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001. fax	Jean Logan to Elizabeth Drye re: DOB [partial] (1 page)	01/23/1997	b(6)
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COLLECTION:

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

FOLDER TITLE:

Fact Sheets - Q and A January Announcement

2014-0046-S

rc1368

RESTRICTION CODES

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

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

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]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
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]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

REPORT

FOOD SAFETY INITIATIVE

Q. Why is this initiative needed?

A. Foodborne disease is a major public health issue; outbreaks are increasing in seriousness and new disease-causing organisms are appearing in foods not previously associated with "food poisoning" (such as the contaminated raspberries of last summer). It is estimated that thousands of deaths and millions of illnesses a year are food related (according to a 1994 report entitled *Foodborne Pathogens: Risks and Consequences*, published by the Council for Agricultural Science and Technology, a private non-profit organization).

Q: How much will this initiative cost?

A. This initiative would provide an additional \$43 million for food safety to the FY '98 budget. Of that, \$11.5 million is for the new Early Warning System: \$10 million for the CDC; \$1 million for the FDA, and \$500,000 for USDA.

Q: What about the other \$31.5 million?

A: FDA will get \$23 million for seafood safety inspections, research, risk assessment and education; USDA will get \$8.5 million for training, research and education.

Q. What are the major sources of foodborne contamination?

A. Disease-causing organisms can contaminate food at many points. Examples are accidental contact of cow manure on fallen apples, contamination of meat with disease-causing organisms during and after slaughter, or seafood contaminated with naturally occurring microorganisms and toxins.

Q. Are foodborne disease outbreaks increasing?

A. It is hard to get really good estimates of this trend, but there is evidence that cases and outbreaks are increasing in frequency, and it is certainly clear that they are starting to involve increasingly dangerous bacteria, such as the *E. coli* strain that has caused serious illness and death in recent years.

Q. What foodborne hazards are targeted by this initiative?

A. We will focus on bacteria, parasites, and viruses that can cause serious diarrhea disease, not just the relatively short term, unpleasant intestinal distress usually thought of as "food poisoning." We are also targeting organisms that can cause death, spontaneous abortion, birth defects, and long-lasting illness such as reactive arthritis, and life-threatening paralysis.

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Q. What are the benefits of this initiative?

A. We can't make precise estimates, but we believe that this initiative will result in significant reductions in food-related deaths, disease, and health-care costs over the next several years.

Q. How will the food industry and consumer groups be involved in the initiative?

A. President Clinton charged Secretaries Shalala and Clickman and Administrator Browner with recommending further food safety improvements in consultation with all sectors of the food industry, with State and local governments, and with producer and consumer groups.

Q. Will this initiative result in new legislation or new regulations?

A. We don't know yet, perhaps neither. But if new legislation is needed, we will work with the Congress to draft the appropriate bill; and we'll consider the need for new regulations as the agencies make their recommendations over the next 90 days.

Q. Is the Administration planning regulatory action to address the recent incident with apple juice that was contaminated by E coli?

A. FDA recently held a public meeting to seek advice on options for regulatory action to ensure the safety of fruit juices. Obviously, requiring preventive controls for that industry was an approach discussed. A decision should be announced soon.

Q: Where are the current active foodborne disease surveillance sites and what was their role in the Odwalla outbreak?

A: The five foodborne disease active surveillance sites that are currently in operation are the Atlanta, GA metropolitan area, selected counties in Connecticut selected counties in northern California, and the states of Oregon and Minnesota. The first cases in the Odwalla outbreak of apple juice-associated E. coli O157 infections were identified in Washington state. While Washington is not currently an active surveillance site, the health department there uses cutting edge technology and works with CDC's expanding network of collaborating public health laboratories. (In October, the Connecticut site did detect an outbreak of E. Coli caused by apple cider produced in that state.)

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Q. Why is DNA "fingerprinting" of bacteria so important?

A: Disease-causing organisms can differ in subtle ways. Fingerprinting allows scientists to identify, match and track microbes, and more quickly link illnesses to specific food products. Digitizing the fingerprints and transmitting them over the Early Warning System's new communications network will allow scientists to work with one another from remote locations, eliminating the need to ship specimens.

Q. What can consumers do now to protect themselves from foodborne illness?

A. There are a number of things that consumers can do, and the initiative will include an educational campaign to inform consumers about these health-protective actions, including such things as cleaning utensils and food-preparation surfaces

Q. Will this new initiative include action against "Mad Cow Disease" that has so frightened Europe?

A. BSE, or "Mad Cow Disease," has not been detected in U.S. cattle. Earlier this month FDA proposed new regulations to help ensure it does not occur here. Those new rules should be finalized later this year.

Q: What does the new food-safety system the President spoke about for meat, poultry and fish entail?

A: The Administration has put in place a regulatory system of preventive controls. This new approach identifies hazards that can threaten food during handling or production and sets up procedures to ensure that those hazards don't occur or are within acceptable limits. These procedures might be as simple as cooking food to a high enough temperature, or ensuring a clean manufacturing line. This approach was first developed for the space program in the 1960s to ensure that safety was built into the product rather than learn of a failure after an astronaut got sick in the space capsule.

Q. The Vice President addressed food safety in his National Performance Review of 1993. He recommended merging USDA's meat inspection program with the FDA's food safety program. Do you intend to implement that recommendation?

A. The Vice President's report made a number of recommendations aimed at improving the efficiency of the nation's food safety programs. Some, such as moving toward a system of preventive controls, have already been achieved. We are also doing everything we can to improve coordination and cooperation among agencies involved in food safety, but we do not intend to make major structural changes as part of this initiative.

Q. Will the E Coli testing requirements for meat and poultry that take effect next week catch all dangerous E Coli?

A. Next week meat and poultry slaughter plants must start testing for generic E Coli. Although generic E Coli is not by itself dangerous, it is an indicator of contamination, and testing for generic E Coli will help us reduce contamination that carries dangerous E Coli bacteria.

NOT FOR DISTRIBUTION**FOOD SAFETY INITIATIVE**

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Joan Mondshein
720-4150 —



United States Department of Agriculture
Food Safety and Inspection Service

FAX

To: Elizabeth Drye

Fax #: 456-5581

Subject:

Date:

Pages: including this cover sheet.

COMMENTS:

Final US

No changes in groups - only
a change in the grouping on
Day 4 + Day 6 ~~in Red~~

Also cleared by CFSAW -
Janice Oliver

From the desk of

John Marksch
~~Thomas J. Billy~~

~~Administrator~~

331 E Jamie L. Whitten Building
Washington, DC 20250

202-720-8217

or 720-7025

Fax 690-4437

3/31, 4/1, 4/2

At USDA

March 5th 9-1

CONSTITUENT GROUP CONTACTSDAY 2
SMALL PLANTS**North American Meat Processors**

Deven Scott, Exec VP
(703) 758-1900

American Association of Meat Processors

Steve Krut, Executive Director; Bernie Shire
(717) 367-1168

National Meat Association

Rosemary Mucklow, Executive Director
(510) 763-1533

Southwest Meat Association

Mary Holmes, President
(817) 640-7728

National Association for Speciality Food Trade

Marcia Echols
(202) 625-1451

Monday
3:00

No

* John/Tom - Bring copies of report

* Tom issues
- user fee
- budget
- other

Three areas of focus

- Regs (deregulation) - USDA on that track - Tom Billey
- Competition -
 - What would help smaller guys
 - cope with charges
 - communication
- Industry basis -
 - more sustainable for small plants

KEY CONSTITUENT GROUP CONTACTS**DAY 1
PRODUCER GROUPS**T
C
104**National Cattleman's Beef Association**

John Lacey, President; Chuck Schroeder, CEO;
Chandler Keys, Dr. Gary Weber (DC Office)
(303) 694-0305; (202) 347-0228

National Pork Producers Council

Al Tank (DC Office), Dr. Beth Lautner, Dr. Margaret Hardin
(800) 456-7675; (202) 347-3600

American Sheep Industry

John Olson, Executive Director
(303) 771-3500

Paul Rogers - Regulatory Contact called 2/24

American Farm Bureau Federation

Richard Newpher (DC Office Head)
(202) 484-3600

National Farmers Union

Larry Mitchell
(202) 554-1600

United Fresh Fruit & Vegetable Association

Tom Stenzel, President
(703) 836-3410

Produce Marketing Association

Robert L. Carey, President
(302) 738-7100

National Milk Producers Federation

John Adams
(703) 243-6111

KEY CONSTITUTENT GROUP CONTACTS

DAY 5

CONSUMER ORGANIZATIONS**Safe Food Coalition**

Carol Tucker Foreman, Coordinator; Heather Klinkhamer
(202) 822-8060

Center for Science in the Public Interest

Caroline Smith DeWaal
(202) 332-9110, ext. 366

Safe Tables Our Priority (STOP)** Eric Olsen*

Elaine Dodge, Exec Dir, (415) 493-4395
Rainer Mueller, President, (619) 439-2969
Nancy Donley (773) 404-3556; (773) 286-4324 (H)
Mary Heersink (334) 671-1984
Roni Rudolph (619) 944-6718 or (619) 436-3484
Lori Girand (408) 867-9300 or (408) 867-1221 (H)

Consumer Federation of America

Diana Neidle
(202) 387-6121

*Richard and Robin Dimiock**303-773-8220***National Consumers League**

Linda Golodner, President
(202) 835-3323

Public Citizen

Susanna Goodman
(202) 546-4996

Public Voice for Food and Health Policy

Bob Hahn
(202) 371-1840

Government Accountability Project

Tom Devine or Felicia Nestor
(202) 408-0034

Consumers Union

Mark Silbergeld
(202) 462-6262

Community Nutrition Institute

Rod Leonard, Exec. Director
(202) 776-0599

CONSTITUTENT GROUP CONTACTS**DAY 4 - MORNING
INDUSTRY GROUPS****National Food Processors Association**

John Cady, President; Dane Bernard
(202) 639-5900

*Need 3:40***Food Marketing Institute**

Timmothy Hammonds, President
(202) 452-8444

Grocery Manufacturers of America

C. Manly Molpus, President; Steven Ziller
(202) 337-9400

National Restaurant Association

William Fisher, President
(202) 331-5900

International Dairy Foods Association

Linwood Tipton, Pres. & CEO
(202) 737-4332

DAY 4 - AFTERNOON**National-American Wholesale Grocers' Association**

John Block, President
(703) 532-9400

International Food Information Council

Sylvia Rowe, Pres.
(202) 296-6540

American Institute of Baking

James P. Vettters, Vice Pres.
(913) 537-4750

*Thurs, 4:30***American Bakers Association**

Paul C. Abernamte, Pres.
(202) 789-0300

American Frozen Food Institute

Steven C. Anderson, Pres.
(703) 821-0770

Day 4 continued**International Food Additive Council**

Rick Cristol, Assoc. Director
(202) 785-3232

National Council of Chain Restaurants

Chet England
(301) 378-7038

National Grocers Association

Thomas Zaucha, President
(703) 437-5300

KEY CONSTITUTENT GROUP CONTACTS**DAY 3****MISCELLANEOUS GROUPS****National Turkey Federation**

Stuart Proctor, President; Joel Brandenberger
(202) 898-0100

National Broiler Council

George Watts, President; Steve Pretanik
(202) 296-2622

USA Poultry and Egg Association

Don Dalton, Executive Vice President
(770) 493-9401

United Egg Producers

Al Pope, President
(770) 535-9901

American Meat Institute

Patrick Boyle, President; Jim Hodges and Sara Lilygren, Sr. VPs
(703) 841-2400

Excel Corporation

Del Allen
(316) 291-2525

Cargill

Mike Mullins
(202) 452-9307

IBP, Inc.

Robert Peterson, Chairman
(402) 494-2061

ConAgra

Philip Fletcher, CEO; Paul Korody
(202) 223-5115

Farmland Foods

Scott Shearer
(202) 783-5330

National Fisheries Institute

Lee Weddig, Exec. Director
(703) 524-8880

KEY CONSTITUTENT GROUP CONTACTS**DAY 6 - MORNING****HEALTH/PROFESSIONAL/SCIENTIFIC/TECHNICAL GROUPS/OTHERS****American Veterinary Medical Association**

Roland Dommert, Executive Vice President; Dr. Lyle Vogel
(847) 925-8070

Association of American Veterinary Medical Colleges

Dr. Lester Crawford, Executive Director
(202) 371-9195

American Society of Microbiology

Stanley Falkow, Ph.D, Pres.
(202) 737-3600

Federation of American Societies for Experimental Biology

David Schnakenberg, Ph.D.
(301) 530-7110

American Institute of Biological Sciences

Anna Maria Gilles
(202) 628-1500

American Society of Animal Science

Robert Zimbelman, Exec. Vice Pres.
(301) 571-1875

**National Association of State Universities & land Grant Colleges
Board on Human Sciences**

Karen Craig, Chair
(402) 472-2913

Poultry Science Association

Henry Engster (from Perdue Farms), Pres.
(410) 543-3411

Institute of Food Technologists

Daniel Weber, Exec. Director
(312) 782-8424

1890 Institutions' Family & Consumer Science Administrators

Raphenia D. Pace, Chair
(334) 727-8443

Council of State and Territorial Epidemiologists

David W. Fleming, M.D., President
Willis r. Forrester, M.P.A. 770-458-3811

DAY 6 - AFTERNOON**Interstate Shellfish Sanitation Conference**

Ken Moore 803-788-7559

Infectious Diseases Society of America

P. Frederick Sparling, M.D.

Melissa Sordyl, MBA, Executive Director 703-299-0200

Native American Water Association

Tim Crawford 702-782-6636

P.O. Box 511

Minden, NV 89432

American Public Health Association

Now to am
Eric Juzenas

(202) 789-5600

Coalition of Hispanic Health & Human Services Organizations

Jane Delgado, Pres/CEO

(202) 387-5000

Assn. Of State and Territorial Public Health Laboratory Directors

Now to am
Berton w. Wilcke, Ph.D., President

Carl H. Blank, Dr. P.H., Acting Executive Director 202-822-5227

Association of Food and Drug Officials

Betsy Woodward

(904) 488-0670

National Association of State Departments of Agriculture

Rich Kirchoff, Executive Vice President; Mark Nestlen

(202) 296-9680

Conference for Food Protection

Tom Leitzke, Chair

(608) 224-4711

National Environmental Health Association

Peter Thornton, President

(904) 822-6247

CENTERS FOR DISEASE CONTROL AND PREVENTION
February 14, 1997

Interagency Food Safety Initiative

As requested: CDC suggestions of constituent participants for
White House Meeting to discuss issues of IFSI during week of
February 17, 1997

Council of State and Territorial Epidemiologists (CSTE)
2872 Woodcock Boulevard, Suite 303
Atlanta, Georgia 30341
Executive Director: Willis R. Forrester, M.P.A.
(770) 458-3811
President: David W. Fleming, M.D.

Association of State and Territorial Public Health Laboratory
Directors (ASTPHLD)
1211 Connecticut Avenue, N.W.
Suite 608
Washington, D.C. 20036
Acting Executive Director: Carl H. Blank, Dr.P.H.
(202) 822-5227
President: Berton W. Wilche, Ph.D.

American Society for Microbiology (ASM)
1325 Massachusetts Avenue, N.W.
Washington, D.C. 20005
Executive Director: Michael Goldberg, Ph.D.
(202) 942-9265
President: Stanley Faklow, Ph.D.

Association of State and Territorial Health Officials (ASTHO)
415 Second Street, N.E. Suite 200
Washington, D.C. 20002
Executive Vice-President: Cheryl Beversdorf, RN, MHS, CAE
(202) 546-5400
President: Jack Dillenberg, D.D.S., M.P.H.

American Public Health Association (APHA)
1015 Fifteenth Street, N.W., Suite 300
Washington, D.C. 20005
Executive Director: Mohammad Akhter, M.D., M.P.H.
(202) 789-5658
President: Barry Lezy, M.D.

Infectious Diseases Society of America (IDSA)
11 Canal Center Plaza
1st Floor
Alexandria, Virginia 22314
Executive Director: Melissa Sordyl, M.B.A.
(703) 299-0200
President: P. Frederick Sparling, M.D.

Table 4-2. PROPOSED USER FEES AND OTHER COLLECTIONS—Continued
(In millions of dollars)

	1998	1999	2000	2001	2002	1998-2002
Department of the Interior:						
Bureau of Land Management:						
Extend and index hardrock mining holding fees on public lands	1	32	33	34	35	135
Establish hardrock mining royalties on public lands (5% on net-smelter return)	—	42	63	35	35	175
National Park Service:						
Increase Hetch Hetchy Dam rental payments	1	1	1	1	1	5
Extend demonstration authority to collect recreation and related fees—(also affects Fish and Wildlife Service, Bureau of Land Management and Forest Service)	—	—	77	79	87	243
Establish Everglades sugar assessment	35	35	35	35	35	175
Department of Justice/Federal Trade Commission:						
Increase Hart-Scott-Rodino merger filing fees	70	70	70	70	70	350
Department of Transportation—Coast Guard:						
Extend vessel tonnage fees	—	62	62	62	62	248
Department of the Treasury—Financial Management Service:						
Establish fee on vendors for cost of payments by paper check	15	10	5	5	5	40
Department of Veterans Affairs—Veterans Benefits Administration:						
Conform fees for non-veterans in the home loan program to match Federal Housing Administration fees	26	26	26	26	27	131
Extend provisions that maintain higher loan fees and reduce resale losses on foreclosed properties	—	204	198	197	192	791
Federal Deposit Insurance Corporation/Federal Reserve:						
New examination fees for FDIC-insured banks and bank holding companies:						
Bank Insurance Fund—Collections net of premium reduction	79	82	-161	—	—	—
Federal Reserve—Collections (governmental receipt)	96	100	104	109	114	523
Subtotal, new and increased mandatory user fees	343	804	653	793	803	3,396
Total, existing user fees reclassified as, or dedicated to, discretionary spending	1,063	903	950	999	1,047	4,962
New and increased user fees:						
Federal Aviation Administration fees	300	8,734	8,862	9,099	9,342	36,337
All other new and increased user fees	1,282	2,373	2,279	2,461	2,526	10,921
Total, new and increased user fees	1,582	11,107	11,141	11,560	11,868	47,258

*\$500,000 or less

Discretionary: The following proposed fees are classified as discretionary because the Appropriations Committees are being requested to authorize the fees and make them available for expenditure. In two cases—VA medical care third party collections and SSA State Administrative fees—the fees would be included in authorizing legislation but classified as discretionary under the Administration's proposed new rule.

Department of Agriculture

Food Safety and Inspection Service.—The 1998 Budget proposes a new user fee for USDA's Food Safety and Inspection Service (FSIS). Under the proposed fee, the meat, poultry and egg industries would be required to reimburse the Federal government for the cost of the salaries and benefits and other direct costs for all in-plant inspection. This new fee is estimated to generate approximately \$390 million in new, annual revenues or approximately 70 percent of the current cost of the inspection system. Although presented in the budget as discretionary offsetting collections requiring Appropriations Committee action, the Administration will propose authorizing legislation to authorize the fees and, upon enactment, a budget amendment to the current appropriations language to make the fees available for expenditure. The treatment will be consistent with that proposed for FDA user fees.

Animal and Plant Health Inspection Service (APHIS).—The budget proposes to establish five APHIS fees for certain activities:

- Fees to cover cost of providing animal welfare inspections would be charged to recipients of APHIS services such as animal research centers, humane societies, and kennels.
- Fees to cover cost of issuance of biotechnology certificates would be charged to firms that manufacture biotechnologically-derived products.
- Fees to cover cost of veterinary biologics licensing, inspection, and testing activities of medications would be paid by veterinary biologic companies.
- Fees to cover inspections to ensure that garbage fed to swine is properly cooked to avoid contamination would be charged to establishments regulated under the Swine Health Protection Act.
- Fees would be charged to users to cover the costs of the pink bollworm eradication program.

Grain Inspection, Packers and Stockyards Administration (GIPSA) licensing fees.—GIPSA will pass on to the grain industry the costs to develop, review and maintain standards used by the grain industry. In addition, an annual licensing fee would be proposed to cover costs associated with administration of the Packers and Stockyards Act. In 1998 only, annual collections would be offset by \$3 million in start-up costs.

scoring under the Budget Enforcement Act of 1990 (BEA). It includes user fees classified as offsetting collections and governmental receipts. The budget includes several specific proposals to fund discretionary spending with existing or new user fees that are governmental or offsetting receipts. Legislation will be proposed to authorize the fees and, upon enactment of the authorization, a budget amendment to the current appropria-

tions language will be proposed to make the fees available for expenditure. Because the current requirements of the Budget Enforcement Act of 1990 make it difficult to fund discretionary programs with receipts not authorized in appropriations acts, the Administration is proposing a change in the requirements to facilitate enactment of such proposals.

Table 4-2. PROPOSED USER FEES AND OTHER COLLECTIONS

(In millions of dollars)

	1998	1999	2000	2001	2002	1998-2002
User fees:						
Discretionary fee proposals:						
New and increased fees:						
Department of Agriculture:						
Food Safety and Inspection Service—New meat, poultry, and eggs inspection fees	390	390	390	390	390	1,950
Animal and Plant Health Inspection Service—Establish new fees	10	10	10	10	10	50
Grain Inspection, Packers and Stockyards Administration— New standardization and licensing fees	16	19	19	19	19	92
Department of Transportation:						
Federal Railroad Administration—Extend railroad safety inspection fees	60	60	60	60	60	300
Surface Transportation Board—New fees to offset expenses	13	14	14	14	14	69
Department of Veterans Affairs—Veterans Health Administration:						
Medical care collections—extend expiring provisions	123	362	394	421	451	1,751
Social Security Administration:						
Increase user fees for SSA to administer State supplementation of SSI benefits to \$7.25	40	70	80	80	90	360
Army Corps of Engineers:						
Increase wetlands dredging permit application fees	7	14	14	14	14	63
Federal Emergency Management Agency:						
Extend fee to cover 100% of radiological emergency preparedness program	12	12	12	12	12	60
National Capital Planning Commission:						
Establish Geographic Information System fees	•	•	•	•	•	5
Nuclear Regulatory Commission:						
Extend nuclear facility fees	—	310	310	310	310	1,240
Subtotal, new and increased discretionary user fees	671	1,261	1,303	1,330	1,370	5,935
Existing mandatory fees reclassified as discretionary:						
Department of Veterans Affairs—Veterans Health Administration:						
Medical care current law collections	468	308	355	404	452	1,987
Governmental receipts dedicated to discretionary spending:						
New and increased fees:						
Department of Health and Human Services—Food and Drug Administration:						
Extend prescription drug user fees; establish new fees for medical device reviews, import inspections, and other FDA activities	237	252	267	282	297	1,335
Department of Labor—Employment and Training Administration:						
New alien labor certification user fee charged to employers	25	50	50	50	50	225
Department of Transportation:						
Federal Aviation Administration—establish cost-based fee system	300	8,734	8,862	9,099	9,342	36,337
National Transportation Safety Board:						
New accident investigation user fees	6	6	6	6	6	30
Subtotal, new and increased governmental receipts dedicated to discretionary spending	568	9,042	9,185	9,437	9,695	37,927
Existing governmental receipts dedicated to discretionary spending:						
Department of State:						
Immigration, passport and other fees	455	455	455	455	455	2,275
Machine readable visa fee	140	140	140	140	140	700
Subtotal, current law amounts dedicated to discretionary	595	595	595	595	595	2,975
Mandatory fee proposals:						
New and increased fees:						
Department of Agriculture—Agricultural Marketing Service:						
Recover costs for oversight of marketing agreements and orders	10	11	11	11	11	54
Department of Commerce:						
Patent and Trademark Office—Extend patent surcharge	—	119	119	119	119	476
Department of Health and Human Services:						
Health Care Financing Administration—New Medicare initial survey and certification fees (governmental receipt)	10	10	10	10	10	50

4. USER FEES AND OTHER COLLECTIONS

In addition to collecting taxes and other governmental receipts by the exercise of its sovereign powers, the Federal Government earns income from its various business-type activities. Examples of this income include the sale of postage stamps and electricity, the collection of fees for admittance to national parks, premiums for deposit insurance, and rents and royalties for the right to extract oil from the Outer Continental shelf. Because these collections stem from business-type activities, as opposed to exercise of sovereign powers, they are subtracted from gross outlays rather than added to the taxes and other governmental receipts discussed in the previous chapter. Because these collections reduce outlays, they are called "offsetting collections." The purpose of this treatment is to produce budget totals for receipts, outlays, and budget authority in terms of the amount of resources allocated governmentally, through collective political choice rather than through the market.

Offsetting collections are classified into two major categories: offsetting receipts, which are deposited in receipt accounts; and offsetting collections credited to appropriations (expenditure) accounts, which are deposited directly in these accounts and usually can be spent without further action by the Congress. Both categories include collections from other accounts within the Government as well as the public. Chapter 24, "Budget System and Concepts," explains the budgetary treatment of these collections more fully.

The term "user fee" is not a separate budget category for collections. It is a general term referring to fees charged to users directly availing themselves of, or subject to, a government service, program, or activity, in order to cover the government's costs. Depending primarily on whether the user charge is based on the Government's sovereign power or business-type activity, it may be classified as a governmental receipt or an offsetting collection.

As shown in Table 4-1, total offsetting collections from the public (including those proposed in this budget) are estimated to be \$209.1 billion 1998. This is only 13 percent as large as the governmental receipts discussed in the previous chapter. Table 4-1 divides this total between offsetting receipts and offsetting collections credited to appropriations accounts and shows major subcategories of each. Table 4-3 provides more detail for offsetting receipts collected from the public and offsetting receipts collected from other accounts within the Government.

The budget contains a variety of user fee and other collections proposals that would yield \$1.6 billion in 1998 and \$47.3 billion from 1998 through 2002. In addition, the Administration proposes dedicating \$1.1 billion of existing collections in 1998, and \$5.0 billion from 1998 through 2002 to discretionary spending. These proposals establish, increase, or extend fees in order to recover more of the costs of providing government services. Table 4-2 splits the proposals between discretionary and mandatory categories for the appropriate

Table 4-1. OFFSETTING COLLECTIONS FROM THE PUBLIC

(In millions of dollars)

Type	1996 actual	Estimate	
		1997	1998
Collections deposited in receipt accounts:			
Medicare premiums	20,038	20,293	21,772
Military assistance trust fund property sales	14,747	13,760	13,400
Outer Continental Shelf payments, naval petroleum reserve lease and other undistributed offsetting receipts	3,742	4,152	9,817
Spectrum auction proceeds, undistributed	342	7,961	11,459
Sale of property and services, interest income and all other collections deposited in receipt accounts	20,139	23,401	26,194
Subtotal, collections from the public deposited in receipt accounts	59,008	69,567	82,642
Collections credited to appropriations accounts:			
Postal Service Stamp sales and other collections	55,477	56,801	58,533
Deposit insurance funds	10,320	12,363	4,524
Tennessee Valley Authority and Power Administration collections	9,440	8,096	9,284
Commodity Credit Corporation loan repayments and other collections	7,360	7,056	8,154
Other loan repayments	7,867	7,195	6,296
Loan guaranty and other insurance premiums, interest income and all other collections credited to appropriations accounts	46,927	43,529	39,661
Subtotal, collections from the public credited to appropriation accounts	137,391	135,040	126,452
Offsetting collections from the public	196,399	204,607	209,094
Offsetting collections from the public excluding off-budget Postal Service collections	140,922	147,806	150,561

Food Safety Initiative Budget Request

Total \$43 Million

CDC -- \$10 M for the Early Warning System

FDA -- \$24 M

\$1 M for Early Warning System

\$19 M for foods program -- seafood inspection program, research, risk and education

\$ 4 M for Animal Drugs and Feeds Program

USDA -\$9.0 M

\$0.5 M for Early Warning System

\$8.5 M for training, research, and education

**President Clinton Announces New Measures to
Reduce Foodborne Illness
January 25, 1997**

Announcement

- . **President Clinton announced a new Early Warning System to help catch and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks. The Administration will:**
 - . increase the number of active food safety surveillance sites across the country from 5 to 8 (the current sites are in Northern California, Oregon, Minnesota, Georgia, and Connecticut);
 - . equip these "sentinel" sites and other state health departments with state-of-the-art technology, including DNA "fingerprinting" to identify infectious agents and additional expert disease detectives to trace outbreaks to their source;
 - . link the sites, other state health departments, and Federal public health agencies electronically to allow rapid sharing of lab data -- including digitized fingerprinting data -- nationwide; and
 - . at the sentinel sites, investigate foodborne illnesses in depth to strengthen the scientific basis for our hazard prevention programs.
- . **President Clinton announced he will request an increase of \$43 million in his 1998 budget for food safety to fund the Early Warning System (\$11.5 million), increase seafood safety inspections, and expand food safety research, training and education.**
- . **The President asked for further recommendations.** He directed the Secretaries of Health and Human Services and Agriculture, and the Administrator of the Environmental Protection Agency -- working with consumers, producers, industry, states, universities, and the public -- to identify new ways to advance food safety through government and private sector actions, including public-private partnerships. The President asked for recommendations in 90 days.

Background

- . Although America's food supply is unmatched in quality and quantity, we can do more to eliminate disease caused by foodborne microorganisms. It is estimated that thousands of deaths and millions of illnesses each year are food related, imposing substantial health care costs.
- . We face new challenges involving food safety as we enter the 21st Century. Novel pathogens are emerging. Familiar ones are growing resistant to treatment. Americans eat in restaurants more. And we eat more imported foods, some of which comes from across the globe overnight. These changes require strengthened systems of coordination, surveillance, prevention, inspections, research, risk assessment and education.

Building on Our Accomplishments

- . President Clinton took a number of steps in his first four years to modernize food safety programs and prevent foodborne illnesses.
- . **Building on the recommendations of the Vice President's National Performance Review, the President put in place new science-based, hazard prevention systems for seafood, meat, and poultry.** In late 1995 the Administration issued new rules to ensure seafood safety. In July, 1996 President Clinton announced new regulations -- that begin to take effect next week -- to modernize the nation's meat and poultry inspection system for the first time in 90 years. The Early Warning System announced today will gather critical scientific data to further improve these prevention systems.
- . **In August, 1996 President Clinton signed the Food Quality Protection Act -- a comprehensive overhaul of our laws that regulate pesticides in food.** The new law establishes a single, strong health-based standard, creates special safeguards for children, protects public health and safety by using the best science available, and, for the first time, provides Americans with the "right-to-know" about health risks from pesticides.
- . **Last August, President Clinton also signed a new safe drinking water law** that strengthens protections to ensure that American families have clean, safe tap water to drink.

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

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

A NEW INTERAGENCY STRATEGY TO PREVENT FOODBORNE DISEASE

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

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

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

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

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

BACKGROUND

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

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

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

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

HISTORY OF THE FOOD SAFETY INITIATIVE

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

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

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

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

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

Questions:

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

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

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

FOODBORNE ILLNESS: A SIGNIFICANT PUBLIC HEALTH PROBLEM

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

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

Sources of Foodborne Contamination

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

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

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

Salmonella

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

Campylobacter

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

***Escherichia coli* O157:H7**

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

Toxoplasma gondii

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

Cryptosporidium parvum

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

Norwalk virus

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

THE CURRENT SYSTEM FOR PROTECTING FOOD

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

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

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

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

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

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

IMMEDIATE ACTIONS TO IMPROVE FOOD SAFETY

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

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

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

A NEW “EARLY WARNING SYSTEM” FOR PUBLIC HEALTH SURVEILLANCE

Background

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

Preliminary Problem Identification

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

Current Thinking

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

1) Enhance and expand the Active Foodborne Disease Surveillance Program

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

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

2) Enhance early detection of foodborne disease nationwide

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

3) Modernize public health laboratories

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

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

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

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

5) Increase national surveillance for antimicrobial resistance of foodborne pathogens

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

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

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

COORDINATION

Background

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

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

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

Preliminary Problem Identification

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

Current Thinking

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

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

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

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

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

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

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

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

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

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

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

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

RISK ASSESSMENT

Background

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

Preliminary Problem Identification

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

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

Current Thinking

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

1) Establish a risk assessment consortium

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

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

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

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

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

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

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

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

BIOSCIENCE RESEARCH

Background

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

Preliminary Problem Identification

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

Current Thinking

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

1) Improved detection methods

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

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

2) **Understanding antimicrobial resistance**

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

3) **Understanding antibiotic drug resistance**

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

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

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

- Develop drugs and other therapies to prevent initial colonization.

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

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

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

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

INSPECTIONS

Background

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

Preliminary Problem Identification

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

Current Thinking

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

1) Enhance development of HACCP procedures

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

2) Upgrade FDA's food inspection program

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

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

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

3) Enhance federal/state inspection partnerships

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

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

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

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

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

EDUCATION

Background

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

Preliminary Problem Identification

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

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

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

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

Current Thinking

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

1) Improve consumer education

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

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

2) Improve retail, food service, and institutional education

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

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

3) Improve veterinary and producer education

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

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

4) Improve industry education in the transportation area

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

A STRATEGIC PLAN FOR REDUCING FOODBORNE ILLNESS OVER THE LONG TERM

Background

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

Preliminary Problem Identification

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

Current Thinking

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

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

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

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

Food and Drug Administration
Highlights -- FY 1998 Budget Request
(Dollars in Millions)

Includes 134 M user fees
↓ non-user fee authority by 67.14

	FY 1997 Appropriation	Increase/ Decrease	FY 1998 Request
FDA, (Program Level)	<u>\$995.9 M</u>	+\$ 68.5 M	\$1,064.4 M
FDA, (Non-User Fee Budget Authority)	\$887.6 M	-\$ 67.5 M	\$ 820.1 M
FDA, (User Fees Subject to Reauthorization)	\$100.9 M	+\$ 4.3 M	\$ 105.2 M
FDA, (Existing User Fees)	\$ 7.4 M	+\$.1 M	\$ 7.5 M
FDA, (Proposed User Fees)	\$ 0.0 M	+\$131.6 M	\$ ^{232.8} 131.6 M
<i>FTEs</i>	9,180	--	9,180

The FY 1998 President's Budget request for FDA is \$1,064,388,000, more than a seven percent increase over the FY 1997 enacted, including: \$820,116,000 in budget authority, \$105,170,000 in user fees -- Prescription Drug User Fee Act and Mammography Quality Standards Act -- that require reauthorization legislation, \$7,459,000 in existing user fees for exports and the certification fund, and \$131,643,000 in proposed new user fees, borne by the regulated industry, to cover a portion of the cost of FDA programs. The request focuses on key elements of FDA's mission to protect and promote the health of the American people through our core activities of premarket approval and postmarket surveillance.

Food Safety Initiatives -- \$24.0 million

FDA is requesting a \$24,000,000 increase in the FY 1998 budget over the FY 1997 enacted level to begin implementation of a series of initiatives to reduce the annual incidence of foodborne illness and resultant economic losses to consumers and industry by enhancing the safety of the nation's food supply. This includes \$20,000,000 for the Foods program and \$4,000,000 for the Animal Drugs and Feeds program.

Meeting this goal involves the collaborative efforts of several agencies, including FDA, CDC, EPA, and USDA. The goal is in concert with the objectives of the HHS strategic goals, the Vice

President's National Performance Review, the Office of Science and Technology Policy's "Meeting the Challenge," Healthy People 2000, the CDC emerging infectious diseases initiative, and Presidential directives focused on enhancing the health and well-being of children and the elderly.

Although the U.S. food supply is unmatched in quantity and quality, 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. The Council for Agricultural Science and Technology -- a private, nonprofit scientific organization -- estimated in its 1994 report entitled, "Foodborne Pathogens: Risks and Consequences," that between 6.5 and 33 million illnesses and up to 9,000 deaths occur each year in the United States, because of microbial contamination of food. Hospital stays associated with microbial foodborne illnesses are estimated to cost society more than \$3 billion a year. The estimated total costs of foodborne illness are at least \$5.6 billion. 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. Cost of foodborne illness are borne by those who become ill and their families, coworkers, and employers, as well as the food industries and taxpayers.

In response to this growing problem, the Administration -- through a coordinated DHHS (FDA and CDC), USDA, and EPA effort -- is planning a Food Safety Initiative to implement new, and bolster existing, food safety intervention measures. These efforts involve key components of the Federal food safety system -- Federal, State, and local public health agencies -- and integrate elements pivotal to food safety such as inspections, consumer and industry education, surveillance, risk assessment, and research. These activities will lay a foundation of cooperation and communication to rapidly deal with emerging public health hazards. The overall benefit and outcome of this initial phase of the national Food Safety Initiative is a reduced incidence of foodborne illness and all of the resulting benefits such as reduced health care costs for consumers and industry, lower costs to industry in recalled products and loss of reputation, reduced productivity losses, and increased awareness and knowledge of appropriate behavior to combat foodborne illness.

Youth Tobacco Prevention Initiative -- \$34.0 million

On August 23, 1996, President Clinton approved FDA's final rule for the regulation of nicotine-containing tobacco products. The final rule limits the availability and appeal of tobacco products to younger people. FDA's budget request includes \$34,000,000 for the costs associated with implementing this regulation -- a \$29,386,000 increase over the FY 1997 level. FDA will primarily engage in two activities: outreach and enforcement. More than half of the funds will be provided to State and local officials who will help enforce the rule by conducting investigations to ensure tobacco products are not sold to minors. \$34

Our goal is to promote and protect the health of our nation's youth by reducing the easy access and strong appeal of these products to children, before they become addicted. Seven years after implementation of the rule, our goal is a 50 percent reduction in the use of tobacco products by these children. The average teenage smoker starts at 14 ½ years old and becomes a daily smoker by age

18. Every year, another one million young people become regular smokers, and one-third of them will eventually die prematurely as a result of their smoking. Smoking is the leading preventable cause of death in the United States. Tobacco products are responsible for more than 400,000 deaths annually due to cancer, respiratory illness, heart disease, and other health problems. According to CDC, health care costs associated with smoking soared to more than \$50 billion in 1993.

Continued investments in promoting and protecting the health of our youth is essential to our nation's future well-being. Nowhere can we realize a greater health return on investment than in those dollars targeted at keeping tobacco out of the hands of children and ensuring safe passages for our youth. FDA's activities will focus on the appeal and accessibility of these products to children through regulation of sales and distribution, and labeling, advertising and education.

Construction Funding for the Arkansas Regional Lab (ARL) -- \$14.6 million

The requested funding of \$14,550,000 will provide for Phase II construction of the ARL for FDA's field operation in Jefferson, Arkansas. The FY 1997 appropriation included \$13,000,000 to begin Phase I construction. The estimated construction cost of ARL, including office and administrative space, is \$37,400,000. The laboratory phases of the project total \$27,550,000. In FY 1997, Phase I begins construction and provides the laboratory foundation, substructure, superstructure, exterior enclosure and roofing. Major building systems, such as fire protection, HVAC, electrical and some site work, is included. Phase II completes the building systems and provides the entire laboratory fit-out. Future phases would address the renovation of existing administrative space and complete the restoration of the common mall area. Construction of the laboratory at ARL is a cornerstone of FDA's Field Lab Consolidation Plan (ORA 21). ARL will provide state-of-the-art laboratory analytical services currently or in part conducted at four existing laboratory facilities (Chicago, Dallas, Detroit, and Minneapolis). Completion of ARL is scheduled to coincide with the current facility lease expiration dates.

User Fees -- \$244.3 million

Consistent with the recommendations of the Vice President's 1993 National Performance Review report, the budget proposes \$236,813,000 in reauthorized and new user fees to finance FDA activities. Combined with the \$7,459,000 in fees already authorized for export certification and the certification of insulin and color additives, this brings the FY 1998 user fee level to \$244,272,000. Specifically, the budget proposes to reauthorize PDUFA and MQSA and to collect new fees in each of the major programs. These fees will be dedicated to FDA program activities and will be implemented in conjunction with performance measures and goals. FDA will work with its many constituencies, including the regulated industry, to develop appropriate performance goals to ensure that these fees will be used to finance and enhance program activities.

FDA provides a public service by protecting consumers from unsafe and impure foods and ensuring that drugs, medical devices, and biological products are safe and effective. Further, industries with products under the regulatory jurisdiction of FDA profit enormously from a strong and efficient FDA

capable of conducting product reviews in a timely manner. PDUFA is regarded as a success by industry and the Congress, so FDA actually has a strong track record in this area, primarily because PDUFA's stringent performance measures focused FDA on lowering review times and FDA has met or exceeded all the measures. User fees can be used to accelerate the FDA's review and approval process and reduce FDA budget authority as long as strategic plans, performance measures, and goals are an integral part of any user fee proposal.

Further, fees from other agencies are raised in the FY 1998 Budget, including fees in the department of Labor, Transportation, Agriculture, and State. These proposals all highlight the importance of user fees that tie in performance measures in maintaining important government functions expected by the public, while achieving a balanced budget by 2002. Legislation will be proposed to authorize the fees and, upon enactment of the authorization, a budget amendment to the current appropriations language will be proposed to make fees available for expenditure. Because the current requirements of the Budget Enforcement Act of 1990 make it difficult to fund discretionary programs with receipts that are not authorized in appropriations acts, the Administration is proposing a change in the requirements to facilitate the enactment of proposals such as this one. The following are the types of user fees being proposed by the Administration. We intend to work with Congress and FDA's many constituencies, including the regulated industry, to develop these or other proposals to achieve the goal of collecting a total of \$244,272,000 in user fees in 1998.

User Fees -- FY 1998 Budget

	<u>User Fee Level (\$000s)</u>
<i>Reauthorized Fees:</i>	
Prescription Drug User Fees	\$91,204
Mammography Quality Standards Act	13,966
<i>Existing Fees:</i>	
Export Certification	2,000
Certification Fund/Color Additive & Insulin	5,459
<i>Proposed New Fees:</i>	
Food Additive Petitions	12,543
Generic Drugs	13,000
Over-the-Counter Drugs	5,000
Animal Drugs	10,100
Medical Devices	25,000
Import Inspection	15,000
Postmarket Surveillance Activities:	51,000
<i>Foods & Cosmetics</i>	(19,024)
<i>Human Drugs</i>	(7,508)
<i>Biologics</i>	(2,233)
<i>Animal Drugs & Feeds</i>	(2,493)
<i>Medical Devices</i>	(19,742)
Total Fees	\$244,272

User Fees Subject to Reauthorization -- \$105.2 million

FDA is proposing reauthorization of \$91,204,000 from collection of prescription drug user fees (PDUFA), and \$13,966,000 from collection of inspection cost user fees authorized by the Mammography Quality Standards Act (MQSA). Included in these costs is an inflationary increase of \$3,676,000 for PDUFA and \$563,000 for MQSA over the FY 1997 enacted level.

Public Law 102-571, the Prescription Drug User Fee Act of 1992, was enacted on October 29, 1992 and sunsets on October 1, 1997. Public Law 102-532, the Mammography Quality Standards Act of 1992 was enacted on October 27, 1992 and also sunsets on October 1, 1997. These pieces of legislation set increasingly stringent performance goals for FDA and provided the resources to meet those goals.

PDUFA and MQSA have provided benefits to all affected entities -- the public, industry, and FDA. The public benefits because drugs are approved much more quickly, while not sacrificing long-held national standards for safety and efficacy, and from the assurance of consistent quality and safety of mammography facilities. Industry benefits economically from a quicker and more predictable process and increased consumer confidence. FDA benefits in that our process has become much more efficient. We seek reauthorization so that we may continue this "win-win-win" proposition.

Reauthorization of the Prescription Drug User Fee Act (PDUFA)

The Prescription Drug User Fee Act of 1992 (PDUFA) authorized the collection of user fees to enhance the review process for new human drug and biological products through FY 1997. The Act established fees for applications, establishments, and approved products. FDA committed to twenty-nine aggressive performance-based goals spanning the five-year term of the statute. These goals directed FDA management efforts toward three broad priorities: eliminating overdue backlogs, building excellence into the review process, and achieving measurable, high performance. Just as the Agency has improved under PDUFA, so has industry. Sponsors are submitting more new product applications to the Agency, and the quality of these is greatly improved. As a result, more review decisions are positive, and record proportions of submissions are receiving approval.

PDUFA is a success. The Agency and the industry have forged a working relationship based upon a commitment to excellence that is producing measurable benefits for the American consumer. For the third year in a row, the Agency has exceeded all performance goals. We met and surpassed a major 1997 performance goal in FY 1994 -- a full three years ahead of schedule. We continue to meet or exceed each of the performance goals established as a result of PDUFA. The Agency's record-setting results -- achieved without sacrificing the Agency's high review standards -- lead us to believe PDUFA to be a model for reinventing government, where Congress, the agency, the industry and consumer groups work together to provide necessary resources, set performance goals, and hold the government accountable.

User fees have enabled FDA to dramatically improve its performance for drug review and approval times. The median approval time for human drug applications in 1991 was 21 months. Since the enactment of PDUFA, the median approval time for PDUFA original applications in the FY 1993 and FY 1994 cohorts has decreased to 17 months. Approval times for priority applications have been even quicker, averaging only 12 months for the 22 priority applications approved under PDUFA. The highlight of 1996 was a 60 percent increase in the approval of new drugs over the previous year -- at a rate 7 percent faster.

Reauthorization of the Mammography Quality Standards (MQSA) User Fees

To ensure that women continue to have access to quality mammography -- an effective tool in reducing mortality from breast cancer -- FDA requests an increase in MQSA authorized inspection user fees of \$563,000 to cover inflation, for a total of \$13,966,000. MQSA required that mammography facilities be certified by October 1, 1994, to remain in operation and inspected annually to ensure compliance with national quality and safety standards. In FY 1998, Federal and State personnel will continue to conduct annual inspections of 10,000 facilities and certifications of 6,000 facilities as well as provide training for new inspectors. The fees collected will pay for the costs of the inspections.

Existing User Fees

Currently authorized user fees include \$5,341,000 in fees for certification activities and Freedom of Information Act (FOIA) services. We are requesting inflationary increases of \$118,000 for these activities.

Public Law 104-134, the FDA Export Reform and Enhancement Act of 1996, enacted as part of the Omnibus Consolidated Rescissions and Appropriations Act of 1996, allows FDA to collect up to \$175 for each export certification granted. We anticipate annual collections of \$2,000,000 a year beginning in FY 1997. These collections would offset costs associated with granting these certificates, and provide these approvals in a timely manner.

Proposed User Fees -- \$131.6 million

The industries regulated by FDA derive valuable benefits from some FDA activities, including increased customer confidence in their products and significant protection from liability. FDA's reputation also improves the competitive position of American firms in overseas markets. It is appropriate that the regulated industries contribute a share of FDA's cost of ensuring the safety and effectiveness of their products. A new basis for collecting these fees is offered in this budget. These proposed user fees will contribute to achieving performance goals as discussed in the program sections. We propose that user fees be applied to a wide range of FDA activities. The following are the types of user fees being proposed by the Administration. We intend to work with Congress, industry and other affected parties to develop these or other proposals to help achieve the goal of collecting a total of \$244 million in user fees in FY 1998.

Foods -- \$46.6 million

Proposals include: premarket approval activities for food and color additive petitions (\$12,543), to support FDA import monitoring activities (\$15,000), and to partially fund postmarketing regulatory activities (\$19,024).

Drugs -- \$25.5 million

Proposals include: review of original generic drug product applications (\$13,000), evaluation of submissions from drug firms requesting switches from prescription to over-the-counter (OTC) status (\$5,000), and to partially fund postmarketing regulatory activities (\$7,508).

Biologics -- \$2.2 million

Proposals include: partially funding postmarketing regulatory activities (\$2,233).

Animal Drugs -- \$12.6 million

Proposals include: review of premarket applications (\$4,000), FDA activities which substantiate that industry's clinical and non-clinical investigations are properly conducted (\$6,100), and to partially fund other postmarketing regulatory activities (\$2,493).

Medical Devices -- \$44.7 million

Proposals include: activities related to review and evaluation of premarket approval applications, premarket notification (510(k)s), and investigational device exemptions (IDEs) for all medical and radiological devices to ensure that new devices meet the statutory requirements prior to commercial marketing (\$25,000), and to partially fund postmarketing regulatory activities (\$19,742).

Postmarketing regulatory activities include not only traditional domestic postmarketing activities but also emerging strategies. These include partnering with state, local, professional and industry groups and individuals, to enhance the quality and safety of products. In addition, by increasing information sharing and technical assistance so that establishments are operating with strong quality assurance systems, the Agency anticipates that less formal regulatory intervention may be required. Traditional domestic postmarketing activities such as inspections, investigations, sample collections and analyses, regulatory analytical methods development, field exams, recall effectiveness checks, and injunctions and seizures will continue to play a role in postmarketing regulation.

- More up American Bales Ass?
- Second person listed?
- Tuesday on carriers
- 3-4 - Wednesday on - including my
Caroline ^{Smith & Wall}
 Families separate?
 which can we do Monday?

1/30/97

TO: Elizabeth Drye

FROM: Ruth Faden

PAGES (INCLUDING COVER) 5

Jan-31-97 12:46P

1/30/97

Dear Elizabeth:

Thanks very much for the chance to review this. As you might expect, I remain concerned with the language on p.23, and especially, with the impression created by the use of "however" in line 5 of the first paragraph under the heading Discussion. In the interests of legibility, I have made my suggested changes to that paragraph and the paragraph that follows on retyped text.

I hope you will find these changes acceptable. Again, many, many thanks for all the hard work you and Diane have put in to bring this all together.

Best,



Ruth

(Should you wish to talk to me on Friday I will be attending a meeting on (interestingly) battlefield radiation exposure criteria at the National Academy of Sciences, 202-334-2825, where I am sure I am reachable. I should be home by 5.)

Part 3: Righting Past Wrongs

Overview

The ACHRE report reviewed in detail several case studies of government-supported human radiation research including: the injections of plutonium into 18 hospital patients during and after World War II; research with prisoners and research on patients who had previously been exposed to total body irradiation in clinical settings.

The Advisory Committee also considered issues related to certain radiation exposures associated with government activities that the Advisory Committee concluded should not be considered "Experiments." These exposures were sustained as a result of government activity undertaken for purposes other than human radiation research. The exposed populations include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from U.S. weapons testing.

human

The ACHRE report reviewed in detail several case studies of government-supported human radiation research

The Committee recommended several steps that the government should take to make amends for the specific wrongs for which the government bears moral responsibility.

This section of the report discusses ACHRE's findings and recommendations in the areas of notification, apology, and compensation and presents the Administration's response. Within the discussion of compensation, the report addresses individual cases, uranium miners, other populations covered under the Radiation Exposure Compensation Act, veterans, and Marshall Islanders.

ACHRE Findings and Recommendations on Notification

The Advisory Committee found "no subjects of biomedical experiments for whom there is a need to provide notification and medical follow-up for the purpose of protecting their health." In addition, the Committee found no evidence that participants of subjects of human radiation experiments have a greater likelihood of inheriting genetic effects.

The Advisory Committee recommended that (Recommendation 4):

- For any newly-discovered experiments the government should notify participants and provide medical follow-up for "those

Discussion

ACHRE was charged to make a recommendation about notification for the specific purpose of protecting the health of subjects or their descendants. After careful consideration of its specific charge, ACHRE recommended that decisions about notification be based on "evaluation of both the level of risk from radiation exposure and the potential medical benefit from medical follow-up in exposed individuals." In discussing this recommendation, ACHRE observed that notification can impose new burdens on subjects that must be weighed against the potential for medical benefit from notification, including anxiety; medical harm; inconvenience; possible stigmatization by friends, family, employers, or insurance carriers; and cost of seeking medical testing or follow-up. In light of these considerations, and the difficulty in tracing subjects, ACHRE recommended notification in the limited circumstances where their criteria for medical benefit were satisfied. ACHRE also endorsed the principle that citizens are entitled to know if they or a relative was a subject in a radiation experiment and included in their Report a citizen's guide to pursuing answers to this important question.

ACHRE's recommendation on notification has generated controversy among stakeholders, including those who participated in the Stakeholders Workshop of February 26-27, 1996, held by the Federal departments. As the Advisory Committee made plain, many of the wrongs in experimentation were independent of considerations of effects on health and involved the failure to obtain the consent of subjects and the failure to provide them with a full and fair disclosure of the risks and benefits (or lack of benefit).

P. 23 "a"

Part 3: Righting Past Wrongs

For all of these reasons, the process of locating individuals or next of kin many years after the experiments took place is difficult, time consuming, costly to the taxpayer, and likely to have limited success. Where individuals can be found, it is difficult to assess their exposure and risk given the limited data available.

Notwithstanding the difficulties of undertaking individual notification, the government reaffirms its continuing commitment to openness. Where the government does not undertake individual notification it will continue to make public material relating to human radiation experiments, to respond to individual inquiries relating to these experiments, and to carefully review any newly identified experiments in the light of the Advisory Committee notification criteria.

Discussion

Many of the wrongs in experimentation involved failure to provide subjects with a full and fair disclosure of the risks and benefits (or lack of benefits). At first impression, the solution to this lack of disclosure seems evident, namely, disclose now what was not disclosed in the past. After careful consideration, however, ACHRE recommended that decisions about notification be based on "evaluation of both the level of risk from radiation exposure and the potential medical benefit from medical follow-up in exposed individuals."

NO - THIS - WE
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Part 3: Righting Past Wrongs

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This recommendation has generated controversy among stakeholders. Including those who participated in the Stakeholders Workshop of February 26-27, 1996, held by the federal departments, some stakeholders believe the government has a responsibility to notify and provide medical follow-up to all who were wronged by the government; not only those who were physically harmed by the government's conduct. Although it is difficult to generalize about the diversity of views presented at the Workshop, the stakeholders generally advocate that the government pursue some form of notification, and provide medical care by physicians of their own choice. Many subjects or families of subjects do not have confidence that the government can honestly make a judgment about notification, or that the government can, without bias or intimidation of subjects, implement any needed medical follow-up. Others have also suggested that subjects would want notification whether or not they were harmed. See "Hearings on Human Radiation Experiments."

NO - THIS - WE
MISLEADING -
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THIS WAY

Even where more detailed records have survived, information about individuals is generally fragmentary and does not include anything about their current whereabouts.

FOOD SAFETY INITIATIVE

Q. Why is this initiative needed?

A. Foodborne disease is a major public health issue; outbreaks are increasing in seriousness and new disease-causing organisms are appearing in foods not previously associated with "food poisoning" (such as the contaminated raspberries of last summer). It is estimated that thousands of deaths and millions of illnesses a year are food related (according to a 1994 report entitled *Foodborne Pathogens: Risks and Consequences*, published by the Council for Agricultural Science and Technology, a private non-profit organization).

Q: How much will this initiative cost?

A. This initiative would provide an additional \$43 million for food safety to the FY '98 budget. Of that, \$11.5 million is for the new Early Warning System: \$10 million for the CDC; \$1 million for the FDA, and \$500,000 for USDA.

Q: What about the other \$31.5 million?

A: FDA will get \$23 million for seafood safety inspections, research, risk assessment and education; USDA will get \$8.5 million for training, research and education.

Q. What are the major sources of foodborne contamination?

A. Disease-causing organisms can contaminate food at many points. Examples are accidental contact of cow manure on fallen apples, contamination of meat with disease-causing organisms during and after slaughter, or seafood contaminated with naturally occurring microorganisms and toxins.

Q. Are foodborne disease outbreaks increasing?

A. It is hard to get really good estimates of this trend, but there is evidence that cases and outbreaks are increasing in frequency, and it is certainly clear that they are starting to involve increasingly dangerous bacteria, such as the E. coli strain that has caused serious illness and death in recent years.

Q. What foodborne hazards are targeted by this initiative?

A. We will focus on bacteria, parasites, and viruses that can cause serious diarrhea disease, not just the relatively short term, unpleasant intestinal distress usually thought of as "food poisoning." We are also targeting organisms that can cause death, spontaneous abortion, birth defects, and long-lasting illness such as reactive arthritis, and life-threatening paralysis.

- 2 -

Q. What are the benefits of this initiative?

A. We can't make precise estimates, but we believe that this initiative will result in significant reductions in food-related deaths, disease, and health-care costs over the next several years.

Q. How will the food industry and consumer groups be involved in the initiative?

A. President Clinton charged Secretaries Shalala and Clickman and Administrator Browner with recommending further food safety improvements in consultation with all sectors of the food industry, with State and local governments, and with producer and consumer groups.

Q. Will this initiative result in new legislation or new regulations?

A. We don't know yet, perhaps neither. But if new legislation is needed, we will work with the Congress to draft the appropriate bill; and we'll consider the need for new regulations as the agencies make their recommendations over the next 90 days.

Q. Is the Administration planning regulatory action to address the recent incident with apple juice that was contaminated by E coli?

A. FDA recently held a public meeting to seek advice on options for regulatory action to ensure the safety of fruit juices. Obviously, requiring preventive controls for that industry was an approach discussed. A decision should be announced soon.

Q: Where are the current active foodborne disease surveillance sites and what was their role in the Odwalla outbreak?

A: The five foodborne disease active surveillance sites that are currently in operation are the Atlanta, GA metropolitan area, selected counties in Connecticut selected counties in northern California, and the states of Oregon and Minnesota. The first cases in the Odwalla outbreak of apple juice-associated E. coli O157 infections were identified in Washington state. While Washington is not currently an active surveillance site, the health department there uses cutting edge technology and works with CDC's expanding network of collaborating public health laboratories. (In October, the Connecticut site did detect an outbreak of E. Coli caused by apple cider produced in that state.)

- 3 -

Q. Why is DNA "fingerprinting" of bacteria so important?

A: Disease-causing organisms can differ in subtle ways. Fingerprinting allows scientists to identify, match and track microbes, and more quickly link illnesses to specific food products. Digitizing the fingerprints and transmitting them over the Early Warning System's new communications network will allow scientists to work with one another from remote locations, eliminating the need to ship specimens.

Q. What can consumers do now to protect themselves from foodborne illness?

A. There are a number of things that consumers can do, and the initiative will include an educational campaign to inform consumers about these health-protective actions, including such things as cleaning utensils and food-preparation surfaces

Q. Will this new initiative include action against "Mad Cow Disease" that has so frightened Europe?

A. BSE, or "Mad Cow Disease," has not been detected in U.S. cattle. Earlier this month FDA proposed new regulations to help ensure it does not occur here. Those new rules should be finalized later this year.

Q: What does the new food-safety system the President spoke about for meat, poultry and fish entail?

A: The Administration has put in place a regulatory system of preventive controls. This new approach identifies hazards that can threaten food during handling or production and sets up procedures to ensure that those hazards don't occur or are within acceptable limits. These procedures might be as simple as cooking food to a high enough temperature, or ensuring a clean manufacturing line. This approach was first developed for the space program in the 1960s to ensure that safety was built into the product rather than learn of a failure after an astronaut got sick in the space capsule.

Q. The Vice President addressed food safety in his National Performance Review of 1993. He recommended merging USDA's meat inspection program with the FDA's food safety program. Do you intend to implement that recommendation?

A. The Vice President's report made a number of recommendations aimed at improving the efficiency of the nation's food safety programs. Some, such as moving toward a system of preventive controls, have already been achieved. We are also doing everything we can to improve coordination and cooperation among agencies involved in food safety, but we do not intend to make major structural changes as part of this initiative.

- Q. Will the E Coli testing requirements for meat and poultry that take effect next week catch all dangerous E Coli?
- A. Next week meat and poultry slaughter plants must start testing for generic E Coli. Although generic E Coli is not by itself dangerous, it is an indicator of contamination, and testing for generic E Coli will help us reduce contamination that carries dangerous E Coli bacteria.

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A: The Administration has put in place a regulatory system of preventive controls. This new approach identifies hazards that can threaten food during handling or production and sets up procedures to ensure that those hazards don't occur or are within acceptable limits. These procedures might be as simple as cooking food to a high enough temperature, or ensuring a clean manufacturing line. This approach was first developed for the space program in the 1960s to ensure that safety was built into the product rather than learn of a failure after an astronaut got sick in the space capsule.

Q. The Vice President addressed food safety in his National Performance Review of 1993. He recommended merging USDA's meat inspection program with the FDA's food safety program. Do you intend to implement that recommendation?

A. The Vice President's report made a number of recommendations aimed at improving the efficiency of the nation's food safety programs. Some, such as moving toward a system of preventive controls, have already been achieved. We are also doing everything we can to improve coordination and cooperation among agencies involved in food safety, but we do not intend to make major structural changes as part of this initiative.

Q. Will the E Coli testing requirements for meat and poultry that take effect next week catch all dangerous E Coli?

A. Next week meat and poultry slaughter plants must start testing for generic E Coli. Although generic E Coli is not by itself dangerous, it is an indicator of contamination, and testing for generic E Coli will help us reduce contamination that carries dangerous E Coli bacteria.

EMBARGOED UNTIL SATURDAY, JANUARY 25 AT 10:06 AM

**President Clinton Announces New Measures to
Reduce Foodborne Illness**

January 25, 1997

Announcement

- . **President Clinton announced a new Early Warning System to help catch and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks.** The Administration will:
 - . increase the number of active food safety surveillance sites across the country from 5 to 8 (the current sites are in Northern California, Oregon, Minnesota, Georgia, and Connecticut);
 - . equip these "sentinel" sites and other state health departments with state-of-the-art technology, including DNA "fingerprinting" to identify infectious agents and additional expert disease detectives to trace outbreaks to their source;
 - . link the sites, other state health departments, and Federal public health agencies electronically to allow rapid sharing of lab data -- including digitized fingerprinting data -- nationwide; and
 - . at the sentinel sites, investigate foodborne illnesses in depth to strengthen the scientific basis for our hazard prevention programs.
- . **President Clinton announced he will request an increase of \$43 million in his 1998 budget for food safety** to fund the Early Warning System (\$11.5 million), increase seafood safety inspections, and expand food safety research, training and education.
- . **The President asked for further recommendations.** He directed the Secretaries of Health and Human Services and Agriculture, and the Administrator of the Environmental Protection Agency -- working with consumers, producers, industry, states, universities, and the public -- to identify new ways to advance food safety through government and private sector actions, including public-private partnerships. The President asked for recommendations in 90 days.

Background

- . Although America's food supply is unmatched in quality and quantity, we can do more to eliminate disease caused by foodborne microorganisms. It is estimated that thousands of deaths and millions of illnesses each year are food related, imposing substantial health care costs.
- . We face new challenges involving food safety as we enter the 21st Century. Novel pathogens are emerging. Familiar ones are growing resistant to treatment. Americans eat in restaurants more. And we eat more imported foods, some of which comes from across the globe overnight. These changes require strengthened systems of coordination, surveillance, prevention, inspections, research, risk assessment and education.

Building on Our Accomplishments

- President Clinton took a number of steps in his first four years to modernize food safety programs and prevent foodborne illnesses.
- **Building on the recommendations of the Vice President's National Performance Review, the President put in place new science-based, hazard prevention systems for seafood, meat, and poultry.** In late 1995 the Administration issued new rules to ensure seafood safety. In July, 1996 President Clinton announced new regulations -- that begin to take effect next week -- to modernize the nation's meat and poultry inspection system for the first time in 90 years. The Early Warning System announced today will gather critical scientific data to further improve these prevention systems.
- **In August, 1996 President Clinton signed the Food Quality Protection Act -- a comprehensive overhaul of our laws that regulate pesticides in food.** The new law establishes a single, strong health-based standard, creates special safeguards for children, protects public health and safety by using the best science available, and, for the first time, provides Americans with the "right-to-know" about health risks from pesticides.
- **Last August, President Clinton also signed a new safe drinking water law that strengthens protections to ensure that American families have clean, safe tap water to drink.**

FOOD SAFETY INITIATIVE

Q. Why is this initiative needed?

A. Foodborne disease is a major public health issue; outbreaks are increasing in seriousness and new disease-causing organisms are appearing in foods not previously associated with "food poisoning" (such as the contaminated raspberries of last summer). It is estimated that thousands of deaths and millions of illnesses a year are food related (according to a 1994 report entitled *Foodborne Pathogens: Risks and Consequences*, published by the Council for Agricultural Science and Technology, a private non-profit organization).

Q: How much will this initiative cost?

A. This initiative would provide an additional \$43 million for food safety to the FY '98 budget. Of that, \$11.5 million is for the new Early Warning System: \$10 million for the CDC; \$1 million for the FDA, and \$500,000 for USDA.

Q: What about the other \$31.5 million?

A: FDA will get \$23 million for seafood safety inspections, research, risk assessment and education; USDA will get \$8.5 million for training, research and education.

Q. What are the major sources of foodborne contamination?

A. Disease-causing organisms can contaminate food at many points. Examples are accidental contact of cow manure on fallen apples, contamination of meat with disease-causing organisms during and after slaughter, or seafood contaminated with naturally occurring microorganisms and toxins.

Q. Are foodborne disease outbreaks increasing?

A. It is hard to get really good estimates of this trend, but there is evidence that cases and outbreaks are increasing in frequency, and it is certainly clear that they are starting to involve increasingly dangerous bacteria, such as the E. coli strain that has caused serious illness and death in recent years.

Q. What foodborne hazards are targeted by this initiative?

A. We will focus on bacteria, parasites, and viruses that can cause serious diarrhea disease, not just the relatively short term, unpleasant intestinal distress usually thought of as "food poisoning." We are also targeting organisms that can cause death, spontaneous abortion, birth defects, and long-lasting illness such as reactive arthritis, and life-threatening paralysis.

- 2 -

Q. What are the benefits of this initiative?

A. We can't make precise estimates, but we believe that this initiative will result in significant reductions in food-related deaths, disease, and health-care costs over the next several years.

Q. How will the food industry and consumer groups be involved in the initiative?

A. President Clinton charged Secretaries Shalala and Clickman and Administrator Browner with recommending further food safety improvements in consultation with all sectors of the food industry, with State and local governments, and with producer and consumer groups.

Q. Will this initiative result in new legislation or new regulations?

A. We don't know yet, perhaps neither. But if new legislation is needed, we will work with the Congress to draft the appropriate bill; and we'll consider the need for new regulations as the agencies make their recommendations over the next 90 days.

Q. Is the Administration planning regulatory action to address the recent incident with apple juice that was contaminated by E coli?

A. FDA recently held a public meeting to seek advice on options for regulatory action to ensure the safety of fruit juices. Obviously, requiring preventive controls for that industry was an approach discussed. A decision should be announced soon.

Q: Where are the current active foodborne disease surveillance sites and what was their role in the Odwalla outbreak?

A: The five foodborne disease active surveillance sites that are currently in operation are the Atlanta, GA metropolitan area, selected counties in Connecticut selected counties in northern California, and the states of Oregon and Minnesota. The first cases in the Odwalla outbreak of apple juice-associated E. coli O157 infections were identified in Washington state. While Washington is not currently an active surveillance site, the health department there uses cutting edge technology and works with CDC's expanding network of collaborating public health laboratories. (In October, the Connecticut site did detect an outbreak of E. Coli caused by apple cider produced in that state.)

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Q. Why is DNA "fingerprinting" of bacteria so important?

A: Disease-causing organisms can differ in subtle ways. Fingerprinting allows scientists to identify, match and track microbes, and more quickly link illnesses to specific food products. Digitizing the fingerprints and transmitting them over the Early Warning System's new communications network will allow scientists to work with one another from remote locations, eliminating the need to ship specimens.

Q. What can consumers do now to protect themselves from foodborne illness?

A. There are a number of things that consumers can do, and the initiative will include an educational campaign to inform consumers about these health-protective actions, including such things as cleaning utensils and food-preparation surfaces

Q. Will this new initiative include action against "Mad Cow Disease" that has so frightened Europe?

A. BSE, or "Mad Cow Disease," has not been detected in U.S. cattle. Earlier this month FDA proposed new regulations to help ensure it does not occur here. Those new rules should be finalized later this year.

Q: What does the new food-safety system the President spoke about for meat, poultry and fish entail?

A: The Administration has put in place a regulatory system of preventive controls. This new approach identifies hazards that can threaten food during handling or production and sets up procedures to ensure that those hazards don't occur or are within acceptable limits. These procedures might be as simple as cooking food to a high enough temperature, or ensuring a clean manufacturing line. This approach was first developed for the space program in the 1960s to ensure that safety was built into the product rather than learn of a failure after an astronaut got sick in the space capsule.

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FAX TRANSMISSION

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PRESIDENT CLINTON ANNOUNCES THE CREATION OF A NEW NATIONAL EARLY WARNING SYSTEM FOR FOODBORNE DISEASE

Today, President Clinton announced that his administration will create a new national early warning system to help catch outbreaks of foodborne illness early, preventing illness and possibly deaths. The President directed the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) to work with state and local health departments and take the following steps to establish the new system: enhance and expand the number of "sentinel" surveillance sites from five to eight; create a communications network to link federal, state, and local health experts; and increase resources for "disease detectives" -- scientists who investigate incidences and causes of foodborne illness.

Building on a Solid Foundation. The foodborne diseases active surveillance network, a collaborative effort between HHS' Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), USDA, and five state health departments, was established in 1995 to conduct in-depth surveillance at clinical microbiology laboratories in five "sentinel" surveillance sites. Since January 1996, information has been collected on every laboratory diagnosed case of *Salmonella*, *Shigella*, *Campylobacter*, *Escherichia coli* 0157, *Listeria*, *Yersinia*, and *Vibrio* infection among the residents of these five areas. This information is then transmitted electronically to CDC, where it is compiled into a comprehensive and timely database of foodborne illness in a well-defined population. Since becoming operational in 1996, the network has already identified an outbreak of *Salmonella* infections caused by contaminated alfalfa sprouts and two outbreaks of *E. coli* 0157 infections linked to contaminated lettuce and apple cider. The network has also provided the infrastructure for quickly responding to new and emerging diseases, such as rapidly determining that the new *variant-Creutzfeldt disease* (recently associated with BSE in the United Kingdom) was not occurring in the United States, and collaborating in the investigation of a multistate outbreak of *Cyclospora* infections associated with consumption of raspberries from Guatemala.

Enhancing and Expanding the Number of Sentinel Sites. Today, President Clinton strengthens the existing surveillance network -- expanding the network to cover all regions of the United States. With this new Administration initiative, President Clinton will increase the number of active foodborne disease surveillance sites from five to eight to improve the system's geographic coverage, and will expand investigation of foodborne illness agents to include parasitic and viral foodborne pathogens. The Clinton Administration will also upgrade laboratory capacity at sentinel sites so that sites can utilize DNA "fingerprinting" and other highly sophisticated techniques to identify infectious agents or other causes of illness. This new capacity will allow health authorities to identify the same fingerprint on bacteria from two widely separated cases, and will provide a basis for subsequent epidemiological investigation and development of strategies to prevent future outbreaks. The sentinel sites will also gather more extensive data to advance our understanding of foodborne illness and to further our efforts to not only react quickly to foodborne illness, but to prevent illness from occurring at all.

Creating a Nationwide Communications Network. As a key element of the new early warning system, the Clinton Administration will create a new electronic and computer communications network that will allow rapid dissemination of epidemiologic and laboratory data throughout the country -- among sentinel sites and to public health agencies. As part of this effort, CDC, FDA, and USDA will fund a new computer network and database system that will capture DNA "fingerprints" from bacteria and other microorganisms in a centralized database and will electronically link the sentinel sites and the three government agencies. This database, which will be similar to the fingerprint libraries maintained by law enforcement agencies, will allow immediate recognition of relationships among isolates (samples isolated and identified from individual disease cases).

Increasing Resources for "Disease Detectives." While sophisticated laboratory studies can identify causes of illness and show relationships among isolates, there is still a need for people to ensure that samples are collected correctly and to investigate the causes of illness outbreaks so that preventative measures can be put in place. To fill this need, CDC, FDA, and USDA will fund additional experts to investigate and control foodborne

FOOD SAFETY INITIATIVE

Q. Why is this initiative needed?

A. Foodborne disease is a major public health issue; outbreaks are increasing in seriousness and new disease-causing organisms are appearing in foods not previously associated with "food poisoning" (such as the contaminated raspberries of last summer).

Q. Aren't federal agencies working well to protect the food supply?

A. Federal agencies work together (along with State and local governments) to prevent food contamination through research and prevention activities, such as inspection and enforcement, and to respond to outbreaks when they occur, but we need to do a better job to reduce redundancies and more intelligently target our use of resources.

Q. Is foodborne illness a significant public health problems?

A. The U.S. food supply is safe compared to those of most nations, but it could be safer. With up to 33 million illnesses and 9,000 deaths per year, foodborne illnesses contribute significantly to the escalating cost of health care.

Q. How much will this initiative cost?

A. This initiative would add an additional \$42 million for food safety to the FY '98 budget.

Q. If this is such a big problem, why is the Clinton Administration only budgeting \$42 million?

A. This Administration has already made significant contributions to improving food safety, through the implementation of innovative food-safety regulations for meat, poultry, and seafood; through achievement of new pesticide legislation with special protections for our children, and through improved, reauthorized safe drinking water legislation. The FY '98 budget request will build on these advances and move us further down the path of significant improvements in food safety.

Q. Does the Clinton Administration intend to make food safety a continuing budget priority in coming years?

A. Improving the safety of the food supply has been and remains a priority for this administration. We are committed to continuing this work.

Q. The Vice President addressed food safety in his National Performance Review of 1993. He recommended merging USDA's meat inspection program with the FDA's food safety program. Do you intend to implement that recommendation?

A. We do not believe that we must make structural changes to improve food safety. We are focusing instead on making the current structure more efficient and improving coordination among the agencies responsible for food safety.

Q. The Vice President's 1993 report noted that FDA has responsibility for 90% of the food supply, but only 10% of the inspectors, while USDA has 90% of the inspectors for 10% of the food supply. He recommended more resources for FDA. What do you intend to do about that?

A. The FY '98 budget will have additional inspection resources for FDA, as well as additional resources to improve coordination with State inspectors. The broader plan that the President is requesting today will also include recommendations for further strengthening FDA's inspection capabilities.

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Q. What foodborne hazards are targeted by this initiative?

A. We will focus on bacteria, parasites, and viruses that can cause serious diarrheal disease, not just the relatively short term, unpleasant intestinal distress usually thought of as "food poisoning." We are also targeting organisms that can cause death, spontaneous abortion, birth defects, and long-lasting illness such as reactive arthritis, and life-threatening paralysis.

Q. What are the benefits of this initiative?

A. We expect significant reductions in death and disease and in health care costs over the next several years -- on the order of 1-2 million fewer cases, up to 1,500 fewer deaths, and cost savings of many millions of dollars in health care cost savings.

Q. How will the food industry and consumer groups be involved in the initiative?

A. Secretaries Shalala and Glickman and Administrator Browner have been charged with developing a comprehensive plan for further food safety improvements in consultation with all sectors of the food industry, with State and local governments, and with consumer groups.

Q. Are our disease tracking systems inadequate?

A. The Centers for Disease Control and Prevention (CDC) works with State health and agriculture officials to track cases and outbreaks through what is currently a passive reporting system that certainly results in significant underestimates of foodborne disease.

Q. How would this initiative change disease tracking?

- A. CDC, with funding from FDA and USDA, will begin intensively and actively looking for foodborne disease cases and outbreaks in 8 sites around the country, greatly increasing the chances that outbreaks can be stopped before they spread.**
- Q. Are you doing anything to better coordinate the federal government's response to outbreaks of foodborne illness?**
- A. Yes. An Interagency Coordination Group is being created to coordinate among FDA, CDC, USDA and with the States to effectively investigate and respond to outbreaks of foodborne illness.**

Q/As for the National Early Warning System

1. In the National Early Warning System the President announced, he talked about improvements in active surveillance sites and in State health departments. What's the difference?

The active surveillance sites provide opportunities for the in-depth studies on foodborne diseases necessary to identify precise sources of infection, the relative importance of various foods, and other key factors necessary to make food safer in the future. However, these sites cover only part of the U. S. population, and strengthening the capacity of other State health departments is necessary to identify and interrupt foodborne disease outbreaks that occur anywhere in the country.

2. What are the key elements of the National Early Warning System?

The National Early Warning System will increase federal support to State health departments to detect foodborne diseases by increasing the number of scientists available to investigate foodborne outbreaks and by enhancing laboratory-based surveillance of important foodborne pathogens through improved diagnostic reagent availability, diagnostic and subtyping development, standardization, and training. It will expand the number and scope of the enhanced food safety surveillance sites to improve the geographic and pathogen coverage. And it will link federal and State public health laboratories with sophisticated computer technology that will enhance communications and data sharing, including the digitized fingerprints of foodborne pathogens.

3. Why is it important to increase the number of active surveillance sites?

The studies conducted in the foodborne diseases active surveillance sites describe the epidemiology of new and emerging foodborne pathogens, estimate the frequency and severity of foodborne disease, and determine how much foodborne illness results from eating different kinds of foods. Because people from different backgrounds in different parts of the country have different eating habits, it is important to have information from many different geographical areas to be certain that the information reflects the nation as a whole.

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1. Why is this initiative important? Are the food safety problems getting worse in the United States?

Changes in the types and origins of foods we consume and how they are produced, processed, and prepared are changing the character of the food safety problems we face. In addition, as our population ages, and the number of people with chronic and immunosuppressive conditions increases, consumers are becoming more likely to become ill from foodborne exposure to pathogens. Therefore, the resources and methods we use to learn about, control, and prevent foodborne diseases must also change.

2. It has been four years since the Jack-in-the-Box outbreak of *E. coli* O157 infections. What has CDC been doing during that time to decrease the risk of foodborne diseases?

CDC, with its partners in State and local health departments, first discovered the foodborne pathogen *E. coli* O157 in 1982. By the time the JIB outbreak occurred a decade later, CDC had already learned a number of things about this microorganism that made a rapid response to the outbreak possible, including a quick way to identify O157, and that it has a bovine reservoir.

Since the JIB outbreak, CDC has continued to investigate other outbreaks and conduct studies on *E. coli* O157, and has identified a large number of ways *E. coli* O157 can infect people, and has developed diagnostic and subtyping techniques that are in widespread use to diagnose infections and track the spread of outbreaks. In addition, CDC has recently demonstrated that fresh produce also can be an important source of foodborne infections, and is working with regulators, the food industry, and consumers to prevent these produce-associated diseases.

3. Congress is in a belt-tightening mood. What happens in the interagency food safety initiative is not funded?

Traditional methods of monitoring disease and investigating outbreaks can only detect the tips of the foodborne disease icebergs. Establishing the risk associated with specific foods is critical in preventing illness. The improved monitoring and forward-looking investigations that are part of the IFSI are needed to document the true magnitude of the problem and the risk posed by various foods, and to precisely target the prevention measures needed to protect the public. However, if full funding is not possible, CDC, USDA, FDA, and our partners in State health departments will continue to work together to learn what we can from the active surveillance sites already in place, and CDC will

continue to develop new diagnostic and subtyping techniques that can be shared with State health departments and federal laboratories to improve the overall capacity of our public health infrastructure.

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Reduce Foodborne Illness**
January 25, 1997

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A. Disease-causing organisms can contaminate food at many points. Examples are accidental contact of cow manure on fallen apples, contamination of meat with filth after slaughter, or seafood contaminated with naturally occurring microorganisms and toxins.

Q. Are foodborne disease outbreaks increasing?

A. It is hard to get really good estimates of this trend, but there is evidence that cases and outbreaks are increasing in frequency, and it is certainly clear that they are starting to involve increasingly dangerous bacteria, such as the E. coli strain that has caused such serious illness in recent years.

Q. What foodborne hazards are targeted by this initiative?

A. We will focus on bacteria, parasites, and viruses that can cause serious diarrheal disease, not just the relatively short term, unpleasant intestinal distress usually thought of as "food poisoning." We are also targeting organisms that can cause death, spontaneous abortion, birth defects, and long-lasting illness such as reactive arthritis, and life-threatening paralysis.

Q. What are the benefits of this initiative?

A. We expect significant reductions in death and disease and in health care costs over the next several years -- on the order of 1-2 million fewer cases, up to 1,500 fewer deaths, and cost savings of many millions of dollars in health care cost savings.

Q. How will the food industry and consumer groups be involved in the initiative?

A. Secretaries Shalala and Glickman and Administrator Browner have been charged with developing a comprehensive plan for further food safety improvements in consultation with all sectors of the food industry, with State and local governments, and with consumer groups.

Q. Are our disease tracking systems inadequate?

A. The Centers for Disease Control and Prevention (CDC) works with State health and agriculture officials to track cases and outbreaks through what is currently a passive reporting system that certainly results in significant underestimates of foodborne disease.

Q. How would this initiative change disease tracking?

- A. CDC, with funding from FDA and USDA, will begin intensively and actively looking for foodborne disease cases and outbreaks in 8 sites around the country, greatly increasing the chances that outbreaks can be stopped before they spread.**
- Q. Are you doing anything to better coordinate the federal government's response to outbreaks of foodborne illness?**
- A. Yes. An Interagency Coordination Group is being created to coordinate among FDA, CDC, USDA and with the States to effectively investigate and respond to outbreaks of foodborne illness.**

Q/As for the National Early Warning System

1. In the National Early Warning System the President announced, he talked about improvements in active surveillance sites and in State health departments. What's the difference?

The active surveillance sites provide opportunities for the in-depth studies on foodborne diseases necessary to identify precise sources of infection, the relative importance of various foods, and other key factors necessary to make food safer in the future. However, these sites cover only part of the U. S. population, and strengthening the capacity of other State health departments is necessary to identify and interrupt foodborne disease outbreaks that occur anywhere in the country.

2. What are the key elements of the National Early Warning System?

The National Early Warning System will increase federal support to State health departments to detect foodborne diseases by increasing the number of scientists available to investigate foodborne outbreaks and by enhancing laboratory-based surveillance of important foodborne pathogens through improved diagnostic reagent availability, diagnostic and subtyping development, standardization, and training. It will expand the number and scope of the enhanced food safety surveillance sites to improve the geographic and pathogen coverage. And it will link federal and State public health laboratories with sophisticated computer technology that will enhance communications and data sharing, including the digitized fingerprints of foodborne pathogens.

3. Why is it important to increase the number of active surveillance sites?

The studies conducted in the foodborne diseases active surveillance sites describe the epidemiology of new and emerging foodborne pathogens, estimate the frequency and severity of foodborne disease, and determine how much foodborne illness results from eating different kinds of foods. Because people from different backgrounds in different parts of the country have different eating habits, it is important to have information from many different geographical areas to be certain that the information reflects the nation as a whole.

continue to develop new diagnostic and subtyping techniques that can be shared with State health departments and federal laboratories to improve the overall capacity of our public health infrastructure.

ifsi.qa
01/17/97

1. Why is this initiative important? Are the food safety problems getting worse in the United States?

Changes in the types and origins of foods we consume and how they are produced, processed, and prepared are changing the character of the food safety problems we face. In addition, as our population ages, and the number of people with chronic and immunosuppressive conditions increases, consumers are becoming more likely to become ill from foodborne exposure to pathogens. Therefore, the resources and methods we use to learn about, control, and prevent foodborne diseases must also change.

2. It has been four years since the Jack-in-the-Box outbreak of *E. coli* O157 infections. What has CDC been doing during that time to decrease the risk of foodborne diseases?

CDC, with its partners in State and local health departments, first discovered the foodborne pathogen *E. coli* O157 in 1982. By the time the JIB outbreak occurred a decade later, CDC had already learned a number of things about this microorganism that made a rapid response to the outbreak possible, including a quick way to identify O157, and that it has a bovine reservoir.

Since the JIB outbreak, CDC has continued to investigate other outbreaks and conduct studies on *E. coli* O157, and has identified a large number of ways *E. coli* O157 can infect people, and has developed diagnostic and subtyping techniques that are in widespread use to diagnose infections and track the spread of outbreaks. In addition, CDC has recently demonstrated that fresh produce also can be an important source of foodborne infections, and is working with regulators, the food industry, and consumers to prevent these produce-associated diseases.

3. Congress is in a belt-tightening mood. What happens in the interagency food safety initiative is not funded?

Traditional methods of monitoring disease and investigating outbreaks can only detect the tips of the foodborne disease icebergs. Establishing the risk associated with specific foods is critical in preventing illness. The improved monitoring and forward-looking investigations that are part of the IFSI are needed to document the true magnitude of the problem and the risk posed by various foods, and to precisely target the prevention measures needed to protect the public. However, if full funding is not possible, CDC, USDA, FDA, and our partners in State health departments will continue to work together to learn what we can from the active surveillance sites already in place, and CDC will



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Pages (w/o cover): 5

Comments:

Final draft Qs & As -- incorporating
 USDA's comments.

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FOOD SAFETY INITIATIVE

Q. Why is this initiative needed?

A. Foodborne disease is a major public health issue; outbreaks are increasing in seriousness and new disease-causing organisms are appearing in foods not previously associated with "food poisoning" (such as the contaminated raspberries of last summer).

Q. Aren't federal agencies working well to protect the food supply?

A. Federal agencies work together (along with State and local governments) to address food safety through research and prevention activities, such as inspection and enforcement, and to respond to outbreaks when they occur, but we need to do a better job to reduce redundancies and more intelligently target our use of resources.

Q. Is foodborne illness a significant public health problems?

A. The U.S. food supply is safe compared to those of most nations, but it could be safer. With up to 33 million illnesses and 9,000 deaths per year, foodborne illnesses contribute significantly to the escalating cost of health care.

Q. How much will this initiative cost?

A. This initiative would provide an additional \$42 million for food safety to the FY '98 budget.

Q. If this is such a big problem, why is the Clinton Administration only budgeting \$42 million?

A. This Administration has already made significant contributions to improving food safety, through the implementation of innovative food-safety regulations for meat, poultry, and seafood; through achievement of new pesticide legislation with special protections for our children, and through improved, reauthorized safe drinking water legislation. The FY '98 budget request will build on these advances and move us further down the path of significant improvements in food safety.

Q. If food safety has been such a big problem, why is the Clinton Administration just beginning to deal with it?

A. This Administration has, in fact, made significant progress toward improving the safety of the food supply, such as new food-safety (HACCP) regulations for meat, poultry, and seafood, new legislation to better control pesticides in our food, with special protections for our children, and the new Safe Drinking Water Act.

- Q. The Vice President's 1993 report also noted that FDA's food safety resources, particularly its number of inspectors, had been greatly depleted and should be strengthened if the agency was to do its job well. What do you intend to do about that?**
- A. The FY 98 budget will have additional inspection resources for FDA, as well as additional resources to improve coordination with State inspectors. The broader plan that the President is requesting today will also consider the need for further strengthening FDA's inspection capabilities.**
- Q. If you are not going to reorganize, then will any of the agencies' responsibilities change as a result of this initiative?**
- A. No, but we do intend to significantly improve coordination among agencies with responsibilities for food safety so that their cumulative effectiveness is greatly enhanced.**
- Q. What are the major sources of foodborne contamination?**
- A. Disease-causing organisms can contaminate food at many points. Examples are accidental contact of cow manure on fallen apples, contamination of meat with disease-causing organisms during and after slaughter, or seafood contaminated with naturally occurring microorganisms and toxins.**
- Q. Are foodborne disease outbreaks increasing?**
- A. It is hard to get really good estimates of this trend, but there is evidence that cases and outbreaks are increasing in frequency, and it is certainly clear that they are starting to involve increasingly dangerous bacteria, such as the E. coli strain that has caused such serious illness in recent years.**
- Q. What foodborne hazards are targeted by this initiative?**
- A. We will focus on bacteria, parasites, and viruses that can cause serious diarrheal disease, not just the relatively short term, unpleasant intestinal distress usually thought of as "food poisoning." We are also targeting organisms that can cause death, spontaneous abortion, birth defects, and long-lasting illness such as reactive arthritis, and life-threatening paralysis.**
- Q. What are the benefits of this initiative?**
- A. We can't make precise estimates, but we believe that this initiative will result in significant reductions in food-related deaths, disease, and health-care costs over the next several years.**

Q. How will the food industry and consumer groups be involved in the initiative?

A. Secretaries Shalala and Glickman and Administrator Browner have been charged with developing a comprehensive plan for further food safety improvements in consultation with all sectors of the food industry, with State and local governments, and with producer and consumer groups.

Q. Will this initiative result in new legislation or new regulations?

A. We don't know yet, perhaps neither. But if new legislation is needed, we will work with the Congress to draft the appropriate bill; and we'll consider the need for new regulations as the agencies make their recommendations over the next 90 days.

Q. Are our disease tracking systems inadequate?

A. The Centers for Disease Control and Prevention (CDC) work with State health and agriculture officials to track cases and outbreaks through what is currently a passive reporting system that doesn't produce the data we really need to effectively target the highest-risk areas.

Q. How would this initiative change disease tracking?

A. CDC, with funding from FDA and USDA, will begin intensively and actively looking for foodborne disease cases and outbreaks in 8 sites around the country, greatly increasing the chances that outbreaks can be stopped before they spread.

Q. Are you doing anything to better coordinate the federal government's response to outbreaks of foodborne illness?

A. Yes. An Interagency Coordination Group is being created to coordinate among FDA, CDC, USDA and with the States to effectively investigate and respond to outbreaks of foodborne illness.

Q. Is the Administration planning regulatory action to address the recent incident with apple juice that was contaminated by E coli?

A. FDA recently held a public meeting to seek advice on options for regulatory action to ensure the safety of fruit juices. Obviously, requiring HACCP for that industry was an approach discussed. A decision should be announced soon.

Q. Would the kind of enhanced early warning system you're describing today have caught the Odwalla apple juice outbreak?

A. Yes, the same type of system that did catch the Odwalla outbreak is the kind of system that we hope to make more widely available through the early warning and expanded

surveillance network that we're talking about today.

Q. What can consumers do now to protect themselves from foodborne illness?

A. There are a number of things that consumers can do, and the initiative will include an educational campaign to inform consumers about these health-protective actions, including such things as cleaning utensils and food-preparation surfaces

Q. Will new labeling of foods result from this, such as warning consumers about particular foods or hazards?

A. We don't foresee the need for new labeling, but our consumer education efforts will likely result in brochures, school curricula and the like to inform consumers about food safety.

Q. Will this new initiative include action against "Mad Cow Disease" that has so frightened Europe?

A. Earlier this month FDA proposed new regulations to further reduce the risk that BSE (or, Mad Cow Disease, as its often called) does not occur in this country. Those new rules should be finalized later this year.

HAZARD ANALYSIS CRITICAL CONTROL POINTS (HACCP)

HACCP is a concept originally developed by the food industry for the U.S. space program. It is a system of preventive controls designed to ensure that quality is built in to the food's production. It was developed because incidences of diarrhea or vomiting during a weightless space flight could be catastrophic.

HACCP is fairly simple in concept. The concept is to identify where food can become threatened, minimize the threats and monitor production to ensure that the controls in place work.

For example, if a cooked food is most susceptible to contamination via undercooking, a HACCP program would identify cooking temperature as a "critical control point" and constant monitoring of the cooking temperature would be done to ensure that all of the foods cooked reached the necessary temperature level. Records of temperature levels would be kept, so that if a subsequent illness pointed to that food, the manufacturer could check to make sure that temperatures never dropped to dangerous levels. In the case of the Jack-in-the-Box E-coli outbreak, a HACCP process to ensure that the hamburgers were cooked to government-recommended temperatures would have likely mitigated the illnesses.

HACCP is being implemented worldwide. Europe, Canada and others have already begun requiring HACCP controls by their food processors. In the United States, FDA promulgated regulations in late 1995 to require HACCP for seafood processors. That was followed by similar USDA regulations for meat and poultry that were announced in the summer of 1996 by President Clinton. FDA expects to expand HACCP across the food supply in the coming years.

HACCP has often been described as a fundamental shift in the way food is regulated in the United States. In the past, FDA's and USDA's role in food safety was largely a "cops and robbers" approach in which Federal inspectors attempted to "catch" food processors producing food that was contaminated or being produced in unsanitary facilities, or to find foods already in distribution that were unsafe. With HACCP, food firms reach agreement with Federal inspectors on a "plan" to identify and control hazards, then keep records to show that they are guarding against such hazards. [Hazards can be anything from bacteria to viruses to broken glass to pesticides in the food.]

When the Federal inspectors check the plant, they review the records to ensure that the controls have been constantly monitored and thus implemented. In this way, the industry shares with the government the responsibility for ensuring that the food is safe. And, by building in quality during production, the food produced is less subject to contamination and is safer.

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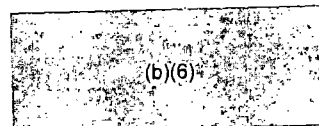
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[001]

- Vice President Gore has been at the forefront of U.S. government efforts to protect the health of Americans and the global community from new infectious diseases, including foodborne infections. In June of 1996 the Vice President called for the creation of a world-wide infectious disease surveillance and response system. The Early Warning System announced today will form a critical component of this network. In addition, these food safety initiatives reflect the efforts of the Vice President's National Performance Review to reinvent government: Federal agencies working closely with state and local governments, forming partnerships with stakeholders, and putting the best available technology to work for the American people.

*November '96 Draft***Questions and Answers on Food Safety Announcement***For
Internal
Use Only.*

Q: What exactly did the President announce today?

A: Today, the President took two important steps to improve the safety of the food supply in the United States. First, the President announced that the Administration will establish five new surveillance sites for tracking foodborne illness throughout the country, doubling the number of sites currently in operation from five to 10. This expanded system will use the latest science to identify and track contaminants in food and speed critical information to public health officials throughout the United States to prevent outbreaks of illness. Second, the President directed the Secretaries of the Departments of Health and Human Services and Agriculture and the Administrator of the Environmental Protection Agency to recommend within 60 days a comprehensive food safety initiative based on the most likely present and future risks to food safety in this country. The President asked that these recommendations include measures to improve inspections, research, education, and coordination among local, state, and federal health authorities.

Q: How was the E. coli outbreak in Washington state detected?

A: The recent E. coli outbreak in Washington state was detected through routine surveillance by the Seattle/King county health department. The state health department then contacted the CDC and the Sentinel sites in California and Oregon to alert them to the outbreak, and the CDC and FDA helped organize the voluntary recall of the apple juice and notify other health departments and the public of the possible contamination. (These are the same health department that detected the large West Coast outbreak of E. coli from undercooked hamburgers in 1993).

Q: What has the CDC and FDA done in reaction to the outbreak?

A: As soon as the federal government got the news of the outbreak, CDC began working with local health officials and notified the six other states in which the juice was distributed. The FDA announced the voluntary recall of the contaminated apple juice from supermarket shelves and sent out a public alert. CDC and FDA have also sent officials to the apple juice plant in California, and both agencies are working with the juice industry to develop long-term prevention measures to keep similar outbreaks from occurring.

Q: Did the Sentinel site in northern California help identify the E. coli outbreak?

A: The Sentinel sites in California and Oregon were contacted when the cases of E. coli were first detected. The Sentinel sites are currently involved in isolating the E. coli bacteria and performing laboratory tests to identify the exact strain of the organism in order to prevent future outbreaks. (In October, the Connecticut Sentinel site did detect an outbreak of E. coli from apple cider produced in that state).

Q: What do the Sentinel sites actually do?

A: The Sentinel sites work to catch outbreaks of foodborne diseases sooner, to investigate their potential source, and to develop effective prevention and control strategies. These sites apply a variety of powerful epidemiologic and laboratory tools, including laboratory-based surveillance of disease-causing organisms, surveys of physicians and communities, and the use of modern laboratory techniques to track illnesses caused by contaminated foods.

Q: Where are the five operating Sentinel sites located?

A: The five sites are located in Northern California, Oregon, Connecticut, Minnesota, and Atlanta. However, these sites do not adequately cover the United States -- there is underrepresentation of the mid-Atlantic, south, and south-west regions. That's why we're expanding the number of sites, from five to 10.

Q: Will the expansion you're proposing to the Sentinel project make a difference in detecting future contaminations before they spread?

A: These new Sentinel sites will expand our ability to catch outbreaks of foodborne diseases, such as those caused by E. coli, sooner, to investigate their potential source, and to develop effective prevention and control strategies.

Q: Which five states will get the new Sentinel sites?

A: A request for applications from states will be published in the federal register. CDC will review the applications and determine, through a competitive process, which five states will receive the five new Sentinel sites.

Q: With all the foodborne illness cases cited, is the food supply really safe?

A: Yes, the food supply is safe, in general. The U.S. food supply is among the safest in the world. The number of foodborne illnesses must be viewed in perspective. U.S. consumers spend over \$619 billion for food every year. We have more than 260,000 products made or processed by more than 30,000 manufacturers available to us on grocery shelves, and approximately 15,000 new products are introduced each year. In addition, the U.S. imported more than 3.5 million foods (not including meat and poultry products) this past year.

The complex system of delivering food from the farm to the tables of American consumers offers opportunities along the route for contamination or mishandling. The important thing to remember is that contamination is preventable, and that the actions we are taking today will help create an even safer food supply.

Q: Why are so many of these food safety initiatives just now being started or considered?

A: These initiatives are part of an ongoing effort by the Administration to enhance the safety of the food supply. For example, we created the Sentinel surveillance project in 1995 through the CDC, FDA, and USDA, which we are expanding from 5 to 10 sites today. In December 1995, the Administration updated the requirements for seafood by incorporating new science-based approaches to prevent food contamination, and did the same for meat and poultry inspection in July 1996. The President also signed legislation to strengthen the Safe Drinking Water Act in July 1996. Finally, in August, the President signed the Food Quality Protection Act, based on a new approach that streamlines the regulation of pesticides and emphasizes public health protection for children.

Today's actions will help to strengthen these existing food safety programs, enhance coordination between public agencies to ensure the safety of the food supply, and redouble efforts to decrease the incidence of foodborne illness in the U.S.

Q: Are any initiatives now underway or under consideration going to change the basic responsibilities that Federal agencies (FDA, USDA, CDC, EPA) have in protecting the food supply?

A: No, the basic responsibilities of FDA, USDA, CDC, and EPA will remain the same. The President's action will increase the number of surveillance sites currently run by the CDC, FDA, and USDA, and his directive to agencies will help find ways to make the food supply even safer.

Q: Are there any estimates on how much these food safety programs will cost (including costs to industry and consumers)? How long will they take to implement?

A: The expansion of the surveillance system from five to ten sites will cost about \$2.5 million dollars in FY 1997. We will have more details on further actions when the Departments of Health and Human Services and Agriculture make their recommendations to the President, within the next 60 days.

Q: Are there any estimates on how many foodborne illnesses may be prevented through newly implemented or future food safety efforts?

A: According to recent estimates by CDC and others, between 6.5 and 33 million cases of foodborne illness occur every year, with up to 9,000 deaths. These illnesses range in severity from stomach aches lasting a few hours to life-threatening illness. While we can't estimate exactly how many foodborne illnesses will be prevented by this or future food safety efforts, we anticipate that these actions will help identify foodborne illnesses more quickly and result in better protection of the public.

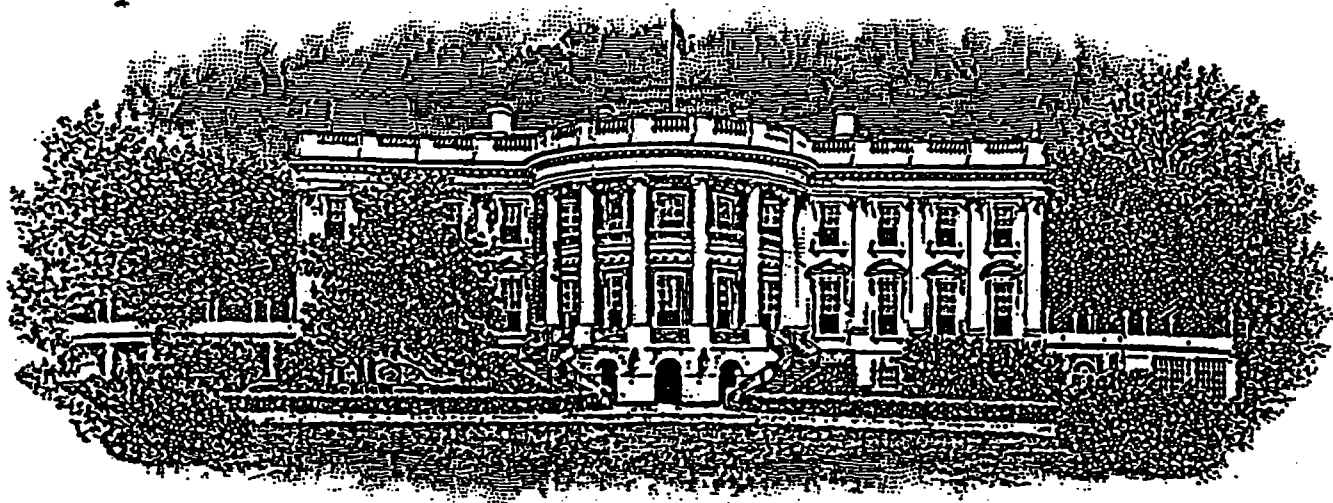
Q: Would the new food safety initiatives require new legislation or regulations?

A: In keeping with Vice President Gore's National Performance Review, a primary objective of the President's directive is to achieve more efficient use of resources through coordinated efforts of public health agencies at the Federal and state levels. A wide variety of options will be considered in determining the most effective, timely way to accomplish this. Again, we will wait to see the specific recommendations of the Departments of Health and Human Services and Agriculture and the EPA.

Q: What type of steps can consumers take now to help protect themselves against foodborne illness?

A: There are a number of things consumers can do to protect themselves against foodborne illness, starting at the grocery store. Foods should be stored at the proper temperature - the old advice to keep cold foods cold and hot foods hot is as true today as it was 30 years ago. Meat, poultry, and eggs should be thoroughly cooked. Home food handling and preparation should always begin with clean hands. Use clean utensils and food preparation surfaces, including cutting boards, for all food preparation. Don't use the same utensils and preparation surfaces used for raw and cooked foods without cleaning them thoroughly in between.

The White House



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**President Clinton Announces New Measures to
Reduce Foodborne Illness**
January 25, 1997

Announcement

- . **President Clinton announced a new Early Warning System to help catch and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks. The Administration will:**
 - . increase the number of active food safety surveillance sites across the country from 5 to 8;
 - . equip these "sentinel" sites and other state health departments with state-of-the-art technology, including DNA "fingerprinting" to identify infectious agents and additional expert disease detectives to trace outbreaks to their source;
 - . link the sites, other state health departments, and Federal public health agencies electronically to allow rapid sharing of lab data -- including digitized fingerprinting data -- nationwide; and
 - . at the sentinel sites, investigate foodborne illnesses in depth to strengthen the scientific basis for our hazard prevention programs.
- . **President Clinton announced he will request an increase of \$43 million in his 1998 budget for food safety to fund the Early Warning System (\$11.5 million), increase seafood safety inspections, and expand food safety research, training and education.**
- . **The President asked for further recommendations.** He directed the Secretaries of Health and Human Services and Agriculture, and the Administrator of the Environmental Protection Agency -- working with consumers, producers, industry, states, universities, and the public -- to identify new ways to advance food safety through government and private sector actions, including public-private partnerships. The President asked for recommendations in 90 days.

Background

- . Although America's food supply is unmatched in quality and quantity, we can do more to eliminate disease caused by foodborne microorganisms. An estimated thousands of deaths and millions of illnesses each year are food related, imposing substantial health care costs.
- . We face new challenges involving food safety as we enter the 21st Century. Novel pathogens are emerging. Familiar ones are growing resistant to treatment. Americans eat in restaurants more. And we eat more imported foods, some of which comes from across the globe overnight. These changes require strengthened systems of coordination, surveillance, prevention, inspections, research, risk assessment and education.

Building on Our Accomplishments

- . President Clinton took a number of steps in his first four years to modernize food safety programs and prevent foodborne illnesses.
- . **Building on the recommendations of the Vice President's National Performance Review, the President put in place new science-based, hazard prevention systems for seafood, meat, and poultry.** In late 1995 the Administration issued new rules to ensure seafood safety. In July, 1996 President Clinton announced new regulations -- that begin to take effect next week -- to modernize the nation's meat and poultry inspection system for the first time in 90 years. The Early Warning System announced today will gather critical scientific data to further improve these prevention systems.
- . **In August, 1996 President Clinton signed the Food Quality Protection Act -- a comprehensive overhaul of our laws that regulate pesticides in food.** The new law establishes a single, strong health-based standard, creates special safeguards for children, protects public health and safety by using the best science available, and, for the first time, provides Americans with the "right-to-know" about health risks from pesticides.
- . **Last August, President Clinton also signed a new safe drinking water law** that strengthens protections to ensure that American families have clean, safe tap water to drink.

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- . **Building on the recommendations of the Vice President's National Performance Review, the President put in place new science-based, hazard prevention systems for seafood, meat, and poultry.** In late 1995 the Administration issued new rules to ensure seafood safety. In July, 1996 President Clinton announced new regulations -- that begin to take effect next week -- to modernize the nation's meat and poultry inspection system for the first time in 90 years. The Early Warning System announced today will gather critical scientific data to further improve these prevention systems.
- . **In August, 1996 President Clinton signed the Food Quality Protection Act -- a comprehensive overhaul of our laws that regulate pesticides in food.** The new law establishes a single, strong health-based standard, creates special safeguards for children, protects public health and safety by using the best science available, and, for the first time, provides Americans with the "right-to-know" about health risks from pesticides.
- . **Last August, President Clinton also signed a new safe drinking water law** that strengthens protections to ensure that American families have clean, safe tap water to drink.

**President Clinton Announces New Measures to
Reduce Foodborne Illness
January 25, 1997**

Announcement

- . **President Clinton announced a new Early Warning System to help catch and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks. The Administration will:**
 - . increase the number of active food safety surveillance sites across the country from 5 to 8 (the current sites are in Northern California, Oregon, Minnesota, Georgia, and Connecticut);
 - . equip these "sentinel" sites and other state health departments with state-of-the-art technology, including DNA "fingerprinting" to identify infectious agents and additional expert disease detectives to trace outbreaks to their source;
 - . link the sites, other state health departments, and Federal public health agencies electronically to allow rapid sharing of lab data -- including digitized fingerprinting data -- nationwide; and
 - . at the sentinel sites, investigate foodborne illnesses in depth to strengthen the scientific basis for our hazard prevention programs.
- . **President Clinton announced he will request an increase of \$43 million in his 1998 budget for food safety to fund the Early Warning System (\$11.5 million), increase seafood safety inspections, and expand food safety research, training and education.**
- . **The President asked for further recommendations. He directed the Secretaries of Health and Human Services and Agriculture, and the Administrator of the Environmental Protection Agency -- working with consumers, producers, industry, states, universities, and the public -- to identify new ways to advance food safety through government and private sector actions, including public-private partnerships. The President asked for recommendations in 90 days.**

Background

- . **Although America's food supply is unmatched in quality and quantity, we can do more to eliminate disease caused by foodborne microorganisms. It is estimated that thousands of deaths and millions of illnesses each year are food related, imposing substantial health care costs.**
- . **We face new challenges involving food safety as we enter the 21st Century. Novel pathogens are emerging. Familiar ones are growing resistant to treatment. Americans eat in restaurants more. And we eat more imported foods, some of which comes from across the globe overnight. These changes require strengthened systems of coordination, surveillance, prevention, inspections, research, risk assessment and education.**

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