

FDA Food Budget / User Fees

Announcement - Total \$43 million request.

- 11.5 Early warning system

10 - CDC

1 - FDA

0.5 - USDA

23 M seafood safety inspections ^{etc.} FDA

8.5 M training, research, education.

CDC

10

FDA

\$24

USDA

\$0

FDA Foods Budget - User Fees

Food and Color additive petitions \$12,543

Import monitoring activities \$15,000

Postmarketing regulatory activities \$19,024

46.6 million

1-3 Billion overall in new 1998 user fees

Non-arrivals - 10,981

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

300 M

FDA Budget overall

134 M new user fees

46 M Food

↓ non user-fee authority by
67-million

- What we asked for
 - 98 budget
 - Broader agenda
- Budget context
- public meetings / key players.
- Next steps
- Strategy for Hill. -

U.S. DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY

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FROM: Erz

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Elizabeth, Adrienne, and Lisa:

I am faxing you the following documents:

Draft Q and A on USDA's 98 budget relative to food safety initiative

FSIS and REE explanation of 98 budget

Draft Q and A we received from FDA. We are still reviewing the document here at USDA. However, I thought you all might be interested in reviewing this as soon as possible rather than waiting. I will coordinate USDA's review, including the numbers, and hope to have that completed by early tomorrow afternoon.

You will note that we inadvertently left off additional HACCP training funds from our earlier budget summary. I do not know if this changes the "\$42 million" figure or not.

We are awaiting the draft press release and backgrounder on HACCP from FDA.

Please let me know if I can be of any assistance or if you have questions on our material.

Thanks.

Eric

Q & A for Food Safety Event

Question: The President noted that his 98 budget will request an additional \$42 million for food safety. How much of these funds are in USDA's budget?

Answer: I can't get into any details, but it's safe to say that USDA's FY 98 budget proposal will contain funds:

- (1) to assist in HACCP training and implementation
- (2) to conduct additional research on important food safety issues
- (3) to enhance USDA's contribution to the early warning system the President announced today; and
- (4) to expand food safety education activities.

Question: Does USDA's budget include funds to implement new regulatory measures?

Answer: No. The Department is busy implementing HACCP. In fact, two new food safety requirements kick in next week. On January 27th, all plants must implement Sanitation Standard Operating Procedures, and all slaughter plants must begin testing for E. Coli.

We have been holding extensive dialogue with all constituents to ensure the smooth implementation of these new safety rules.

Question: Does USDA's budget include user fees for meat and poultry inspection?

Answer: I can't comment on that at this point. Obviously, the Administration has proposed user fees before, but Congress has not adopted them for a number of reasons. You'll have to wait for the release of the budget to get the specifics on this issue.

I would say that I was extremely pleased that the Congress provided our full food safety budget request for this fiscal year (97), and I look forward to working with Congress in support of the Administration's budget request for FY 98.

U.S. DEPARTMENT OF AGRICULTURE/ RESEARCH, EDUCATION AND ECONOMICS

FY 1998 BUDGET

INTERAGENCY FOOD SAFETY INITIATIVE

Agricultural Research Service

An increase of \$1,614,000 for research in Food Safety (Pre-harvest) will support research methods to develop detection methods for Campylobacter, Salmonella and E. Coli 0157:H7. The dynamics of Campylobacter transmission will be delineated to identify control points and strategies to limit infection in poultry and meats. An increase of \$2,500,000 for research on Food Safety (Post-harvest) will facilitate the development of effective HACCP programs in slaughter and processing of meat and poultry. The research will provide the means for food processing industries to deliver food products free of the pathogens identified in the Interagency Food Safety Initiative, including Campylobacter. The research will also provide technologies to reduce the presence of pathogens in fruits and vegetables, while maintaining their fresh appearance and consumer acceptability.

Cooperative State Research, Education and Extension Service

An increase of \$2,000,000 for Ensuring Food Safety (Special Research Grant) will be used to establish a new competitive food safety research program that would expand the base of knowledge needed to solve problems and develop information needed to address high priority issues facing industry and consumers. Current programs provide education and training in the development and implementation of HACCP programs for meat, poultry, food irradiation, microbiological pathogens, pesticide residues, and safe food handling for industry and consumers. The increase of \$2,000,000 for Food Safety (Extension) will be used to further enhance food safety education programs and the capacity of the research and extension system at CSREES and the land-grant institutions to address the ongoing critical issues in food safety.

FOOD SAFETY AND INSPECTION SERVICE

For 1998, USDA's Food Safety and Inspection Service (FSIS) is requesting an increase of \$0.5 million in its agreement with the Centers for Disease Control and Prevention (CDC) to include baseline data on the incidence of foodborne illness resulting from the pathogen *Campylobacter*. The current \$1 million agreement provides baseline data on the pathogens *Salmonella* and *E. coli* 0157:H7. The CDC has shared preliminary data from the sentinel sites with FSIS which indicate that *Campylobacter* is the most common foodborne pathogen. The requested increase is needed to study the impact of *Campylobacter* on public health in order to design, implement, and evaluate the effectiveness of strategies to prevent future outbreaks of foodborne illness.

The 1998 President's Budget ^{also} requests \$565,000 for the Food Safety and Inspection Service (FSIS) to establish a two-year program to train State and local food regulators ⁱⁿ HACCP principles. Jurisdiction for ensuring food safety in restaurants and retail establishments resides with State and local governments. To ensure food safety from the farm to the table, this increase is needed to enhance the knowledge base of State and local regulators so that they can apply HACCP principles to the retail distribution of meat, poultry, and egg products.



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To: ELIZABETH DRYE

Fax Number: 456 5581

From: Bill Hubbard & KAREN HUBBARD

Pages (w/o cover):

Comments: THE FDA & FBIS EARLY WARNING ~~IS~~ ARE (11.5 new)

FDA \$500K FY97
\$1M FY98

FBIS \$1M FY97
\$1.5M FY98

→ 1 base 1/2

WE'LL SEND CDC'S \$\$\$ TOMORROW MORNING.

- ATTACHED IS THE # ON FDA ACTIVITIES TO BE UNDERTAKEN WITH THE REMAINING \$25M.

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P.S. Thanks for holding firm on "risk assessment."

42 million -

8 - 1/2

24 - 1

10

97

98

CDC .75

1.0

FDA .5

1.5

JSDA 1

12.5

2.75

(11.5 new)

In addition to funds to expand and improve the early warning system for foodborne illness, FDA's budget request will be increased by \$23 million to improve coordination among Federal and State agencies responsible for food safety; enhance bioscience research to learn what causes these diseases and how to combat their causes; develop risk assessments so that regulators can make the most cost-effective regulatory decisions; restore some of FDA's inspection capability to enable the agency to successfully implement the new HACCP prevention system; and create a coordinated education campaign that can empower consumers to know how to prevent foodborne illness.

Seafair

42 million
11.5 million

CDL - 1.5
-10 - 1.5

30.5 million

7.5

→ USDA

CDC's contribution to the Early Warning System:

\$750K FY '97
\$10M FY '98 increment

CDC's paragraph regarding the expenditure of these funds:

CDC will allocate all of the resources it gets through this initiative to build components of the early warning system/surveillance. Broad efforts in public health capacity-building that CDC has made in recent years in its response to the threat of emerging infectious diseases (some of which are foodborne) have created a supporting frame work for these specifically directed resources to assure their maximum public health impact.

FOOD AND DRUG ADMINISTRATION
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The Food Safety Initiatives represent a comprehensive interagency approach to reduce the number of foodborne related deaths by 550 to 2,600 and the incidence of foodborne related illness by 1.6 million to 8.8 million each year. The cost of FDA's portion of the Food Safety Initiatives is \$72.512 million with 293 FTEs. Of the total, \$19.1 million and 190 FTEs would be transferred to FDA from the National Marine Fisheries Service under the Department of Commerce. The Centers for Disease Control and Prevention (CDC) is requesting an additional \$24.5 million and 42 FTEs. The U.S. Department of Agriculture (USDA) is requesting \$12.5 million.

We anticipate interactive effects between the various components of the Food Safety Initiatives. Some benefit estimates are impossible to separate from those related to the other critical initiative activities.

Coordination -- The Coordination segment requests for FDA: \$1.000 million and 2 FTEs, and for CDC: \$27.000 million and 2 FTEs. This portion of the initiative will unify the considerable existing expertise of Federal, State, and local health authorities.

- Create a Federal emergency response system designed to better manage outbreaks, ensure interagency collaboration, and provide advanced communications networks with the capability to speed information to experts nationwide.
- Enhance infrastructure for foodborne illness surveillance and coordination at State health departments.

Surveillance -- The Surveillance segment requests for FDA: \$4.680 million and 15 FTEs, and for CDC: \$15.675 million and 30 FTEs. Improve strategies to ensure rapid and early detection of foodborne illness outbreaks and dissemination of information to facilitate response, thereby decreasing the total number of cases of foodborne related deaths and illness by 2 percent.

- Create national electronic network for comparison of bacterial "fingerprints".
- Expand the Sentinel Site project to assure appropriate geographic diversity of the network, cover a greater portion of the nation's population and larger spectrum of foodborne pathogens.
- Create a foodborne disease electronic communications network.
- Increase the number of experts to investigate and control foodborne disease outbreaks.
- Enhance surveillance for foodborne pathogens in food animals and feed; monitor laying hens and egg products before pasteurization for Salmonella.

Inspections -- The Inspections segment requests for FDA: \$27.602 million and 201 FTEs. Establish an effective infrastructure for a nationwide HACCP-based system for meat, poultry, and seafood, and expand Federal/State inspection partnerships to monitor the nation's food supply. Twenty percent of all foodborne related deaths and illness can be eliminated via this enhanced inspection partnership program.

- Enhance foodborne pathogen testing by all HACCP programs.
- Provide a greater coverage of the ever-increasing imported food-product supply.
- Upgrade food inspection programs by transferring 190 inspectors from the National Marine Fisheries Service.

Education -- The Education segment requests for FDA: \$7.030 million and 23 FTEs, for USDA: \$2.500 million, and for CDC: \$7.600 million and 10 FTEs. This portion of the initiative launches an educational campaign focused on preventive measures for improved food safety. More than 50 percent of food related deaths and illnesses may be caused by unsafe preparation practices. The education portion of this initiative could reduce food related death and illness by 1 percent per year.

- Improve numerous food safety education campaigns
 - Consumer
 - Retail, food service, and institutional
 - veterinary and producer
 - Industry (transportation)
 - Laboratory scientists in State and local health departments

Risk Assessment -- The Risk Assessment segment requests for FDA: \$10.330 million and 21 FTEs. Improve risk assessment methodology to develop and evaluate surveillance plans, risk reduction strategies, implementation of HACCP practices, and research programs. The result is a more focused critical control point and far less costly than the current "scattershot" approach.

- Establish an interagency risk assessment consortium to further develop and strengthen food safety risk assessment research and methods development.
- Ensure development of high-quality, high-priority biological data and develop/validate exposure data and models.
- Initiate research on the use of biomarkers of exposure and effect.
- Initiate research on target-dose toxicokinetics, the actual behavior of hazardous substances as they move through the body to reach the target organ.

Bioscience Research -- The Bioscience Research segment requests for FDA: \$13.870 million and 31 FTEs, for USDA: \$10.000 million, and for CDC: \$0.525 million. Enhance research science capabilities to develop new and improved methods for rapid testing of microbial and chemical contaminants, and better understanding of antibiotic resistance. Research activities are pivotal to the success of the Inspection and Risk Assessment parts of the initiative.

- Strengthen scientific programs to achieve a more comprehensive collaborative food safety program.
- Improve methods to detect, control, reduce and eliminate foodborne pathogens.
- Develop data for strategies to counter development of antibiotic resistance in pathogens.

Premarket Activities -- Enhance activities required to process applications for new food animal drugs and for petitions for new food additives. For each of these activities FDA is requesting \$4.000 million.

- New Animal Drug Applications -- Within five years, virtually eliminate the backlog of applications for new animal drugs, while concurrently streamlining the review process.
- New Food Additive Petitions -- Develop and publish comprehensive guidelines for petition preparation, provide industry with enhanced customer service, while streamlining the petition review process.

**Food & Drug Administration
Responses to OMB Questions on the FY 1998 Budget Amendment**

Tobacco Initiative

2. How many FTE's and how much money were used by FDA for tobacco work in FY's 1995, 1996, and 1997?

Answer. For FY 1995, we have documented in previous responses that the resources spent were \$3.5 million and 27 FTEs. For FY 1996, we expended about \$___ million and ___ FTEs. We have not yet finalized our plans for FY 1997, but to date we have allocated about \$4 million and 21 FTEs.

3. The HHS request includes \$3 million for an education program targeted to young people.
- a. If tobacco companies will be required to create notification programs advising teenagers of the health problems related to smoking cigarettes, then how will the \$3 million be used?

Answer. FDA plans to work closely with the tobacco companies to help with development of an effective educational program. FDA would also use this small investment of resources to work in conjunction with CDC to evaluate and select appropriate messages that communicate health information in a relevant manner to young people, so as to maximize their effect on tobacco-susceptible youth.

Food Safety Initiative

3. HHS' food safety request includes the transfer of 190 FTEs from the National Marine Fisheries Service under the Department of Commerce to the FDA (p.1).
- a. Has HHS discussed this transfer with Commerce?

Answer. FDA has discussed the transfer of the 190 FTEs from the National Marine Fisheries Service (NMFS) with the NMFS parent organization, the National Oceanographic and Atmospheric Administration (NOAA) General Counsel, but has not coordinated with anyone at the Department of Commerce level.

- b. If not, has Commerce ever given HHS any indication that they would be amenable to a transfer of FTEs from its National Marine Fisheries Service to the FDA?

Answer. In the past, NMFS have offered FTEs to both FDA and USDA. We have been told the NOAA/NMFS program has begun downsizing and that the inspectors are being RIFFED. They are anxious to find a program which could more effectively utilize these FTEs.

4. HHS states that the revised request reflects resources needed for FDA to implement HACCP regulations for seafood, meat and poultry, to encourage an expanded HACCP-based system for other food products and establishments, and expand Federal/State inspection partnerships to monitor the Nation's food supply.
- a. Since USDA has the primary role in the inspection of meat and poultry, why does FDA need resources for meat and poultry HACCP implementation?
 - b. Does FDA envision a new role for itself in the inspection of meat and poultry?
 - c. Has the USDA asked for FDA involvement in meat and poultry inspections?

Answer. The interagency budget request for Food Safety Initiatives represents a more universal approach to food safety. The document includes information from the other Federal agencies involved (CDC, USDA, and EPA). FDA's request for resources does not affect USDA's meat and poultry HACCP implementation.

One goal of the initiative is to accomplish a more efficient and effective means of monitoring the safety of the nation's food supply. We envision full implementation of the seafood HACCP regulations, expanded use of HACCP systems to non-seafood establishments, and a move to apply HACCP principles to retail food service operations, and to all slaughter animals used for food. Also included is the implementation of a joint FDA/USDA strategy to assure the safety of foods transported in interstate commerce.

5. HHS states that the goal of the food safety initiative is 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.
- a. What is the objective of the initiative, e.g., reduce the incidence of food borne illness by half?

Answer. We estimate that successful implementation of the food safety initiative could, for the targeted pathogens, result in a reduction of up to 2,600 deaths and 8.8 million illnesses annually. These numbers should not be considered precise, but rather representative of the kinds of public health benefits a relatively small investment might obtain.

- b. By when will the objective be achieved?

Answer. We estimate that within five years we would achieve the significant reductions in deaths and illness cited above. In the interim, we would certainly reduce the number of deaths and illness at least marginally, but the full effects of these new initiatives would take time to develop.

8. How would the effectiveness of this activity be measured?

a. How effective are our current efforts in this area?

Answer. To be provided from CFSAN

9. HHS states that part of the food safety initiative will require the formation of partnerships with State and local governments to achieve better Federal/State Coordination on food borne illness outbreaks.

a. What type of Federal/State/local partnerships currently exist to track and respond to food borne illness outbreaks?

Answer. During 1996, FDA had approximately 90 negotiated partnership agreements with various state and local health and agriculture regulatory agencies, industry associations, academia and the regulated industry. These partnerships are intended to enhance consumer protection by reducing consumer risk, eliminating duplication, defining regulatory roles and enhancing channels of communication. Of this total, about 60 were related to various aspects of food safety, and two specifically address foodborne illness. One short term agreement with the Illinois and Chicago Departments of Public Health pertained to protecting public health and preventing foodborne illness during the 1996 Democratic Convention. The second is a multi-year agreement with the Oklahoma State Department of Health which emphasizes in part that the State will conduct immediate investigations of all food related complaints involving illness or injury.

b. What role do State and local health departments play in this area? Isn't this traditionally their responsibility? How would this proposal encourage them to play a greater role?

Answer. In the overwhelming majority of foodborne illness outbreaks, state and local health departments are the initial and, for most incidents, the only investigators of foodborne illness. The federal agencies perform a secondary role in these investigations in supporting the state and local agency with product trace back, coordination of multi-state outbreaks, on-site investigations in support of local efforts, specialized support, laboratory support, etc. when requested by the state or when it involves a Federally regulated product.

The Food Safety Initiative would provide support to the state and local efforts through training, improved communications for outbreak response, and the development of federal cooperation models that would be used by the state and local agencies in coordinating and reporting foodborne illness outbreaks. It is estimated that 20 percent or less of foodborne illnesses are reported and collected into data systems. This initiative would improve that system of reporting, develop better investigation and complaint tracking systems and provide more training to the all the way to the local inspector on foodborne illness investigation techniques, reporting and support. The initiative would help to develop better state systems

to investigate and report foodborne illness incidents and outbreaks thereby improving the protection of the consuming public and the food safety system.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

10-Dec-1996 02:22pm

TO: Nancy-Ann E. Min
TO: Richard J. Turman
TO: Jim R. Esquea

FROM: Elizabeth E. Drye
 Domestic Policy Council

CC: Sarah A. Bianchi

SUBJECT: FDA Food Safety Budget Request

I understand you are meeting with HHS/FDA/CDC at 3:00 re. budget. Here are some (unfortunately last-minute) questions that might be helpful re. food safety in this or later meetings.

1. EARLY WARNING SYSTEM. FDA and CDC have requested 45 additional FTE and \$20 million to increase surveillance of foodborne illness. In October HHS prepared a proposal for an early warning sytem that would catch coutbreaks earlier and gather data to better implement HAACP. Specifically, HHS proposed to

- double the number of "sentinel" surveillance sites from 5-10;
- create an electronic and communication network among sites;
- introduce state-of-the-art lab capabilities like "DNA fingerprinting" of bacteria;
- increase the number of epidemiologists in states investigating disease outbreaks.

The total budget estimate for the early warning system was \$3-6 million in FY97 and FY98 funds. The funding was expected to come from USDA and FDA -- the regulatory agencies that have a direct need for better data and that have funded the Sentinel Site program to date.

Q. Does the budget request for surveillance fund the early warning system as conceived earlier?

Q. If so, will FDA/USDA fund the system and have a role in its implementation, or will it be managed solely by CDC?

2. USE OF CDC SURVEILLANCE FUNDS. The supplemental request breaks out FDA surveillance activities but does not indicate how CDC will use FTEs and funds.

How will CDC use the additional 30 FTEs and \$15.7 million? Will CDC pass any or all of the funds to the states? How will CDC ensure states don't decrease spending on surveillance as CDC increases its surveillance activities?