

		<u>FY98</u>	<u>FY99 Request</u> <u>FY99 Enacted</u>	<u>FY2000 Request</u>	<u>Delta from FY99 Enacted</u>
<u>Food Safety</u> (FSI)		43	101	87	7
			79 (agency enacted)		
USDA			49	21	-28
FDA			25	48	23
CDC			5 ?	18	13
<hr/>					
<u>Plant Genom</u> (Total)		40	55	40	
			55 (agency enacted)		
USDA			5	??????	??????
NSF			50	40	-10
<u>ERI</u> (Total)			75	25	
			25 (agency enacted)		
Ed			0	??????	??????
NSF			25	25	0

Draft numbers should bring up to ~\$125 million

any.

Here is my copy of the MOU + what little I know about the FSI FY2000 request. I'd like to bump it up to about \$125 million.

Cliff

I'll be out of the office from 11:00 am on today, so please page me if you need to get in touch.

Cliff

10-14-86 11:25 AM 2010000010

**DRAFT September 14, 1998**

**MEMORANDUM OF UNDERSTANDING**

Between The

**FOOD SAFETY AND INSPECTION SERVICE  
UNITED STATES DEPARTMENT OF AGRICULTURE**

And The

**FOOD AND DRUG ADMINISTRATION  
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**I. PURPOSE**

This agreement between the Food and Drug Administration, Department of Health and Human Services (FDA) and the Food Safety and Inspection Service, United States Department of Agriculture (FSIS), is intended to facilitate an exchange of information between the agencies about establishments and operations that are subject to the jurisdiction of both agencies. This exchange of information will permit more efficient use of both agencies' resources and will contribute to improved public health protection.

**II. BACKGROUND**

In a May 1997 Report to the President entitled "Food Safety From Farm to Table - A National Food-Safety Initiative," the agencies primarily responsible for food safety made several recommendations to improve public health protection from foodborne illness. Several recommendations also addressed the issues of increasing cooperation among agencies, ensuring that the resources and experience of FDA and FSIS are used as efficiently as possible, and avoiding duplication of efforts.

To advance the purposes of the President's Food Safety Initiative, FDA and FSIS have re-evaluated a previous Memorandum of Understanding on coordination of inspectional efforts signed by FSIS on July 14, 1983 and by FDA on July 25, 1983. The agencies have determined that changes in inspectional activities, available resources, and food safety hazards necessitate updating that agreement. Therefore, FDA and FSIS have entered into this Memorandum of Understanding to address today's public health needs.

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**DRAFT September 14, 1998**

### III. STATUTORY AUTHORITIES

FSIS is responsible for implementing and enforcing the Federal Meat Inspection Act (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451, *et seq.*), and parts of the Egg Products Inspection Act (21 U.S.C. 1031, *et seq.*). In carrying out its responsibilities under these acts, FSIS places inspectors in meat and poultry slaughterhouses and in meat, poultry, and egg processing plants. FSIS also conducts inspections of warehouses, transporters, retail stores, restaurants, and other places where meat, poultry, and egg products are handled and stored. In addition, FSIS conducts voluntary inspections under the Agriculture Marketing Act (7 U.S.C. 1621, *et seq.*).

FDA is responsible for implementing and enforcing the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, *et seq.*), the Public Health Service Act (42 U.S.C. 201, *et seq.*), the Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*), and parts of the Egg Products Inspection Act. In carrying out its responsibilities under these acts, FDA conducts inspections of establishments that manufacture, process, pack, or hold foods, with the exception of certain establishments that are regulated exclusively by FSIS. FDA also inspects vehicles and other conveyances, such as boats, trains, and airplanes, in which foods are transported or held in interstate commerce.

Nothing in this agreement shall lessen the responsibilities or authorities of FSIS or FDA under their statutory authorities.

### IV. SUBSTANCE OF AGREEMENT

#### 1. List of District Level Contacts

The agencies agree to develop, maintain, and annually update a list of their districts and of persons to contact at the district management level. Attached as Appendices A and B, respectively, are the current lists of FDA and FSIS districts and contacts. In addition to the annual updates to these lists, each district agrees to promptly inform its counterpart district of any change in the contact person for that district. The agencies also agree to develop and maintain a list of the district offices responsible for each state and territory. The current list is attached as Appendix C. Each agency agrees to promptly inform the other agency of any changes in the jurisdiction of district offices or in the field organization of the agency. These lists are to be distributed to the district managers of both FSIS and FDA.

#### 2. List of Dual Jurisdiction Establishments

The agencies agree to develop, maintain, and annually update a list of dual jurisdiction establishments (hereinafter "DJE's"), that is, establishments that prepare, pack, hold, or otherwise

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## DRAFT September 14, 1998

handle both foods regulated by FSIS and foods regulated by FDA. This list is to be organized by state and territory. The current list is attached as Appendix D and is to be distributed to the district managers of both FSIS and FDA. When updating this list, each agency agrees to identify all DJEs that have discontinued operations that are under its jurisdiction.

### 3. System of Communication

The district offices of each agency agree to promptly report to their counterpart district offices certain findings, as set forth in paragraphs 5, 6, and 7, relating to DJEs. The district office receiving the report agrees to respond with information regarding any planned or completed follow-up action relating to the reported information. District management of both agencies are encouraged to initiate contact and to meet annually, or as frequently as necessary, to facilitate the exchange of information about establishments and foods prepared, packed, held, or otherwise handled by these establishments. The agencies agree to work together to develop, put in place, and maintain a system of electronic communication at the district level to facilitate the exchange of information about the DJEs.

### 4. Notification of Periodic Inspection

Each agency agrees to attempt to notify the appropriate contact identified in paragraph 1 of this section prior to conducting an inspection of a DJE that is not under continuous FSIS inspection.

In addition, FDA agrees to attempt to notify the FSIS inspector prior to inspecting a DJE that is under continuous inspection and to invite the FSIS inspector to accompany the FDA inspector on the inspection.

### 5. Findings Involving DJEs That Are To Be Reported By Both Agencies

The district office of each agency is to notify its counterpart district office of the following findings in a DJE:

- a. Foods implicated in outbreaks of foodborne illness, injuries or adverse reactions.
- b. Foods found to be contaminated or mislabeled such that there is a reasonable probability that the use of or exposure to such products will cause serious adverse health consequences. Hazards that constitute contamination or mislabeling covered under this paragraph are attached as Appendix E.
- c. A processing condition or failure that is likely to result in food contamination leading to outbreaks of foodborne illness, injuries, or adverse reactions.
- d. Foods that have been recalled.

# DRAFT September 14, 1998

- e. Reports of tampering or threats of tampering.
- f. A food handler diagnosed as having a communicable disease that is likely to result in food contamination or outbreaks of foodborne illness (e.g., hepatitis).

## 6. Findings Involving DJEs That Are To Be Reported By FSIS to FDA

In addition to the findings in paragraph 5, the FSIS district office is to notify its counterpart district office of FDA of the following finding in a DJE:

- a. FSIS action to withhold the mark of inspection or to suspend or withdraw the grant of inspection.

## 7. Findings Involving DJEs That Are To Be Reported By FDA to FSIS

In addition to the findings in paragraph 5, the FDA district office is to notify its counterpart district office of FSIS of the following findings:

- a. Any other processing condition in a DJE that could render foods bearing a USDA mark of mandatory or voluntary inspection adulterated or mislabeled. Reports of FDA enforcement actions associated with such conditions should be provided to FSIS.
- b. Reason to believe that an FDA-regulated ingredients that would adulterate a meat, poultry, or egg product if used in it has been sent to or received by an FSIS-regulated establishment.
- c. Convictions of a DJE, or any officer or key employee of a DJE, for any felony or more than one misdemeanor involving the DJE or any food prepared, packed, held, or otherwise handled in the DJE.
- d. Convictions of an establishment preparing, packing, holding, or otherwise handling both meat, poultry or egg products solely under state regulation and foods regulated by FDA, or any officer or key employee of such an establishment, for any felony or more than one misdemeanor involving the establishment or any food prepared, packed, held, or otherwise handled in the establishment.

## 8. Follow-Up Action

- a. The agency receiving notification of a finding listed in paragraphs 5, 6, or 7 agrees to evaluate it and take appropriate action.

## DRAFT September 14, 1998

b. For all reported findings listed in paragraphs 5, 6, or 7, the agency receiving the notification agrees to track and use the information in program evaluation, work planning, and consideration of whether action against the establishment is warranted.

c. The agency receiving the notification of a finding listed in paragraphs 5, 6, or 7 agrees to respond to the notification within 30 days by communicating the disposition of the notification to the notifying agency at the district management level, including, if appropriate, any and all actions planned and taken by the agency receiving notification. In addition, the agencies agree to explore the feasibility of granting each other access to appropriate computer monitoring systems to permit interagency tracking of findings listed in paragraphs 5, 6, or 7.

### 9. Information Sharing and Confidentiality

To promote increased cooperation and efficient use of enforcement resources, each agency agrees to share documents and information for enforcement purposes upon request by the other agency, to the extent permitted by applicable law. All non-public information shared between the two agencies pursuant to this agreement is subject to all applicable limitations established by statute or regulation on interagency sharing of information. The current policies and procedures for sharing such information are attached as Appendix F.

### 10. Training

The agencies agree to develop and provide appropriate training in the inspectional techniques and processes of each agency as the agencies determine is necessary to implement this agreement successfully. The agencies agree to develop and initiate the training as quickly as possible. The district managers of both agencies are encouraged to evaluate training needs during annual meetings, or as frequently as necessary, to determine whether additional training is warranted.

*Put in purpose*

### 11. Joint Enforcement Activities

The agencies agree to establish a group to explore the feasibility of joint enforcement activities. This group is to report its findings and recommendations by December 31, 1998 to the Commissioner of FDA and the Administrator of FSIS.

### 12. Re-evaluation of the Agreement

The agencies agree to re-evaluate the effectiveness of this agreement after it has been in effect for one year. The agencies also agree to explore the feasibility of expanding their cooperative activities after one year, or sooner if the agencies agree that it is appropriate to do so.

**DRAFT September 14, 1998**

**V. PERIOD OF AGREEMENT**

The agencies agree to begin implementing this agreement within 30 days from execution by both parties. This agreement will be effective indefinitely. It may be modified by mutual consent or terminated by either party upon 30 days' written notice to the other.

**VI. PREVIOUS AGREEMENTS**

This agreement supersedes the Memorandum of Understanding on coordination of inspectional efforts signed by FSIS on July 14, 1983 and by FDA on July 25, 1983. This MOU does not modify any other existing agreements between USDA and FDA.

**VII. NAME AND ADDRESS OF PARTICIPATING AGENCIES**

Food Safety and Inspection Service  
1400 Independence Ave., S.W.  
Washington, DC 20250-3700

Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

**VIII. LIAISON OFFICERS**

For FSIS:  
John McCutcheon  
Associate Deputy Administrator,  
Office of Field Operations  
Food Safety Inspection Service  
1400 Independence Ave., S.W.  
Washington, DC 20250-3700  
(202) 720-5190

For FDA:  
Gary Pierce  
Director, Division of Emergency and  
Investigational Operations  
Food and Drug Administration  
5600 Fishers Lane (HFC-130)  
Rockville, MD 20857  
(301) 827-5655

APPROVED AND ACCEPTED FOR  
THE FOOD SAFETY INSPECTION  
SERVICE

APPROVED AND ACCEPTED FOR  
THE FOOD AND DRUG  
ADMINISTRATION

By: \_\_\_\_\_

By: \_\_\_\_\_

Title: Administrator, FSIS

Title: Acting Commissioner, FDA

Date: \_\_\_\_\_

Date: \_\_\_\_\_



J. Patrick Boyle  
President and C.E.O.

cc: JH, KR, JR, RP

cc: Caren Wilcox  
10/13/98

October 9, 1998

The Honorable Catherine E. Woteki, Ph.D.  
Undersecretary for Food Safety  
U.S. Department of Agriculture  
14<sup>th</sup> St. and Independence Ave., SW  
Washington, DC 20250

Dear Secretary Woteki:

AMI applauds your efforts and those of your federal colleagues on the President's Council on Food Safety. We support your vision of a "seamless food safety system that uses farm-to-table preventive strategies and integrated research, surveillance, inspection and enforcement" to assure consumer safety and confidence.

Toward that end, AMI strongly urges the Council to take on as its first priority the harmonization of food recall policies and procedures between the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS). As you can see from AMI's attached comments on FSIS recall policies, major differences in food recall policies between these agencies is the first problem that needs to be addressed. There is no better forum for resolving these discrepancies, in our view, than the President's Council on Food Safety.

AMI pledges its support towards the Council's efforts to bring uniformity to federal food recall policy. We look forward to working with you in this endeavor.

Sincerely,

J. Patrick Boyle

Attachment

Cc: The Honorable Daniel Glickman  
Secretary, U.S. Department of Agriculture  
The Honorable Donna Shalala  
Secretary, U.S. Department of Health of Human Services  
James O'Hara, Deputy Assistant Secretary for Health, U.S. Department of Health and Human Services  
Thomas J. Billy, Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture

Post Office Box 3556, Washington, DC 20007 - 1700 North Moore Street, Arlington, VA 22209  
Phone: 703/841-2400 Fax: 703/527-0938 [Http://www.meatami.org](http://www.meatami.org)



J. Patrick Boyle  
President and C.E.O

October 9, 1998

FSIS Docket Clerk  
Food Safety and Inspection Service  
U.S. Department of Agriculture  
Room 102, Cotton Annex  
300 12<sup>th</sup> Street SW  
Washington, DC 20250-3700

Re: Docket #98-029N

**American Meat Institute Comments on  
FSIS Recall Policy Working Group Recommendations**

The American Meat Institute (AMI) is pleased to recommend ways to improve the effectiveness and efficiency of meat and poultry product recalls. AMI strongly agrees with the Working Group that **companies should be responsible for conducting recalls**, including identifying affected product and, if necessary, notifying customers and/or consumers. In this regard, AMI opposes efforts to give the Secretary of Agriculture new statutory authority to mandate meat and poultry recalls. Instead, we believe the **Food Safety and Inspection Service (FSIS) should verify that companies have fulfilled their recall responsibilities** and, if they have not, FSIS should use its existing authorities to prevent product from moving in commerce or seize product in the marketplace. Within these parameters, there is much the industry and government can do to facilitate the swift and complete removal from the market of any meat or poultry product believed to present a public health hazard.

AMI is the national organization representing meat and poultry packers and processors and their suppliers throughout North America. Our members produce the majority of meat and poultry products manufactured in the United States. AMI has been active in federal government relations since its inception in 1906.

In the past 92 years, we have helped hundreds of companies conduct product recalls. Without exception, our experience is that companies want to retrieve recalled products promptly, that they want to notify their own customers in a way that maintains the best possible relationship, that they want to provide accurate information to all affected parties and that they want to correct any problems which may have led to the recall so that it does not happen again. Finally, companies want to cooperate with FSIS to ensure that both industry and government are working from the same base of facts and toward the same goal.

### Need for More Consistent Government Approach to Food Recalls

The agency's new focus on improving product recalls is helpful, but it does not go far enough. Federal food recall policy demands a broader approach. We have been troubled by inconsistent FSIS and Food and Drug Administration (FDA) actions during various food product recalls. To some limited degree this can be explained by the unique circumstances of each recall. However, we believe this problem is caused by the absence of uniform, consistent recall policies for both FSIS and FDA. Thus, the agency's current Working Group activities are welcome, but insufficiently comprehensive.

**Specifically, now is the time for the nation's food regulatory agencies to devise a new, consistent approach to improving food recalls – not agency by agency, but together, in a single, united effort through the President's Council on Food Safety.**

As Secretary Glickman stated August 25, the President ordered that "we move toward a seamless government-wide strategy that cuts through bureaucratic barriers to improving public health." We need such a seamless government-wide approach to food product recalls, and the President's Council on Food Safety is the most appropriate entity for devising such a uniform approach.

Our industry conducts on average approximately 40 recalls annually, each one averaging approximately 270,000 pounds with an average recovery rate of 40 percent. Most of these recalls are triggered by company findings. Just over 60 percent (average 22 per year) of meat and poultry recalls are ranked Class I by FSIS. In most cases, Class I recalls involve product which has not yet reached the consumer marketplace, thus in most cases no press releases are issued by either the recalling company or FSIS.

FDA-regulated food companies conduct on average 785 product recalls annually. Most of these are triggered by company findings. Of these recalls, 34 percent (average 268 per year) are Class I. FDA issues press releases on all Class I recalls where the product is in consumer channels and publishes all classes of recall in FDA's Weekly Enforcement Report.

At present, there are numerous discrepancies between recall policies at FSIS and FDA. Among the major differences is the level of recall oversight exerted by each agency. A food company generally notifies FDA that the company is conducting a recall. FDA then requests all relevant information, including any public notices, and suggests modifications if necessary. FDA typically relies on companies to determine the scope of a product recall and monitor and report on the progress of its recall to the agency. In this way, FDA-regulated companies generally experience less pressure and intrusion from FDA regulators than FSIS-regulated companies experience. In contrast, meat and poultry companies generally notify FSIS that a problem has been found which may trigger a recall. FSIS then begins to conduct its own problem solving exercise, requesting documentation on product production, distribution, storage and sales. Companies experience enormous pressure from FSIS to produce records and documents within timeframes dictated by the agency on a case-by-case basis. This pressure can lead to animosity, misunderstanding and incomplete or inaccurate information being disseminated among regulators. Under these less than desirable circumstances, FSIS then typically issues its own press release on Class I recalls to the public, even after the firm has issued its own public notice.

In general, FDA relies much more heavily on the industry to conduct, monitor and report upon product recalls. In contrast, FSIS inserts itself into a company's recall process and operates in an enforcement and compliance mode throughout the recall from inception to completion. This discrepancy is illogical and counterproductive. There is no reason to believe that FSIS-regulated products pose a greater threat to public health and welfare than FDA-regulated products. Therefore, there is no compelling reason for FDA and FSIS recall procedures to differ in any meaningful way.

Given the acknowledged resource discrepancies between FDA and FSIS, the recall monitoring and oversight function is ripe for review by the President's Council on Food Safety, with the hope that such a review would yield a more uniform approach to food product recalls. In the meantime, we strongly recommend that FSIS take no further action on modifying its current recall policy until such a review is completed.

#### Responses to FSIS Working Group Recommendations

Although it is premature to "reinvent" FSIS recall policies prior to an effort to coordinate unified FDA/FSIS regulatory policy on recalls, AMI has some specific responses to the Working Group's recommendations. What follows are the agency's recommendations, with AMI's responses in italics.

1. The recalling establishment should be responsible for effecting the recall, including identifying the product to be recalled, notifying customers and, if product is already in commercial distribution, notifying the public. *AMI agrees completely.*

2. FSIS should ask each establishment to identify a recall contact person. *AMI suggests that each company should also identify a back-up recall contact person.* Through this person, FSIS should provide the establishment with as much advance notice as possible that the FSIS Recall Committee will be meeting to consider whether to request a recall of product shipped by the establishment. *AMI agrees completely.*
3. FSIS should institute rulemaking to require that all entities that handle meat, poultry or egg products include in their records information that will enable them to trace all product from its entry into their facility to its shipment from the facility to a specific customer. *AMI agrees that those in the meat and poultry production and distribution chain should be able to trace products to customers. However, we disagree with a regulatory mandate. Instead, industrial good manufacturing practices would address the need to trace product so that a manufacturer can quickly recall it.* The Working Group also recommended that FSIS institute rulemaking to require that establishments have a written plan that defines how they will conduct a recall should the need arise. *AMI agrees that plants should have written plans for recalling product. However, we disagree with a regulatory mandate. Again, good manufacturing practices outlining general principles of sound recall management would provide meaningful guidance to the industry. No demonstrated need exists to regulate how a company conducts a recall. In fact, every company that has effectively removed product from distribution or sale has done so without a mandated recall plan.*
4. FSIS should prepare and issue guidance materials on a firm's responsibility in a recall. These materials should advise firms to contact the Emergency Response Division (ERD), Office of Public Health and Science (OPHS), or their District Manager, to discuss a recall. They should also explain what FSIS would do if an establishment refuses to recall and explain what are acceptable dispositions of recalled product. FSIS should include in these guidance materials a model letter establishments can use to notify consignees and subconsignees of a recall. *AMI agrees that guidance materials would be useful. Industry should collaborate with FSIS to provide constructive model communications vehicles to establishments.*
5. FSIS should create a Standard Operating Procedure to capture its procedures for deciding whether to request a recall, and it should update its 1992 directive. It should also address in the revised directive how FSIS will respond to a finding by an outside laboratory of a pathogen in an inspected product. *AMI generally agrees. Standard operating procedures are used effectively in FDA recalls; FSIS should develop similar procedures and abide by them. Caution should be exercised before blindly accepting outside laboratory results without proper verification of laboratory practices and confirmation of results to assure accuracy.*
6. FSIS should update the checklist that ERD faxes to establishments when it notifies them that the Recall Committee plans to meet, so that the checklist fully reflects the Agency's data needs. ERD should also work with the Technical Service Center to develop more extensive work sheets to use in questioning a firm about a possible recall. *AMI strongly agrees.*

FSIS Docket Clerk  
October 9, 1998  
Page 5

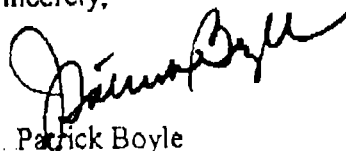
- 7. FSIS should expand the Recall Committee to include representatives from the Technical Service Center, the relevant District Offices, and the Food Safety Executive Management and Coordination Staff. A representative from CDC should be included on the committee for matters that involve a pathogen, as well as when an illness has been associated with a meat, poultry or egg product. Members should be given as much time as possible to prepare for a Recall Committee meeting. *AMI strongly agrees.* (This was originally part of the Working Group's recommendation #2.) The Recall Committee should permit the establishment to make a presentation to it about whether a recall is warranted if the establishment wished to do so and is able to do so in a timely manner. *AMI strongly agrees.*
- 8. The Director of ERD, OPHS, should be delegated the authority to decide whether to request Class II and Class III recalls. *AMI agrees. However, it should be made clear who is authorized to decide on Class I recalls.*
- 9. FSIS should expand the role of compliance officers (Compliance and Investigations Division, Office of Field Operations) in a recall to include actions before and during, as well as after, the Recall Committee's deliberations. Compliance officers should be dispatched to the establishment as soon as a possible need for a recall is identified. Compliance officers should be available at the establishment to answer the Recall Committee's questions and to resolve issues while the Recall Committee deliberates. They also should verify the records relied upon by the establishment. *AMI strongly disagrees. Compliance officers should have more clearly defined responsibilities in recall situations; however, their responsibilities should be limited to monitoring company recall activities outside the official establishment. In-plant inspection personnel should be charged with monitoring plant activities.*
- 10. Except when the source of a problem is apparent at the recalling establishment, FSIS should regularly trace product back one level from the recalling entity. However, a more extensive traceback, even to the producer of the animals that were the source of the product involved, may be appropriate in some circumstances. *AMI agrees.*
- 11. FSIS should continue to defer, if possible, to State and local agencies in recalls involving retail-prepared product. *AMI strongly disagrees. All who process and distribute meat, poultry and egg products should be subject to Federal recall oversight.*

12. FSIS should issue a press release if it will advance the purpose of the recall – to remove product that there is reason to believe is adulterated or misbranded from commerce. For all other recalls, FSIS should notify the public by making the Recall Notification Report available through constituent communications and on the Agency's website. *AMI has major concerns. Since food companies are responsible for recalling products, it is they who should issue press releases to the public in cases where recalled product is available in the consumer marketplace. FSIS should issue press releases only when the recalling company fails to issue its own press release. FSIS press releases should be written according to clearly defined and standardized guidelines, such as prominent information about how to contact the recalling company, no listing of the recalling company's customers and no use of dramatic terms such as "deadly," or "fatal." If FSIS issues a press release instead of the recalling company, FSIS should review the proposed press release with the recalling company to ensure its accuracy, and should provide the release to the company immediately prior to releasing it to the public. The Recall Notification Report should be used to notify essential government personnel and should be modified to include more detailed information about whom to contact at the recalling company for specific types of information (i.e., a contact for retail customers, for consumer questions, for state health departments, for media). The Report should not list the recalling company's customers. It should be posted on the FSIS website only after the recalling company has notified its customers. Finally, in today's technology dependent society, the issuing of a press release is often not enough to respond to the many questions from consumers, customers, state health officials and others. Thus, we believe both industry and FSIS should work together to identify practical means of making appropriate recall information available through other channels – i.e., websites, pre-recorded phone messages, toll-free hotlines, etc. In this way, both industry and government can facilitate the most important element of any recall: prompt, accurate availability of information to those who need to know. AMI looks forward to working with FSIS in this area.*
13. FSIS should use the Recall Notification Report, which is prepared by the Media Communications Office, to provide early notification about a recall to State and local agencies, and to all FSIS Deputy Administrators and District Offices. *AMI has major concerns. Recent experience shows that this Report does not provide adequate useful information about the recalling company, making it very difficult for the company to respond to an avalanche of questions that emerge from the Agency's distribution list. (See suggestions above) The Agency should provide the recalling company a copy of the Report immediately prior to its distribution so the company can be prepared to respond appropriately. A distribution list should also be provided to the recalling company. Finally, FSIS should never include on this Report any customer list of the recalling company.*
14. FSIS should maintain and improve its communications about recalls with the FDA, CDC and other Federal agencies. *AMI strongly agrees. In fact, FSIS should adopt revised recall procedures that more closely mirror those used by FDA.*

15. District Offices should be responsible for recalls of imported product by official import establishments that are located in their districts. *AMI disagrees. FSIS headquarters should be responsible for recalls of imported products in order to protect a uniform approach to recalls.*
16. After a recall, the establishment should be responsible for determining the disposition of the recovered product, subject to FSIS verification. FSIS must determine whether the fact that the establishment shipped adulterated product evidences a HACCP system failure that would justify enforcement action against the establishment. *AMI generally agrees. However, shipping adulterated product that resulted from an unforeseen hazard or a hazard that cannot be controlled under best available practices to a zero tolerance performance standard should not result in a determination of a HACCP system failure.*
17. FSIS should regularly assess whether a recall provides evidence of a need to change Agency policies, and whether the Agencies recall procedures worked effectively and efficiently in the recall. *AMI agrees. Further, AMI believes FSIS and industry should regularly consult on the most effective means by which industry and government can cooperate when recalling products - especially Class I recalls where public health is most threatened. Since a recall is ultimately a company's responsibility, it would benefit both the private and public sectors to share observations, recommendations and experiences in order to improve continuously the speed and efficiency of recall operations.*

The industry and government commitment to HACCP demonstrates our mutual desire to prevent health hazards in foods. We must work continuously to improve our prevention systems. One net result of such improvement will be, we believe, a reduction in the number of food safety-related product recalls. But even if only a handful of recalls were to be necessary in the meat and poultry industry each year, each of those recalls is extremely important and should be handled quickly, professionally and with accurate information. Toward this end, AMI pledges its participation to the President's Council on Food Safety and to FSIS, as you work to define a uniform approach to food product recalls.

Sincerely,

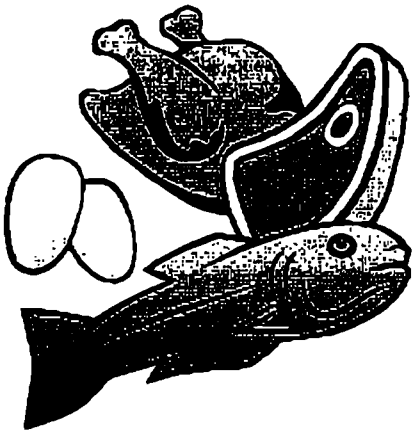


J. Patrick Boyle

*Ww*

# PRESIDENT'S FOOD SAFETY INITIATIVE

## USDA FY 2000 BUDGET



October 20, 1998

UNITED STATES DEPARTMENT OF AGRICULTURE  
 FOOD SAFETY INITIATIVE  
 (Dollars in Thousands)

	1998 Approp.	1999 Budget	1999 Voted Bill	1999 Omnibus	2000 Department Allowance	Change 2000 Allowance from 1999 Budget
<b>A. EARLY WARNING SYSTEM FOR PUBLIC HEALTH SURVEILLANCE</b>						
1. Enhance/Expand active foodborne disease surveillance program						
Economic Research Service (ERS).....	\$32	\$285	\$282		\$285	0
Food Safety and Inspection Service (FSIS).....	1,500	1,500	1,500		1,500	0
DEPARTMENT SUBTOTAL, A.....	1,532	1,785	1,782		1,785	0
<b>B. RISK ASSESSMENT</b>						
1. Establish a Risk Assessment Consortium						
Cooperative State Research, Education, and Extension Service (CSREES).....	0	962	1,612		962	0
Economic Research Service (ERS).....	33	686	236		686	0
Office of the Chief Economist (OCE).....	3	3	3		3	0
2. Develop better data and modeling techniques to assess exposure to microbial and chemical contaminants, including animal drug residues, through the food supply						
Agricultural Research Service (ARS).....	4,498	4,818	4,818		7,218	\$2,400
Cooperative State Research, Education, and Extension Service (CSREES).....	150	1,000	1,000		1,000	0
Food Safety and Inspection Service (FSIS).....	0	0	0		0	0
National Agricultural Statistical Service (NASS).....	0	0	0		2,500	2,500
Office of the Chief Economist (OCE).....	51	149	149		149	0
3. Develop dose-response assessment models (also called hazard characterization) for use in risk assessment						
Food Safety and Inspection Service (FSIS).....	0	0	0		1,000	1,000
Office of the Chief Economist (OCE).....	6	6	6		6	0
4. Identify control measures for reducing foodborne illness losses in agricultural production and processing.						
Food Safety and Inspection Service (FSIS).....	0	1,000	1,000		1,000	0
AGENCY SUBTOTAL, B (ARS).....	4,498	4,818	4,818		7,218	2,400
AGENCY SUBTOTAL, B (CSREES).....	150	1,962	2,612		1,962	0
AGENCY SUBTOTAL, B (ERS).....	33	686	236		686	0
AGENCY SUBTOTAL, B (FSIS).....	0	1,000	1,000		2,000	1,000
AGENCY SUBTOTAL, B (NASS).....	0	0	0		2,500	2,500
AGENCY SUBTOTAL, B (OCE).....	60	158	158		158	0
DEPARTMENT SUBTOTAL, B.....	4,741	8,624	8,824		14,524	5,900

UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY INITIATIVE (Continued)

	(Dollars in Thousands)					
	1998 Approp.	1999 Budget	1999 Vetoed Bill	1999 Omnibus	2000 Department Allowance	Change 2000 Allowance from 1999 Budget
<b>C. BIOSCIENCE RESEARCH</b>						
1. Improved detection methods						
Agricultural Research Service (ARS).....	11,115	12,815	11,897		12,815	0
Cooperative State Research, Education, and Extension Service (CSREES).....	1,260	2,258	3,108		2,653	395
2. Understanding antimicrobial resistance						
Agricultural Research Service (ARS).....	508	808	608		2,308	1,500
Cooperative State Research, Education, and Extension Service (CSREES).....	500	740	1,240		740	0
3. Understanding antibiotic drug resistance						
Agricultural Research Service (ARS).....	92	892	492		2,692	1,800
Cooperative State Research, Education, and Extension Service (CSREES).....	0	0	0		395	395
4. Prevention techniques: pathogen control, reduction, and elimination						
Agricultural Research Service (ARS).....	29,710	38,810	34,290		43,030	4,220
Cooperative State Research, Education, and Extension Service (CSREES).....	3,810	5,940	8,940		6,599	659
5. Food handling, distribution, and storage						
Agricultural Research Service (ARS).....	8,926	10,676	10,126		10,856	180
Cooperative State Research, Education, and Extension Service (CSREES).....	680	1,500	1,500		1,764	264
6. Test samples of fruits and vegetables for microbial pathogens						
Agricultural Marketing Service (AMS).....	0	6,257	0		6,257	0
<hr/>						
AGENCY SUBTOTAL, C (AMS).....	0	6,257	0		6,257	0
AGENCY SUBTOTAL, C (ARS).....	50,351	64,001	57,413		71,701	7,700
AGENCY SUBTOTAL, C (CSREES).....	6,250	10,438	14,788		12,151	1,713
<hr/>						
DEPARTMENT SUBTOTAL, C.....	56,601	80,696	72,201		90,109	9,413

UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY INITIATIVE (Continued)

(Dollars in Thousands)

	1998 Approp.	1999 Budget	1999 Vetoed Bill	1999 Omnibus	2000 Department Allowance	Change 2000 Allowance from 1999 Budget
<b>INSPECTIONS</b>						
1. Enhanced Federal-State inspection partnerships						
Food Safety and Inspection Service (FSIS).....	565	8,412	5,796		8,778	366
2. Expand training and technical assistance to countries exporting produce to U.S.						
Foreign Agricultural Service (FAS) .....	0	0	0		1,000	1,000
AGENCY SUBTOTAL, D (FAS).....	0	0	0		1,000	1,000
AGENCY SUBTOTAL, D (FSIS).....	565	8,412	5,796		8,778	366
DEPARTMENT SUBTOTAL, D.....	565	8,412	5,796		9,778	1,366
<b>EDUCATION</b>						
1. Improve consumer education						
Cooperative State Research, Education, and Extension Service (CSREES).....	1,115	3,461	1,645		3,725	264
Economic Research Service (ERS).....	420	420	420		420	0
Food Safety and Inspection Service (FSIS).....	0	500	500		720	220
Office of the Chief Economist (OCE).....	28	28	28		28	0
2. Improve retail, food service, and institutional education						
Cooperative State Research, Education, and Extension Service (CSREES).....	900	2,799	1,330		3,194	395
Office of the Chief Economist (OCE).....	10	10	10		10	0
Food and Nutrition Service (FNS).....	0	2,000	2,000		2,000	0
3. Improve veterinary and producer education						
Cooperative State Research, Education, and Extension Service (CSREES).....	350	1,105	525		1,368	263
Food Safety and Inspection Service (FSIS).....	0	2,000	2,000		2,000	0
AGENCY SUBTOTAL, E (CSREES).....	2,365	7,365	3,500		8,287	922
AGENCY SUBTOTAL, E (ERS).....	420	420	420		420	0
AGENCY SUBTOTAL, E (FNS).....	0	2,000	2,000		2,000	0
AGENCY SUBTOTAL, E (FSIS).....	0	2,500	2,500		2,720	220
AGENCY SUBTOTAL, E (OCE).....	38	38	38		38	0
DEPARTMENT SUBTOTAL, E.....	2,823	12,323	8,458		13,465	1,142

UNITED STATES DEPARTMENT OF AGRICULTURE  
 FOOD SAFETY INITIATIVE (Continued)

(Dollars in Thousands)

	1998 Approp. -----	1999 Budget -----	1999 Vetoed Bill -----	1999 Omnibus -----	2000 Department Allowance -----	Change 2000 Allowance from 1999 Budget -----
<b>F. EMERGENCY OUTBREAK RESPONSE COORDINATION</b>						
1. District Epidemiology Officers						
Food Safety and Inspection Service (FSIS).....	0	0	0		1,450	1,450

UNITED STATES DEPARTMENT OF AGRICULTURE  
 FOOD SAFETY INITIATIVE

21-Oct-98

(Dollars in Thousands)

	1998	1999	1999	1999	2000	Change 2000
	Approp.	Budget	Vetoed	Omnibus	Department Allowance	Allowance from 1999 Budget
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AMS .....	0	\$6,257	0	\$2,831	\$6,257	0
ARS .....	\$54,849	68,819	\$62,231	67,219	78,919	\$10,100
CSREES .....	8,765	19,765	20,900	24,765	22,400	2,635
ERS .....	485	1,391	938	938	1,391	0
FAS .....	0	0	0	0	1,000	1,000
FNS .....	0	2,000	2,000	2,000	2,000	0
FSIS .....	2,065	13,412	10,796	18,532	16,448	3,036
NASS .....	0	0	0	0	2,500	2,500
OCE .....	98	196	196	196	196	0
TOTAL, USDA .....	66,262	111,840	97,061	116,481	131,111	19,271

# President's Food Safety Initiative -- FY 2000 Budget

## USDA AGRICULTURAL RESEARCH SERVICE

	<u>1998</u> <u>Actual</u>	<u>1999</u> <u>Budget</u>	<u>2000</u> <u>Proposal</u>	<u>Proposed</u> <u>Increase</u>
<i>Risk Assessment:</i>				
<i>Data Modelling Techniques (\$000)</i>	\$4,498	\$4,818	\$7,218	\$2,400

### Risk Assessment: Data Modelling Techniques

Hazard Analysis and Critical Control Point (HACCP) programs need to be supported by quantitative risk assessment to understand the potential for each step in the farm-to-table chain to either enhance or reduce the risk of illness. Risk assessment will help determine which steps are critical, what degree of control the step must provide, and the critical control points for each step. An expert system and specific, appropriate quantitative data is required to accomplish risk assessments. Quantitative microbiological data is needed to carry out the mathematical computations and to develop and validate predictive microbiology models which are a necessary component of these risk assessments.

Risk assessment modelling supported by the 2000 budget will evaluate the effects of various on-farm production practices, processing systems, and transportation systems on the contamination of food-producing animals, including cattle, swine and poultry, as they are presented for slaughter. The proposed research will result in improved information for the animal industry to base decisions on production practices that will result in fewer pathogens in food animals being presented for slaughter. This research will be closely coordinated with the regulatory responsibilities and research needs of the Food Safety and Inspection Service, in particular their Animal Production Food Safety activities, and with the Food and Drug Administration through the Risk Assessment Consortium.

The 2000 budget request extends risk assessment modelling to include the production or pre-harvest phase. Previous modelling has addressed only the data needs of post-harvest operations. Other research has obtained data and developed models on normal contamination levels in raw food ingredients, food composition parameters (pH, water activity and processing operations) to calculate the temperature profile of a beef roast being cooked in an oven. This information has begun providing the basis for a workable expert system for food microbiologists in the industry and regulatory agencies to use without extensive software training. This post-harvest modelling activity must continue, but it must also be extended to pre-harvest to develop data for use in assessing risk in predictive microbiological models which will describe the

## President's Food Safety Initiative -- FY 2000 Budget

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effects of various production practices, processing, and transportation systems on the behavior and subsequent contamination of poultry, beef, and swine as they are presented for slaughter.

### FY 2000 Activities:

- Develop a system that will contain data banks with models for the growth rates, lag times, survival, thermal inactivation, and radiation inactivation as appropriate for additional pathogens. For post-harvest operations, it will contain information on normal contamination levels in raw food ingredients and food composition parameters (pH, water activity and processing). For pre-harvest operations it will contain data describing risk of various food animal production and transportation practices and interventions.
- Gather data on the incidence and number of pathogens on food producing animals at various critical stages in production and management systems. With this data the research will develop predictive models for the risk of transmission of zoonotic pathogens through farm management systems to the presentation of the animals for slaughter. In addition to production practices, microbiological and animal behavioral data on various systems used for transporting swine will be generated and evaluated in relation to the subsequent contamination of the animals at slaughter. The research will also develop predictive models for the risk of transmission of zoonotic parasites through farm management systems, animal manure, and water run off.

# President's Food Safety Initiative -- FY 2000 Budget

## USDA NATIONAL AGRICULTURAL STATISTICS SERVICE

	<u>1998 Actual</u>	<u>1999 Budget</u>	<u>2000 Proposal</u>	<u>Proposed Increase</u>
<i>Risk Assessment:</i>				
<i>Fruits And Vegetables Food Safety Survey (\$000)</i>	\$0	\$0	\$2,500	\$2,500

### **Risk Assessment: Data Modelling Techniques**

On October 2, 1997, the President announced a plan to further ensure the safety of the Nation's food supply. The main objective of the *Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables* is to ensure food safety in the production and processing of domestic and imported fruits and vegetables.

As a result of this initiative, USDA, the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and representatives from the fruit and vegetable industries recommended that National Agricultural Statistics Service (NASS) be responsible for conducting a survey of fruit and vegetable growers and packinghouses handling practices with regard to food safety. A primary use of these data would be to establish a baseline of agricultural practices related to microbial food safety and to provide a benchmark to measure future industry changes. Survey data reported by producers would inform domestic and international data users on U.S. grower food safety practices. The survey information would also be used by FDA and USDA to target specific industry educational outreach programs to increase fruit and vegetable industry awareness on microbial food safety. Economic data collected would be the basis for cost/benefit analyses for food safety related agricultural practices.

This initiative supports the *Research, Education, and Economics Mission Area Goal 2, A Safe and Secure Food and Fiber System*, by providing accurate and timely statistical data which can be used to establish a baseline for agricultural practices as they relate to microbial food safety issues for fruits and vegetables.

### **FY 2000 Activities:**

- Design survey materials and plans based on a 1999 pilot study to be conducted in California and New York. These two pilot States were chosen based on distinct differences in crops grown, growing conditions, and agricultural practices.

## President's Food Safety Initiative -- FY 2000 Budget

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- Conduct a statistical survey of approximately 10,000 fruit and vegetable growers, as well as fruit and vegetable packinghouses, to establish a baseline for good agricultural practices as they relate to microbial food safety issues. The survey would be conducted in major fruit and vegetable States which account for nearly 85 percent of the Nation's acreage. The survey would consist of core questions covering water, manure management, facility sanitation, worker sanitation and hygiene, and transportation practices. The survey would also include questions related to specific practices and the related cost data to allow the calculation of associated cost/benefit analyses.

10/20/00 10:10 AM

# President's Food Safety Initiative -- FY 2000 Budget

## USDA FOOD SAFETY AND INSPECTION SERVICE

	<u>1998 Actual</u>	<u>1999 Budget</u>	<u>2000 Proposal</u>	<u>Proposed Increase</u>
<i>Risk Assessment:</i>				
<i>Dose-Response Assessment Models (\$000)</i>	\$0	\$0	\$1,000	\$1,000

### Risk Assessment: Dose Response Assessment Models

The Food Safety and Inspection Service's (FSIS) goal is to reduce the incidence of foodborne illness by 25 percent. Up to 5 million illnesses are estimated to occur annually with up to 4,500 related deaths. To reduce illness and death from foodborne illness, FSIS, in cooperation with other agencies, and industry, must identify hazards and reduce the risk of regulated products becoming contaminated with bacterial pathogens, such as *Salmonella enteritidis*, *E. coli* O157:H7, and *Campylobacter*.

In order to make FSIS policies and programs risk-based, it is important to estimate human health consequences of hazards in meat, poultry, and egg products. It is equally important to know how hazards entering the food chain can be controlled and how these controls affect the human health outcome. A quantitative risk assessment is the best way to estimate foodborne illnesses associated with USDA regulated products and to identify and evaluate the most effective strategies to prevent them. Microbial risk assessors require better information about the number of bacteria that it takes to make a person ill. This dose-response information is critical for risk assessments and is needed to strengthen current estimates of risk, rather than relying on existing dose-response information.

Risk assessment requires dedicated resources and rapid response to illness investigations while the implicated food is available and patient recall is accurate. This is only possible at the most local level within the State. FSIS is proposing cooperative agreements with five States to collect food specimens during investigations of foodborne disease to help determine the occurrence, distribution, and level of contamination associated with illness. This collaborative effort will also strengthen FSIS relations with State health departments, and improve information sharing and rapid responses when problems do occur.

## President's Food Safety Initiative -- FY 2000 Budget

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### FY 2000 Activities:

- Enter into cooperative agreements with five States to collect food specimens during investigations of foodborne disease epidemics. Information at the local level is necessary to accurately determine the exposure to pathogens in suspect foods. These specimens will be sent to FSIS laboratories to isolate, identify and enumerate pathogens. FSIS will use this information to support selection of appropriate dose-response model forms that will be used to assist the agency in policy decisions. Potential applications include determining acceptable pathogen levels on/in regulated meat, poultry, and egg products.

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**President's Food Safety Initiative -- FY 2000 Budget**

**USDA  
COOPERATIVE STATE RESEARCH, EDUCATION AND EXTENSION SERVICE**

	<u>1998 Actual</u>	<u>1999 Budget</u>	<u>2000 Proposal</u>	<u>Proposed Increase</u>
<i>Bioscience Research:</i>				
<i>Improved Detection Methods (\$000)</i>	\$1,260	\$2,258	\$2,653	\$395

**Bioscience Research: Improved Detection Methods**

Continued outbreaks of food-borne illness due to a variety of pathogens of fecal origin in various foods (ground beef, poultry, eggs, and fresh fruits and vegetables) have sustained a high level of awareness among the public about the issue of food safety. Changes, such as the implementation of Hazard Analysis and Critical Control Point (HACCP) systems in meat and poultry plants by FSIS and the Guidance Document on Production Practices for Fresh Fruits and Vegetables by the Federal Drug Administration (FDA), have enhanced the awareness of the potential role of production practices in contamination of various food products.

This awareness means that food animal and fruit and vegetable producers must be more involved in reducing the opportunity for contamination by pathogens of fecal origin, whether from domestic or wild animal species or human beings. In order to accomplish better control of these pathogens, their presence needs to be detected in a variety of sample matrices. The tests must be rapid, accurate, and usable in field settings. The Cooperative State Research, Education and Extension Service (CSREES) and its partners in the land-grant universities are well positioned, through their interactions with the production community and other segments of the food system, to conduct the applied research and related educational programs to implement these improved detection systems.

Improved detection methodologies will enable producers, processors, and others in the food system to monitor various food products in a more effective manner. It will also enable regulatory officials to have an improved monitoring system for the impact of HACCP implementation throughout the food system. Outcomes of this program can include sampling of animals under different management strategies and at time of shipment for slaughter, as well as monitoring of microbial contamination of carcasses following the slaughter process. In the fruits and vegetables sector, similar sampling will inform us about the benefits of specific interventions and the economic benefits to be derived. Cooperation on this program would occur with FSIS through their Animal Production Food Safety Unit. It should be noted that improved detection systems may give an initial impression of an increase in microbial contamination due to their increased efficiency in detecting microorganisms.

## **President's Food Safety Initiative -- FY 2000 Budget**

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Research efforts on detection methods in the 1998 and 1999 programs have been focused on improving the accuracy and sensitivity of various kinds of tests. The program in 2000 will direct its focus to refining testing methods now being developed to make them more user friendly and able to be used in field testing situations where rapid results are a major concern.

### **FY 2000 Activities:**

- Improved detection methods for the most prevalent pathogens by making them more adaptable for quick, on-site testing of products, and more able to identify specific pathogens, rather than simply indicating presence of fecal contamination.
- Develop better sampling strategies that minimize incorrect results due to sampling errors in order make testing methods more effective.

10/20/00 10:21 AM

## President's Food Safety Initiative -- FY 2000 Budget

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### USDA AGRICULTURAL RESEARCH SERVICE

	<u>1998</u> <u>Actual</u>	<u>1999</u> <u>Budget</u>	<u>2000</u> <u>Proposal</u>	<u>Proposed</u> <u>Increase</u>
<i>Bioscience Research:</i>				
<i>Understanding Antimicrobial Resistance (\$000)</i>	\$508	\$808	\$2,308	\$1,500

#### Bioscience Research: Understanding Antimicrobial Resistance

Food has been preserved for many years using traditional preservation technologies, including heat or cold, low pH, high salt content, and disinfectants. Since these technologies kill or otherwise control bacterial growth, bacteria may become resistant to them just as they do to the much newer antibiotics.

To preserve the effectiveness of traditional preservation technologies, a greater understanding of how and why resistance may develop to these technologies, as well as an understanding of the relationship of this resistance to antibiotic resistance. New ways to apply existing pathogen prevention technologies or new intervention technologies that are more effective and sustainable in mitigating pathogen presence must be developed.

The 2000 budget request will extend the present Agricultural Research Service (ARS) research in antimicrobial resistance, which has thus far focused primarily on acid resistance, to include additional traditional preservation technologies. It will also include the relationship of this resistance to other methods of pathogen control, and it will develop new pathogen prevention/intervention technologies where necessary. The budget increase will for the first time provide for establishment of new culture collections of resistant and non-resistant bacterial and fungal food pathogens. This research will be closely coordinated with the research and regulatory programs including the Food and Drug Administration and the Food Safety and Inspection Service.

## **President's Food Safety Initiative -- FY 2000 Budget**

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### **FY 2000 Activities:**

- Define physiological and/or genetic mechanisms that microbes utilize to become resistant to traditional food safety barriers such as heat or cold, low pH, low water activity and disinfectants. ARS will use this information to develop prevention/intervention pathogen control strategies which delay or prevent the acquisition of resistance, which would compromise the safety of food products which have relied on these control techniques. Acid susceptibility is important when fermentation is used to preserve both animal and plant based foods.
- Establish culture collections of resistant and non-resistant bacterial and fungal pathogens. These resources will be used to develop molecular characterization methods to facilitate (1) the identification of the resistant bacterial pathogens detected in food products, and (2) the tracing of these organisms to their source (e.g. environment, manure, water, animal feed).

## President's Food Safety Initiative -- FY 2000 Budget

### USDA AGRICULTURAL RESEARCH SERVICE

	<u>1998 Actual</u>	<u>1999 Budget</u>	<u>2000 Proposal</u>	<u>Proposed Increase</u>
<i>Bioscience Research:</i>				
<i>Understanding Antibiotic Drug Resistance (\$000)</i>	\$92	\$892	\$2,692	\$1,800

#### Bioscience Research: Understanding Antibiotic Drug Resistance

The effectiveness of antibiotic drugs for both human and animal use is compromised by the development of antibiotic resistance in drugs used for treatment, in many cases to only one pathogen, but also in increasing frequency to multiple drugs such as with *Salmonella typhimurium* DT 104. The resistance of pathogens to antibiotics, particularly the DT 104 pattern of resistance in *Salmonella* sp. to multiple antibiotics has been increasingly recognized by the public health and medical communities and antibiotic use in animals is identified as a contributing factor. In a few cases only one drug is available for successful treatment of diseases caused by certain pathogens. Antibiotic resistance is an important factor that must be controlled in both animal health and the use of animals and their products as foods. Research is needed to develop the knowledge to prevent the development of this antibiotic drug resistance. The development of resistant human pathogenic bacteria is closely associated with the use of antimicrobial agents in human medicine, but it is also likely that food producing animals are sources or vectors of resistant bacteria that may be transmitted directly or indirectly to humans. To maintain the effectiveness of antibiotics in the therapy of life-threatening human disease, effective strategies must be devised to prevent both the emergence and the maintenance in food producing animals of pathogenic and non-pathogenic antibiotic resistant bacteria.

A major impediment to determining the effect of antibiotic use in food animals on human health risk is the complexity of the food-animal drug treatment and subsequent food processing and handling. The 2000 budget request will support research that will lead to a better understanding of how the use of antibiotics in food-producing animals increases the risk of emergence of microorganisms that are resistant to specific antibiotics, and how the emergence of resistance in bacteria in animals that received antibiotics is related to the concentrations of the drugs to which the bacteria are exposed and also to the duration of treatment or exposure. Efforts will also be undertaken to establish whether an increase in resistance detection is due to the use of antibiotics in food animals or to the perpetuation of resistant species in food animals, the environment, or other reservoirs.

## President's Food Safety Initiative -- FY 2000 Budget

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The budget increase will provide for research to determine the concentration, length of use, and other selective factors or conditions favoring the acquisition and dissemination of resistance genes among pathogens and nonpathogens, particularly in relation to poultry, cattle and swine. As necessary, the Agricultural Research Service (ARS) will conduct prospective ecological studies that better define sources of resistant bacteria in the environment, and determine if increase of morbidity and mortality sometimes associated with antibiotic resistant organisms are due to genetic factors for increased virulence accompanying the bacterial resistance genes.

Current research activities of ARS support both the interagency National Antimicrobial Susceptibility Monitoring Program, which prospectively monitors changes in antibiotic susceptibilities of zoonotic pathogens, and a small program which is determining the basis for multiple antibiotic resistance factors associated with DT 104. The budget request will extend the present ARS research program, which has focused primarily on *Salmonella*, to include additional pathogens and it will include development of new pathogen prevention/intervention technologies. Research will be closely coordinated with the research and regulatory programs and responsibilities of the Food and Drug Administration, the Food Safety and Inspection Service, and the Centers for Disease Control and Prevention.

### **FY 2000 Activities:**

- Determine the concentration, length of use, and other selective factors or conditions favoring the acquisition and dissemination of resistance genes among pathogens and non-pathogens in food producing animals. Basic information will be developed using chemostat model systems, on the time and dose dependency of various antibiotics which favor the emergence of resistant organisms in the gastrointestinal tract of food animals species.
- Develop technologies and controls, including competitive exclusion, that will prolong the usefulness of antibiotics for both human and animal use, and prevent food products of animal origin from being carriers of resistant organisms.

**President's Food Safety Initiative -- FY 2000 Budget**

**USDA  
COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE**

	<u>1998 Actual</u>	<u>1999 Budget</u>	<u>2000 Proposal</u>	<u>Proposed Increase</u>
<i>Bioscience Research:</i>				
<i>Understanding Antibiotic Drug Resistance (\$000)</i>	\$0	\$0	\$395	\$395

**Bioscience Research: Understanding Antibiotic Drug Resistance**

Continued outbreaks of foodborne illness due to a variety of pathogens of fecal origin in various foods (ground beef, poultry, eggs, and fresh fruits and vegetables) have sustained a high level of awareness among the public about the issue of food safety. Changes, such as the implementation of Hazard Analysis and Critical Control Point (HACCP) systems in meat and poultry plants by the Food Safety and Inspection Service (FSIS) and the Guidance Document on Production Practices for Fresh Fruits and Vegetables by the Food and Drug Administration (FDA), have enhanced the awareness of the potential role of production practices in contamination of various food products.

The increasing problem with bacterial isolates that exhibit resistance to one or more antibiotics has caused significant concern because of the difficulty of treating any human that becomes infected with such an organism. This emphasis has increased the need for much more research on management practices that will reduce the prevalence of pathogens, e.g., *Salmonella*, *E. coli*, and *Campylobacter* as well as provide resources for educating producers on the implementation of such practices.

Through grant awards to experienced research groups with a significant background in mechanisms of drug resistance, the Cooperative State Research, Education, and Extension Service (CSREES) can cause rapid changes in our knowledge base and immediately translate these findings into educational programs that can be delivered through the Cooperative Extension System and the land grant universities. Projects which combine research activities and extension programs in a single project are most likely to have the desired impact and will ensure the needed linkage between research outcomes and their application by producers. Cooperation on this program would occur with FSIS through their Animal Production Food Safety Unit and, through an Inter Agency Working Group, all efforts are also coordinated with FDA. Outcomes will be measured by monitoring the antibiotic resistance patterns of bacterial isolates from a variety of sources, both animal and human. The primary source of information about the isolates will come from on-going surveillance programs being operated by FDA and FSIS.

## President's Food Safety Initiative -- FY 2000 Budget

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This area of research has not been given major support during 1998 and 1999. Therefore, the research effort in 2000 will represent a new emphasis on this increasingly important topic in public health.

### **FY 2000 Activities:**

- Determine the process by which antibiotic resistance may develop in bacteria and how that resistance may be transferred among different bacterial populations.
- Determine the effectiveness of best management practices interventions in the production setting related to control of antibiotic usage in food. This knowledge will also be used to as a basis to develop educational programs for producers.

# President's Food Safety Initiative -- FY 2000 Budget

## USDA AGRICULTURAL RESEARCH SERVICE

	<u>1998 Actual</u>	<u>1999 Budget</u>	<u>2000 Proposal</u>	<u>Proposed Increase</u>
<i>Bioscience Research:</i>				
<i>Prevention Techniques: Pathogen Control, Reduction, and Elimination (\$000)</i>	\$29,710	\$38,810	\$43,030	\$4,220

### Bioscience Research: Prevention Techniques -- Pathogen Control, Reduction, and Elimination

Exposure and infection of animals by zoonotic pathogens during production, which is accentuated by the increasing animal density of present day livestock operations, is a major source of the contamination in meat-based foods. These pathogens may also contaminate fruits and vegetables produced for human consumption fertilized with animal manure. Effective handling systems for animal manures will help break the cycle of enteric infections with human pathogens in food producing animals and will also help assure that pathogens from these animal manures do not contaminate drinking and food processing waters and are not available to contaminate fruits and vegetables. Manure handling systems are needed to assure effective inactivation, including identification of sources and reservoirs on the on-farm and in the environment, development of pathogen reduction processes suitable to farm size and manure production levels, and reduction of farm level transport, dissemination, and vectoring of pathogens. Because many fruits and vegetables are eaten raw without cooking, it is critical we develop post-harvest technologies that suppress or control zoonotic pathogens, while not destroying freshness and other quality attributes, to help assure the safety of fruits and vegetables.

The proposed research provided by this budget request will address interventions which can be utilized throughout the farm-to-table continuum to assure safety of both meat, poultry, fruits, and vegetables. The budget request provides for the first time for investigations into the control of pathogens in animal manure. Effective methods to handle and treat poultry, swine and cattle manure during production will prevent transmission of pathogens to agricultural lands and to crops used for human food, and will help prevent possible distribution of pathogens to crops or other animals from surface runoff and irrigation waters. Where appropriate the research will investigate wild animals and other vectors as potential sources of contamination of animal wastes.

## President's Food Safety Initiative -- FY 2000 Budget

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The request will provide for extension and expansion of the present Agricultural Research Service (ARS) research with fruits and vegetables to permit greater in depth investigation of the ecology of food borne pathogens, including their environmental sources. Traditional and non-traditional methods of inhibiting pathogens of fruits and vegetables will be optimized, to include both outer and inner surfaces as appropriate. Both chemical and physical control techniques and strategies, including irradiation, radio frequency radiation, steam pasteurization, and competitive exclusion will be investigated. The effects of phytochemical and environmental conditions on growth and survival of *E. coli* O157:H7, *Salmonella*, and *Campylobacter* on the surface of fruits and vegetables will be quantified, particularly in relationship to biofilm development.

The active and passive manure treatments or composting techniques developed will reliably, predictably and consistently reduce or eliminate pathogens in manure, and thus prevent their transmission to food products of both plant and animal origin. These techniques, coupled with technologies to control zoonotic pathogens on fruits and vegetables will increase consumer confidence in the safety of their food supply and promote the consumption of a healthful diet. This research will be closely coordinated with the research and regulatory programs and responsibilities of the Food and Drug Administration and the Food Safety and Inspection Service.

### **FY 2000 Activities:**

- Design effective control programs for zoonotic bacteria and parasites. This proposed preharvest research will develop practical and economical pathogen reduction processes for manure from food producing animals. Different processes are needed and will be developed for each major type of animal production facility, and the processes will be suitable to farm size and manure production levels and have well-defined process parameters.
- Determine how bacteria and fungi normally present on plants influence the growth and survivability of human pathogens that may be present. Data will be developed on the characteristics of fruits and vegetables associated with high quality products that resist growth of pathogens.
- Develop technologies to control pathogens on fruits and vegetables, including proper handling procedures, rinses, and other procedures to reduce pathogen population on fresh cut produce.

**President's Food Safety Initiative -- FY 2000 Budget**

**USDA  
COOPERATIVE RESEARCH, EDUCATION, AND EXTENSION SERVICE**

	<u>1998 Actual</u>	<u>1999 Budget</u>	<u>2000 Proposal</u>	<u>Proposed Increase</u>
<i>Bioscience Research:</i>				
<i>Prevention Techniques: Pathogen Control, Reduction, and Elimination (\$000)</i>	\$3,810	\$5,940	\$6,599	\$659

**Bioscience Research: Prevention Techniques – Pathogen Control, Reduction, and Elimination**

Continued outbreaks of food-borne illness due to a variety of pathogens of fecal origin in various foods (ground beef, poultry, eggs, and fresh fruits and vegetables) have sustained a high level of awareness among the public about the issue of food safety. Changes, such as the implementation of Hazard Analysis and Critical Control Point (HACCP) systems in meat and poultry establishments by the Food Safety and Inspection Service (FSIS) and the Guidance Document on Production Practices for Fresh Fruits and Vegetables by the Food and Drug Administration (FDA), have enhanced the awareness of the potential role of production practices in contamination of various food products. Food animal and fruit and vegetable producers must be much more involved in reducing the opportunity for contamination by pathogens of fecal origin, whether from domestic or wild animal species or human beings. This emphasis has brought more attention to management practices that will reduce the prevalence of pathogens, e.g., *Salmonella*, *E. coli*, and *Campylobacter*, as well as provide resources for educating producers on the implementation of such practices.

The Cooperative State Research, Education, and Extension Service (CSREES) can facilitate rapid changes in our knowledge base by funding established research groups and immediately translate these findings into educational programs that can be delivered through the Cooperative Extension System and the land-grant universities. Outcomes of this program can include sampling of animals under different management strategies and at time of shipment for slaughter, as well as monitoring of microbial contamination of carcasses following the slaughter process. In the fruits and vegetables sector, similar sampling will inform us about the benefits of specific interventions and the economic benefits to be derived. Cooperation on this program would occur with FSIS through their Animal Production Food Safety Unit. We are already working cooperatively, including CSREES serving as the funding and management agent for FSIS activities on implementation of improved management practices in livestock production. Similarly, we have a close working relationship with FDA in developing applied research and educational programs in support of their new Guidance Document for fruit and vegetable growers.

## President's Food Safety Initiative -- FY 2000 Budget

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In the 1998 and 1999 budgets, we are focusing the research component on developing epidemiologic information about several of the most prevalent pathogens (*E. coli*, *Salmonella*, *Campylobacter*), which can then be used as the basis for the proposed activities in 2000. The education program has been more directly focused on the consumer and food handler sectors and, while that will continue, added funds (see Safe Food Handling Education section) will permit the addition of more program efforts directed to the production segment of the food chain. In this manner, we intend to be successful in preventing the contamination of the food products in the first instance, rather than trying to impose decontamination procedures later in the process.

### FY 2000 Activities

- Conduct epidemiologic studies to determine risk factors in the production unit that are related to the presence of specific organisms in the digestive tract of animals and the subsequent shedding of these organisms in the feces.
- Evaluate the management practices, which are determined to be most effective in initial experiments, through monitored field experiments and facilitate the transfer of these new methodologies through demonstration or extension efforts.

# President's Food Safety Initiative -- FY 2000 Budget

## USDA AGRICULTURAL RESEARCH SERVICE

	<i>1998 Actual</i>	<i>1999 Budget</i>	<i>2000 Proposal</i>	<i>Proposed Increase</i>
<i>Bioscience Research:</i>				
<i>Food Handling, Distribution, and Storage (\$000)</i>	\$8,926	\$10,676	\$10,856	\$180

### Bioscience Research: Food Handling, Distribution, and Storage

Food products spend long hours in storage and being transported over long distances before they arrive at the consumer's plate. Temperature control is often not adequate, and pathogen growth results. Adequate information is not available on the conditions under which food products may be transported and handled and how this handling influences their acquiring contaminants and the possible growth of these contaminants that may occur. Research is needed to develop methods and technology to minimize those conditions and therefore the likelihood of such contamination developing.

The 2000 budget supports Agricultural Research Service research projects to develop enhanced procedures and products to be used during food handling, distribution and storage. These treatments, primarily for fruits and vegetables, will include rinses and other procedures to reduce pathogen populations and eliminate cross-contamination. The proposed research will result in decreased pathogen growth particularly for fruits and vegetables, as these food products are handled, distributed and stored. Thus fewer pathogens will contaminate fruits and vegetables that come to the table of American consumers. This research will be closely coordinated with the research and regulatory programs and responsibilities of the Food and Drug Administration.

#### FY 2000 Activities:

- Investigate the ecology of foodborne pathogens during handling, distribution and storage, including their environmental sources.
- Determine if inhibitors of normal surface flora can effect some control of pathogen growth.
- Investigate proper handling procedures and the efficacy of rinses and other procedures to reduce pathogen populations on fresh cut produce during handling, distribution, and storage.

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## President's Food Safety Initiative – FY 2000 Budget

### USDA COOPERATIVE RESEARCH, EDUCATION, AND EXTENSION SERVICE

	<u>1998 Actual</u>	<u>1999 Budget</u>	<u>2000 Proposal</u>	<u>Proposed Increase</u>
<i>Bioscience Research:</i>				
<i>Food Handling, Distribution, and Storage (\$000)</i>	\$680	\$1,500	\$1,764	\$264

#### Bioscience Research: Food Handling, Distribution, and Storage

Continued outbreaks of foodborne illness due to a variety of pathogens of fecal origin in various foods (ground beef, poultry, eggs, and fresh fruits and vegetables) have sustained a high level of awareness among the public about the issue of food safety. While progress has been made in improving the processing sector, the transport and storage sector of the food system has received much less attention. Now, processors are requesting help in ensuring that products which are known to be free of microbial contamination after the processing stage, are maintained in a similar high quality status during the subsequent movement of products into the hands of the consumer. The Cooperative State Research, Education, and Extension Service (CSREES) and its partners in the land-grant universities are well positioned to conduct the applied research and the related educational programs to effect the needed changes in transport, handling, and storage practices.

Through grant awards to experienced research groups with a significant background in such work, CSREES can cause rapid changes in our knowledge base and immediately translate these findings into educational programs that can be delivered through the Cooperative Extension System and the land grant universities. Projects which combine research activities and extension programs in a single project are most likely to have the desired impact and will ensure the needed linkage between research outcomes (knowledge of control strategies) and their application as a result of well-planned educational programs. Close working relationships will be maintained with regulatory agencies to monitor the progress of this program and gain feedback on needed changes in the direction or focus of the program. Microbial status of various food items can be determined prior to, and after, movement of the product from producer/processor and consumer.

With the 2000 funds, more attention will be directed to issues of how to maintain close monitoring of conditions during shipping via various kinds of remote sensor technology. Funding in 1998 and 1999 focused on methods to detect contamination at specific times rather than establishing continuous monitoring of conditions.

## President's Food Safety Initiative -- FY 2000 Budget

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### FY 2000 Activities:

- Extend studies on contamination of food products to the distribution and storage phase of the food system to ensure that safe and wholesome products are not rendered unsafe due to poor storage or handling practices.
- Evaluate the management practices, which are determined to be most effective in initial experiments, through monitored field experiments and facilitate the transfer of these new methodologies through demonstration or extension efforts.

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## President's Food Safety Initiative -- FY 2000 Budget

### USDA FOOD SAFETY AND INSPECTION SERVICE

	<u>1998 Actual</u>	<u>1999 Budget</u>	<u>2000 Proposal</u>	<u>Proposed Increase</u>
<i>Inspections:</i>				
<i>Enhanced Federal-State Inspection Partnerships (\$000)</i>	\$565	\$8,412	\$8,778	\$366

#### Inspections: Enhanced Federal-State Inspection Partnerships

All federally and State inspected establishments must operate under the provisions of the Hazard Analysis and Critical Control Point (HACCP) final rule by January 25, 2000. This includes some 6,000 establishments under Federal inspection and more than 2,000 under State inspection. To achieve a seamless national inspection program covering all establishments, FSIS is proposing legislation that would provide for State meat and poultry inspection programs to enforce Federal meat and poultry inspection laws and regulations within their States. State inspected product that is inspected under Federal HACCP requirements would then be permitted to move in interstate commerce, rather than intrastate commerce only. To assure compliance with Federal requirements and improve consumer confidence in the national food supply, FSIS must conduct pathogen testing on State inspected product and validate the capability of State laboratory programs to conduct other critical microbial testing.

FSIS is currently working to assure that State programs implement HACCP requirements that are "at least equal to" the Federal program. The legislative proposal on interstate shipment of State inspected meat and poultry products will increase the cooperative relationship with States by providing for a one-year transition period from enforcing "at least equal to" requirements to enforcing Federal laws and regulations. The transition to Federal requirements will increase the ability of very small establishments to compete in the marketplace and ensure the viability of State meat and poultry inspection programs.

In 2000, the State inspection programs will be the focus of HACCP implementation efforts. The \$2.4 million included in the 2000 budget for assisting the States with pathogen testing and laboratory validation will build on 1999 efforts to assist the States in preparing for HACCP implementation. One-time special assistance of \$2.0 million to the States for 1999 will include: (1) implementation of the Field Automation Information Management (FAIM) project to provide States FSIS off-the-shelf inspection automation infrastructure that will accommodate HACCP requirements; (2) laboratory equipment for pathogen detection required by the HACCP final rule; and (3) HACCP training for State inspectors. These efforts are intended to assist State programs in implementing HACCP requirements that are

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## President's Food Safety Initiative -- FY 2000 Budget

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"at least equal to" Federal requirements. Working to assure that State inspection programs are "at least equal to" Federal requirements will facilitate the transition to a seamless national inspection system and interstate shipment of State inspected product. For 2000, FSIS is proposing legislation to permit State inspected product to move in interstate commerce. To assure compliance with Federal requirements and improve consumer confidence in the national food supply, FSIS must conduct pathogen testing on State inspected product.

### FY 2000 Activities:

- Conduct pathogen testing on 56,000 samples of State inspected meat and poultry products in FSIS laboratories to determine the compliance of some 2,000 State inspected establishments with pathogen reduction performance standards.
- Conduct comprehensive reviews and audits of 20 State laboratories as well as private laboratories used by State programs.

## President's Food Safety Initiative -- FY 2000 Budget

### USDA FOREIGN AGRICULTURAL SERVICE

	<u>1998 Actual</u>	<u>1999 Budget</u>	<u>2000 Proposal</u>	<u>Proposed Increase</u>
<i>Inspections:</i>				
<i>Training and Technical Assistance to Countries Exporting Produce to the U.S. (\$000)</i>	\$0	\$0	\$1,000	\$1,000

#### **Inspections: Training and Technical Assistance to Countries Exporting Produce to the U.S.**

Following recent foodborne illness outbreaks associated with raspberries from Guatemala and the alleged association with Mexican strawberries, US consumers have become more vocal and have expressed concern about the safety of imported food products, particularly those products regulated by the Food and Drug Administration (FDA). Congressional action (H.R. 3052) has been initiated mandating that FDA increase inspection and compliance activities, particularly in foreign markets supplying food products to the United States.

Several agencies within USDA, including the Foreign Agricultural Service (FAS), have been working closely with FDA to improve food safety under the President's Food Safety Initiative. FAS, in particular, has been directly involved in implementing the Presidential Directive of October 2, 1997, to Ensure the Safety of Imported and Domestic Fruits and Vegetables. In accordance with the 90-day Fresh Produce Status Report, FAS will facilitate visits of FDA investigators and scientists to visit foreign operations to ascertain the source of problems that may pose a safety hazard in produce imported into the United States. In addition, FAS is to facilitate the development of international research, education and training programs. FAS meets bi-weekly with FDA staff to coordinate this effort.

FAS did not have a specific budget allocation to support this initiative in 1998 or for 1999. Activities to date have been limited to facilitating FDA visits to Guatemala and Mexico and organizing international briefings and seminars on the President's Food Safety Initiative. Given that 40-50 different countries export produce to the United States, the impact of expanded FDA in-country inspections on FAS field office operations will increase dramatically as FDA moves to fully implement the initiative. FDA at present has no plans for posting FDA investigators or scientists in U.S. Embassies and will draw on FAS field staff to support their in-country activities as appropriate.

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## President's Food Safety Initiative -- FY 2000 Budget

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### FY 2000 Activities:

- Facilitate the collection of data, report on good agricultural production and manufacturing practices within the food sector, and support FDA field staff visits, primarily in Latin America and Asia.
- Negotiate equivalency understandings with foreign governments.
- Conduct international risk assessment workshops and other training activities to facilitate understanding of the risks associated with microbial contamination on food and the control measures needed to reduce incidence of foodborne illness. These activities will be self-initiated or done in cooperation with the International Institute for Cooperation in Agriculture, the Food and Agriculture Organization, and/or the World Health Organization as appropriate.

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## President's Food Safety Initiative -- FY 2000 Budget

### USDA COOPERATIVE RESEARCH, EDUCATION, AND EXTENSION SERVICE

	<u>1998 Actual</u>	<u>1999 Budget</u>	<u>2000 Proposal</u>	<u>Proposed Increase</u>
<i>Safe Food Handling Education:</i>				
<i>Consumer Education (\$000)</i>	\$1,115	\$3,461	\$3,725	\$264

#### **Safe Food Handling Education: Consumer Education**

Many Americans continue to fall victim to foodborne illness in the United States. As a result, there is a need for an increased effort to fully integrate food safety research and education to inform the public about preventive measures. Increased levels of funding will be imperative for the Cooperative State Research, Education, and Extension Service (CSREES) to strengthen existing links between food safety research and education, and to establish new links that mobilize the vast resources of the land-grant universities and other public institutions. CSREES is in a unique position, because of its partnership with the land-grant universities, to fully integrate food safety research and education in a way that attracts broad support and addresses complex issues with economic, social, and health consequences.

There continue to be areas of unmet needs in food safety education targeted to consumers. Research results that identify sources of contamination, bacterial reservoirs, and new prevention methods will need to be communicated to consumers. Public education and outreach programs that focus on the adoption of recommended food handling practices resulting from research need to be developed. Furthermore, there are targeted populations who are at an increased risk for developing foodborne illnesses (older Americans, pregnant or nursing mothers, young children, the chronically ill, the immune-suppressed). These are "hard to reach" populations for whom education and training about proper food selection, preparation, storage, and handling is crucial.

Funding increases in 2000 will provide the impetus needed to ensure that relevant research results are interpreted and translated to all consumers, but particularly those at increased risk for developing food borne illness. In 1998, funds were used to develop educational programs and resources targeting high-risk or under served populations. Increased funding would ensure that vulnerable populations receive critical information necessary to make informed decisions about food safety.

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## President's Food Safety Initiative -- FY 2000 Budget

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### FY 2000 Activities:

- Increase efforts to integrate research and education in food safety through technology transfer and through the development of educational programs that focus on the adoption of recommended food handling practices consistent with the current knowledge base.
- Develop educational programs for consumers that focus on the role of the consumer in ensuring and improving the safety of the nation's food supply.
- Increase efforts to develop education and outreach programs that target high-risk, under-served populations who are at increased risk for developing food borne illnesses.

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## President's Food Safety Initiative -- FY 2000 Budget

### USDA FOOD SAFETY AND INSPECTION SERVICE

	<u>1998 Actual</u>	<u>1999 Budget</u>	<u>2000 Proposal</u>	<u>Proposed Increase</u>
<i>Safe Food Handling Education:</i>				
<i>Consumer Education (\$000)</i>	\$0	\$500	\$720	\$220

#### Safe Food Handling Education: Consumer Education

Safe food handling is an increasingly major issue with U.S. consumers and spans all ages from pre-school aged children to senior citizens. To address concerns expressed by consumers about food safety, the Food Safety and Inspection Service (FSIS) is taking a major role in educating the public about how to handle domestically produced and imported food more safely.

FSIS needs to ensure that it is meeting the public's demand for food safety education, that educational materials are consistent with current research findings, and that the Meat and Poultry Hotline is fully accessible to the public. From 1996 to 1997, Hotline calls increased by more than 22 percent to 138,120. Call volume has also been high in 1998 due to power outages associated with "El Nino". In addition to maintaining the Hotline, examples of current efforts in food safety education include FSIS support for the Public/Private Partnership in the "Fight BAC!" campaign and working cooperatively with FDA to distribute an educator's package for Food Safety Education Month. FSIS also produces and distributes the "Food Safety Educator", which is a vehicle for sharing information from FSIS, the Food and Drug Administration (FDA) and the Cooperative Research, Education, and Extension Service (CSREES), and supports the National Agricultural Library database on food safety education with FDA. For 1999, FSIS estimates that it will reach 158 million people with food safety information.

The 1999 initiatives include updating and strengthening safe food handling messages, improving dissemination of existing educational information to school children, and developing a visual graphic depicting basic safe food handling principles primarily for children and youth. In 2000 FSIS will build on these efforts to reach an estimated 170 million adults and children, in cooperation with State and local governments, FDA and CSREES. The 2000 initiatives will expand outreach efforts and include food-handling messages in educational materials that reflect the latest research findings. Also, FSIS will procure the necessary equipment and services to increase the call capacity of the Meat and Poultry Hotline, which will accommodate the estimated increase in the number of calls that are expected to be received.

## President's Food Safety Initiative -- FY 2000 Budget

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### FY 2000 Activities:

- Develop, produce, and distribute materials for cooking, vocational and public schools, and community leaders that focus on the third quadrant of the "Fight BAC!" educational graphic "Cook to Proper Temperatures."
- Produce and distribute radio public service announcements addressing safe food handling practices.
- Provide Cooperative Extension agents across the Nation a packet of safe food handling education materials that can be used by family and consumer science teachers.

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## President's Food Safety Initiative -- FY 2000 Budget

### USDA COOPERATIVE RESEARCH, EDUCATION, AND EXTENSION SERVICE

	<u>1998 Actual</u>	<u>1999 Budget</u>	<u>2000 Proposal</u>	<u>Proposed Increase</u>
<i>Safe Food Handling Education:</i>				
<i>Retail, Food Service, an Institutional Education (\$000)</i>	\$900	\$2,779	\$3,194	\$395

#### Safe Food Handling Education: Retail, Food Service, an Institutional Education

Recent outbreaks of food-borne illness have heightened public sensitivity about food safety, including the safety of fresh fruits and vegetables. In recent years, a new Hazard Analysis and Critical Control Points (HACCP) based method for inspecting meat and poultry products has addressed some concerns about *E. coli* O157:H7. To address the issue of produce safety, the President's Fruit and Vegetable Initiative will target producers and growers of domestic and imported produce. Good Management Practices are being developed and adapted for the fruit and vegetable industry that will significantly expand the need for education and outreach programs focusing on preventing microbial contamination during growing, harvesting, processing, and transportation of fresh produce.

There has been consistent progress made toward providing HACCP education and training to large retailers through the various retail organizations. However, there are several under-served groups for whom HACCP education and training is critical. For example, there is a large unmet need for HACCP and food safety training and education for very small retailers who are often not participating members of major retail organizations. CSREES will need to develop methods to identify and target this under-served group, and to provide them with critically needed HACCP education and training consistent with new HACCP regulations. In addition, there is a need to increase the focus on developing and implementing training and education programs for growers and producers of fresh fruits and vegetables. These programs will need to be based on established good manufacturing practices and they will require a collaborative effort across all Federal agencies with a role in ensuring the safety of the food supply.

In 1998, funds were used develop food safety training and education programs for retail and commercial food service establishments. Additional funds are needed to expand HACCP education and training to under-served groups, such as very small retailers not currently affiliated with trade organizations. Additional funds are also necessary to build an education and outreach component that addresses the needs of growers and producers of fresh fruits and vegetables.

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## President's Food Safety Initiative -- FY 2000 Budget

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### FY 2000 Activities:

- Develop educational programs that focus on providing HACCP education and training for very small retailers.
- Increase efforts to provide food safety education and training to key segments of the retail market, including food transportation and food distribution sectors.

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## President's Food Safety Initiative – FY 2000 Budget

### USDA COOPERATIVE RESEARCH, EDUCATION, AND EXTENSION SERVICE

	<u>1998 Actual</u>	<u>1999 Budget</u>	<u>2000 Proposal</u>	<u>Proposed Increase</u>
<i>Safe Food Handling Education:</i>				
<i>Veterinary and Producer (\$000)</i>	\$350	\$1,105	\$1,368	\$263

#### Safe Food Handling Education: Veterinary and Producer Education

Continued outbreaks of food-borne illness due to a variety of pathogens of fecal origin in various foods (ground beef, poultry, eggs, and fresh fruits and vegetables) have sustained a high level of awareness among the public about the issue of food safety. Changes such as the implementation of Hazard Analysis and Critical Control Point (HACCP) systems in meat and poultry plants by the Food Safety and Inspection Service (FSIS) and the Guidance Document on Production Practices for Fresh Fruits and Vegetables by the Food and Drug Administration (FDA) have enhanced the awareness of the role of production practices in contamination of various food products.

The awareness of food safety issues means that food animal and fruit and vegetable producers and their consultants must be much more involved in reducing the opportunity for contamination with pathogens of fecal origin, whether from domestic or wild animal species or human beings. This emphasis has increased the need for more research on management practices that will reduce the prevalence of pathogens, e.g., *Salmonella*, *E. coli*, and *Campylobacter*, and has also given marked impetus to the efforts to provide resources for educating producers and veterinarians on the implementation of such practices. The Cooperative State Research, Education, and Extension Service (CSREES) and its partners in the land-grant universities are well positioned through their interactions with the production community, to conduct the applied research and, via the extension system and production consultants, the related educational programs to effect the needed changes in on-farm practices.

Initial efforts will focus on developing educational programs for veterinarians and livestock producers to cause a reduction in the incidence of human pathogens present within the livestock production system. In this manner, we expect to reduce the shedding of such pathogens in the feces of animals and reduce the likelihood that food products, whether animal or plant derived, are contaminated with these organisms. Outcome measurements will include monitoring of animals going to slaughter for presence of foodborne pathogens prior and following implementation of management systems due to educational programs. Similarly, outcomes for

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## President's Food Safety Initiative -- FY 2000 Budget

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educational programs for fruit and vegetable growers about best production practices can include implementation of these practices and impact on contamination levels of harvested crops.

For 2000, the program would begin to focus on the producer of fruits and vegetables. Currently, pilot programs are being conducted on how to proceed with educational programs for food animal producers and these would then be more fully implemented in 2000. The fruit and vegetable sector would have an increased level of training programs in 2000 as compared to the anticipated efforts in 1999.

### **FY 2000 Activities:**

- Develop educational programs for veterinarians on how to function as auditors or certifiers of Best Management Practices (BMP's) for livestock production units.
- Develop educational programs and provide them to producers on the management systems needed to reduce or eliminated specific pathogens that can cause human illness through contamination of food products.
- Increase efforts in educating fruit and vegetable growers on how to minimize contamination of their crops and be in compliance with the proposed guidance document from FDA.

# President's Food Safety Initiative -- FY 2000 Budget

## USDA FOOD SAFETY AND INSPECTION SERVICE

	<u>1998 Actual</u>	<u>1999 Budget</u>	<u>2000 Proposal</u>	<u>Proposed Increase</u>
<i>Emergency Outbreak Response Coordination:</i>				
<i>District Epidemiology Officers (\$000)</i>	\$0	\$0	\$1,450	\$1,450

### Emergency Outbreak Response Coordination: District Epidemiology Officers

To further reduce illness and death from foodborne disease, improved detection of foodborne illness outbreaks is needed, as well as stronger capability to appropriately handle an increasing number of product recalls. This calls for increasing the presence and scientific expertise of field epidemiologists who conduct recalls and coordinate with the States in investigating outbreaks. The Food Safety and Inspection Service (FSIS) has determined that the 8 existing field epidemiology personnel are insufficient to cover this workload, which grew by 25 percent from 40 recalls in 1996 to 50 recalls in 1997.

The request is needed to increase the number and preparedness of the Agency's field epidemiologists. An additional 10 field epidemiologists, along with the current 8, would serve as District Epidemiology Officers (DEO) to cover all 18 inspection districts. The increased number of DEO's will provide FSIS with expertise to respond effectively in unexpected crises. DEO's will be in regular contact with State health and agriculture departments and will assist in foodborne outbreak investigations. This will require specialized education to acquire microbiological investigative skills, as well as instruments for complicated analytical work and mobile communication devices. Mobility among the States, FSIS headquarters, and the Centers for Disease Control and Prevention (CDC) will also be necessary to achieve the level of preparedness that will significantly improve the FSIS response to foodborne illness.

FSIS expects to expand ongoing coordination with States and the Food and Drug Administration to facilitate mutually beneficial exchanges of laboratory and technical expertise. This effort will further assist Federal, State and local integration in support of a seamless national food safety program. DEO's will also participate in the Foodborne Outbreak Response Coordinating Group (FORCG), which is a combined State and Federal effort.

## President's Food Safety Initiative -- FY 2000 Budget

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### FY 2000 Activities:

- Increase the number of District Epidemiology Officers by 10 for a total of 18 epidemiologists.
- Conduct investigations associated with product recalls.
- Investigate foodborne illness outbreaks in cooperation with other Federal and State public officials.
- Promote food safety during production by working with farmers and others to reduce the risk of future contamination.



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- CATHERINE E. WOTEKI, UNDER SECRETARY
  - KRISTIE D. KELM
  - CAREN A. WILCOX, DEPUTY UNDER SECRETARY
  - JOYCE E. SMITH
  - \_\_\_\_\_

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1400 Independence Avenue, SW - Room 227-E  
Washington, D.C. 20250

**PRESIDENT'S FOOD SAFETY INITIATIVE  
FY 2000 PROPOSAL**

	1997	1998	1999	2000 Proposal	Proposed Increase
ACTIVITY	Dollars in Thousands				
<b><u>SURVEILLANCE:</u></b>					
<b>USDA:</b>					
Food Safety and Inspection Service	\$1,000	\$1,500	\$1,500	\$1,500	\$0
Economic Research Service	<u>32</u>	<u>32</u>	<u>282</u>	<u>285</u>	<u>3</u>
Subtotal, USDA	1,032	1,532	1,782	1,785	3
<b>HHS:</b>					
Food and Drug Administration	737	3,897	3,897	10,297	6,400
Centers for Disease Control and Prevention	<u>4,500</u>	<u>14,500</u>	<u>19,000</u>	<u>29,000</u>	<u>10,000</u>
Subtotal, HHS	<u>5,237</u>	<u>18,397</u>	<u>22,897</u>	<u>39,297</u>	<u>16,400</u>
Subtotal, Surveillance	6,269	19,929	24,679	41,082	16,403
<b><u>COORDINATION:</u></b>					
<b>USDA:</b>					
Food Safety and Inspection Service	0	0	0	500	500
<b>HHS:</b>					
Food and Drug Administration	<u>7,173</u>	<u>7,723</u>	<u>7,723</u>	<u>7,723</u>	<u>0</u>
Subtotal, Coordination	7,173	7,723	7,723	8,223	500
<b><u>INSPECTIONS:</u></b>					
<b>USDA:</b>					
Food Safety and Inspection Service	0	565	10,113	12,513	2,400
<b>HHS:</b>					
Food and Drug Administration	<u>73,244</u>	<u>81,114</u>	<u>105,614</u>	<u>122,514</u>	<u>16,900</u>
Subtotal, Inspections	73,244	81,679	115,727	135,027	19,300

	1997	1998	1999	2000 Proposal	Proposed Increase
<b>ACTIVITY (Cont.)</b>	<b>Dollars in Thousands</b>				
<b><u>RISK ASSESSMENT:</u></b>					
<b>USDA:</b>					
Agricultural Research Service	5,461	4,499	4,909	7,309	2,400
Cooperative State Research, Education, and Extension Service	145	150	2,612	3,702	1,090
Food Safety and Inspection Service	0	0	3,260	3,260	0
Economic Research Service	33	33	236	566	450
National Agricultural Statistics Service	0	0	0	2,500	2,500
Office of the Chief Economist	62	60	152	158	0
Subtotal, USDA	5,701	4,741	11,175	17,615	6,440
<b>HHS:</b>					
Food and Drug Administration	2,599	6,539	6,539	7,039	500
Subtotal, Risk Assessment	8,290	11,280	17,714	24,654	6,940
<b><u>EDUCATION:</u></b>					
<b>USDA:</b>					
Cooperative State Research, Education, and Extension Service	2,365	2,965	7,265	8,267	922
Food Safety and Inspection Service	0	0	3,659	3,659	0
Food And Nutrition Service	0	0	2,000	2,000	0
Office of the Chief Economist	27	38	38	38	0
Economic Research Service	420	420	420	420	0
Subtotal, USDA	2,812	2,823	13,482	14,404	922
<b>HHS:</b>					
Food and Drug Administration Centers for Disease Control and Prevention	4,800	6,870	6,870	8,370	1,500
	0	0	476	476	0
Subtotal, HHS	4,800	6,870	7,346	8,846	1,500
Subtotal, Education	7,612	9,693	20,828	23,250	2,422
<b><u>RESEARCH:</u></b>					
<b>USDA:</b>					
Agricultural Research Service	44,185	50,351	64,959	74,279	9,320
Cooperative State Research, Education, and Extension Service	3,724	6,250	14,788	23,799	9,011
Agricultural Marketing Service	0	0	112	6,297	6,185
Subtotal, USDA	47,910	56,601	79,859	104,375	24,516
<b>HHS:</b>					
Food and Drug Administration	20,793	27,193	27,693	32,399	4,700
Subtotal, Research	68,703	83,794	107,552	136,768	29,216
<b>TOTAL, INITIATIVE</b>	<b>171,291</b>	<b>214,098</b>	<b>294,223</b>	<b>369,004</b>	<b>74,781</b>

**PRESIDENT'S FOOD SAFETY INITIATIVE  
FY 2000 PROPOSAL**

	1997	1998	1999	2000 Proposal	Increase Over 1999
<b>TOTAL INITIATIVE</b>	<b>Dollars in Thousands</b>				
<b>USDA:</b>					
Agricultural Research Service	\$49,647	\$54,849	\$69,868	\$61,588	\$11,720
Cooperative State Research, Education, and Extension Service	6,234	8,765	24,765	35,788	11,023
Agricultural Marketing Service	0	0	112	6,297	6,185
Food Safety and Inspection Service	1,000	2,065	18,532	21,432	2,800
Economic Research Service	485	485	938	1,391	453
Office of the Chief Economist	89	98	196	196	0
National Agricultural Statistics Service	0	0	0	2,500	2,500
	<u>0</u>	<u>0</u>	<u>2,000</u>	<u>2,000</u>	<u>0</u>
Food and Consumer Service					
	57,455	66,262	116,411	151,192	34,781
<b>Subtotal, USDA</b>					
<b>HHS:</b>					
Food and Drug Administration	109,336	133,336	158,336	188,336	30,000
Centers for Disease Control and Prevention	<u>4,500</u>	<u>14,500</u>	<u>19,476</u>	<u>29,476</u>	<u>10,000</u>
<b>Subtotal, HHS</b>	<u>113,836</u>	<u>147,836</u>	<u>177,812</u>	<u>217,812</u>	<u>40,000</u>
<b>TOTAL, INITIATIVE</b>	<u>171,291</u>	<u>214,098</u>	<u>294,223</u>	<u>369,004</u>	<u>74,781</u>

**FOOD SAFETY ACTIVITIES**  
(Dollars in Millions)

	1998	1999	Change from 1998	2000 Budget	2000 Change from 1999
<b>Food Safety Initiative:</b>					
<b>USDA:</b>					
ARS	54.8	69.9	15.0	81.6	11.7
CSREES	8.8	24.8	16.0	35.8	11.0
AMS	0.0	0.1	0.1	6.3	6.2
FSIS	2.1	18.5	16.5	21.4	2.9
ERS	0.5	0.9	0.5	1.4	0.5
OCE	0.1	0.2	0.1	0.2	0.0
FNS	0.0	2.0	2.0	2.0	0.0
NASS	0.0	0.0	0.0	1.5	1.5
<b>Subtotal, USDA</b>	<b>66.3</b>	<b>116.4</b>	<b>50.1</b>	<b>150.2</b>	<b>33.8</b>
<b>HHS:</b>					
FDA	133.3	158.3	25.0	188.3	30.0
CDC	14.5	19.5	5.0	29.5	10.0
<b>Subtotal, HHS</b>	<b>147.8</b>	<b>177.8</b>	<b>30.0</b>	<b>217.8</b>	<b>40.0</b>
<b>Total, FSI</b>	<b>214.1</b>	<b>294.2</b>	<b>80.1</b>	<b>368.0</b>	<b>73.8</b>
<b>Food Safety and Inspection Service (Net FSI):</b>	<b>587.2</b>	<b>598.5</b>	<b>11.3</b>	<b>631.6</b>	<b>33.1</b>
<b>TOTAL, Food Safety Activities</b>	<b>801.3</b>	<b>892.8</b>	<b>91.5</b>	<b>999.6</b>	<b>106.9</b>
<b>RECAP:</b>					
<b>Food Safety Activities:</b>					
<b>USDA:</b>					
ARS	54.2	69.9	15.0	81.6	11.7
CSREES	8.8	24.8	16.0	35.8	11.0
AMS	0.0	0.1	0.1	6.3	6.2
FSIS	589.3	617.1	27.8	653.0	36.0
ERS	0.5	0.9	0.5	1.4	0.5
OCE	0.1	0.2	0.1	0.2	0.0
FNS	0.0	2.0	2.0	2.0	0.0
NASS	0.0	0.0	0.0	1.5	1.5
<b>Subtotal, USDA</b>	<b>653.5</b>	<b>715.0</b>	<b>61.5</b>	<b>781.8</b>	<b>66.9</b>
<b>HHS:</b>					
FDA	133.3	158.3	25.0	188.3	30.0
CDC	14.5	19.5	5.0	29.5	10.0
<b>Subtotal, HHS</b>	<b>147.8</b>	<b>177.8</b>	<b>30.0</b>	<b>217.8</b>	<b>40.0</b>
<b>TOTAL, Food Safety Activities</b>	<b>801.3</b>	<b>892.8</b>	<b>91.5</b>	<b>999.6</b>	<b>106.9</b>