramatic increase in HUS cases suggests an actual increase in the occurrence of *E. coli* O157:H7 during this period.

E. coli O157:H7 and HUS have been reportable in Minnesota since 1988. The number of cases of infection with *E. coli* O157:H7 reported to the Minnesota Department of Health increased from 48 in 1989 to 129 in 1992. In contrast, the number of HUS cases reported to the Minnesota Department of Health decreased from 28 in 1988 to nine in 1991 and 1992. We believe that the increase in cases of *E. coli* O157:H7 infection that was concurrent with a decrease in HUS cases was due to the increasing availability of laboratory testing for *E. coli* O157:H7 in Minnesota during this period. Nonetheless, only 28% of major clinical microbiology laboratories in Minnesota surveyed during 1992 screened for *E. coli* O157:H7. As many as one-third of *E. coli* O157:H7 infections in persons who sought medical attention and from whom stool specimens were collected during 1992 may have gone unrecognized due to lack of appropriate laboratory testing and reporting. Until laboratories routinely culture all stool specimens for *E. coli* O157:H7, until *E. coli* O157:H7 and HUS are made reportable in all states, and until national surveillance is implemented, it will be difficult to evaluate trends in the occurrence of these diseases and the impact of public health measures to reduce their occurrence.

S. enteritidis and eggs. The emergence of egg-associated *S. enteritidis* infection in the United States demonstrates that the epidemiology of illness caused by well-known pathogens is subject to change. During 1988, investigators from the CDC and several eastern state health departments reported a sevenfold increase in the rate of *S. enteritidis* infections between 1976 and 1986 in the northeastern United States. In addition, they noted a large increase in the number of *S. enteritidis* outbreaks associated with the consumption of eggs and egg-containing foods. The sources of eggs associated with a number of these outbreaks were traced to several large farms where laying hens infected with *S. enteritidis* were identified.

In Minnesota, where *S. enteritidis* has historically been one of the most common serotypes of *Salmonella*, the incidence of reported *S. enteritidis* infections doubled from 1.0 per 100,000 person-years from 1980 to 1983 to 2.4 per 100,000 person-years from 1987 to 1990. However, no egg-associated outbreaks of salmonellosis have been identified in Minnesota. A case-control study of adults in Minnesota that was conducted during 1989 and 1990 demonstrated that sporadic cases of both *S. enteritidis* infection and *Salmonella typhimurium* infection were more likely to have consumed

undercooked eggs or egg-containing foods during the 3 days before the onset of illness than were controls during a similar reference period. The frequent consumption of individual fried eggs by cases in this study suggests that the inoculum in the egg at the moment it was cracked into the frying pan was sufficient to cause infection. The proportion of reported sporadic cases of salmonellosis among adults in Minnesota that were attributable to the consumption of undercooked eggs was 37% for *S. enteritidis* infection and 16% for *S. typhimurium* infection. Our findings demonstrate that eggs are an important vehicle for *S. enteritidis* and *S. typhimurium*, even in the absence of recognized outbreaks, and may have a broader role in the epidemiology of human salmonellosis.

Food-borne diseases with atypical clinical presentation. Three separate outbreaks demonstrate the occurrence of novel food-borne diseases that were not initially suspected because the clinical presentation was not typical of food-borne disease. The first was an outbreak of Brainerd diarrhea, a previously undescribed chronic diarrhea syndrome that affected 122 residents of Brainerd, Minnesota, between December 1983 and July 1984. The illness lasted at least 1 year for 75% of cases and was characterized by acute onset, marked urgency, a lack of systemic symptoms, and a failure to respond to antimicrobial agents. Consumption of raw milk from a single dairy was associated with the illness. Extensive laboratory examination did not identify an etiologic agent. The outbreak went unrecognized for 6 months before clinicians suspected the possibility of a common relationship between the patients. Following the description of this outbreak, numerous other outbreaks in the United States that were similar in epidemiology were recognized to have occurred both before and after this one occurred. In addition to raw milk, two outbreaks of Brainerd diarrhea were associated with contaminated water. This illness appears to represent a previously unrecognized but important clinical entity.

Similarly, an outbreak of thyrotoxicosis caused by the consumption of bovine thyroid glands in ground beef occurred between April 1984 and August 1985 among residents of southwestern Minnesota and adjacent areas of South Dakota and Iowa. One hundred twenty-one cases were identified through surveillance of medical clinics, laboratories, hospitals, and physician's offices. A case-control study implicated ground beef patties prepared from neck trimmings from a local beef slaughter plant. The cause of the outbreak was confirmed by the findings of bovine thyroid tissue in samples of beef trimmings from the plant, high concentrations of thyroid hormone in case samples but not in control samples of ground beef, and the demonstration of prompt increases in concentrations of serum thyroid hormone in volunteers who ate the implicated ground beef. The outbreak ended after gullet trimming was discontinued at the plant. The practice was subsequently prohibited by the United States Department of Agriculture (USDA). The clinical features of the illness suggested the diagnosis of silent thyroiditis, and it is possible that sporadic cases, or even outbreaks, of thyrotoxicosis factitia caused by this mechanism may have occurred in the past but were not recognized.

A final outbreak that brings together many of the issues previously discussed is the occurrence of EMS. This outbreak demonstrates that public health action based on results of epidemiologic investigation can prevent occurrence of disease, even when the specific pathogens or other causative agents cannot be identified.

The occurrence of these outbreaks suggests that other diseases in our communities today could be due to the consumption of contaminated food but are not recognized as such. Thus, general disease surveillance and outbreak investigations are critical to understanding the pathogenesis of disease.

Food Safety Issues for the 1990s and Beyond

Requirements of Public Health Surveillance

Low-level contamination of mass-produced or distributed food products poses considerable challenges to public health surveillance of food-borne disease. Responding to these challenges requires redefining infectious disease surveillance in this country and providing the infrastructure support to carry out that surveillance activity.

Consumers who become ill (whether related to airline food, cantaloupes, cheese, tomatoes, or any of the more common vehicles of food-borne disease) and clinicians need to be aware of the potential for food-borne illness. However, the current cost-containment climate in health care may mean that clinicians and their patients will be less likely to request or obtain appropriate stool samples for culture. For any surveillance system for food-borne disease to succeed, clinicians must act on their clinical suspicions and notify local or state health departments. In addition, the public health infrastructure needs to be capable of responding to these reports by providing both the laboratory resources to confirm the agent and the epidemiologic resources to investigate the potential outbreak, no matter how small or localized it may seem. As demonstrated by airline-associated shigellosis, investigating a small outbreak may be the key to identifying a very large outbreak. In turn, this investigation may lead to the prevention of numerous additional cases of disease.

Epidemiologists must work with laboratorians to develop new detection and identification methods, evaluate the results of existing methods, and increase the likelihood for the productive use of limited public health resources. However, epidemiologists should not be constrained by the lack of laboratory support when epidemiologic results provide a clear description of events. Epidemiologic methods may be inherently more sensitive than bacteriologic methods in identifying the source of outbreaks resulting from the sporadic or low-level contamination of a widely distributed food prod-

uct. Therefore, FDA and state regulators should consider epidemiologic results as sufficient grounds for initiating and determining the scope of product recalls.

Developing and maintaining a public health infrastructure capable of conducting surveillance for food-borne disease is a key issue of food safety for the 1990s. As described above, the epidemiologic requirements and the need for laboratory support of food-borne disease surveillance are substantial. However, coordinated surveillance efforts on the local, state, and national levels are critical for detecting changes in the occurrence of food-borne disease. Currently, there is no federal categorical support for food-borne disease such as there is for AIDS, tuberculosis, sexually transmitted diseases, and vaccine-preventable diseases. As new agents (such as *E. coli* O157:H7) enter the food supply, as the scale of production of cold food items increases (such as in the flight kitchen involved with the outbreak of shigellosis), and as distribution networks for food items become more complex (such as in the distribution of cheese contaminated with *S. javiana* and *S. oranienburg*), a dedicated surveillance system is needed for identifying problems and suggesting potential strategies that will control and prevent similar occurrences in the future.

The American diet has changed in response to concerns relating diet to health. The increased demand for fresh fruits and vegetables has increased the potential for exposure to a wide variety of enteric pathogens, both foreign and domestic. The cumulative magnitude of exposure is such that even sporadic or low-level contamination of individual food items results in a significant public health burden of enteric disease. Interventions aimed at improving hygienic conditions in the production of fresh fruits and vegetables and improving food handling practices on the part of individual consumers may reduce the risk of food-borne disease associated with these foods. However, the use of new technologies, such as irradiation to pasteurize fruits, vegetables, and raw meat and poultry products, may play a critical role in ensuring the microbial safety of the food supply in the future.

The Consumer and Health Education

The final control in any system of food safety is the consumer. In a free society, individuals may choose to put themselves at risk for food-borne disease by eating undercooked eggs or undercooked hamburger or by drinking raw milk. However, the public health community should strive to eliminate unexpected hazards and make risk-taking choices informed ones. In 1969, a report of the USDA and FDA identified eggs as an important source of *Salmonella*. In October 1988, the Minnesota Department of Health and the Minnesota Department of Agriculture issued a joint news release advising against consumption of raw eggs because of the risk of acquiring salmonellosis. Despite this effort, only 17% of cases and 14% of controls enrolled in the case-control study of sporadic salmonellal infections during 1989 to 1990 identified eggs as a potential source of *Salmonella*.

Media publicity of food-borne disease problems can heighten the public's awareness. However, information does not immediately lead to behavior change. This circumstance may be due in part to the optimistic view that people have that they are less likely to develop a food-borne illness than is someone else. Food safety officials concerned with changing the eating behaviors of the public need to adapt the models of behavior change that have helped reduce cardiovascular disease risks in the population, particularly as they relate to diet.

In conclusion, the public health agenda for the 1990s must include a comprehensive review of food safety. We must develop and support new regulatory and public health programs to prevent food-borne disease that are tailored to the unique aspects of producing, processing, and distributing food in the 1990s. Those of us in the public health field must accept, as part of any basic public health program, responsibility for disease surveillance, and we must pursue the necessary resources for rapid investigation of potential outbreaks.

Acknowledgments

The authors are indebted to the ideas and hard work of our colleagues at the Minnesota Department of Health, the Council of State and Territorial Epidemiologists, the Centers for Disease Control and Prevention, the National Institutes of Health, and local public health agencies throughout Minnesota; to the physicians of Minnesota for their support over the years and their primary role in food-borne disease surveillance; and to the citizens of Minnesota who so willingly participate in our investigations of outbreaks.

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Suggested Readings

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501-821-4741

[illegible]

DRAFT

DRAFT

WORKGROUPS

HAZARDS (Identification, Sources)

Conveners:	Flamm and Oliver (FDA) and Potter (CDC)
FDA	Tollefson, Geyer, Bolger, Madden
CDC	Potter
USDA	
EPA	

SURVEILLANCE

Conveners:	Tauxe (CDC) and Falci (FDA)
FDA	McChesney, Barclay, Sherman, Miller, Cerniglia, [ORA to be named]
CDC	Tauxe
USDA	
EPA	

PREVENTION/INSPECTION

Conveners:	Chesemore and Shank and Hubbard (FDA)
FDA	Vince, Mitchell, Reynolds, Spiller, Lowell, Mayl
CDC	No representative to be named
USDA	Danford, Gioglio
EPA	

PREVENTION/APPLIED RESEARCH

Conveners:	USDA and Sundlof (FDA) and Page (FDA)
FDA	Page, Madden, Guidos, [ORA to be named]
CDC	Swaminathan
USDA	
EPA	

PREVENTION/RISK ASSESSMENT RESEARCH

Conveners:	Shank (FDA), Gaylor (FDA), Wachsmuth (USDA)
FDA	[CFSAN to be named], Guidos
CDC	Potter
USDA	Coleman
EPA	

DRAFT

COORDINATION

Conveners:	Mande and Lake (FDA) and Ostroff (CDC)
FDA	Lindan Mayl, Guidos, [ORA to be named]
CDC	Ostroff
USDA	Stafko
EPA	

EDUCATION

Conveners:	Connolly (USDA) and Oliver and Mayl (FDA)
FDA	Durham, Schiffman, Miller, Leggett, [ORA to be named]
CDC	[to be named]
USDA	Davidson
EPA	

SPECIAL INITIATIVES/PRIORITY SETTING

Conveners:	Hulebak and Lake (FDA) and Potter (CDC)
FDA	Sundlof, Flamm, Madden, Bolger, Spiller, Ralston
CDC	Potter
USDA	Morris
EPA	

- What about a form to table type strategy?

I think he's right in saying in 2 months you might look at 1-2 ~~communities~~ narrow, specific actions to illustrate approach. Mike's right — have to be as concrete as possible.

Could this — 1 or 2 themes be addressed in the State of Union — as developed by this group

No. Cal
Minnesota
CT
Oregon, Atlanta
Greatest value - long term research

- will allow you tailor preventive measures

But also operates - could save a child from getting sick
- catch problem sooner
- once you catch problem, able to identify it.

- advances in molecular biology / telecommunications

- cluster recognition -

Sentinel Site
Ids distribution to molecular labs
Analysis
Epidemiologists to set labs
at food outbreaks.

Shorter
- identify outbreak
- more sites
- catching

Research
- information
Preventive -
- improve our approach to food safety.
- molecular biology

- Identify outbreak before anyone else
- pick cases out by noise - molecular subtyping.
- don't have to trace them to common cause.
- Multiple sites - have higher likelihood of finding.

Carol Tucker Foreman
Ann Lewis
Safe Food Coalition

~~to Peop~~

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary
Office of Public Health and Science
Office of Disease Prevention and Health Promotion
200 Independence Ave, S.W., Room 738-G
Washington, D.C. 20201

FACSIMILE TRANSMISSION

TOTAL PAGES (including this cover page): 1

DATE: October 18, 1996

TO: Philip Lee, HHS/OPHS, 690-6960
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William Raub, HHS/ASPE, 202 401-7321
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FROM: Dalton Paxman

TELEPHONE: 202/205-5829 | FAX: 202/205-9478

Message: The Interagency Food Safety Initiative meeting set for Wednesday will be rescheduled for either November 4 from 2-4 or November 5 from 10-12 , in room 729G (same room), Humphrey Bldg., 200 Independence Ave., S.W. We will confirm the date shortly. Please call me with any questions.

Dalton Paxton

- Helpful
- DPC - coordinates r&d

Report format

Problem

What we need to do

Cost

Time line

Purpose

- Food safety cmt. Dr. Lee Chair's NSTC - developed document in FoS — outlines 5 priority areas — one investment

↓ Incidence of food borne illness

↑ Infrastructure

↑ Scientific understanding

- Thoughts about priorities

- reduce resources forward

- Future risks

- focused research

- anticipating future risks

Outcomes

- Pathogen ↓

- better use of resources

- avoided quantitative goals

R.A. — surveillance, research ← Hazard id.
exposure id.
R.M. —
R.C. — education initiative

Schedule —

by Tuesday — Themes for circulation
workgroups — crash on outline next week
this group — meets in 2 weeks —

— 5-6 food borne illness —

Mtg Notes | 10-15

Mike - Questions —

- Food Product Streams. (But look at what kind of cases)

Where is the biggest risk —

- What ~~does~~ do people perceive —

- Systems to collect more data?
  - benefit to patient of seeing physician. —

Schwan's Outbreak
Minnesota ice cream outbreak
- home delivery by name.
< 1/2 ~~%~~ .5% got reported in well-publicized case

Do you have to know what kind of cases, or do these bugs travel in packs?

Day care - associated E-Coli. —
E-coli

Surveillance —

intervention methods

outbreak in

— More surveillance —

— Pasturization in foods other than milk

— worker education. —

— Reactive / Proactive. —

Prevention - applied research

— Pasturized egg product. —

Characterization of bugs doesn't help patient —
but helps target source. —

- Big outbreaks

- Classic EPA (+)
  Good microbiology
  CDC -
  FDA/USDA help in investigational -

  Products
  Bugs
  Techniques

- + Infrastructure -

  Tom (RA guy)
  Pick time bombs
  - Cyclospora —
  - pasteurized egg —
  - response —
    Not $ — coordination
  - Irradiation

  - Response to
    - Data in Epi —
    Surveillance
    ~~Analysis~~

  - VFC program -
    Short steps in a longer journey —

Rob Tauxe

Food Safety for the 21th Century

Vulnerabilities of the Current Situation

- Factors influencing food safety
  - -Changes in the US population
  - -Changes in technology and industry
  - -Increasing international commerce and travel
  - -Changing microorganisms
  - -Eroding food safety infrastructure

Food Safety for the 21th Century

Factors Influencing Food Safety

- Changes in the US population
  - Increased susceptible persons
    - Aging
    - Cancer
    - AIDS
    - Immunosuppressive drugs
  - Increased problems with organisms like *Listeria monocytogenes*

Food Safety for the 21th Century

Factors Influencing Food Safety

- Changes in technology
  - Animal production– BSE, antibiotic resistance
  - Keep refrigerated foods– botulism, listeriosis
- Changes in industry
  - Consolidations, increased distribution– interstate and international salmonellosis

Food Safety for the 21th Century

Factors Influencing Food Safety

- International commerce and travel
  - Rapid spread of foodborne diseases by people, foods, and transporting vehicles– salmonellosis, cholera, shigellosis

Food Safety for the 21th Century

Factors Influencing Food Safety

- Changing microorganisms
  - new diseases, increasing virulence, increasing antibiotic resistance– salmonellosis, *E. coli* O157:H7

Food Safety for the 21th Century

Factors Influencing Food Safety

- Eroding Food Safety Infrastructure
  - Complancy towards food safety
  - Aging or inadequate water and sanitation systems
  - Decreasing resources and competing priorities at local, state, and federal levels

A sampler of recent foodborne outbreaks still waiting for definitive control measures

- U.S. nationwide: Hundreds sickened after eating alfalfa sprouts, a "health food", grown from contaminated seed.
- U.S. nationwide: *Cyclospora* outbreaks in the U.S. Guatemalan raspberries sprayed with contaminated water the most likely source.
- U.S. nationwide: Thousands all over the U.S. sickened from ice cream trucked in dirty trucks that also hauled raw eggs.
- Mass: Dozens of kids sickened by apple cider squeezed from dirty apples.
- Midwest: Dozens sickened after eating green onions imported from Mexico, probably rinsed in dirty water, or shipped on dirty ice.
- U.S. nationwide: Dozens of outbreaks each year in nursing homes, restaurants, and institutions due to undercooked eggs, 10 years after this hazard was identified (More than caused by *E. coli* O157).

Preventing foodborne disease in the 21st century - the central challenge

- Our food is a mass-produced industrial product:
  - How many hundreds of animals in one hamburger?
  - How many people had a hand in your lunch?
  - When things go wrong, many people over a wide area are affected
- Our food supply is not the safest in the world:
  - Increasingly, our food supply is the world.
- Trends towards "fresh" and "organic":
  - "fresh" means fewer barriers to contamination
  - "organic" often means grown in manure
  - Challenge: Insert multiple steps to make food clean and keep it clean in a microbial world

Preventing foodborne disease in the 21st century - the various roles

- Surveillance for infections and investigation of outbreaks - done by local and State Epidemiology offices and CDC
- Primary mission is to prevent human illness - we investigate individual illnesses and outbreaks to learn what went wrong, so that it can be fixed for the future.
- CDC and States depend on the regulatory agencies - FDA and USDA to
  - provide expert assistance in investigations,
  - act on the epidemiologic evidence,
  - devise workable prevention strategies for each food industry via applied research,
  - work with industries they regulate to improve food safety.

The role of CDC and States in monitoring and prevention of foodborne disease

- Monitoring for new and emerging problems
  - Early warning system
  - Diagnosing new infections, identifying new hazards
- Defining where the solutions lie
  - Focus on risky foods and risky practices
  - Understanding how contamination occurs well enough to prevent it
- Taking emergency measures to halt outbreaks
- Assessing the success of the solutions
- To do this - must have an independent monitoring and investigative agency, not the regulatory agency itself

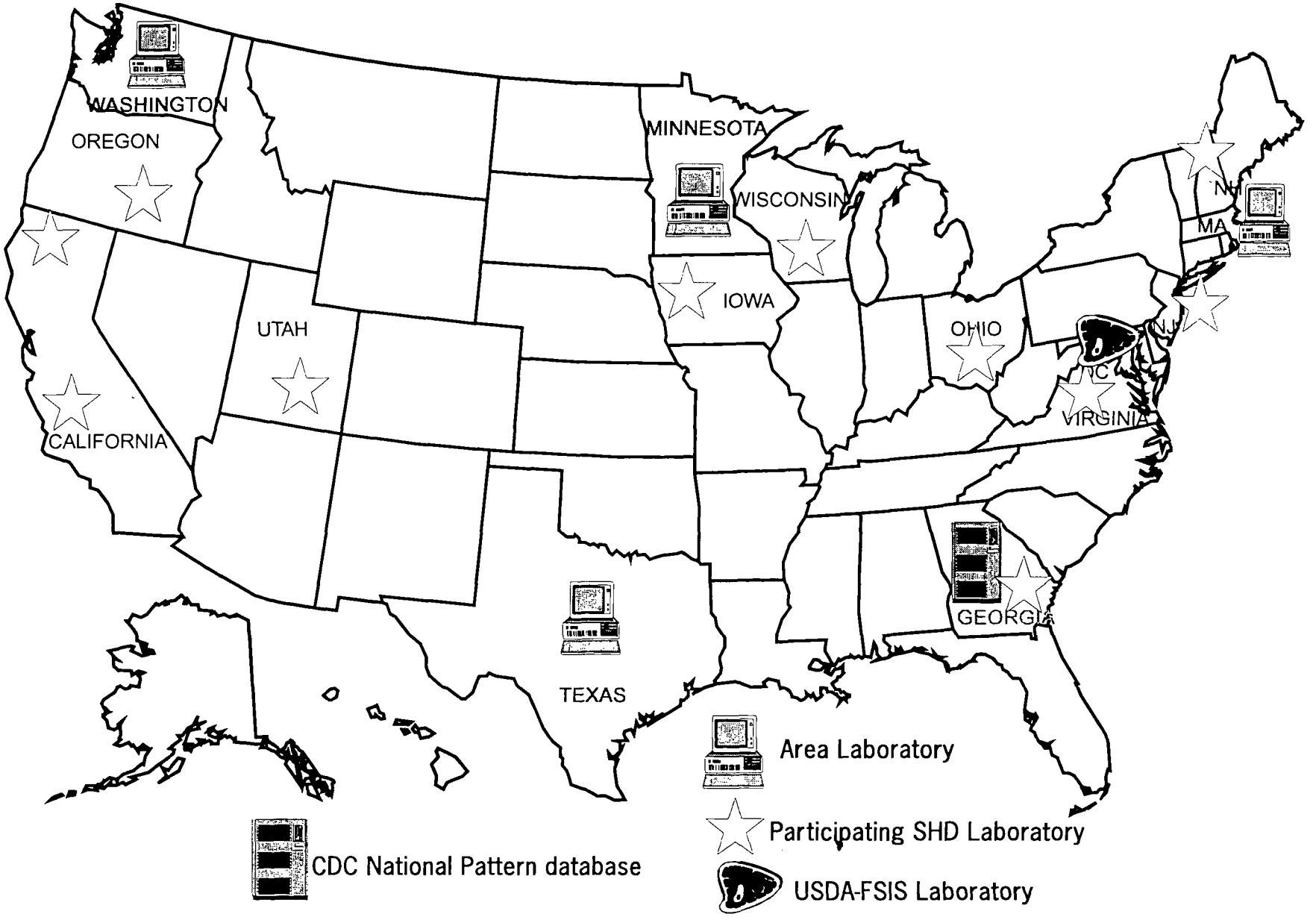
Making food clean and keeping it clean: Prevention industry by industry *The critical arena for the regulatory agencies*

- Meat and poultry:
  - The new meat inspection safety measures that include microbiologic testing are an important first step
  - An excellent example of the new systems approach
- Seafood:
  - The new seafood regulation is a start, but there is more
- Eggs (Salmonellosis):
  - A national plan exists, but little has been done
  - Immediate measures are needed
- Fresh fruit and vegetables, a growing problem:
  - Very little current regulation or review
  - Much applied research needs to be done soon

Monitoring foodborne disease - improving surveillance, the early warning system

- Basic surveillance of infectious diseases via local and State health department epidemiologists and CDC
- There is a plan to improve foodborne disease surveillance:
  - Active surveillance program at five sentinel sites.
  - New molecular technologies to subtype ("fingerprint") pathogens, detect subtle outbreaks.
  - Monitoring of antimicrobial resistance.
  - Better coordination with regulatory agencies.
- Future plans:
  - New national network for "fingerprints"
  - Surveillance for serious sequelae: hemolytic uremic syndrome
  - Stronger and swifter public health infrastructure
  - Systematic search for new pathogens

The National Molecular Subtyping Network for Foodborne Disease Surveillance



Preventing foodborne disease: Building safety in from farm to table - proactive process control efforts by industry and regulators

- Doable now:
  - Implement the new meat safety program widely and assess it
  - Use better processing machinery to prevent contamination
  - Ship produce on clean ice, in clean trucks
  - Require nursing homes to use pasteurized eggs
  - Refrigerate eggs
  - License alfalfa sprouters as food producers
  - Monitor presence of toilets on oysterboats
- Doable with more research on how to:
  - Make manure safe for use on produce
  - Decontaminate produce (can you wash dirty lettuce?)
  - Raise cows without *E. coli* and egg laying hens without *Salmonella*
  - Detect new and emerging pathogens in food
  - Use new pasteurizing technologies for meat, eggs and produce

Food Safety for the 21th Century

Addressing the Vulnerabilities

- Enhanced surveillance of animals, foods, and people
- Rapid and coordinated outbreak response
- Applied research in food science and public health
- Rebuild the food safety infrastructure

① Introductions

Mike Osterholm — Minnesota State Epidemiologist
— States are on the front line —
10-15 min presentation —

— Current epi of food borne illness

Mitch Cohen and Rob Tauxes from CDC

Glen Morris — USDA

President signed PDD on emerging infectious diseases.

Goal — This Admin broad food safety intiative would be a major theme of 1998 budget
— how do we achieve it —
— coordinate / facilitate —
— policy / technical people
— involves USDA

— Impt to work with colleagues in the state
— frontlines.

Appreciate their being here —
to bring us up to date.

Happy to provide forum. —

Laura Efros
Caroline Hewitson

Pros Decora Director

FOOD SAFETY INITIATIVE (FSI)

Steering Committee Meeting

FINAL AGENDA
October 4, 1996

- Opening comments and introductions
- Discussion of process for developing the FSI
  - Discussion of outline
  - Workgroup structure
  - Review of FSI schedule
- Review of required immediate actions
  - Meeting of priority setting/special initiatives workgroup on Monday morning, October 7
  - Meeting (phone conference) of working group conveners on Monday afternoon, October 7
  - Schedule next meeting of steering committee (Oct 18)
- Coordination of outreach to and involvement of potential non-federal participants in FSI
  - State and local governments
  - Non-governmental organizations
  - Food industry, trade organizations
  - International organizations

****
*** ACTIVITY REPORT ***
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1540	AUTO RX ECM	12023315301	NAT CNTR NBHD EN	10/15 15:55	00'34	2	OK

TELEFAX TRANSMITTAL SHEET

JEROLD R. MANDE

Executive Assistant to the Commissioner
Food and Drug Administration
Rm. 14-95 HF-1
5600 Fishers Lane
Rockville, MD 20857

TEL 301-827-3448 FAX 301-594-6777

DATE: 10/15/96

TO: Elizabeth Drye

TELEFAX NUMBER: 202-456-7028

COMMENTS: Clearance List #2

NUMBER OF PAGES, EXCLUDING COVER: 1

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002. list	re: Clearance (1 page)	10/15/1996	b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10451

FOLDER TITLE:
Food Safety Background
Food Safety - Background

2014-0046-S
rc1408

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
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b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Phone
x66742

Fax
x553449

TELEFAX TRANSMITTAL SHEET

JEROLD R. MANDE

Executive Assistant to the Commissioner
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Rockville, MD 20857

TEL 301-827-3448 FAX 301-594-6777

mmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmm

DATE: 10/15/96

Karen Hulebak (sp.?)
Hulebak

TO: Elizabeth Drye

TELEFAX NUMBER: 202-456-7028

COMMENTS: Clearance List

NUMBER OF PAGES, EXCLUDING COVER: 1

Food Safety Initiative Strawperson Outline

SPECIAL INITIATIVES TO REDUCE DISEASE

- o SURVEILLANCE INITIATIVE
- o INSPECTION INITIATIVE
- o COORDINATION INITIATIVE
- o APPLIED RESEARCH INITIATIVE
- o RISK ASSESSMENT RESEARCH INITIATIVE
- o EDUCATION INITIATIVE

****

I. FOOD SAFETY HAZARDS

A. Food-safety hazards include pathogens, natural toxins, and chemical contaminants
   1. Drinking water (EPA)
   2. Meat and poultry (USDA)
   3. All other foods (FDA)

B. Emerging pathogens

   1. E. coli O157:H7
   2. S.E. in eggs
   3. Cryptosporidium
   4. Cyclospora
   5. Salmonella typhimurium DT 104
   6. Others?

C. Contamination can occur from farm or fishery to fork

D. Food-borne illness affects millions of Americans
   1. Changes in consumer behavior (eating out more)
   2. Changes in types of food products (i.e., deli, partially cooked foods, etc.)

E. Some populations are especially vulnerable
   1. Children
   2. Elderly persons
   3. Immuno-compromised persons

F. Food supply is global
   1. Unfamiliar foods
   2. Imports from everywhere

G. Technology issues

1. Aquaculture
2. New packaging
3. Animal production practices
4. Food constituents

H. Role of risk assessment (prioritizing serious hazards)

II. SURVEILLANCE

A. Disease surveillance (mostly CDC)
1. How adequate is the current surveillance infrastructure for detecting common food-borne illness, as well as emerging organisms?
2. Sentinel Sites program (Phase II will identify foods)
3. General disease data evaluation and transfer
4. Epidemiology on emerging pathogens
5. Food production and consumption
6. Antimicrobial resistance monitoring (humans and animals)

III. PREVENTION/Inspection

A. Food surveillance (mostly FDA and FSIS)
1. Inspection - HAACP system verification, non-HACCP investigation
2. Targeted sample collection and analysis
   a. Sentinel site follow-up
   b. HACCP verification samples
   c. Non-MOU import samples
3. Expanded Market Basket Survey (better baseline)

B. Inspection problems
1. The current state of food-plant inspection coverage is poor (except for meat and poultry)
2. What would be <u>adequate</u> coverage?
3. What are the special issues associated with imported and exported foods?
4. What are the issues associated with preparation, distribution, and storage?

C. Develop adequate level of inspection for foods
1. Need for food safety
2. Need for public and international credibility
3. Would provide regular <u>FEEDBACK</u> to the industry especially under <u>HACCP</u>

D. Expanding partnerships
1. Invest in state partnerships (provide training, databases, and technology)
2. Absorb seafood inspectors from NMFS?
3. Invest in Mutual Recognition Agreements for imported foods
4. Fully implement seafood HACCP regulation

F. Identify what the hazards are (emerging pathogens, emerging technologies in food processing, etc.)

G. Provide information to industries on how to prevent hazards, i.e., develop Hazard Guide

H. Provide guidance on developing HACCP plans and how to implement them (HACCP Library)

I. Development and assessment of new prevention technologies (i.e. pasteurization of in-shell eggs, pasteurization of oysters)

J. Develop model control programs for harvesting waters, farms, manufacturing, transportation and retail food safety

K. Legal actions, publicity, warnings, and recalls

L. Regulations and/or guidance documents

M. Civil money penalties (CVM)

IV. PREVENTION/Applied Research

A. Contaminant bioassay research and development
   1. Rapid Methods - Bacteria, antibiotics, pesticides, mycotoxins, seafood toxins, chemicals
   2. Screening tests

B. Antimicrobial resistance

C. HACCP verification (validation) technologies

D. Transportation
   1. Stress to animals
   2. Other issues

E. Emerging pathogens

F. Food security

G. Secondary (indirect) carcinogens

H. Dietary modulation of toxicity

I. Predictive strategies

V. PREVENTION/Risk Assessment

A. Risk assessment challenges
   1. How to use risk assessment for microbiological (emerging pathogen) concerns
   2. Better exposure assessments and predictors

a. Microbial ecology at harvest - (e.g. eggs, aquacultured fish)
b. Virulence assessment

B. Risk assessment potency and exposure methodologies

C. Risk communication (how to communicate with consumers)

D. Other?

VI. COORDINATION

A. Greater effectiveness (rapid-response capabilities)
1. Prompt notification of incidents among all agencies
2. Clarification of agency roles and better training of all concerned
3. Development of rapid analytical methods and screening tests
4. Interagency rapid response teams and better electronic communication

B. Resource leverage points
1. Other federal agencies
2. State governments
3. Local governments
4. Food industry
5. Non-governmental organizations
6. International organizations

VII. EDUCATION

A. Consumer education
1. Relevant agencies to develop a coordinated consumer education effort for safe food preparation in the home
2. Work with the Department of Education to revitalize in-school education efforts for young children - various grades (e.g. kitchen contamination, refrigeration, cooking)

B. Food safety for retail
1. Food code adoption
2. Safety training
3. Food preparation and storage

C. Veterinary practitioner and producer education
1. Prescribing surveys
2. Resistance
3. Residues
4. Pesticides

VIII. EVALUATION

A. Measures of health impact

B. Measures of economic impact

C. Information management

D. Further needs and research

Food Safety Initiative - Contaminants List

10/4/96 DRAFT

Bacteria

Campylobacter jejuni/coli
Salmonella species
  Salmonella enteritidis
  Salmonella typhimurium DT 104
Escherichia coli 0157:H7

Parasites

Toxoplasma gondii
Cryptosporidium parvum
Cyclospora cayetanensis

Viruses

Norwalk Virus

Elemental Contaminants

Methylmercury

Food Allergens (e.g., nuts)

Organic Contaminants

Aldicarb (pesticide)

Mycotoxins

Vomitoxin

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003. note	re: Food Safety [partial] (1 page)	n.d.	b(6)

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Food Safety

Carolyn Heinzoor
- Middle of November — report done
- Fold into NSTC report —
- will be a budget component
- Kessler is chairing a working grp to prepare the report. — OSTP —

Karen C. Hulebak (b)(6) [003]

Minnesota Department of Health
Division of Disease Prevention and Control
FACSIMILE TRANSMISSION: Cover Sheet/ Transmittal Form

Date: 10/14/96

To: Elizabeth Dreyer

Location: DPC / White House

FAX # 202-456-7028

From: Michael Osterholm

Location:
- ☐ **DP&C Administration (612) 623-5363**
- ☐ **Acute Disease Epidemiology (612) 623-5414**
- ☐ **Epidemiology Field Services (612) 623-5414**
- ☐ **Acute Disease Prevention Services (612) 623-5237**
- ☐ **AIDS/STD Prevention Services (612) 623-5698**
- ☐ **Chronic Disease and Environmental Epidemiology (612) 623-5216**

This transmission consists of 11 pages (including cover sheet).

If transmission is incomplete or illegible, please call the sender at the number listed above.

717 Delaware St. SE / Box 9441 / Minneapolis, MN 55440
FAX: (612) 623-5743

Message:

Jerry asked that I send this to you before tomorrow's meeting. Look forward to seeing you. Thanks

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary
Office of Public Health and Science
Office of Disease Prevention and Health Promotion
200 Independence Ave, S.W., Room 738-G
Washington, D.C. 20201

FACSIMILE TRANSMISSION

TOTAL PAGES (including this cover page):1

DATE: October 3, 1996

TO:
William Raub, HHS/ASPE, 202 401-7321
William Shultz, HHS/FDA, 301 443-5930
Karen Hulebak, HHS/FDA, 301 443-6906
Jerold Mande, HHS/FDA, 301 594-6777
Mike Friedman, HHS/FDA, 301 443-3100
Lynn Goldman, EPA/OPPPTS, 202 260-1847
Karen Woteki/Jaleh Daic, USDA/REE 202 690-2842
Mike Taylor USDA/FS, 202 690-4437
Clif Gabriel/Carolyn Huntoon, OSTP, 456-6027
Lisa Grove/ Jonathon Winer/David Rostker, OMB, 202 395-7285
Elibeth Drye, DPC, 202 456-7028

FROM: Dalton Paxman

TELEPHONE: 202/205-5829	FAX: 202/205-9478

Message: The Food Safety Initiative meeting set for Friday, October 4, at 3:00 will be held in room 729G (note room change), Humphrey Bldg., 200 Independence Ave., S.W.
Please call me with any questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

NOV 26 1996

MEMORANDUM TO NANCY-ANN MIN

From: John J. Callahan
Assistant Secretary for Management and Budget

Subject: Amendment to FY 1998 HHS Budget Request

As I have indicated, we have conducted comprehensive assessments of our needs to combat underage access to tobacco products, to increase the Government's response to foodborne illness and disease threats, and to reduce substance abuse among teenagers. Consequently, the Secretary has determined that additional resources are needed beyond what was included in the original request forwarded to OMB last September.

- Tobacco: As part of our effort to reduce the availability and appeal of tobacco products to children and teenagers, and as a follow-up to the Executive Order calling for the regulation of nicotine-containing tobacco products, the Food and Drug Administration (FDA) has developed a full strategy for implementing and enforcing this final rule. A total of $63 million ($58 million over the September submission) and an additional 54 FTE are now needed. The elements of this plan include developing a strong outreach program geared to retailers, State and local health and law enforcement officials, the public and the media; enforcement of the rule by training and commissioning State and local officials; establishing a way to evaluate our efforts, as well as a reporting system. In addition, an education program will be targeted to young people as an essential component of this initiative.

- Food Safety: Since September, representatives of the core food safety components of our Government - FDA, CDC, USDA, and EPA - have been engaged in an intensive reassessment of how to successfully protect the public and prevent outbreaks of foodborne illness. A product of this assessment has been a total examination of budgetary resources, with the conclusion

that an additional $97 million and 335 FTEs are needed in FY 1998 for FDA and CDC. This represents an increase of $49 million over our September submission. The plan envisions that 190 of these FTEs would be transferred from the National Marine Fisheries Service (NMFS) under the Department of Commerce. These additional resources would strengthen our surveillance and "early warning" of foodborne illness; increase inspections of food processors; enhance interagency and intergovernmental communication and coordination; expand education and research; and improve our risk assessment tools.

- Youth Substance Abuse: In response to discussions this Fall with your staff and the Office of National Drug Control Policy (ONDCP) concerning the increasing drug use among youths, we are amending the budget request for FY 1998 to include an additional $137 million. Based on social trends among youth that indicate reduced perception of harm, easy access and availability of drugs, and intentional glamorization of drug use, it is clear that prevention efforts must be redoubled. The Substance Abuse and Mental Health Services Administration (SAMHSA) has proposed a three-prong strategy that builds upon and complements ongoing programs and activities. This includes a media/public education component; a State Incentive Grant Program involving community prevention; and finally, an effort to enhance partnerships with national and community groups to amplify their messages on drug prevention. In addition, we will need to build a State-based measurement system to help compare prevention performance among States. Finally, we are requesting an additional $5 million to mothball vacant Federal buildings on the west campus of St. Elizabeths Hospital until such time as these can be transferred to the District of Columbia or disposed of through surplus. This is a preliminary estimate of the cost to mothball these buildings. A more rigorous engineering study will be completed.

Attached are materials providing a more detail explanation of these new program initiatives. In addition, my staff will send separately the technical budget summaries requested by your staff.

Attachment

Attachment

Department of Health and Human Services

Amendment to FY 1998 Budget Request

(Dollars in millions)

	Amendment	
	Dollars	FTE
FDA:		
o Food Safety.....	+$28	+293
o Tobacco.....	+$58	+54
CDC:		
o Food Safety.....	+$21	+42
SAMHSA:		
o Youth Substance Abuse....	+$137	--
o St. Elizabeths.....	+$5	--

EXECUTIVE SUMMARY

Enclosed is the FY 1998 interagency budget request for Food Safety Initiatives, which represents a "bigger picture" for food safety -- beyond what was included in the original request to OMB forwarded last September. This document includes information from the other Federal agencies involved (CDC, USDA, and EPA), where possible. Sections that are FDA only are labeled as such.

This request for additional resources seeks to increase the effectiveness and efficiency of the government's response to, and control of, the incidence of foodborne illness and disease threats, as well as improve FDA's process for reviewing food additive petitions and animal drug applications. Resources would improve **coordination** between Federal and State agencies in the management of response to foodborne illness; enhance the infrastructure for **inspections** and **surveillance** activities to strengthen regulatory capabilities; and improve **education, risk assessment**, and **research** efforts. The end result of these investments is to realize significant financial savings for the American public in the form of illnesses prevented and food safety costs saved. Because these initiatives would continue beyond the first year of implementation, resources would be additive to our base.

This request, in terms of FDA, supersedes sections of the OMB budget submission which was forwarded in September of this year. In that original request, FDA included increases for food safety and improvements in the food additive review process, improvements in the review process for animal drug applications, and increases to enhance and strengthen international activities. (The table on page 5, entitled FY 1998 Budget Summary, lists the related items from the original request, including dollar amounts and the relevant page from that document.) Further, FDA included two pilot programs under GPRA -- one for Seafood HACCP and the other on food additive petitions. Both of these pilots will be subsumed by these new initiatives.

This revised Food Safety Initiatives request has a much broader scope than the original request and represents a comprehensive approach to reducing the incidence of foodborne illness and disease threats in the United States. For FDA, specifically, the original request included $44.82 million with no FTEs for food safety and pre-market activities. Our revised request for food safety and pre-market activities is $72.512 million with 293 FTEs. (Of the 293, 190 are for FTEs which would be transferred to FDA from the National Marine Fisheries Service under the Department of Commerce). The Centers for Disease Control and Prevention (CDC) is requesting $24.5 million and 42 FTEs -- an increase of $21.5 million and 42 FTEs over the initial FY 1998 request to OMB.

Within the FDA request, pre-market activities are considered as part of the overall discussion of food safety. However, they are discussed separately in this document. While the Food Safety Initiative addresses the incidence of foodborne illness and disease threats, inclusion of pre-market activities provides a more complete picture of FDA's food safety activities.

Coordination. Improved coordination of foodborne illness response among Federal agencies, between Federal and State agencies and among the various State agencies is needed to ensure that responses are rapid and effective, ensure the best use of interagency collaboration, avoid unnecessary duplication of effort, and enhance the level of public health protection. Resources are needed to

create a Federal emergency response system, to form partnerships with State and local governments, and to provide States with additional epidemiological resources.

Surveillance. Improved strategies are needed for foodborne disease surveillance to ensure the rapid detection of foodborne illness outbreaks and dissemination of information to facilitate control mechanisms. This is key to reducing the incidence of foodborne illness and threat of disease. FDA requests funds to enhance its surveillance systems for detecting foodborne pathogens in food animal populations and antimicrobial resistance in foodborne pathogens. The revised request also includes resources for CDC to expand the Sentinel Site project to allow appropriate geographic diversity of the network, and cover a greater proportion of the U.S. population and a greater spectrum of new and re-emerging pathogens, including parasites and viruses that can be transmitted through foods. It will also improve the capacity of CDC and State and local health departments to detect and swiftly respond to widespread or subtle outbreaks of foodborne illness ranging from identifying new agents, to evaluation of prevention strategies.

Inspections. Another aspect of the revised request is an increase in resources to improve the quality and number of inspections. FDA's original request mainly dealt with the immediate need to establish an effective infrastructure (training programs for inspectors, development of better coordination with Federal and State agencies, and educational activities) for a nationwide HACCP-based system for inspection of seafood processors. A "pilot" HACCP program for non-seafood segments of the food industry was also part of the request. For FDA, the revised request reflects resources needed to implement HACCP regulations for seafood, meat and poultry, to encourage an expanded HACCP-based system for other food products and establishments, and expand Federal/State inspection partnerships to monitor the Nation's food supply.

Education. Research shows that prevention is the most effective means of reducing the incidence of illness and disease outbreak, and thereby improving the nation's general public health. FDA, as well as CDC, propose to launch educational campaigns that focus on preventive measures for achieving improved food safety. The goal of this campaign is to develop food safety programs and materials aimed at improving food handling practices used in the home, food service and institutional operations, and by retail food workers, as well as minimizing the occurrence of bacterial pathogens and residues in edible animal tissues. This prevention strategy covers everyone who has a role in ensuring the safety of the food supply from the farm to the table, whereas, the initial request targeted educational media for consumers and food retailers on seafood safety only. CDC, in particular, will provide training for epidemiologists and laboratorians in State and local health departments, and educate practicing physicians and clinical microbiologists.

Risk Assessment. Risk assessment is an integral component of FDA's scientific program to ensure the safety of the food supply. Resources are needed to improve existing capabilities of rapidly and accurately assessing risks associated with foodborne hazards. Improved risk assessment methodology will be used to develop and evaluate surveillance plans, risk reduction strategies, implementation of HACCP practices, and research programs. Funds originally requested for risk assessment activities in FDA's budget were geared toward developing more accurate risk assessment models utilizing extramural research contracts. The revised request is for resources to broaden this effort by developing in-house expertise, as well as extramural research contracts, in the areas of exposure

assessments and dose-response assessments for use with both microbiological and chemical contaminants. The revised request also includes the establishment of an interagency Risk Assessment Consortium to further develop and strengthen food safety risk assessment methodology.

Bioscience Research. To develop a comprehensive food safety program, scientific capabilities must be improved. Resources will be utilized to increase research to develop new and improved detection methods for rapid testing of microbial and chemical contaminants, better understand microbial antibiotic resistance in order to reduce the risk of antibiotic-resistant foodborne disease, accurately identify mechanisms mediating persistence of pathogens, and develop techniques for the reduction or elimination of contamination in animal feeds. FDA's original request outlined a plan to improve scientific capacity with the development of the Joint Institute for Food Safety and Applied Nutrition -- a collaborative venture with the University of Maryland, which is now underway. Additional resources would allow FDA to strengthen and enhance its scientific programs, thus developing a stronger posture in its collaboration with other Federal agencies, State and local governments, and academia to achieve a more comprehensive food safety program.

Pre-Market Activities. FDA's September submission included $15 million for improving the process for the review of food additive petitions, and $5.25 million for improving the process for review of animal drug applications. In the revised request, these numbers have been adjusted to $4 million each for the Foods Program and the Animal Drugs Program.

Due to recent Departmental changes in food safety priorities, it was necessary to reduce the budget request for premarket approval activities for the FY 1998 Food Safety Program. The reforms the Agency has made to date in premarket review need to be continued. We have, however, modified the focus of this effort in light of the significance of the need to address issues associated with the increasing incidence of foodborne illness. Premarket approval activities continue to be a top Agency priority, but need to fit in with the Agency's overall program directions.

For food additive petitions, part of the original funding was intended for contracts to develop and implement better guidance and clearer criteria for industry submitted petitions, provide for more extensive and thorough pre-filing assistance, provide more assistance for post-filing review questions, and to develop data needed to resolve safety issues. Therefore, the primary impact of the reduction will be on petition review output. The following revisions to performance goals for FY 1998 (and beyond) will need to be made:

- The current goals of completing review and publishing a decision on 50 percent of direct additive petitions within 360 days and 60 percent of indirect additive petitions within 180 days must be revised down to 40 percent of direct additive and 50 percent of indirect additive petitions within the appropriate time frames. This will result in a corresponding delay in reaching out-year projected performance levels.

- The reduction in the Mid-1995 petition inventory will be slowed resulting in a delay in reaching full performance levels for timeliness in petition review. As a result, we would expect to have 90 petitions remaining from the Mid-1995 inventory at the end of FY 1998.

- The publication of the second edition of "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food," on the World Wide Web will be delayed.

FDA will try to mitigate the negative impact of this reduced funding by implementing a stronger refusal to file policy in FY 1997. In addition, policy will be developed to deny industry petitions when they are found to be inadequate to support regulation. This policy will target inadequacies in petitions that will require longer than 180 days to address and in situations where the petitioner refuses to withdraw the petition or to hold the petition in abeyance until the required data may be developed. It is hoped that these actions will help FDA as it seeks to improve its food petition review process.

Since the original estimate of $5.25 million was derived, FDA's Center for Veterinary Medicine has identified additional efficiencies such that roughly the same outcomes can be expected despite the reduced dollar figure from $5.25 million to $4 million. However, FDA's bottom line concern is getting these drugs approved. While some of the expected benefits will be slightly reduced, the overall impact -- improving the animal drug review process -- should be the same.

FDA's original submission also included increases for a number of areas not covered by food safety. Despite the high priority given to funding these initiatives under food safety, FDA still feels strongly that these requested increases also receive some consideration. They are as follows: 1) $24.476 million for medical device reviews, $6 million of which is in the budget authority, $16.476 of which is in user fees; 2) $14.5 million for construction of Phase II of the Arkansas Regional Lab; 3) $25.5 million for construction of the Los Angeles lab; 4) $5.4 million for leveraging resources through partnerships; 5) $19.2 million for strengthening international alliances (The original request was for $20.5 million, but a portion of that falls under food safety.); and 6) $19.6 million for current services. This document is divided into the following sections:

1) FY 1998 Budget Summary (p. 5) -- Display of the related funding request included in the original September submission to OMB;
2) FDA Base Resources (p. 6) -- Current spending in the relevant areas addressed under Food Safety, plus a listing of activities currently undertaken;
3) FDA Budget for Food Safety Initiatives (p. 13) -- A summary table showing the request in line-item detail;
4) Inter-agency Food Safety Budget Justification (p. 15) -- Broken down by section: Coordination, Surveillance, Inspections, Education, Risk Assessment, and Research;
5) A matrix summarizing the projected costs of these initiatives and savings to both industry and consumers (p. 37);
6) Comparative analysis of projected benefits from implementation of the Food Safety Initiative (p. 38); and
7) Pre-Market Approval Budget Justification for both the Foods and Animal Drugs Programs (p. 48).

Food & Drug Administration
FY 1998 Budget Summary
(As Submitted to OMB, September 1996)
($ in millions)

Budget by Section	Total	Foods	Animal Drugs
FOODS (p. 15)			
Food Safety	$23.30	$23.30	$0.00
Food Additive Petitions	$15.00	$15.00	$0.00
ANIMAL DRUGS AND FEEDS (p. 53)			
Animal Drugs/Feeds	5.25	0.00	5.25
INTERNATIONAL ALLIANCES (p. 90)			
Emerging Infectious Diseases 1/	0.57	0.57	0.00
Antibiotic Resistance	0.25	0.00	0.25
Global Marketplace 2/			
Harmonization	0.22	0.17	0.05
Technical Assistance	0.17	0.17	0.00
Trade Policy	0.06	0.06	0.00
GRAND TOTAL	**$44.82**	**$39.27**	**$5.55**

1/ Represents the percentage applicable to Food Safety Initiatives (from the CFSAN total on the table found on page 100).

2/ Represents the percentage applicable to Food Safety Initiatives (from the CFSAN/CVM totals on the table found on page 100).

Note: The net incremental increase over the FY 1998 OMB submission is $27.7 million.

BASE RESOURCES

Food & Drug Administration Only
Food Safety Initiative
Base Requirements: FY96, FY97 and FY98 Request
Foods, Animal Drugs and Feeds Safety
($ in thousands)

Initiative/Activity	FY96 Enacted		FY97 Enacted		FY98 FSI Increase		FY98 TOTAL Request[1]	
	$000	FTE	$000	FTE	$000	FTE	$000	FTE
Coordination[2]	$6,506	74	$ 6,598	73	$ 1,000	2	$ 7,598	75
Surveillance[3]	$ 577		$ 678	1	$ 4,680	15	$ 5,358	16
Inspections	$67,509	864	$ 67,376	837	$27,602	201[4]	$94,978	1,038
Education[5]	$ 4,343	50	$ 4,415	50	$ 7,030	23	$11,445	73
Risk Assessment[6]	$ 2,310	23	$ 2,382	23	$10,330	21	$12,712	44
Research	$18,964	212	$19,127	208	$13,870	31	$32,997	239
TOTAL	100,209	1,223	$100,576	1,192	$64,512	293	$165,088	1,485

[1]Increase is based on the $64.512 million request for the Food Safety Initiatives (FSI).

[2]Reflects 60% of Food Program Education/Liaison resources identified in the FY98 Justification of Budget Estimates to OMB.

[3]Resources devoted to surveillance activities, as defined in the Food Safety Initiatives. (Example: CDC Sentinel Sites) Surveillance activities are identified under the Compliance/Regulation category in the FY98 Justification and Budget Estimates to OMB.

[4]Includes 190 FTEs from the National Marine Fisheries Service (NMFS).

[5]Reflects 40% of Food Program Education/Liaison resources identified in the FY98 Justification of Budget Estimates to OMB.

[6]Risk Assessment reflects 17% of resources associated with headquarters research.

Food & Drug Administration Only
Food Safety Initiative
Base Requirements FY96, FY97 and FY98 Request
Foods, Animal Drugs and Feeds
($ in thousands)

Initiative/Activity	FY96 Enacted		FY97 Enacted		FY98 FSI Increase		FY98 TOTAL Request[7]	
	$000	FTE	$000	FTE	$000	FTE	$000	FTE
Food Safety Initiative Related Activities	$100,209	1,223	$100,576	1,192	$64,512	293[8]	$165,088	1,485
Other Program Activities	$163,065	1,816	$163,272	1,767	N/A	N/A	$163,272	1,770
TOTALS	**$263,274**	**3,039**	**$263,848**	**2,959**	**$64,512**	**293**	**$343,019**	**3,255**

[7]Increase is based on the $64.512 million request for the Food Safety Initiatives (FSI). The increase is added to the FY98 base request but excludes the $44.3 million requested in the Food Safety Initiatives proposed in the original OMB submission.

[8]Includes 190 FTEs from the National Marine Fisheries Service.

FY 1996

The following are activities, similar to those identified in the Food Safety Initiative, conducted by FDA in FY 1996 for assuring the safety, sanitation, and wholesomeness of foods available to American consumers.

Foods Program

- Conducted research to improve the speed and accuracy of methods for the detection and enumeration of foodborne biological hazards, which included efforts to apply DNA technologies to improve systems for detecting and assessing the virulence of foodborne pathogens.

- Continued effort to develop and implement new strategies for improving the efficiency and effectiveness of regulatory and research programs for food safety.

- Developed and implemented programs to more effectively address food safety risks associated with microbial pathogens such as *Salmonella enteritidis, Vibrio vulnificus,* staphylococcal enterotoxin, etc.

- Inspected establishments, collected and analyzed samples, and took legal action, where necessary in order to prevent domestically or imported foods which may be hazardous or insanitary from entering the U.S. marketplace.

- Developed and implemented programs including analytical procedures to more effectively address important health risks associated with foodborne chemical contaminants such as methyl mercury, plant toxins, seafood toxins, toxic elements and pesticides. Also developed and implemented programs to address in-vitro methods for toxic chemicals.

- Worked with NOAA to implement a jointly sponsored program designed to improve the safety, quality, and labeling of the Nation's seafood supply as an example, developed a training course for Federal and State regulators and industry on HACCP for the seafood industry.

- Worked cooperatively with State and local governments to assure the safety and wholesomeness of milk and milk products as well as implementation of the retail Food Code.

- Provided training to field investigators, worked with seafood manufacturers, State and local governments to ensure the successful implementation of the Seafood HACCP regulation.

- Developed and implemented programs to increase the effectiveness of food and cosmetic programs through consumer education and industry outreach activities-calcium and osteoporosis, expanded Seafood Hotline, World Wide Web, etc.

- Provided consistent and effective leadership for key foods-related activities of international bodies such as Codex, NAFTA, and WTO.

Animal Drugs and Feeds

- Established the Antimicrobial Susceptibility Monitoring Program activities among CVM/FDA, USDA and CDC.

- Limited educational activities on proper animal drug use directed towards veterinarians and food animal producers.

- Pre-approval evaluation of food safety concerns associated with the use of drugs in food producing animals.

FY 1997

The following are activities, similar to those identified in the Foods Safety Initiative, that will be conducted by FDA in FY 1997 to assure the safety, sanitation, and wholesomeness of foods available to American consumers.

Foods Program

- Provide training to State and Federal regulators and industry on seafood HACCP.

- Develop rapid, sensitive, facile methods for the detection and identification of biological and chemical contaminants that may be found in the food supply.

- Continue communications and consultations with developers of new plant varieties, including those developed using recombinant DNA methods. Address questions pertaining to the use of antibiotic resistance markers.

- Develop a training course and provide training for Federal and State regulators on how to audit the HACCP systems for seafood processors.

- Work with ORA to develop a model Federal/State partnership agreement for seafood HACCP-based inspections.

- In cooperation with ORA, conduct a full policy and program review of the FDA molluscan shellfish program identifying goals and objectives and the extent to which they are being met now.

- Develop evaluation criteria to assess the effectiveness of new controls for minimizing the risk of infection from Vibrio vulnificus in raw shellfish.

- Perform the analyses necessary to reevaluate the FDA action level for methyl mercury, taking into account the significant quantity of new epidemiological data that has become available since the action level was established.

- Collaborate with the University of Maryland on establishing the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) to initiate joint food safety research projects and establish future collaborative goals.

Animal Drugs and Feeds Program

- CVM is coordinating a scaled-down version of the Antimicrobial Susceptibility Monitoring Program activities among CVM/FDA, USDA, and CDC.

- Limited education activities. CVM will conduct a nationwide teleconference with the American Veterinary Medical Association to make available information concerning the implementation of the Animal Medicinal Drug Use Act and the Animal Drug Availability Act.

FY 1998

FY 1998 Activities to be Supported with Food Safety Initiative Increase

Foods Program

- Upgrade the national surveillance system for foodborne infections in humans.

- Enhance the Sentinel Site project.

- Enhance microbiologic monitoring and surveillance activities related to pathogen reduction under HACCP.

- Better characterize foodborne pathogen isolates and monitor layer hens and bulk liquid egg products for SE before pasteurization.

- Enhance inspection of commercial food processing establishments and food service establishments by regulatory authorities.

- FSIS and FDA will jointly develop procedures for overseeing the safety of food in transport.

- Improve the coordination of foodborne illness response and investigation.

- Conduct research to improve analytical methodology to reduce the time required for sensitive detection of pathogens in finished products and raw materials.

- Develop tools for monitoring the occurrence or introduction of microbial and chemical contamination at all points of food production.

- Develop measures that can be taken to augment the traditionally used protective measures in the complex handling, distribution, and storage process.

- Establish a Risk Assessment Consortium.

- Develop and improve risk assessment methodologies.

- Address data gaps in exposure assessments and dose-response assessments.

- Develop a comprehensive food safety education program that will focus on changing the consumers' unsafe food handling behaviors.

- Develop new and innovative methods for sharing information related to food safety.

- Develop improved education materials and services for food service operations.

Animal Drugs and Feeds Program

- Enhance surveillance for foodborne pathogens in food animal populations and antimicrobial resistance in foodborne pathogens.

- Enhance monitoring and surveillance of animal food source diseases.

- Conduct scientific studies on antibiotic resistance in order to reduce the risk of foodborne disease transmitted through agriculture and aquaculture.

- Conduct scientific studies to develop methodologies to rapidly detect pathogens in animal feeds and to reduce/eliminate pathogens in animal feeds.

- Develop a veterinary and producer education program addressing issues and concerns surrounding safe food products. Use exhibits at various animal health industry meetings around the country, to include video-teleconferencing.

- Participate in an interagency Risk Assessment Consortium.

- Address data gaps in exposure assessments and dose response assessments relating to animal drugs, pathogens and chemicals.

Food & Drug Administration
Food Safety Initiatives -- FY 1998 Budget Request

Activity	Dollars (Ms)	FTEs
Coordination	**$1.000**	**2**
Management Response to Foodborne Illness	0.329	2
Improve Coordination Between Federal & State Agencies	0.273	0
Enhance Basic Infrastructure for Foodborne Disease Surveillance	0.398	0
Surveillance	**4.680**	**15**
Enhance Foodborne Surveillance	0.250	0
Microbiological Monitoring & Surveillance HACCP	0.000	0
Surveillance for Antimicrobial Resistance	1.640	3
Enhance Monitoring & Surveillance of Human Foodborne Disease	1.000	1
Monitor Layer Hens and Bulk Egg Products	0.990	9
Enhance Surveillance for Foodborne Pathogens in Food Animals	0.800	2
Better Characterize Pathogen Isolates	0.000	0
Inspections	**27.602**	**201**
Clearing House for HACCP	0.500	0
HACCP Implementation	19.102	196
Partnerships/Training Food State Inspectors	5.500	0
Seafood Early Warning for Toxins	0.500	0
Private Lab Certification	0.500	5
Imports	1.500	0
New Statutory Authority	0.000	0
Joint FSIS/FDA Inspection of Meat/Non-Meat Plants	0.000	0
Education	**7.030**	**23**
Consumer Education	5.400	15
Veterinary Producer Education	1.630	8
Activity	Dollars (Ms)	FTEs
Risk Assessment	**10.330**	**21**
Risk Assessment Consortium	2.630	19
Exposure Assessment	4.480	2
Dose Response Assessment	3.000	0

Research	**13.870**	**31**
Development of Improved Analytical Methods	9.830	20
Emerging Pathogens: Antibiotic Resistance	1.500	3
Pathogen Control/Reduction/Elimination/Prevention	2.100	6
Food Handling, Distribution, & Storage	0.440	2
Total – Food Safety	**64.512**	**293**
Pre-Market Activities	**8.000**	**0**
Grand Total – Food Safety	**$72.512**	**293**

Centers for Disease Control & Prevention
Food Safety Initiatives – FY 1998 Budget Request

Activity	Dollars (Ms)	FTEs
Coordination	$.7	2
Surveillance	15.7	30
Education	7.6	10
Research	.5	0
Grand Total	**$24.500**	**42**

Budget Justification

Food Safety Initiatives

Interagency Food Safety Initiatives
Budget Justification

Goal:

Reduce, to the greatest extent possible, the annual incidence of foodborne illness, currently estimated to cause between 6.5 and 33 million illnesses and 9,000 deaths, and resultant economic losses to consumers and industry by enhancing the safety of the nation's food supply.

This goal is in concert with the objectives of the HHS strategic goals, Healthy People 2000, the CDC emerging infectious diseases initiative, and Presidential directives focussed on enhancing the health and well-being of children and the elderly.

Problem:

Although the U.S. food supply is safe compared to those of other developed and underdeveloped nations, foodborne illnesses threaten public health and contribute significantly to the escalating cost of health care. Of all the hazards associated with foods, microbial hazards account for 90 percent of the confirmed foodborne outbreaks and cases.[1] Among the various contaminants that may cause foodborne illness are *Escherichia coli* O157:H7, *Salmonella enteritidis, Campylobacter jejuni/coli, Toxoplasma gondii, Cryptosporidium parvum,* Norwalk virus, and chemical hazards such as methyl mercury.

It is estimated that between 6.5 and 33 million illnesses and up to 9,000 deaths occur every year, associated with microbial contamination of foods alone. Chemical hazards more commonly cause chronic health effects which are difficult to estimate. Hospital stays associated with microbial foodborne illnesses are estimated to cost society more than $3 billion a year.[2] The estimated total costs of foodborne illness are $5.6 billion (lower bound).[3] Since foodborne chemical hazards often present chronic rather than acute health threats, specific estimates of their impact on health and the economy are not as readily available.

The costs of the foodborne illnesses are borne by those who become ill and their families, coworkers, and employers, as well as the food industries, and taxpayers. Costs to stricken individuals include medical bills, time lost from work, pain and inconvenience. Food industry costs include possible product recalls, establishment closings and cleanup, and higher premiums for product liability insurance. Perhaps most costly in the long term is loss of product reputation and reduced demand when an outbreak is traced back and publicized. These and other "defensive" industry costs of

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[1]Foodborne Pathogens: Risks and Consequences. 1994. Council for Agricultural Science and Technology.

[2]Ibid.

[3]Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Proposed Rule. Federal Register. February 3, 1995. 60FR6774.

foodborne disease run in the millions of dollars annually and are, for the most part, entirely avoidable. Taxpayer costs include medical treatment for those who cannot afford it and higher health insurance premiums.

One indicator of the breadth of the problem posed by foodborne hazards is the increased number of food product recalls because of life threatening bacteria (Class I recalls due to microbial contamination). The number of these recalls climbed from 79 in 1988 to 378 in 1995. These recalls also impose an economic burden on industry and consumers. FDA estimates that the total annual recall costs (for FDA-regulated products) to industry (and indirectly to consumers) are roughly $42 million.

Solution:

A coordinated HHS (FDA and CDC), USDA (FSIS, APHIS, and CREES), and EPA Food Safety Initiative specifically targets immediate actions to implement new and bolster existing food safety intervention measures. It is critical that this initiative be a highly coordinated effort of the key components of the Federal food safety system -- Federal, State, and local public health agencies -- integrating elements pivotal to food safety such as inspection efforts, consumer and industry (particularly retail level) education, surveillance, risk assessment, and research. These activities will, over the next few years, achieve measurable reductions in the incidence of foodborne illness and death and, for the long-term, lay down a foundation of cooperation and communication to rapidly deal with emerging public health hazards.

Resource Requirements:

Agency	FTEs	Dollars ($M)
FDA	293 [1/]	$64.512
CDC	42	24.500
USDA	5	3.120
Total	340	$92.132

1/ Of this total, 190 FTEs would be transferred from the National Marine Fisheries Service under the Department of Commerce.

Foodborne Illness: A Growing Significant Health Problem

The food supply, as well as consumer tendencies and preferences, are changing in a number of ways that could contribute to an increased risk of foodborne illness. Based on these factors, some experts believe that the risk of foodborne illness is actually increasing. Some of the factors influencing this increased risk are:

- A generation of consumers has grown up with the freezer and a microwave and do not have either the experience or knowledge to recognize or correct potentially hazardous food handling and preparation behavior.

- Modern animal husbandry practices (e.g., crowding large numbers of animals together, transportation over long distances) facilitate the spread of illness and the harboring of human pathogens in animals used for human food.

- The food industry has evolved into a relatively small number of large producers. More retail establishments are processing foods on-site, and food distribution systems are no longer local -- they are national or international. The result is a potentially wide distribution of contaminated products that may cause foodborne illnesses.

- Vulnerable populations (e.g., the immuno-compromised, elderly) are continuing to grow in size. By the year 2020, 25 percent of the U.S. population will be 65 or older. Adding to this number are infants, hospitalized people, individuals receiving immunosuppressive treatments, chronically ill people with diseases such as cirrhosis, and people receiving antimicrobial therapies, such as antibiotics. Also, there are approximately 50 to 60 thousand new cases of HIV/AIDs every year, and the number of cancer patients has increased markedly in the last 20 years[4]. Today, more than 30 million people are likely to be at high risk from foodborne microorganisms[5].

- Microorganisms are adapting to their environments, developing pathogenic characteristics and resistances that contribute to the incidence of foodborne illness (e.g., *Listeria monocytogenes*, *E. coli* O157:H7, and *Campylobacter* species were not recognized foodborne pathogens 20 years ago) and new pathogenic strains continue to emerge (e.g., *S. enteritidis* phagetype 4).

- There have been an increasing number of food product recalls for life threatening bacterial problems (Class I recalls due to microbial contamination). This is a food safety "red flag." A number of factors may contribute to this increasing number of recalls, which jumped from 79 in 1988 to 378 in 1995. Some of these factors are noted above.

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[4]Vogt, D.U., Foodborne Illness: What do the Data Tell Us? CRS Report for Congress. 1994.

[5]Foodborne Pathogens: Risk and Consequences. 1994. Council for Agricultural Science and Technology.

Potential Economic Benefits of the Food Safety Initiative:

In addition to permitting this Nation to respond more effectively to foodborne illnesses and other emerging food safety issues, the activities under the Food Safety Initiative could generate a variety of economic benefits. Realization of these benefits hinges on implementation of the interdependent activities of the Initiative components (coordination, inspection, consumer and industry education, surveillance, risk assessment, and research). Examples of these benefits include:

Benefits to Consumers and Employers: Annually, between 128,000 and 640,000 incidents of illness associated with shell eggs occur at an average (but not typical) cost of $7,000 per case. (This value represents an averaging of the costs of mild cases and very serious cases.) FDA estimates that preventing one percent of these illnesses, which is a conservative estimate based on education efforts alone, would save between $9 million and $45 million in health care costs annually.

Benefit to Industry and Indirectly to Consumers: Improved inspections and risk assessment techniques can reduce implementation costs of HACCP, potentially generating an estimated savings of $9.3 million in the first year and approximately $80.5 million (discounted value) indefinitely into the future by reduced HACCP implementation costs for seafood products. If the same improvement occurs in health benefits, prompt and effective implementation of the Seafood HACCP regulation by FDA will avert an estimated 3,800 illnesses annually for a health benefit of $3.5 million in the first year, increasing to $7.1 million by the third year. The total savings for implementation of HACCP (cost savings plus health benefits) are therefore, 3,800 illnesses and $12.8 million in the first year, rising to $16.4 million by the third year. Approximately half of all recalls involving contaminated seafood products would be prevented at a value to industry of $1.25 million. FDA estimated industry costs associated with implementation of HACCP for seafood products at $677 million to $1.488 billion with benefits ranging from $1.435 to $2.561 billion over a 4-year period.[6]

USDA estimates 20-year industry costs associated with implementation of HACCP for meat and poultry products at $968 million to $1.156 billion with benefits ranging from $6 to $24 billion based upon a ninety percent reduction of USDA target pathogens, *Campylobacter jejuni/coli*, *E. coli* O157:H7, *Salmonella* spp., and *Listeria monocytogenes*.[7] According to USDA estimates, the number of cases of Salmonellosis prevented by HACCP will be 144,072 to 794,880 for a benefit value ranging between $124 and $725 million.

Benefit to Industry and Indirectly to Consumers: FDA estimates that the annual cost that industry incurs in recalling FDA-regulated products is estimated at $42 million. With the proposed initiatives in place, we estimate that the annual cost of recalls of FDA-regulated products could decline by slightly more than $9 million.

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[6]Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products. Federal Register Dec. 18, 1995. 60 FR 65185

[7]Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule. Federal Register. July 25, 1996. 61 FR 38858

Shorter lag times between the identification of a foodborne illness outbreak and initiation of control measures will result in fewer illnesses and deaths and lower associated health care costs. For example, FDA estimates that the value of health benefits and lost productivity gained would be approximately $870,000 for every day that the October-November, 1996 outbreak of *E. coli* O157:H7 associated with unpasteurized apple juice could be shortened. For a large outbreak, such as the 1993 *E. coli* O157:H7 outbreak associated with undercooked hamburger, it is estimated that the health benefits gained would be approximately $4.0 million per day during peak exposure (approximately 8-9 days). (This is a lower bound estimate.) This outbreak actually lasted 90 days, going undetected for one month before the association between illness and the source was even made. Even if we conservatively estimate a reduction of 10 percent, savings from this contaminated hamburger outbreak would have equaled close to $4 million.

The effect of a surveillance system in place to detect foodborne illness outbreaks in combination with intervention efforts, such as product recalls, reduces the number of illnesses in the outbreak and generates health benefits. This was illustrated in the 1993 *E. coli* O157:H7 outbreak in undercooked hamburger. Griffin, et.al. estimated that an additional 800 illnesses were prevented because an in-place surveillance system detected this outbreak, quickly triggering recall of the implicated food, and generating health benefits of $42 million.[8]

More effective food regulations. If regulations embodying improved risk assessment can make food safety regulations one percent[9] more effective -- a conservative estimate -- by targeting high-risk areas, the lower-bound annual value of the resulting health benefits would be $56 million.

Better risk assessment will result in more focused surveillance and research efforts and more focused regulatory initiatives. The ultimate result is identification of trends in causes and sources of foodborne illness and development of methods to rapidly identify specific sources in an outbreak. These two factors will shorten the time to identify an outbreak and its source, speeding control measures into place, and preventing growth of the outbreak, illnesses and possible deaths. As noted in the above examples, even modest improvements in the existing system can yield savings to both industry and consumers of thousands, even millions of dollars.

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[8]Griffin, P., et.al."Large outbreak of *Escherichia coli* O157:H7 Infections in the Western U.S.: The Big Picture: in Recent Advances in Verotoxin-producing *Escherichia coli* Infections. M.A. Karmall, M.A. and A.G. Gaglio, Eds. 1994. Elsevier. p. 8.

[9]Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Proposed Rule. Federal Register. February 3, 1995. 60FR6774.

Summaries of the Goals, Activities and Programmatic Benefits of Each Component of the Food Safety Initiative

Coordination

Goal:

Improved coordination of foodborne illness response, particularly in emergencies, at all levels of government to ensure that responses are rapid and effective, ensure the best use of government resources, and avoid unnecessary duplication of effort.

Objectives:

Create, at the Federal level, an emergency response system which improves existing channels of communication and develops new lines of communication between the Federal agencies responsible for investigating foodborne illness.

Form partnerships with State and local governments to achieve better Federal/State coordination on foodborne illness outbreaks.

Reinforce the basic infrastructure for response to foodborne illness outbreaks by providing the States with additional epidemiological resources. w/ resources to assure better coordination.

Benefits and outcomes:

Overall: Consistent, rapid dissemination of critical outbreak information and actions to implement control mechanisms horizontally across State and Federal jurisdictional lines and horizontally through agency hierarchies. This united assault will result in reduced number of foodborne illnesses, which translates to reduced public health care costs for the consumer and for employers, and reduced losses of productivity and private costs of loss of "good will" for industry. Also, shorter lag times between identification of an outbreak and initiation of control measures by public health agencies, reduces the magnitude of the outbreak, realizing not only reduced numbers of illnesses, but savings in associated health care costs and government resources expended. Shortening any of the foodborne outbreaks the U.S. has experienced in recent years, particularly those that affect vulnerable groups such as children (e.g., E. coli O157:H7 *in hamburgers and apple juice) will save lives, decrease the incidence of foodborne illness, and save hundreds of thousands of dollars in health care costs and lost productivity.*

- Rapid identification of foodborne illness outbreaks and implementation of control measures, as a result of the Federal level Interagency Coordination Group managing the response

- A state-of-the-art communication network between Federal and State agencies for rapid dissemination of data and information on foodborne illness outbreaks.

- Strengthened State agency disease surveillance and investigation capabilities to augment Federal capabilities.

Resource Requirements:

Agency	FTEs	Dollars ($M)
FDA	2	$1.00
CDC	2	.70
USDA	0	0.00
Total	4	$1.70

Surveillance

Goal:

Rapid detection of foodborne illness outbreaks and dissemination of information to facilitate immediate control mechanisms, and compilation of exposure assessment data for risk assessments to guide development of future prevention strategies.

Objectives:

Enhance the monitoring and surveillance of animal and foodborne illness;

Upgrade the national surveillance system for foodborne illnesses in humans;

Expand the Active Foodborne Disease Surveillance Networks;

Enhance capacity in States outside the Active Foodborne Disease Surveillance Networks;

Enhance surveillance for foodborne human pathogens in food animal populations and antimicrobial resistance in foodborne pathogens;

Enhance microbiologic monitoring and surveillance activities related to pathogen reduction under HACCP; and

Increase the monitoring of layer hens and bulk liquid egg products for Salmonella contamination before pasteurization.

Benefits and outcomes:

Overall: A national system for detecting and reporting foodborne illness outbreaks that will enable public health agencies to rapidly put in place measures to control the spread of the outbreak. This system will allow collection of critical data to recognize trends and target prevention strategies and to evaluate the effectiveness of prevention strategies already in place. Collection of data from the now limited Sentinel Sites Survey (in place one year) provided public health agencies with the following information and enabled their decision as to whether preventive action was required: indicated that there was no increase in U.S. CJD cases within a week of the U.K. announcement about their BSE problem, and detected E. coli *O157:H7 multi-state outbreaks associated with apple cider in Illinois and Connecticut and associated with California lettuce. Data from the survey sites also indicate that California has four times the rate of* Campylobacter *spp., indicating a trend that demands attention.*

- Increase scope of the national early-warning system Active Foodborne Disease Surveillance Networks to include illness outbreaks and other foodborne diseases such as cryptosporidiosis and related foodborne parasitic illnesses. These sites will, in collaboration with State and

local health departments, look intensively for cases of foodborne disease to determine how it came to be contaminated.

- Increase nationwide capacity to detect and respond to foodborne disease and outbreaks.

- Expand Antimicrobial Resistance Susceptibility Monitoring Program for antimicrobial resistance in foodborne pathogens isolated from animals used for food and humans to include new geographic locations nationally and *Salmonella* spp., *Campylobacter* spp., and *E. coli*.

- Methods for subtyping pathogens and improved procedures for integrating laboratories into a national network for electronic comparison of subtypes and for monitoring serious sequelae to foodborne infections.

- Creation of a national baseline on the incidence and prevalence of *S. enteritidis* in poultry and eggs and track the emergence or decline of *S. enteritidis* phagetype 4.

- Increased monitoring of animal feed processing and animal rendering facilities to determine the nature and extent of pathogen contamination and the impact of control strategies on pathogen reduction in animals.

- Antibiotic resistance results in difficult to treat infections, untreatable infections. Antibiotic use increases the spread of antibiotic-resistant bacteria by creating selective pressure favoring resistant bacteria. The public health impact of resistance on the population includes increased morbidity and mortality from treatment failures and increased health care costs as newer, more expensive antibiotics are needed to treat infections.

Outcome:

The effect of a surveillance system in place to detect foodborne illness outbreaks in combination with intervention efforts, such as product recalls, reduces the number of illnesses in the outbreak and generates health benefits as shown for the 1993 *E. coli* O157:H7 in hamburger outbreak. Griffin, et.al. estimated that an additional 800 illnesses were prevented because an in-place surveillance system detected the outbreak, quickly triggering recall of the implicated food and generating health benefits of $42 million[10].

[10]Griffin, P., et.al."Large outbreak of *Escherichia coli* O157:H7 Infections in the Western United States: The Big Picture: in Recent Advances in Verotoxin-producing *Escherichia coli* Infections. M.A. Karmall, M.A. and A.G. Gaglio, Eds. 1994. Elsevier. p. 8.

Resource Requirements:

Agency	FTEs	Dollars ($M)
FDA	15	$ 4.680
CDC	30	15.700
USDA	4	1.420
Total	49	$21.800

Inspections

Goal:

More efficient and effective monitoring of the safety of the food supply.

Objectives:

Implement the seafood HACCP regulations, expand the use of HACCP systems to non-seafood establishments, and work to apply HACCP principles to retail food service operations, and to slaughter of animals used for food.

Upgrade the Federal component of inspections of food in interstate commerce through improved cooperation and coordination with USDA.

Expand Federal/State inspection partnerships to ensure consistency in inspection technique across Federal, State, and local levels, that inspections are better coordinated with the States, and that duplication of efforts are eliminated.

Increase sampling of domestic and imported food products.

Benefits and outcomes:

Overall: Enhanced safety of the food supply realized with rapid implementation of HACCP procedures in the seafood, meat, and poultry industries and more comprehensive monitoring of the adequacy of the production, processing, distribution, and storage of other commodities. In recent years, the number of FDA inspections of food establishments has declined substantially, from a peak of 21,000 in 1981 to slightly less than 5,000 in 1996. Today, the average food plant under the jurisdiction of FDA is likely to be inspected only once every ten years. During this period, product recalls for life threatening bacterial problems increased from 79 in 1988 to 378 in 1995, at a cost to industry (and indirectly consumers) of approximately $42 million in 1995. It is anticipated that the value of recalled products may continue to rise if the number of inspections continues its downward trend. In comparison, USDA inspectors, because of its Congressional mandate, conduct continuous inspections of meat and poultry firms.

- More effective, efficient monitoring of the safety of the domestic food supply, including product sampling.
- Development and initiation of plans to achieve a more adequate level of inspections (particularly of firms manufacturing "high risk" products) by FDA.
- Implementation of a joint FDA/USDA strategy for assuring the safety of foods transported in interstate commerce.

- Compilation of inspection data from Federal and State inspections, creation of an early warning network for naturally occurring toxins, and development of a system for certifying private parties to perform food sample analyses.

- National consistency in implementation of HACCP through creation of the HACCP Clearing House to provide guidance to small businesses, importers, States, and others.

Outcome:

- Prompt and effective implementation of Seafood HACCP regulation by FDA will avert an estimated 20-50,000 cases of foodborne illness annually. Costs associated with foodborne illness caused by contaminated seafood are approximately $245 million annually and the estimated savings implementation of HACCP would realize in the third year are $45-116 million. Approximately half of all recalls involving contaminated seafood products will be prevented at a value to industry of $1.25 million.[11]

- Assurance that foods in international trade, particularly imported foods, are manufactured under a food safety system comparable to the U.S. system through expanded use of international agreements, e.g., within the next two years, FDA should enter into MRAs or similar agreements to cover no less than 25 percent of seafood imported into the U.S. Product sampling at port of entry will be used to verify quality of imported products.

- Improved inspections and risk assessment techniques can reduce implementation costs of HACCP, potentially generating an estimated $9.3 million savings in the first year and approximately $80.5 million (discounted value) indefinitely into the future for seafood products. If the same improvement occurs in health benefits, prompt and effective implementation of the Seafood HACCP regulation by FDA will avert an estimated 3,800 illnesses annually for a health benefit of $3.5 in the first year, increasing to $7.1 by the third year. The total savings for implementation of HACCP (cost savings plus health benefits) are therefore, 3,800 illnesses and $12.8 in the first year, rising to $16.4 million by the third year. Approximately half of all recalls involving contaminated seafood products will be prevented at a value to industry of $1,250,000. FDA estimated industry costs associated with implementation of HACCP for seafood products at $677 million to $1.488 billion with benefits ranging from $1.435 to $2.561 billion over a 4-year period.[12]

- USDA estimates 20-year industry costs associated with implementation of HACCP for meat and poultry products at $968 million to $1.156 billion with benefits ranging from $7.13 to $26.59 billion based on eliminating contamination by Campylobacter jejuni/coli, E. coli

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[11]Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products. Federal Register Dec. 18, 1995. 60 FR 65185

[12]Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products. Federal Register. December 18, 1995. 60 FR 65185.

O157:H7, Salmonella spp., and Listeria monocytogenes.[13] According to USDA estimates, the number of cases of Salmonellosis prevented by HACCP will be 144,072 to 794,880 for a value of safety benefit of $124 to $724.5 million.

Resource Requirements:

Agency	FTEs	Dollars ($M)
FDA	201	$27.60
CDC	0	0.00
USDA	0	0.00
Total	201	$27.60

[13]Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule. Federal Register. July 25, 1996. 61 FR 38858.

Education

Goal:

Food safety education programs and materials, demonstrated by research, to:

1) change unsafe food handling behavior used in the home and in retail, food service, and institutional operations; and

2) minimize the occurrence of bacterial pathogens and residues in edible animal tissues.

Objectives:

Develop more effective methods for providing food safety education materials and services to consumers and to food service operations, especially those providing food to populations at high risk in hospitals, nursing homes, assisted living facilities, child day care, and senior day care.

Develop and implement a national food safety education program for all segments of the retail food industry using the concepts set forth in the Food Code.

Develop an education program for producers of animals for human consumption, veterinarians, and State and local regulators on issues and concerns surrounding safe producer practices and the appropriate use of drugs in food animals.

Improve education and training of epidemiologists, microbiologists, and physicians.

Increase the proportion of reported outbreaks of foodborne disease with known etiology from 45 percent to 60 percent.

Benefits and outcomes:

Overall: Improved safe food handling behavior on the part of consumers and workers in the retail/food service/ and institution industries. Studies indicate that food handlers (home and retail) play a role in ensuring the safety of the food supply. Food prepared at home contributes to 20 percent of all reported foodborne illness outbreaks[14]. Moreover sporadic illness is related to the types of food individuals usually eat at home, e.g., 53 percent of the public eats food with raw eggs, 23 percent eat undercooked hamburger, 17 percent eat raw clams and oysters, and 26 percent do not wash their cutting boards after using them with meat or poultry.[15] Foods consumed at retail food service establishments accounted for 37% of the foodborne illnesses reported to CDC in

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[14]Foodborne Pathogens: Risks and Consequences. Council for Agricultural Science and Technology. 1994. p. 31.

[15]Fein, S.B., C.T. Jordan Lin, A. Levy. Foodborne Illness: Perceptions, Experience, and Preventive Behaviors in the United States. Jrnl. of Food Protection. December 1995.

1992.[16] *(Note: It is far more likely that illnesses associated with foods consumed in restaurants and other food service establishments will be reported.) FDA estimates that prevention of even a fraction of these illnesses will reduce the health care and lost productivity costs associated with individual* Salmonella illnesses *($7,000 per illness from contaminated eggs) and* E. coli *O157:H7 outbreaks (ca. $4 million per day). Twelve million people are involved in the retail food preparation business.*[17] *Equipping these people with information necessary to change unsafe food preparation and handling behaviors will have a significant effect on the occurrence of foodborne illnesses.*

- Reduction in the number of foodborne illnesses through the use of a research-based educational approach that will change consumers' and food service workers' use of unsafe food behaviors.

- Implementation of national "Safe Food" Guidelines like the Dietary Guidelines and creation and use of a visual model like the Food Guide Pyramid

- Creation of an alliance, joining expertise of Federal, State and local health agencies, industry, and professional and trade associations to develop improved education activities on food safety issues, promotion of the Food code and/or the food safety parameters.

- Implementation of a national media campaign, using targeted food safety messages. In a 1993 survey conducted by FDA, 33 percent of consumers with primary responsibility for meal preparation cited news stories and programs as their primary source of food safety information, with food labels and packaging (27 percent), cookbooks (26 percent), hotlines and extension service offices (14 percent), grocery store handouts (6 percent) as other sources.[18]

- Development and use of education/communication techniques that overcome current barriers to communicating appropriate food safety behaviors to food service workers.

- Creation of a national clearinghouse which will serve as a focal point and repository for food safety information.

- Targeted guidelines and training programs, that incorporate provisions of the Food Code and HACCP principles, for Federal, State, and local inspectors, as well as a cross-section of the food service industry.

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[16]U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration. Food Code. 1995.

[17]Bean, Nancy H., J.S. Goulding, C. Lao, F.J. Angulo. CDC Surveillance Summaries, MMWR. 1996. 45:SS-5. CDC.

[18]Levy, A. 1993. Phone survey of 1,620 consumers conducted by FDA/CFSAN Consumer Studies Branch.

- Development of strategies to encourage the incorporation of HACCP principles into animal husbandry practices within industry quality assurance programs, including proper use of drugs.

- These initiatives are aimed at reducing the occurrence of zoonotics among food animal populations by encouraging better husbandry practices and enhanced animal health.

- Prudent and judicious use of antimicrobials will also diminish the probability of the emergence of resistant organisms. The emergence of drug-resistant organisms represents an extremely costly problem for human medicine, not only from the toll of morbidity and mortality, but also because the useful "lifespan" of the drugs to treat these organisms are greatly diminished, necessitating costly development of new drugs.

Outcome:

- An estimated 50 million people are now reached with consumer information, only some of which is safe food handling information: it is anticipated that full implementation of this portion of the initiative, along with the other elements of the initiative, will result in an additional 50 million consumers and a large portion of the 12 million food service workers being reached with food safety messages. But, more importantly, this initiative will target changed behavior as its goal rather than information dissemination as previous education initiatives have done. Thus, safe food handling behavior is the outcome.

- Annually, between 128,000 and 640,000 incidents of illness associated with shell eggs occur at an average (but not typical) cost of $7,000 per case. (This value represents an averaging of the costs of mild cases and very serious cases.) Preventing one percent of these illnesses, which is a conservative estimate based on education efforts alone, would save between $9 million and $45 million in health care costs annually.

Resource Requirements:

Agency	FTEs	Dollars ($M)
FDA	23	$7.03
CDC	10	7.60
USDA	0	1.70
Total	33	$ 16.33

Risk Assessment

Goal:

Improved health risk estimates associated with microbial and chemical foodborne hazards to facilitate the development and evaluation of surveillance plans, risk reduction strategies, regulations targeted to specific hazards, implementation of HACCP practices, and research programs to enhance food safety.

Objectives:

Establish a Risk Assessment Consortium to provide leadership, consistency, and transparency in risk assessment.

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

Develop dose-response models for use in risk assessment of both microbiological and chemical hazards.

Develop improved and more standardized risk assessments to facilitate the ranking of food safety concerns to provide for better health protection and more efficient utilization of resources.

A science-based level playing field in support of U.S. positions in international trade.

Benefits and outcomes:

Overall: Better, science-based, risk assessments with which to set priorities and target regulations to hazards, evaluate surveillance plans and data, evaluate risk reduction strategies, design public health policy, and target research programs to improve food safety. Risk assessment is fundamental to identifying where and how a hazard can be introduced into the food supply and how to prevent the hazard. For example, use of a newly developed exposure assessment model for Salmonella enteritidis *in pasteurized liquid whole eggs indicates that a small 1 degree change in pasteurization temperature produces over a millionfold increase in the mean probability of the product causing illness*[19].

- Increased accuracy and speed in making risk assessments through the development and use of new risk assessment models based on better understanding of the gaps in risk assessments data sets, improved targeting of research to fill those gaps, and expanded access to research results needed to improve the value of the models.

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[19]Whiting, R.C. and R.L. Buchanan. Development of a Quantitative Risk Assessment Model for *Salmonella enteritidis* in Pasteurized Liquid Eggs. Accepted for publication in 1997 by Int. J. Food Microbiol.

- More transparent risk analysis which will improve the utility of and confidence in risk assessment among scientists and the general public.

- More transparent risk assessment models to permit peer review and promote professional credibility in government risk assessment models.

- Identification of points that most strongly influence the estimate of risk with attendant uncertainty. These points may be identified as critical control points in a HACCP plan.

- Common definitions and approaches to risk assessment to permit ranking infectious and noninfectious hazards on the same scale, and may help the public understand the relative importance of perceived hazards in the food supply and improve risk communication and education.

Outcome:

- More effective food regulations. For example, if regulations embodying improved risk assessment can make food safety regulations one percent more effective -- a conservative estimate – by targeting high-risk areas, the lower-bound annual value of the resulting health benefits would be $56 million.

- Better risk assessment will result in more focused surveillance and research efforts and more focused regulatory initiatives. The ultimate result is identification of trends in causes and sources of foodborne illness and development of methods to rapidly identify specific sources in an outbreak. These two factors will shorten the time to identify an outbreak and its source, speeding control measures into place, and preventing growth of the outbreak, illnesses and possible deaths. As noted in the above examples, even modest improvements in the existing system can yield savings to both industry and consumers of thousands, even millions of dollars.

Resource Requirements:

Agency	FTEs	Dollars ($M)
FDA	21	$10.33
CDC	0	0.00
USDA	0	0.00
Total	21	$10.33

Research

Goal:

New, improved tools, screening methods and analytical methods to more rapidly and accurately identify and characterize foodborne hazards, evaluate effectiveness of surveillance initiatives, control and prevention strategies, conduct risk assessments, and verify effectiveness of preventive techniques such as HACCP.

Objectives:

Availability of new, rapid, sensitive, and accurate screening and analytical methods for microbial and chemical hazards to:

Detect and identify the source of foodborne illness outbreaks in surveillance and monitoring activities;

Obtain data critical to accurate risk assessments;

Verify critical control points in HACCP programs;

Support development of educational materials; and

Provide scientific underpinning for the execution of Federal and State monitoring, regulatory, and enforcement activities to reduce the incidence of foodborne illness.

Better understand microbial antibiotic resistance in order to reduce the risk of foodborne illness transmitted through agriculture and aquaculture.

Elucidate the mechanisms mediating persistence of pathogens, improve capability for identifying and monitoring changes in microbial resistance to a wide range of factors (e.g., heat, cold, acid, high salt), and develop preventive techniques.

Develop techniques for the reduction or elimination of contamination in feed as a source of animal infections in order to reduce the carry-over of pathogens into the food chain.

Benefits and outcomes:

Overall: Tools to identify and control foodborne outbreaks and to recognize trends that may lead to future outbreaks, data to design technical preventive techniques and education programs, and data to conduct risk assessments. Lack of rapid, sensitive analytical methods stymies immediate initiation of control measures when an illness outbreak is identified, but the source cannot be identified. For example, if a method (in combination with improved surveillance and coordination efforts) for Cyclospora cayatenesis *had existed at the time of the Spring/Summer, 1996 outbreak the*

source could have been identified more rapidly and intervention measures, such as stopping the import of raspberries, immediately imposed.

Genetic changes (and physiological changes of a more temporary nature), make microorganisms tolerant to environmental conditions or chemical conditions that previously either destroyed them or controlled their growth. These resistances negate the effectiveness of traditional preventive measures, such as disinfection methods and processing techniques. In the recent outbreak of E. coli *O157:H7 in apple juice, which resulted in the death of a child, the acidity of the juice should have prevented the growth of the bacteria. However,* E. coli *is one of the microorganisms that has become acid-tolerant, triggering the need for reevaluation of the effectiveness of conventional processing and handling techniques.*

- Improved capability to detect and identify microbial and chemical hazards in a variety of settings in the food chain (farm, processing, distribution) as a basis for formulating preventive strategies and verifying controls in HACCP programs.

- Availability of new and improved rapid, sensitive, and accurate screening and analytical methods, using gene-based (e.g., PCR probes, DNA fingerprinting) and other advanced technologies.

- Improved ability to detect and identify resistant microorganisms and identify determinants that may affect susceptibility and around which analytical methods and preventive techniques, (such as new effective cleaning and disinfection methods for facilities and heat-sensitive foods and new feed and food processing parameters), may be designed.

- Development of effective production practices that reduce levels of or eliminate hazards from food animals and plants prior to harvest or slaughter.

- Improved systems for monitoring package integrity and detecting the presence of toxic substances at all points along the food production, transportation, storage, and distribution chain.

Outcome:

Development of seven to ten new or improved screening and analytical methods to detect, identify, and quantify microbial and chemical hazards. These methods will permit rapid execution of the intertwined coordination, surveillance, inspection, education, and risk assessment elements of an efficient, effective food safety program.

Resource Requirements:

Agency	FTEs	Dollars ($M)
FDA	31	$13.87
CDC	0	.50
USDA	0	0.00
Total	32	$14.37

Cost of FY 1998 Food Safety Initiative vs. Anticipated First Year Benefits
($ in Millions)

Food Safety Initiative Activity	Food Safety Initiative Request
Coordination	$ 1.000
Surveillance	4.680
Inspections	27.602
Education	7.030
Risk Assessment	10.330
Research	13.870
Totals	**$ 64.512**

Area of Savings/Benefits	First Year Projected Benefits	Recipients of Savings/Benefits
Reduce Severity of E.coli O157:H7 Outbreaks	42.870	Industry (Direct) Consumers (Indirect)
Seafood HACCP Implementation	12.800	Consumers (Indirect)
Reduced Cost of Seafood HACCP Implementation	18.600	Industry (Direct) Consumers (Indirect)
Twenty Percent Reduction in Product Recalls	9.000	Industry (Direct) Consumers (Indirect)
Prevention of Illnesses Associated with Shell Eggs	9.000	Consumers Employers
Improved Effectiveness Targeting Food Safety Priority Areas -- One Percent	56.000	Industry (Direct) Consumers (Indirect)
Totals	**$ 148.270**	

ECONOMIC ASSESSMENT OF THE INTERAGENCY FOOD SAFETY INITIATIVE

FDA has estimated the public health impacts of the interagency food safety initiative. The model employed uses the Council for Agricultural Science and Technology (CAST) report for the current annual incidence of foodborne disease. Next, numerous factors such as the growth in susceptible populations, emerging pathogens, immigration, growth in imports, growth in antibiotic resistance, and other factors are used to extrapolate to the likely annual number of cases and deaths that will be present five years from now. Illnesses may grow between 10 to 16 percent in that time period and deaths by as much as 37 percent. Next, the model examines each of the components of the initiative to determine the likely number of reduced cases (illnesses and deaths) the initiative will accomplish. Overall, the increased inspection activity is likely to reduce cases by 20 percent with a 23 percent reduction from the entire initiative. Increased surveillance is likely to reduce the average number of cases per outbreak through quicker detection. Inspections are likely to increase compliance with food safety laws, particularly HACCP, through both detecting contaminated food at plants and on the docks and, perhaps more importantly, providing more of a deterrent than the current low rates of sampling and plant inspections provide now. Education of both consumers and food handlers has the potential for large gains. Poor food handling practices in restaurants has been traced to numerous foodborne disease outbreaks. Coordination and research assessment contribute to helping surveillance and inspection to be more efficient. Finally, risk assessment, will reduce the costs of regulations by producing more targeted approaches, rather than a scattershot approach, when there is substantial uncertainty.

Successful implementation of these initiatives could, for the selected pathogens, result in a reduction of the annual number of cases by between 940,000 and 1.8 million, and the annual number of deaths by between 300 to 1,500 annually. For all pathogens, successful implementation could mean that the number of illnesses can be reduced by 1.6 million to 8.8 million, and the number of deaths can be reduced by between 550 to 2,600 annually. **These numbers should not be considered precise, but rather representative of the kinds of public health benefits a relatively small investment might obtain.**

ECONOMIC ASSESSMENT OF THE INTERAGENCY FOOD SAFETY INITIATIVE

Successful implementation of the Interagency Food Safety Initiative is intended to reduce the number of cases of food borne disease that involve both illness and death. This report makes a preliminary estimate of the effect this initiative is likely to have on selected pathogens and concludes with some possibilities for the larger spectrum of food borne disease. The model uses as a static baseline the number of cases of food borne disease reported in the CAST report.[1] Second, various scientific and socioeconomic changes are evaluated in order to predict a likely growth rate of the selected pathogens that would take place without increased effort to control them. As with any such projection, the numbers are to be regarded as being considerably uncertain. Third, each of the new initiatives are evaluated with regard to the lower and upper bound impact they are likely to make in reducing the number of cases. Finally, the report concludes with an extrapolation to all food borne disease. The data, including the static baseline number of cases from the CAST report, are summarized in the attached tables.

I. Projected Changes in the Number of Cases of Selected Food borne Pathogens

All projections are for the change in the number of cases and deaths as a result of food borne pathogens within the next 5 years; however, benefit estimates in this report are for annual reductions

1) Emerging pathogens. All data used for these estimates is from sources from FDA's Center for Food and Applied Nutrition. For E. Coli, there was a 9,200 percent increase in the number of cases from 1988 to 1993, due entirely to an emerging food borne pathogen. This was deflated by a conservative factor of 100 percent, to 90 percent, to estimate future increases in E. Coli cases within the next 5 years. For Salmonella, there was an increase in the number of cases from 1988 to 1993 of 1,600 percent, also entirely due to an emerging pathogen. This estimate was also deflated by a factor of 100 percent, to 16 percent, to estimate the likely increases in the next five years. No changes were made for any other of the selected pathogens, again, a conservative estimate.

2. Resistance to antibiotics Where antibiotics can make a difference in the course of a food borne disease, the resistance of particular pathogens to those antibiotics will affect the duration and severity of the case. In 1979, 16 percent of the strains of Salmonella showed resistance to antibiotics; in 1990, this number increased to 31 percent. A growth in antibiotic-resistant pathogens is expected to increase the case-fatality-ratio (CFR), the ratio of deaths to total cases. Assuming this rate increases at a constant rate, there would be approximately a 7 percent increase over the next 5 years in antibiotic resistance. This report assumes that 10 percent of the 7 percent in Salmonella change would result in additional deaths per case, or a 0.7 percent increase in deaths.

3. Growth in the susceptible population. Although there is expected to be an increase in large numbers of different susceptible subpopulations, such as an increase in the HIV positive population, the growth in the over 65 population will dwarf all other susceptible subpopulations. This will be particularly true over the next 15 years as the baby boom population reaches this age. Over the next 5 years, DHHS projects that this population will grow by 1 million people each year or 14.7 percent total. Currently, 6 percent of the cases of Salmonella come from nursing homes but over 70 percent of all deaths from Salmonella occur in nursing homes. This analysis assumes that the cases of Salmonella will increase proportionately for illnesses and death, by 0.9 percent and 10 percent,

respectively. The analysis assumes the same rate of increase for the Norwalk virus and Cryptosporidium, as these are also associated strongly with the elderly. For all other pathogens, it is assumed that the numbers would increase by 10 percent of those estimated for salmonella; potentially, a conservative estimate.

4. Immigration. The school age population of immigrants is expected to grow by 20 percent in the next 5 years (DHHS estimate). This analysis assumes this percentage holds for all immigrants. These populations may not be as familiar with safe food handling practices as the current U.S. population and may also have difficulty understanding public health notices related to food handling and food borne disease because of language difficulties. They may also have greater susceptibility to some food borne diseases than the average current U.S. resident. This analysis assumes that these factors will lead to a 10 percent increase for this population or 2 percent of overall food borne illness cases for each pathogen.

5. Imports. As imported foods continue to grow, it is likely that the percentage of contaminated food in the U.S. diet will also increase. Although not part of the calculation of the number of cases, it is important to point out that FDA currently samples only about 2 percent of all imported food lots. The percentage of the reduction in the number of cases is calculated by multiplying the growth in imported food products by the contribution this growth is expected to give to the number of cases. Imported food now accounts for approximately 10 percent of the diet but a higher percentage of the number of cases of food borne disease. For a given food, FDA data indicates that there is a 5 percent increase in the rate of contamination between domestic and imported food. Thus, imported food currently is responsible for 10.5 percent of all cases of food borne disease. Imports are expected to grow at least the same rate as in the past 5 years, or about 55 percent (to about 15 percent of the diet). Thus, if the additional 0.5 percent contaminated food is increased by 55 percent, there is expected to be approximately a .03 percent growth in all cases due to the increase in imported food products.

6. Concentration of Food Production. As production of food for U.S. consumers becomes more concentrated, particularly with larger plants, the size of the average outbreak would be larger. The direction of food borne disease as a result of increased concentration is difficult to predict. Smaller firms cannot afford safety equipment with large fixed costs as easily, are less likely to have specialized quality control staffs, and, in some instances, are less susceptible to court challenges because of a smaller capital investment. On the other hand, they are easier to monitor, have smaller cases in an outbreak, have a greater percentage of their products marketed as brand names, and small business owners have more to lose personally with penalties for non-compliance. Thus, although the number of food processing plants is expected to decrease by 24 percent in the next 5 years, it is unclear how this will affect food safety.[20] Therefore, this report assumes that it will have no impact.

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[20] Connor, John M. Food Processing: An Industrial Powerhouse in Transition, Lexington Books, Lexington, MA, 1988, p. 33.

7. Food Consumed Away from the Home. Currently, approximately 30 percent of the diet is consumed away from the home. The dollar growth in food consumed away from the home grew from 1970 to 1993 by 7 percent.[21] Using this growth rate, food consumed away from home is expected to grow at an annual rate of .35 percent or 1.75 percent over 5 years. The lag between consumption of food in food service institutions and food borne illness is between several hours and several months (such as Listeria). Therefore the failure to detect a foodborne illness closer to the time of consumption of the food does not provide an incentive for restaurant employees to take care in food preparation and are not as strong as for family home preparation. FDA assumes that the risk of exposure is double for food consumed away from the home. Therefore, the growth of food borne illnesses is expected to grow for all pathogens by 3.5 percent.

8. Education of Food Handlers and Food Consumers. Food safety was traditionally learned in high school home economics classes; however, these classes have substantially decreased in secondary schools beginning 15 years ago. In addition, the labor force participation rate for females, traditionally the member of the household most knowledgeable about food safety, has increased from 33 percent in 1948 to 59 percent in 1994.[2] This has brought males more into food preparation in the home without necessarily any increased knowledge of good food safety practices. In addition, because of these situations, children in these households are less likely to be trained in food safety. Consumers with less food safety education may introduce more pathogens into food due to, for example, poor hand washing practices or cross contamination (such as reuse of cutting boards from poultry to raw vegetables). It is unclear whether or not this problem will be worse over the next 5 years so that this analysis conservatively assumes that there will be no change.

9. Changes in Food Packaging Technology. Changes leading to more ready-to-eat foods in packaging such as sous vide may lead to more food borne illnesses. Again, it is not clear how much this will increase food borne disease so that, again, this analysis will assume no change.

II. Benefits from the Interagency Food Safety Initiative

Although there are likely to be interactive effects between the various components of the Food Safety Initiative, this analysis attempts to make rough estimates of the marginal benefits of each component.

1. Surveillance

Increased surveillance will reduce the number of cases of food borne disease by detecting outbreaks earlier. CDC epidemiologists estimate that 800 cases, or about 50 percent, of the potential illnesses in the 1993 E. Coli O157:H7 hamburger outbreak, were prevented by rapid and effective surveillance. This analysis assumes that surveillance as outlined in this initiative will prevent 20 percent of the cases from an additional 10 percent of the number of outbreaks that are detected or 2 percent of cases. Currently, all states do not have comparable surveillance capabilities such as the one that led to detection of this problem. Increased surveillance (such as increased numbers of sentinel sites), coordination and transfer of technology to states will accomplish these reductions.

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[21] Economic Issues Associated with Food Safety, Economic Research Service, No. 9506, Feb. 1995.

2. Inspections and Sampling

Inspections and sampling will reduce the number of cases and outbreaks of food borne microorganisms (pathogens, viruses, and parasites) by both deterrence and actually detecting contaminated food and preventing it from being consumed. It will work for both imported and domestic food. One of the primary mechanisms that will be used will be rapid implementation of HACCP procedures with more comprehensive monitoring of the adequacy of the production, processing, distribution and storage of food commodities.

The lag for food borne illness symptoms to ensue following consumption of contaminated food ranges is anywhere from a few hours to a few months. Because of this, attribution to a food or a specific food is difficult, if not impossible. Even for the preponderance of evidence standard used in courts, consumers are unlikely to obtain judicial relief such that the judicial system plays a minor role in deterrence of food borne disease. For the same reason, brand names are not at great risk of financial loss from food borne outbreaks because trace backs are rare. Furthermore, when food products become more competitive, cutbacks in quality control are an "invisible" method of cutting back production costs to lower food prices. Thus, it is government inspection and sampling which has the largest deterrent effect on the rate of disease.

Inspections for high risk food plants are now done once every 4 years for FDA regulated foods but, with the new initiative, they will be done once a year. High risk food plants include seafood, dairy, and low acid canned foods (LACF). FDA recall and inspection data imply that a one percent increase in inspections leads to a one percent decrease in recalls. If recalls are proportional to illness prevented, then for every one percent increase in the number or effectiveness of FDA inspections, the number of food borne illnesses should fall by one percent.

Yet another way to think about deterrence is to examine the situation of countries who now do less than the United States in terms of inspection, sampling and research. In one study which compared the numbers of outbreaks per 10 million population by country, the U.S. was found to have 1/100 of the number of outbreaks of Salmonella as countries which do not have such a well developed federal food regulatory system.[3] Compared to 2.8 outbreaks of Salmonella per 10 million U.S. consumers, Scotland was reported to have 292, Hungary 124, Spain 119, and England/Wales 89. Although the rate of inspections, sampling and amount of funding spent on food safety research for these countries is not known, it is likely small relative to that spent by the U.S. The result appears to be a noticeable per capita increase in food borne disease.

3. Education

Because of problems mentioned in an earlier section of this document with consumers' lack of knowledge of good food handling practices, education targeted to behavior changes are likely to be particularly effective. Education of food handlers in restaurants, nursing homes, educational and correctional institutions and the military is also likely to provide considerable benefits as many outbreaks have been traced to poor food handling practices in these institutions, particularly for Norwalk and Norwalk-like virus', E. Coli O157:H7, Salmonella enteritidis, Vibrio cholerae, Cryptosporidium, and Giardia lamblia.[4]

The campaign against smoking provides a benchmark for the effectiveness of safety education aimed at consumers. The anti-smoking television campaign of 1967-1970 reduced cigarette consumption per capita by about 6 percent in only three years. A food safety campaign should aim for a similar annual decline -- about 2 percent-- in unsafe food preparation practices. According to Archer and others, over 50 percent of food borne illness may be caused by unsafe preparation practices, the education initiative could reduce food borne illness by one percent per year.

4. Coordination

The information picked up by surveillance and public health organizations at different levels of government -- federal, state, and local -- is often not shared. A computer-based information system will allow public health organizations to more easily share information on outbreaks and emerging pathogens. It is expected to contribute to the effectiveness of surveillance in reducing the number of cases per outbreak. No separable benefit estimates have been produced for this activity as it is impossible to separate it from surveillance, inspection, education and risk assessment.

5. Research

Public health organizations have identified many emerging pathogens, such as Cyclospora. The full nature of the threat to human health, however, has yet to be determined for many of the pathogens. Research can be expected to fill in many of the gaps in our knowledge of these pathogens, particularly by discovering more cost-effective analytical methods that will quickly detect their presence in food. Incentives to develop such methods are weak at best in the food industry because of the lack of liability or brand name effects mentioned earlier. Public health will benefit from detection of pathogens, both new and existing, resulting in quicker recalls and better targeted regulations. For example, if a method (in combination with improved surveillance and coordination efforts) for Cyclospora had existed at the time of the spring/summer, 1996 outbreak, the source could have been rapidly identified and intervention measures -- such as stopping the import of raspberries -- immediately imposed. No separable benefits are estimated for this activity although they may be considered to be part of the benefits estimated in the inspection section..

6. Risk Assessment

Microbial risk assessment is still in its infancy although the GATT requires a risk assessment to justify international food safety standards that differ from a world standard. Regulating microbial risks requires knowing the magnitude and contributing factors to that risk. For example, a recent risk assessment model indicated that a one-degree increase in pasteurization temperature for liquid whole eggs reduces the probability of salmonellosis by a million-fold. This critical control point appeared to have an extremely large net benefit improvement relative to other control points in the chain of production, transportation and consumption. Other microbial risk assessments may find similar if not so striking results. The result may be more targeted critical control points and less costly, "scattershot" regulations. Estimates produced in other sections of this document quantify cost reductions of regulations but not public health benefits, which are the measure produced in this report.

STATIC ANNUAL BASELINE CASES FOR SELECTED PATHOGENS

PATHOGENS	Illnesses Lower Bound	Illnesses Upper Bound	Deaths Lower Bound	Deaths Upper Bound
E. Coli O157:H7	10,000	20,000	160	400
Salmonella Enteriditis	800,000	4,000,000	696	3,840
Campylobacter Jejuni	2,500,000	2,500,000	110	511
Toxoplasma Gondii	2,056	2,056	41	41
Cryptosporidium parvum	403,000	403,000		
Norwalk virus	250	250		
Listeria	1,795	1,860		
Cyclospora	1,500	1,500		
TOTAL	3,718,601	6,928,666	1,007	4,792

Chart 1

PROJECTED BASELINE FOR SELECTED PATHOGENS

PATHOGENS	Illnesses Lower Bound	Illnesses Upper Bound	Deaths Lower Bound	Deaths Upper Bound
E. Coli O157:H7	20,000	40,000	320	900
Salmonella Enteriditis	984,000	4,920,000	900	5,100
Campylobacter Jejuni	2,646,000	2,646,000	120	550
Toxoplasma Gondii	2,000	2,000	40	40
Cryptosporidium parvum	430,000	430,000	0	0
Norwalk virus	270	270	0	0
Listeria	1,900	2,000	0	0
Cyclospora	1,600	1,600	0	0
TOTAL	4,085,770	8,041,870	1,380	6,590
Based on discussion in Section II.				

Chart 2

PERCENT REDUCTIONS OF FOODBORNE DISEASE DUE TO ACTIVITIES

PATHOGENS	Surveillance	Inspections	Education
E. Coli O157:H7	2%	20%	1%
Salmonella Enteriditis	2%	20%	1%
Campylobacter Jejuni	2%	20%	1%
Toxoplasma Gondii	2%	20%	1%
Cryptosporidium parvum	2%	20%	1%
Norwalk virus	2%	20%	1%
Listeria	2%	20%	1%
Cyclospora	2%	20%	1%
Based on discussion in Section III.			

Chart 3

ESTIMATED CASES REDUCED FOR SELECTED AND TOTAL PATHOGENS

PATHOGENS	Illnesses Upper Bound	Illnesses Lower Bound	Deaths Lower Bound	Deaths Upper Bound
E. Coli O157:H7	4,545	9,090	73	183
Salmonella Enteriditis	226,314	1,131,568	212	1,169
Campylobacter Jejuni	608,685	608,685	27	126
Toxoplasma Gondii	501	501	10	10
Cryptosporidium parvum	98,856	98,856	0	0
Norwalk virus	61	61	0	0
Listeria	437	453	0	0
Cyclospora	365	365	0	0
SELECTED PATHOGENS	939,764	1,849,579	322	1,488
TOTAL PATHOGENS	1,650,936	8,845,810	566	2,614

Chart 4

FOOD & DRUG ADMINISTRATION

PREMARKET APPROVAL

FDA -- PREMARKET APPROVAL

Foods Program -- $4 million

The Food, Drug and Cosmetic (FD&C) Act requires premarket approval of food and color additives. Through the premarket approval process, the Agency subjects food and color additive petition data to rigorous scientific evaluations to ensure that food ingredients are safe before sanctioning their use in consumer products. FDA provides guidance and assistance to the public with food ingredient regulatory interpretations, and consultations concerning foods derived from new varieties of crop plants. Extensive efforts are also devoted to international activities associated with harmonization regulations governing the safety of food ingredients.

FDA currently receives approximately 50 food and color additive petitions, 70 threshold of regulation requests, and 2,200 written inquiries per year. Over the past several years, FDA has undertaken a number of initiatives to increase the efficiency of the premarket review process and will continue to implement measures for improvement.

Goal:

Simultaneously streamline the premarket review process and reduce the backlog of petitions to ensure timely completion of petition reviews within statutory guidelines.

Two components critical to accomplishment of this goal are the ability to provide potential petitioners with extensive assistance both prior to filing a petition, as well as during the post-filing process. FDA is requesting an additional $4 million to facilitate this petitioner assistance. In general, this funding would be used to:

(1) Develop and publish a comprehensive guideline for petition preparation;

(2) Design and develop an education program to facilitate industry understanding of the types of studies and safety data required to support a petition;

(3) Enhance FDA's ability to provide extensive pre-filing consultations with potential petitioners; and

(4) Provide extensive interaction and assistance to petitioners during the post-filing review process to resolve issues and concerns in a timely manner.

Specifically FDA, as a part of this initiative, would:

(1) In the arena of enhanced petitioner assistance:

(A) Develop, plan and conduct three workshops annually to provide specific face-to-face guidance to prospective petitioners. Presently, such guidance is provided to individual petitioners on an ad hoc basis. This approach has

proven to be inefficient, often resulting in inconsistent or incomplete communication of information.

(B) Provide continued support to update and assure publication of the Food Chemicals Codex (FCC).

(2) Enhance internal information processing by commitment of additional resources to the preparation and maintenance of petition administrative records.

(A) Design, build, and maintain an "expert system" to perform the initial evaluation of petition data for indirect food additive (food contact material) petitions. This "expert system" would be an integrated electronic data collection allowing rapid search of FDA's petition information base. The system would allow quick identification of safety indicators for given substances.

(B) Modernize the current PC-based exposure data base on substances migrating to foods. This modernization would make such data acquisition compatible with current network capabilities, software and the "expert system."

(C) Conduct a study to establish parameters for submission of petitions in an electronic format. Speed the conversion of CFSAN's petition files to an electronically retrievable format.

(D) Expand, enhance, and maintain FDA's computerized worldwide, food ingredient information base. Compile and maintain the General Standard for Food Additives, for which FDA has primary responsibility, under the Codex Committee on Food Additives and Contaminants.

(E) Perform studies modeling migration of components of food contact substances in actual situations.

Anticipated benefits and outcomes of this initiative include:

The petitioner workshops would provide an efficient mechanism for dissemination of critical information, which would in turn, increase the quality of petitions submitted to the Agency, thereby reducing FDA petition review time.

The FCC is used by the international food industry to ensure that food ingredients meet food-grade specifications. In the absence of this contract, FDA would have to reallocate FTEs from petition review to develop and update food-grade specifications for food ingredients.

If implemented, the "expert system" for the initial evaluation of petition data, would lessen the level of FTEs spent on the review of packaging material petitions, allowing FDA to utilize these FTEs in other areas of petition review.

FDA would conduct a study with several candidate firms to test alternative formats for electronic petition submission, which would be compatible with FDA's hardware and software requirements. The petition format developed as a result of this study would be offered to all petitioners for use in petition submission. These petitions would be accessible by the "expert system." Additionally, information gained as a result of this study would furnish petitioners with explicit guidance which would facilitate the review of their petition data.

Because the U.S. is a signatory to the World Trade Organization Treaty, FDA is required to consider Codex standards for all food ingredients in foods in international commerce. CFSAN's Office of Premarket Approval is the repository of information and expertise for the U.S. government on food ingredient issues, and serves as a resource to U.S. industry and consumers by representing their interests in Codex. Maintenance of the information collections described will aid international harmonization efforts and will assist the U.S. food industry in marketing products overseas.

The data from these studies modeling migration of components of food contact substances in actual situations, will form the basis for predicting the migration of components of packaging materials into food. With this data, FDA can quickly and efficiently model, verify, and critically assess petitioners' submissions, with no loss of safety assurance. This will also help reduce the FTEs now required for the review of packaging materials, allowing the focus of these FTEs to be placed on other petition review activities.

Animal Drugs and Feeds -- $4 million

Goal:

Improve the process for review of animal drug applications.

FDA is requesting an additional $4.0 million to improve the animal drug review process. Reviewers would become more efficient in their reviews of applications with improved automation capabilities. Electronic submissions review would also be implemented including the Computer Assisted New Animal Drug Applications program. The funds would additionally be used to increase contracts with the States for additional inspections to generate needed information on tissue residues on a more timely basis.

FDA's number one priority and the thrust of our ReGo initiative (Reinventing the Animal Drug Review Process) is to make more animal drugs available to the marketplace. With the remainder of the increase we would contract for the services listed below, which would make the process more efficient and productive.

- Contract for additional information resource services and training. This would include training for the reviewers in their scientific specialties and in how to better use their computer equipment and software, provide more resources for our "Help Desk" function and for administration and improvement of our local area network.

- Contract for programming improvements to our Submission Tracking and Review System (STARS) database which will make more information available to reviewers at their desks to make them more efficient in reviewing applications.

- Contract to move the Center to electronic submission review, which would include computer Assisted New Animal Drug Applications and provide for the conversion of paper submissions to electronic files, through scanning.

- Contract for outside experts to develop and write the first drafts of new guidelines and updates of current guidelines. Up-to-date guidelines are critical to improving the review process, because they provide the guidance and knowledge to the sponsors so that they can submit better and easier to review applications. This is a function that is now done by reviewers because they are the only employees with the required knowledge and expertise to write them, and this translated directly into FTE savings that would be used on reviewing applications.

- Contract for support services to hold three workshops per year to facilitate and aid in the implementation of new or significantly revised guidelines. Part of this function is one that would have to be done by review personnel because of the knowledge level required and this would translate directly into FTE savings that would be applied to on reviewing applications.

- Increase contracts with the States for additional inspections which would provide information to reviews more quickly and allow for more efficient follow-up of repeat tissue residue violations.

Expected Outcomes/Benefits

The Agency and industry would benefit from the projected 20 percent reduction in backlogged submissions each year. The review of New Animal Drug Applications (NADAs) would be accelerated with those submitted under the reinvented process being completed within 90 days and those submitted under the old process in 162 days (which is 10 percent faster than the current 180 days). Pre-protocol meetings held with 70 percent of the sponsors would greatly increase the efficiency of industry as would reaching protocol agreements with 70 percent of the sponsors prior to the commencement of studies. The entire process would benefit in terms of increased efficiency through the updating of Agency guidelines which would be accomplished at a rate of about 15 percent each year beginning in FY 1998 with the infusion of these additional resources.

Implementation of these actions would be expected to produce the following results:

- Faster review of applications by reducing the backlog of submissions by 20 percent per year
- Review of NADAs submitted under the reinvented process in 90 days or less instead of the current 180 days
- Review of NADAs submitted under the old process in 162 days (10 percent less than the current 180 days).
- Reduce the uncertainty and wasted effort on the part of industry by holding pre-protocol meetings for 70 percent of the sponsors.
- Further reduce the uncertainty and wasted effort on the part of industry by reaching protocol agreements before the sponsors conduct studies for 70 percent of the sponsors.
- Update at least 15 percent of the Center's guidelines each year to make sure that the sponsors and the reviewers understand and agree on the requirements for approval of new animal drug applications.
- Provide the industry at least three workshops per year to facilitate and aid in the implementation of new or significantly revised guidelines.

Endnotes

• "Food borne Pathogens: Risks and Consequences, Task Force Report No. 122," Council for Agricultural Science and Technology, September, 1994.

•Economic Report of the President, February, 1995, p. 317.

• "Worldwide Surveillance of Food borne Disease: the Need to Improve," Todd, Ewen C. D., Journal of Food Protection, 59 (1), 1996 pp. 82-92

•"Factors Involved in the Emergence and Persistence of Food-Borne Diseases," Smith, James, L. And Pina M. Fratamico, Journal of Food Protection, 58 (6), 1995, pp 696-708.

— Surveillance —
- where is CDC $/FTE going. —
- How
- Current sentinal sites — gaps, funded. USDA, FDA, CDC
- isn't designed as early warning system
  - EWS accomplish two goals for regulatory agencies, that typically wait until they have microbiological confirmation that they are. —
① — FDA has been moving toward using epi. data and relying on that. — Generic fingerprinting allows you to know which cases are related.
② — PFGE systems — through investigations — not only of outbreak but background of cases — "disease detective" capabilities — feeds back into PFGE design and risk assessment.

Fingerprint library?

— Bioscience Research — USDA — (early warning)

Coordination
- outbreak at state level —
- Reports

How much $ is actually going to states

States — Saw the 26 pagers / never saw budget. —