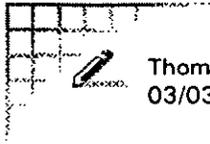


**NLWJC - Kagan**

**DPC - Box 008 - Folder 006**

**Consumer Protection - Food Safety  
Single Agency**

Cons pro - food safety -  
single agency



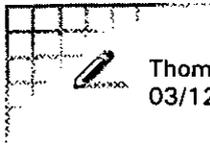
Thomas L. Freedman  
03/03/99 11:30:39 AM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP  
cc: Mary L. Smith/OPD/EOP  
Subject: Morley Winograd and Food Safety

You asked me to check with Morley on the idea of moving inspections from FDA to USDA and re-naming USDA. He likes the idea, particularly if it can take care of the VP's problem with pesticides. (It might, increased inspections in fruit and veggies plants could conceivably decrease the pesticide problem there -- I'll look into it). He asked we put together a short memo and hold a meeting with you and Neal Lane to figure whether and how to break this to HHS. I said sure. I'd like to first set up a Bruce, Elena, Neal Lane meeting for Friday to discuss this and the NAS response. OK?

Pro - food safety -  
single food agency



Thomas L. Freedman  
03/12/99 10:02:16 AM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP  
cc: Mary L. Smith/OPD/EOP  
Subject: Food Response

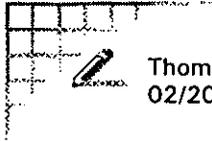
As you recall, HHS insisted on adding to the summary of the NAS response that the Council evaluation of structural models will keep in mind "that the primary goal is food safety and public health **not expanded bureaucracy.**"

I've told O'hara that this was unacceptable, yesterday he said he would take it up with the Secretary. This morning he said the COS said that HHS's position was that this reflects their position, the Secretary has used this language and should not "retreat."

There is some chance that if one of you calls them, they may relent. Their argument is weak. This Response document is promising an objective review of alternatives, it is not the proper venue for HHS to indicate the matter has been pre-judged. We included language in the text of the Response that indicates factors mitigating against a single food agency. HHS will have plenty of opportunity to appropriately weigh in against a single food agency when we evaluate options in the strategic plan.

As I mentioned, Reuters has already run a small item indicating that we are not endorsing a single food agency in the Response. We want to emphasize that this is a positive next step in the process of making sure the food safety system is unified and speaks with a single voice. Caroline Smith-Dewall, the chief advocate of a single food agency, has agreed to put out a release saying the Response is a positive step.

cross pur - food safety -  
single agency



Thomas L. Freedman  
02/20/99 02:54:31 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP

cc: Mary L. Smith/OPD/EOP

Subject: Food reorganization idea and probable reaction



FSPLAN.22



FDA.221

Attached is a one page description of a feasible food safety reorganization plan USDA supports and how we think the major players would react. None of them think we can realistically go for a single food agency. The advocates and USDA do think we have a shot at centralizing the crucial inspection function. The move would be a significant one, there are thousands of meat inspectors in USDA, daily inspection of every plant. There are only a few hundred inspectors in FDA, the average fruit and veggie plant may not be inspected for many years. The crucial opposition is in HHS/FDA.

## DRAFT FOR DISCUSSION PURPOSES ONLY

- I. Move food inspection and standard-setting/regulation for microbial, viral, and parasitic pathogens to FSIS (USDA), including seafood, eggs, milk, fruits and vegetables as well as FDA/State boards on milk, seafood, and the food code.
- II. CFSAN at FDA has responsibility over food additives, dietary supplements, biotechnology, chemical/pesticide/drug residues/standards, and food labeling under NLEA (?), including meat and poultry products. They are also given a budget increase. Consideration is given to promoting preemption, as USDA has for meats, and processor groups would prefer.
- III. Inspection Resources--move small number of field personnel i.e. imports, otherwise all inspection personnel remain for drugs, medical devices. Provide FSIS with base increase of XX million to ensure successful transition.
- IV. USDA becomes U.S. Department of Food and Agriculture (Under Secretary for Public Health and Food Safety).
- V. Underlying Statutes (FFDCA, FMIA etc) remain intact. (Direct development of proposal to unify any conflicts in underlying statutes?).
- VI. Consider other measures to ensure independence from promotion, e.g. statutory advisory board, statutory reaffirmations.
- VII. Public Health and Ag. Committees share full jurisdiction over food safety.

## Reactions of Interested Parties to Food Safety Reorganization

USDA- USDA would support the move. Glickman has told his staff he would support then re-naming his agency the Department of Food and Agriculture.

HHS- Would strongly oppose. O'hara called me to protest when clumsily USDA suggested it in a meeting. On the other hand, FDA recognizes their hand is weak. The Hill is unlikely to give FDA the money they need to inspect adequately. FDA's attempt to delegate to the states is running into opposition from the advocates, who FDA knows they have alienated.

Consumer groups-- The two leaders, Carol Tucker Foreman and Caroline Smith Dewall are strong advocates of a single food agency, and have each told me they support moving inspection to USDA. Caroline says she has now told this to FDA.

Congress: USDA is generally favored on the Hill, FDA is not, and USDA believes it could build support. Currently, however, among most ag. types there is a go slow attitude. For instance, while Harkin's staff confided that while they support a single food agency, they are satisfied there is enough on the plate right now and don't particularly want to go into the issue. Among food safety advocates, Durbin has been a leader in supporting a single food safety agency.

Producer/Processor Groups: Producer groups prefer USDA. I had a wide-ranging conversation with the head of the fruits and veggies processors group in which he said they were not positive about any governmental moves -- they are pretty conservative-- but USDA believes they could be brought around given the association's distaste for FDA and the chance they might get preemption.

Internal WH: OMB, OSTP and WH are all supportive. NEC has been supportive but we haven't talked to Sally about this recently. VP's office was originally charged with sounding out the agencies on a single food agency-- and backed off given HHS's negative reaction.

**PRESIDENT CLINTON SIGNS EXECUTIVE ORDER  
CREATING COUNCIL ON FOOD SAFETY**

**August 24, 1998**

President Clinton today will sign an Executive Order to create a President's Council on Food Safety, which will develop a comprehensive strategic plan for federal food safety activities and ensure that federal agencies annually develop coordinated food safety budgets. The President also will sign a directive to the Council to review the recently issued National Academy of Sciences (NAS) report, "Ensuring Safe Food from Production to Consumption," and to report back with its response to the report, including appropriate additional actions to improve food safety.

**President's Council on Food Safety.** The President will sign an Executive Order establishing a President's Council on Food Safety (Council). The Council will have three primary functions, including: (1) developing a comprehensive strategic federal food safety plan; (2) advising agencies of priority areas for investment in food safety and ensuring that federal agencies annually develop coordinated food safety budgets; and (3) overseeing the recently established Joint Institute for Food Safety Research and ensuring that it addresses the highest priority research needs.

- **Comprehensive strategic federal food safety plan.** The Council will develop a comprehensive plan to improve the safety of the nation's food supply by establishing a seamless, science-based food safety system. The plan will address the steps necessary to achieve this improved system, focusing on key public health, resource, and management issues and including measurable outcome goals. The planning process will consider both short and long-term issues including new and emerging threats and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council will consult with all interested parties, including state and local agencies, tribes, consumers, producers, industry, and academia.
- **Coordinated federal food safety budgets.** Consistent with the comprehensive strategic federal food safety plan, the Council will advise agencies of priority areas for investment in food safety and ensure that federal agencies annually develop coordinated food safety budgets. This coordinated food safety budget process will sustain and strengthen existing activities, eliminate duplication, and ensure the most effective use of resources for improving food safety.
- **Oversight of federal food safety research efforts.** The Council will ensure that the Joint Institute for Food Safety Research addresses the highest priority food safety research gaps. The Institute will report, on a regular basis, to the Council on its efforts to conduct and coordinate food safety research activities and will receive direction from the Council on research needed to establish the most effective possible food safety system.

**Review of NAS Report.** The President will direct the Council, as one of its first orders of business, to review the National Academy of Sciences (NAS) report, "Ensuring Safe Food from

Production to Consumption.” After providing opportunity for public comment, including public meetings, the Council will report back to the President within 180 days with its response to the NAS report. The Council’s report will consider appropriate additional actions to improve food safety, including proposals for legislative reform of the food safety system.

**Public Meeting to Develop Comprehensive Strategic Plan for Federal Food Safety**

**Activities.** The Clinton Administration will publish notice of the first public meeting, to be held on October 2 in Arlington, Virginia, to begin development of the Council’s comprehensive strategic plan for federal food safety activities. The meeting will engage consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process.

## **Clinton Administration Accomplishments In Improving Food Safety**

The President's announcement builds on a strong record of food safety initiatives, ensuring that Americans eat the safest possible food. The Administration has put into place improved safety standards for meat, poultry, and seafood products, and has begun the process of developing enhanced standards for fruit and vegetable juices. The Administration also has expanded research, education, and surveillance activities throughout the food safety system.

\*July 1998. President creates a Joint Institute of Food Safety Research which will develop a strategic plan for conducting and coordinating all federal food safety research activities, including with the private sector and academia.

\*February 1998. Administration announces its proposed food safety budget, which requests an approximate \$101 million increase for food safety initiatives.

\*May 1997. Administration announces comprehensive new initiative to improve the safety of nation's food supply --"Food Safety from Farm to Table" -- detailing a \$43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.

\*January 1997. President announces new Early-Warning System to gather critical scientific data to help stop foodborne disease outbreaks quickly and to improve prevention systems.

\*August 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like Cryptosporidium, and gives people the right to know about contaminants in their tap water.

\*August 1996. President signs Food Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.

\*July 1996. President announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent E.coli bacteria contamination in meat.

\*December 1995. Administration issues new rules to ensure seafood safety, utilizing HACCP regulatory programs to require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety assurance actions.

\*1994. CDC embarks on strategic program to detect, prevent, and control emerging infectious disease threats, some of which are foodborne, making significant progress toward this goal in each successive year.

\*1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.

**QUESTIONS AND ANSWERS ON PRESIDENT'S COUNCIL ON FOOD SAFETY**  
**August 24, 1998**

**Q: What did the Clinton Administration announce?**

**A:** The Clinton Administration announced: (1) an executive order creating a President's Council on Food Safety, which will develop a comprehensive strategic plan for federal food safety activities and ensure that federal agencies annually develop coordinated food safety budgets; and (2) a Presidential directive to the Council to review the National Academy of Sciences (NAS) report, "Ensuring Safe Food from Production to Consumption," and to report back with its response to the report, including appropriate additional actions to improve food safety.

**President's Council on Food Safety**

**Q: What will the President's Council on Food Safety do?**

**A:** The Council will have three primary functions, including: (1) developing a comprehensive strategic federal food safety plan; (2) advising agencies of priority areas for investment in food safety and ensuring that federal agencies annually develop coordinated food safety budgets; and (3) overseeing the recently established Joint Institute for Food Safety Research and ensuring that it addresses the highest priority research needs.

In addition, the Council, as one of its first orders of business, will review the National Academy of Sciences (NAS) report, "Ensuring Safe Food from Production to Consumption." After providing opportunity for public comment, including public meetings, the Council will report back to the President within 180 days with its response to the NAS report. The Council's report will consider appropriate additional actions to improve food safety, including proposals for legislative reform of the food safety system.

**Q: Why did the President create this Council? Is this a response to last week's NAS report advocating greater coordination in the food safety system?**

**A:** The President created the Council as the next logical step in his efforts to modernize and better coordinate federal food safety efforts. He wanted to ensure that all agencies in the federal government with responsibility for food safety issues follow a single food safety plan and develop coordinated budgets. In addition, the Council will provide a mechanism to review the NAS's proposals and determine whether any additional steps are appropriate.

**Q: The Executive Order creates a three-headed council when last week's NAS Report called for a single person to be in charge of food safety. Isn't that what's really**

**needed?**

**A:** The Executive Order creates the most effective mechanism possible, consistent with current law, to achieve coordination in the food safety system. Proposals for a single food safety czar, such as the one the NAS made, require legislation. The President has asked the new council to review that proposal to determine whether legislation of this kind is necessary. In the meantime, the President will take whatever executive action he can to achieve better integration and coordination of the food safety system.

**Q: How does the federal government already coordinate its food safety activities? Why is additional coordination necessary?**

**A:** The Clinton Administration already has taken significant strides toward building a coordinated food safety system. Most recently, the President announced the creation of the Joint Institute for Food Safety Research, which will develop a strategic plan for coordinating government and private food safety research activities. In addition, the Administration announced the Foodborne Outbreak Response Coordinating Group (FORC-G) which brings together federal, state, and local agencies to develop a comprehensive, coordinated, national foodborne illness response system.

What this proposal does is to ensure, for the first time ever, that the entire range of food safety activities and budgetary decisions is reviewed and coordinated by a single entity. Although we believe that we have achieved good coordination in the past, especially in light of the fragmented statutory framework, this new entity will make further progress in this area by insisting on a unified food safety policy and a coordinated food safety budget process.

**Q: Isn't this proposal essentially procedural in nature? Doesn't it just move the boxes around on an organizational chart, rather than giving anyone increased ability to do anything?**

**A:** Increasing integration and coordination among the various parts of the food safety system is vital to making sure food is safe -- just as important as providing needed budgetary resources or enforcement authority. Our food safety system is, by law, highly fragmented: for example, because of the way different foods are regulated by different agencies, the frozen pepperoni pizza you buy is regulated by two separate agencies. We must make sure that all these agencies are working together and pulling in the same direction. Today's executive order will serve just this crucial purpose.

**Q: Who are the members of the Council?**

**A:** The members of the Council are the Secretary of Agriculture, the Secretary of Health and Human Services, the Assistant to the President for Domestic Policy, the Director

of the National Partnership for Reinventing Government, the Assistant to the President for Science and Technology, the Administrator of the Environmental Protection Agency, the Secretary of Commerce, and the Director of the Office of Management and Budget. The Secretary of Agriculture, the Secretary of Health and Human Services, and the Assistant to the President for Science and Technology will serve as Joint Chairs of the Council.

### **NAS Report**

**Q: What Does the NAS report say?**

**A:** The National Academy of Sciences report, "Ensuring Safe Food From Production to Consumption," makes three basic conclusions: (1) an effective and efficient food safety system must be based on science; (2) the current statutes governing food safety should be revised in order to achieve a food safety system based on science; and (3) Congress should enact legislation to establish a unified and central framework for managing federal food safety programs, which should be headed by a single official with responsibility for all federal food safety activities.

**Q: Does the Administration agree with the NAS report?**

**A:** The Administration welcomes the opportunity to review the NAS report and believes that the report will play an important role in leading to further improvements. The Administration is encouraged that the NAS report supports many current Administration initiatives such as:

- new science-based systems to prevent contamination, including the Hazard Analysis and Critical Control Points (HACCP) system for inspections of meat, poultry, and seafood;
- a new science-based early warning system to help detect and respond to outbreaks of foodborne illness; and
- proposed legislation to ensure that the FDA halts imports of fruits, vegetables, and other food products that do not meet U.S. food safety requirements or come from countries that do not provide the same level of protection as is required for U.S. products.

The report's proposal to place a single official in charge of our food safety system, which would require new legislation, is well worth exploring. The President has asked the new Council to report back on this proposal and other ideas for improving the effectiveness of the food safety system within six months.

### **Food Safety Budget**

**Q: What did the President ask for in the FY 1999 Budget request with respect to food**

**safety?**

**A:** The FY 1999 Budget included a \$101 million increase over the FY 1998 level for the Administration's inter-agency food safety initiative. Of this total amount, \$25 million would finance FDA's improved capability to ensure the safety of imported foods and \$5 million would permit the Centers for Disease Control (CDC) to assist state health departments to detect foodborne diseases and to improve foodborne disease surveillance. Another \$24 million of the Initiative would go towards: developing rapid tests for the detection of pathogens; improving slaughter and processing systems to avoid contamination of food products; and establishing baseline data to better assess the risk of contamination in the US food supply. In addition, \$7.8 million would be used to expand consumer education initiatives, especially for high risk populations (the elderly and children).

**Q:** **What is the status of the Food Safety Initiative in the FY 1999 Appropriation bills?**

**A:** So far, Congress has failed to provide full funding of the Administration's food safety initiative. The Senate Appropriations Committee provided only about \$3 million for these efforts, but the full Senate voted by a large bipartisan majority for an amendment offered by Senator Harkin to provide an additional \$66 million. Senator Harkin's amendment required USDA's tobacco program administrative costs to be partially funded by the tobacco industry, and used the savings as the major offset for the cost of expanded food safety programs for both USDA and FDA. The House-passed Agriculture Appropriations bill would provide only \$16.8 million of the requested increase: \$7 million for FDA imported food safety and \$9.8 million for USDA activities. The Administration will continue to work with the conference committee members to urge them to provide full funding for the food safety initiative. The House Labor-HHS Appropriations Committee has approved the \$5 million food safety request for CDC.

**Q:** **Is all of the \$101 million that the President asked for necessary for food safety?**

**A:** Without additional funding for the Food Safety Initiative, the federal food safety agencies will not be able fully to develop appropriate response, prevention, and control strategies for reducing the level of food-borne illness in the United States.

In addition to the funding requested to strengthen FDA's import inspection and expand USDA's and FDA's research and education activities, funding is requested to continue to improve FDA's food safety infrastructure, as started in the FY 1998 Food Safety Initiative. Also, significant resources are targeted to strengthening both USDA's and FDA's risk assessment capabilities. Risk assessment is important in helping to identify foods and processes that are most likely to lead to food-borne illness. Finally, funding is requested to expand the USDA's and HHS's ability to identify and track food-borne illnesses.

## **Legislative Proposals**

**Q: What is Clinton Administration's FDA import legislation?**

**A:** The Administration called on Congress to pass food safety legislation, introduced by Senators Milkulski and Kennedy and Reps. Eshoo and Pallone, that gives the FDA greater authority over imported foods. This legislation will ensure that the FDA halts imports of fruits, vegetables, and other food products that do not meet U.S. food safety requirements or that come from countries that do not provide the same level of protection as is required for U.S. products. The legislation also enables the FDA to halt imports from a country or facility that refuses to allow FDA inspections. This legislation gives FDA authority that is similar to USDA's existing authority to prevent the importation of unsafe meat and poultry.

**Q: What is the Clinton Administration's USDA mandatory recall/civil penalties legislation?**

**A:** The Clinton Administration called on Congress to pass the Food Safety Enforcement Enhancement Act, sponsored by Senators Harkin, Daschle, Johnson, and Leahy, which gives USDA the ability to assess civil fines and to order mandatory recalls of unsafe meat and poultry products. Currently, the USDA can respond to food safety violations only by bringing criminal actions or withdrawing inspections; all recalls are done on a voluntary basis and no civil penalties are available. This new legislation will give USDA additional enforcement tools to enhance food safety.

**Q: Aren't these legislative proposals essentially dead? Has Congress moved on them at all?**

**A:** These proposals are not dead. The Administration is working with members to try to get these vital pieces of legislation passed and expects the Congressional sponsors of these measures to raise the bills on the House and Senate floors.

THE WHITE HOUSE

Office of the Press Secretary  
(Martha's Vineyard, Massachusetts)

For Immediate Release

August 25, 1998

August 25, 1998

MEMORANDUM FOR THE PRESIDENT'S COUNCIL ON FOOD SAFETY

SUBJECT: National Academy of Sciences Report

My Administration is committed to ensuring that the American people enjoy the safest food possible. We have made great progress by implementing science-based prevention control systems for seafood, meat, and poultry; developing a comprehensive initiative to ensure the safety of domestic and imported fruits and vegetables; and launching an interagency food safety initiative that focuses on key food safety issues from the farm to the table. We can and must continue to build upon these efforts.

Under our current food safety system, several different Federal agencies have responsibility for improving food safety. Within the framework of our interagency initiative, we have taken a number of steps to improve the coordination of our food safety efforts. Most recently, we established a Joint Institute for Food Safety Research to develop a strategic plan for conducting food safety research activities and to coordinate all Federal food safety research, including with the private sector and academia.

Today, I signed an Executive Order establishing the President's Council on Food Safety. To strengthen and focus our efforts to coordinate food safety policy and resources and improve food safety for American consumers, the Council will develop a comprehensive strategic plan for Federal food safety activities, ensure the most effective use of Federal resources through the development and submission of coordinated food safety budgets, and oversee the Joint Institute for Food Safety Research.

The National Academy of Sciences (NAS) recently issued a thoughtful and highly informative report on food safety issues, entitled "Ensuring Safe Food from Production to Consumption." This report recommends additional ways to enhance coordination and improve effectiveness in the food safety system, including through reform of current food safety legislation.

I hereby direct the Council to review and respond to this report as one of its first orders of business. After providing opportunity for public comment, including public meetings, the Council shall report back to me within 180 days with its views on the NAS's recommendations. In developing this report, the Council should take into account the comprehensive strategic Federal food safety plan that it will be developing.

I thank the Council for its efforts to improve food safety, and I look forward to the continued leadership of the President's Council on Food Safety.

WILLIAM J. CLINTON

# # #

THE WHITE HOUSE

Office of the Press Secretary  
(Martha's Vineyard, Massachusetts)

For Immediate Release

August 25, 1998

EXECUTIVE ORDER

PRESIDENT'S COUNCIL ON FOOD SAFETY

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs, it is hereby ordered as follows:

Section 1. Establishment of President's Council on Food Safety. (a) There is established the President's Council on Food Safety ("Council"). The Council shall comprise the Secretaries of Agriculture, Commerce, Health and Human Services, the Director of the Office of Management and Budget (OMB), the Administrator of the Environmental Protection Agency, the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy, the Assistant to the President for Domestic Policy, and the Director of the National Partnership for Reinventing Government. The Council shall consult with other Federal agencies and State, local, and tribal government agencies, and consumer, producer, scientific, and industry groups, as appropriate.

(b) The Secretaries of Agriculture and of Health and Human Services and the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy shall serve as Joint Chairs of the Council.

Sec. 2. Purpose. The purpose of the Council shall be to develop a comprehensive strategic plan for Federal food safety activities, taking into consideration the findings and recommendations of the National Academy of Sciences report "Ensuring Safe Food from Production to Consumption" and other input from the public on how to improve the effectiveness of the current food safety system. The Council shall make recommendations to the President on how to advance Federal efforts to implement a comprehensive science-based strategy to improve the safety of the food supply and to enhance coordination among Federal agencies, State, local, and tribal governments, and the private sector. The Council shall advise Federal agencies in setting priority areas for investment in food safety.

Sec. 3. Specific Activities and Functions. (a) The Council shall develop a comprehensive strategic Federal food safety plan that contains specific recommendations on needed changes, including measurable outcome goals. The principal goal of the plan should be the establishment of a seamless, science-based food safety system. The plan should address the steps necessary to achieve this goal, including the key public health, resource, and management issues regarding food safety. The planning process should consider both short-term and long-term issues including new and emerging threats and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council shall consult with all interested parties, including State and local agencies, tribes, consumers, producers, industry, and academia.

more

(OVER)

(b) Consistent with the comprehensive strategic Federal food safety plan described in section 3(a) of this order, the Council shall advise agencies of priority areas for investment in food safety and ensure that Federal agencies annually develop coordinated food safety budgets for submission to the OMB that sustain and strengthen existing capacities, eliminate duplication, and ensure the most effective use of resources for improving food safety. The Council shall also ensure that Federal agencies annually develop a unified budget for submission to the OMB for the President's Food Safety Initiative and such other food safety issues as the Council determines appropriate.

© The Council shall ensure that the Joint Institute for Food Safety Research (JIFSR), in consultation with the National Science and Technology Council, establishes mechanisms to guide Federal research efforts toward the highest priority food safety needs. The JIFSR shall report to the Council on a regular basis on its efforts: (i) to develop a strategic plan for conducting food safety research activities consistent with the President's Food Safety Initiative and such other food safety activities as the JIFSR determines appropriate; and (ii) to coordinate efficiently, within the executive branch and with the private sector and academia, all Federal food safety research.

Sec. 4. Cooperation. All actions taken by the Council shall, as appropriate, promote partnerships and cooperation with States, tribes, and other public and private sector efforts wherever possible to improve the safety of the food supply.

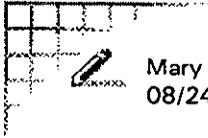
Sec. 5. General Provisions. This order is intended only to improve the internal management of the executive branch and is not intended to, nor does it, create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers or any person. Nothing in this order shall affect or alter the statutory responsibilities of any Federal agency charged with food safety responsibilities.

WILLIAM J. CLINTON

THE WHITE HOUSE,  
August 25, 1998.

###

case pro - first safety -  
single agency



Mary L. Smith  
08/24/98 04:24:07 PM

Record Type: Record

To: Elena Kagan/OPD/EOP  
cc: Laura Emmett/WHO/EOP  
Subject: Caroline Smith DeWaal

I just got off the phone with Caroline Smith DeWaal -- the NY Times had already called her and so she called me. I told her about the change in the co-chairs, and she was a little apprehensive. I told her that it would be a strong group, but she thought that this was a weaker configuration. She is not familiar with OSTP. I tried to allay her concerns and I think I made some headway by emphasizing that for the first time that the planning and budget processes will be coordinated; however, I think she is still a little concerned because she is not familiar with OSTP. I emphasized the legislation, etc. and it seemed to help a little.

Cons pro - food safety -  
single agency

## SAFE FOOD COALITION

888 Seventeenth Street, NW, Suite 800, Washington, DC 20006 (202) 822-8060

FOR IMMEDIATE RELEASE  
AUGUST 25, 1998

CONTACT: Christopher Gould  
202/822-8060

### SAFE FOOD COALITION PRAISES ADMINISTRATION'S FOOD SAFETY COUNCIL; CALLS FOR CONGRESS TO ACT

(WASHINGTON) The Safe Food Coalition today praised the Clinton Administration for its decision to create a President's Council on Food Safety and urged Congress to act on recommendations by the National Academy of Sciences (NAS) to designate a single federal official with responsibility for federal food safety activities.

"The Clinton Administration has done an excellent job in raising the public policy profile of food safety issues," said Carol Tucker Foreman, Coordinator of the Safe Food Coalition and former Assistant Secretary of Agriculture for Food and Consumer Services. "The food safety council will help improve coordination even more."

Last week, the NAS released a report which recommended revising current food safety statutes so that they are uniformly driven by scientific estimates of risk to human health. Among other recommendations, the report called for designating a single federal official with both responsibility for federal food safety activities and authority to allocate resources based on risk to human health. The Safe Food Coalition has long endorsed the creation of a single food safety agency.

"The creation of the council is a productive step toward improving the safety of America's food supply," said Foreman. "It can take steps to coordinate the use of existing resources. However, most of the recommendations made by the Committee to Ensure the Safety of Food from Production to Consumption require congressional action. The Committee was established at the direction of Congress. Now the Committee has given Congress a clear and appropriate set of steps that must be taken to address foodborne illness. Congress should act on those recommendations immediately. We expect that the President Council on Food Safety will encourage and provide leadership for the additional steps that must be taken."

- 30 -

The Safe Food Coalition is a group of consumer, public health, senior citizen and labor organizations that have worked together since 1986 to improve the nation's food safety system. The organization was instrumental in persuading the federal government to revise the hundred year old meat and poultry inspection system.

# SAFE FOOD COALITION

888 Seventeenth Street, NW, Suite 800, Washington, DC 20006 (202) 822-8060

EMBARGOED FOR 12:00 NOON  
AUGUST 20, 1998

CONTACT: Christopher Gould  
202/822-8060

## SAFE FOOD COALITION PRAISES NATIONAL ACADEMY OF SCIENCES REPORT *Urges Congress to Act on Recommendation to Designate a Single Federal Official with Responsibility for Federal Food Safety Activities*

(WASHINGTON, Aug. 20, 1998) The Safe Food Coalition today praised the National Academy of Sciences (NAS) report, *Ensuring Safe Food from Production to Consumption*, and urged Congress to take the steps recommended by the committee to improve the safety of the nation's food supply. Following is a statement regarding the NAS report by Carol Tucker Foreman, coordinator of the Safe Food Coalition and former Assistant Secretary of Agriculture for Food and Consumer Services:

"The National Academy of Sciences has conducted its study as directed by Congress. Its recommendations are clear and appropriate, and mostly require congressional action. The committee has done an admirable job in a very short period of time -- they've told Congress what it must do to reduce food-borne illness. Now Congress must act.

"Every American who has suffered from food poisoning or knows someone who has -- and every mother who has nursed a sick child through a bout of *salmonella* or *E. coli* O157:H7 poisoning -- should demand that Congress act immediately to institute the changes that are needed to improve food safety. The most important of those changes recommended by the committee are:

- Revise current food safety statutes so that they are uniformly driven by scientific estimates of risk to human health;
- Establish by statute a unified and central framework for managing federal food safety programs, headed by a single federal official who has both authority and control of resources necessary to manage food safety efforts; and
- Allocate the necessary resources to carry out the programs vital to protecting public health.

- more -

**"The Safe Food Coalition has earlier endorsed creation of a single food safety agency. Creation of such an agency is the most organizationally effective method for achieving the NAS recommendations.**

**"Congress can respond to the NAS report this year by adding language to the FY 1999 Agricultural Appropriations Committee Report establishing a committee to explore the details of establishing an appropriate structure and advising the President and Congress on language necessary to change existing food safety laws to respond to the NAS Committee's report.**

**"In addition, Congress should act this year to pass the Clinton Administration's proposals to improve the safety of imported fruits and vegetables and to institute improved enforcement authority, including recall of contaminated meat and poultry and institution of civil penalties in meat and poultry processing."**

- 30 -

**The Safe Food Coalition is a group of consumer, public health, senior citizen and labor organizations that have worked together since 1986 to improve the nation's food safety system. The organization was instrumental in persuading the federal government to revise the hundred year old meat and poultry inspection system.**

cons pro - food safety -  
single agency

## THE CLINTON/GORE ADMINISTRATION: WORKING TO ENSURE BETTER FOOD SAFETY

August 25, 1998

*"Today, I signed an Executive Order establishing the President's Council on Food Safety. To strengthen and focus our efforts to coordinate food safety policy and resources and improve food safety for American consumers, the Council will develop a comprehensive strategic plan for Federal food safety activities, ensure the most effective use of Federal resources through the development and submission of coordinated food safety budgets, and oversee the Joint Institute for Food Safety Research."*

President Bill Clinton  
August 25, 1998

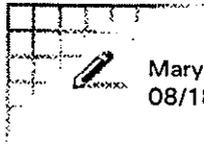
Today, President Clinton signs an Executive Order creating a President's Council on Food Safety. The Council will develop a comprehensive strategic plan for federal food safety activities and ensure that federal agencies annually develop coordinated food safety budgets. The President will also sign a directive instructing the Council to review the recently issued National Academy of Sciences (NAS) report, "Ensuring Safe Food from Production to Consumption," and to report back with its response to the report, including appropriate additional actions to improve food safety.

**THE PRESIDENT'S COUNCIL ON FOOD SAFETY.** The President will sign an Executive Order establishing a President's Council on Food Safety. The Council will have three primary functions, including:

- **Developing A Comprehensive Strategic Federal Food Safety Plan.** The Council will develop a comprehensive plan to improve the safety of the nation's food supply by establishing a seamless, science-based food safety system. The plan will address the steps necessary to achieve this improved system, focusing on key public health, resource, and management issues and including measurable outcome goals. The planning process will consider both short and long-term issues including new and emerging threats and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council will consult with all interested parties, including state and local agencies, tribes, consumers, producers, industry, and academia.
- **Coordinating Federal Food Safety Budgets.** Consistent with the comprehensive strategic federal food safety plan, the Council will advise agencies of priority areas for investment in food safety and ensure that federal agencies annually develop coordinated food safety budgets. This coordinated food safety budget process will sustain and strengthen existing activities, eliminate duplication, and ensure the most effective use of resources for improving food safety.
- **Overseeing Federal Food Safety Research Efforts.** The Council will ensure that the Joint Institute for Food Safety Research addresses the highest priority food safety research gaps. The Institute will report, on a regular basis, to the Council on its efforts to conduct and coordinate food safety research activities and will receive direction from the Council on research needed to establish the most effective possible food safety system.

**PROPOSING REFORMS TO THE FOOD SAFETY SYSTEM.** The President will direct the Council, as one of its first orders of business, to review the National Academy of Sciences (NAS) report, "Ensuring Safe Food from Production to Consumption." After providing opportunity for public comment, including public meetings, the Council will report back to the President within 180 days with its response to the NAS report. The Council's report will consider appropriate additional actions to improve food safety, including proposals for legislative reform of the food safety system.

Food safety - single agency



Mary L. Smith  
08/18/98 05:31:02 PM

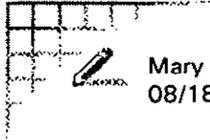
Record Type: Record

To: Elena Kagan/OPD/EOP  
cc: Laura Emmett/WHO/EOP  
Subject: What's in the NAS study

The Hill was briefed on the NAS study yesterday. This is what they say is in the report:

1. Food safety should be based on science
2. The statutes governing food safety need to be modified (although there was no specific recommendation for how this should be done)
3. There needs to be some central framework for dealing with food safety -- this can be done in one of the following three ways:
  - a. a food safety czar
  - b. designate one of the agencies as the lead agency
  - c. create a new food safety agency

Food safety -  
single agency



Mary L. Smith  
08/18/98 12:19:50 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Thomas L. Freedman/OPD/EOP  
cc: Laura Emmett/WHO/EOP  
Subject: Consumer groups re: WH membership on Council

I've talked to two of the groups (Caroline Smith DeWaal from Center for Science and the Public Interest and Heather from Safe Tables Our Priority), and they both say they would prefer that the WH be on the Council because they think the agencies are too much wedded to the status quo. Heather said that in the past the agencies were not particularly forward looking (particularly when they were implementing HACCP). Caroline was particularly adamant that WH participation be on the Council because if WH weren't on the Council, it would send a message to the consumer groups that we were sticking with the status quo. In addition, she was concerned with deadlock between USDA and HHS.

I am still trying to reach Carol Tucker Forman from the Food Safety Coalition. I will send you the latest draft of the executive order in a few minutes.

CSPI pro - food safety -  
single agency

**CSPI** CENTER  
FOR SCIENCE  
IN THE  
PUBLIC INTEREST

Publisher of **Nutrition Action Healthletter**

Contact: Caroline Smith DeWaal; (202) 332-9110, ext. 366  
Penelope Miller; (202) 332-9110, ext. 358

## **Food Safety Council Should Be A Vehicle, Not a Roadblock, to Reform**

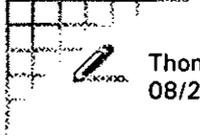
Statement of Caroline Smith DeWaal  
Director of Food Safety  
on the Creation of the President's Council on Food Safety  
August 25, 1998

*Today, the Clinton Administration announced the appointment of an eight-person council to develop a comprehensive, strategic federal food-safety plan and to coordinate the federal food-safety budgets.*

The President's Council on Food Safety represents an important improvement of the existing food-safety system where 12 agencies independently implement over 35 separate laws. However, the council falls short of the changes recommended by the National Academy of Sciences, which called for the appointment of a single person with both the legal authority and budgetary control over food safety.

The council should be a vehicle -- not a roadblock -- in the movement toward a single food-safety agency. It will require close oversight from the White House to ensure that the council doesn't simply rubber stamp the current ineffective system.

cuspro - food safety -  
single agency



Thomas L. Freedman  
08/26/98 11:24:05 AM

Record Type: Record

To: Elena Kagan/OPD/EOP, Bruce N. Reed/OPD/EOP, Mary L. Smith/OPD/EOP  
cc: Laura Emmett/WHO/EOP  
Subject: Re[2]: Thank you

fyi.

----- Forwarded by Thomas L. Freedman/OPD/EOP on 08/26/98 11:23 AM -----



cdewaal @ cspinet.org  
08/26/98 12:09:44 PM

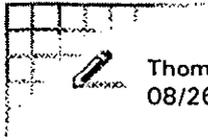
Record Type: Record

To: Thomas L. Freedman/OPD/EOP  
cc:  
Subject: Re[2]: Thank you

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Hi again. Thanks for your call. I talked to the Reuters reporter and will be talking to an editor shortly. She admitted that I did say positive things in the first part of my remarks to her and that she saw my statement later in the day. I will be writing a letter to the editor of the Washington Times to correct our position and will see if Reuters can do something to help me get it corrected in other papers that ran the story. I hope this helps to clarify the inconsistency.

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single agency



Thomas L. Freedman  
08/26/98 10:59:19 AM

Record Type: Record

To: Elena Kagan/OPD/EOP, Bruce N. Reed/OPD/EOP  
cc: Mary L. Smith/OPD/EOP, Laura Emmett/WHO/EOP  
Subject: Food Stories

The food council got mentions on CBS and CNN. The stories in USA Today, WP, and WT were ok, they got our headline out. I was disappointed, though, by Caroline Smith Dewall's quotes in the papers today. FYI. I called her and made several points: that this is not consistent with what she has said (she had sent me an email saying "thank you, thank you, thank you, thank you"), and that it hurts the issue internally. She said: she was unhappy with the way she was quoted and was writing a letter to WT, but doesn't feel confident about OSTP.

EXECUTIVE ORDER

**DRAFT**

-----  
PRESIDENT'S COUNCIL ON FOOD SAFETY

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs, it is hereby ordered as follows:

Section 1. Establishment of President's Council on Food Safety. (a) There is established the President's Council on Food Safety ("Council"). The Council shall comprise the Secretaries of Agriculture, Commerce, Health and Human Services, the Director of the Office of Management and Budget (OMB), the Administrator of the Environmental Protection Agency, the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy, the Assistant to the President for Domestic Policy, and the Director of the National Partnership for Reinventing Government. The Council shall consult with other Federal agencies and State, local, and tribal government agencies, and consumer, producer, scientific, and industry groups, as appropriate.

(b) The Secretaries of Agriculture and of Health and Human Services and the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy shall serve as Joint Chairs of the Council.

Sec. 2. Purpose. The purpose of the Council shall be to develop a comprehensive strategic plan for Federal food safety activities, taking into consideration the findings and recommendations of the National Academy of Sciences report "Ensuring Safe Food from Production to Consumption" and other input from the public on how to improve the effectiveness of the current food safety system. The Council shall make recommendations to the President on how to advance Federal

efforts to implement a comprehensive science-based strategy to improve the safety of the food supply and to enhance coordination among Federal agencies, State, local, and tribal governments, and the private sector. The Council shall advise Federal agencies in setting priority areas for investment in food safety.

Sec. 3. Specific Activities and Functions. (a) The Council shall develop a comprehensive strategic Federal food safety plan that contains specific recommendations on needed changes, including measurable outcome goals. The principal goal of the plan should be the establishment of a seamless, science-based food safety system. The plan should address the steps necessary to achieve this goal, including the key public health, resource, and management issues regarding food safety. The planning process should consider both short-term and long-term issues including new and emerging threats and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council shall consult with all interested parties, including State and local agencies, tribes, consumers, producers, industry, and academia.

(b) Consistent with the comprehensive strategic Federal food safety plan described in section 3(a) of this order, the Council shall advise agencies of priority areas for investment in food safety and ensure that Federal agencies annually develop coordinated food safety budgets for submission to the OMB that sustain and strengthen existing capacities, eliminate duplication, and ensure the most effective use of resources for improving food safety. The Council shall also ensure that Federal agencies annually develop a unified budget for submission to the OMB for the President's Food Safety Initiative and such other food safety issues as the Council determines appropriate.

(c) The Council shall ensure that the Joint Institute for Food Safety Research (JIFSR), in consultation with the National Science and Technology Council, establishes mechanisms to guide

Federal research efforts toward the highest priority food safety needs. The JIFSR shall report to the Council on a regular basis on its efforts: (i) to develop a strategic plan for conducting food safety research activities consistent with the President's Food Safety Initiative and such other food safety activities as the JIFSR determines appropriate; and (ii) to coordinate efficiently, within the executive branch and with the private sector and academia, all Federal food safety research.

Sec. 4. Cooperation. All actions taken by the Council shall, as appropriate, promote partnerships and cooperation with States, tribes, and other public and private sector efforts wherever possible to improve the safety of the food supply.

Sec. 5. General Provisions. This order is intended only to improve the internal management of the executive branch and is not intended to, nor does it, create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers or any person. Nothing in this order shall affect or alter the statutory responsibilities of any Federal agency charged with food safety responsibilities.

THE WHITE HOUSE,

THE WHITE HOUSE  
WASHINGTON

**DRAFT**

MEMORANDUM FOR THE PRESIDENT'S COUNCIL ON FOOD SAFETY

SUBJECT: National Academy of Sciences Report

My Administration is committed to ensuring that the American people enjoy the safest food possible. We have made great progress by implementing science-based prevention control systems for seafood, meat, and poultry; developing a comprehensive initiative to ensure the safety of domestic and imported fruits and vegetables; and launching an interagency food safety initiative that focuses on key food safety issues from the farm to the table. We can and must continue to build upon these efforts.

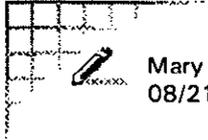
Under our current food safety system, several different agencies have responsibility for improving food safety. Within the framework of our interagency initiative, we have taken a number of steps to improve the coordination of our food safety efforts. Most recently, we established a Joint Institute for Food Safety Research to develop a strategic plan for conducting food safety research activities and to coordinate all Federal food safety research, including with the private sector and academia.

Today, I signed an Executive Order establishing the President's Council on Food Safety. To strengthen and focus our efforts to coordinate food safety policy and resources and improve food safety for American consumers, the Council will develop a comprehensive strategic plan for Federal food safety activities, ensure the most effective use of Federal resources through the development and submission of coordinated food safety budgets, and oversee the Joint Institute for Food Safety Research.

The National Academy of Sciences (NAS) recently issued a thoughtful and highly informative report on food safety issues, entitled "Ensuring Safe Food from Production to Consumption." This report recommends additional ways to enhance coordination and improve effectiveness in the food safety system, including through reform of current food safety legislation.

I hereby direct the Council to review and respond to this report as one of its first orders of business. After providing opportunity for public comment, including public meetings, the Council shall report back to me within 180 days with its views on the NAS's recommendations. In developing this report, the Council should take into account the comprehensive strategic Federal food safety plan that it will be developing.

I thank the Council for its efforts to improve food safety, and I look forward to the continued leadership of the President's Council on Food Safety.



Mary L. Smith  
08/21/98 11:45:08 AM

Record Type: Record

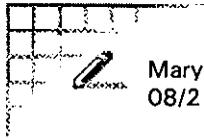
To: Tracey E. Thornton/WHO/EOP  
cc: Elena Kagan/OPD/EOP  
Subject: President's Council on Food Safety

I just touched base with Roger McClung from HHS regarding who we should call. This is his list for both FDA and HHS:

Senate  
Kennedy  
Jeffords  
Collins  
Frist  
Milkulski

House  
Bliley  
Bilirakis  
Sherrod Brown  
Dingell  
Eshoo  
Pallone

Cum p/w - food safety -  
single agency



Mary L. Smith  
08/21/98 09:59:43 AM

Record Type: Record

To: Tracey E. Thornton/WHO/EOP  
cc: Elena Kagan/OPD/EOP  
Subject: President's Council on Food Safety -- possible Hill calls



FOODA081.0 FOODQ082.0 Elena asked me to send you some information about a possible leak of a President's Council for Food Safety on Monday. This Council would prepare a comprehensive strategic plan on food safety, coordinate the budget process (but, not in anyway, change the appropriations process), and review a recent National Academy of Sciences study that recommends that there be a single federal person in charge of food safety and that the federal food safety statutes need to be changed and streamlined.

Attached is draft paper. However, it is only draft and there is still an open question about who would co-chair the Council -- this issue has not yet been resolved.

In terms of Hill outreach, we haven't made any calls yet. Dave Carlin at USDA suggests that the five key persons to call would be:

- Durbin
- Daschle
- Harkin
- Fazio
- Stenholm

There may be a few others, but these are the key five per USDA. Dave is happy to make the calls, but let me know how you want to handle this and whether there is anything else you think we should be doing. Thanks, Mary

*Cons pro - food safety - single agency*

**DEPARTMENT OF AGRICULTURE**

**Food Safety and Inspection Service**

[Docket No. 98-045N]

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Food and Drug Administration**

[Docket No. 97N-0074]

**ENVIRONMENTAL PROTECTION AGENCY**

[Docket No. OPP-00550; FRL-6019-9]

**President's National Food Safety Initiative**

**AGENCY:** Food Safety and Inspection Service, USDA; Research, Education, and Economics, USDA; Centers for Disease Control and Prevention, HHS; Food and Drug Administration, HHS; Environmental Protection Agency.

**ACTION:** Notice: public meeting; establishment of public dockets.

**SUMMARY:** The United States Department of Agriculture (USDA), the Department of Health and Human Services (HHS), and the Environmental Protection Agency (EPA) are announcing a public meeting to discuss and begin development of a comprehensive strategic Federal food safety plan. The purpose of the strategic plan is to reduce the annual incidence of acute and chronic foodborne and waterborne illness by further enhancing the safety of the nation's food supply. USDA, the Food and Drug Administration (FDA), and EPA are also establishing public dockets to receive comments about the Food Safety Initiative's strategic planning process and the plan.

**DATES:** The meeting will be held on October 2, 1998, from 9:30 a.m. to 3 p.m. Comments should be submitted by [insert date 90 days after date of publication in the **Federal Register**].

**ADDRESSES:** The meeting will be held at: National Rural Electric Cooperative Association, 4301 Wilson Boulevard, Arlington, VA.

For instructions on the submission of written and electronic comments, refer to Unit II. of this document.

**FOR FURTHER INFORMATION CONTACT:** To register for the meeting, contact Ms. Traci Phebus, of USDA, at (202) 501-7136, fax: (202) 501-7642, e-mail: [foodsafetymeeting@usda.gov](mailto:foodsafetymeeting@usda.gov). Participants may reserve time for public comments when they register. Space will be allocated on a first come, first served basis. Participants are encouraged to submit a disk along with their written statements in Wordperfect 5.1/6.1 or ASCII file format.

*Alena,  
Here is the  
Federal Register  
notice that  
the president  
will announce  
with the  
exec order.  
Mary*

Questions regarding general arrangements and logistical matters should be addressed to Ms. Torrie Mattes. Additionally, participants who require a sign language interpreter or other special accommodations should contact Ms. Torrie Mattes, of USDA, no later than 10 days prior to the meeting, at (202) 501-7136, fax: 202-501-7642, e-mail: T.Mattes@usda.gov.

For questions about the meeting or to obtain copies of the report, "Food Safety From Farm to Table: A National Food Safety Initiative," contact Ms. Karen Carson, of FDA, at (202) 205-5140, fax: (202) 205-5025, e-mail: kcarson@Bangate.fda.gov. Copies of the report also are available from the following web sites:

FDA at <http://www.cfsan.fda.gov/~dms/fsreport.html>

CDC at <http://www.cdc.gov/ncidod/foodsafety/report.htm>

EPA at <http://www.epa.gov/opptsfrs/home/nfssuppt.htm>

Food Safety and Inspection Service (FSIS) at <http://www.fsis.usda.gov>

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

On January 25, 1997, the President issued a directive to the Secretaries of USDA and HHS and the Administrator of EPA to work with consumers, producers, industry, States, Tribes, universities, and the public to identify ways to further improve the safety of our food supply, and to report back to him in 90 days. The Federal food safety agencies, working with their colleagues in the States, in the food industries, in academia, and with consumers, initially focused on the goal of reducing illness caused by microbial contamination of food and water. This goal was to be reached through systematic improvements in six key components of the food safety system: foodborne outbreak response coordination, surveillance, inspections, research, risk assessment, and education. The plan for meeting this goal was presented to the President in May 1997, in "Food Safety From Farm to Table: A National Food Safety Initiative." In October 1997, the President issued an additional directive to ensure the safety of domestic and imported fresh produce and other imported foods. This second directive was incorporated into the National Food Safety Initiative (NFSI).

In less than 2 years, the agencies have taken significant strides forward in building a strengthened national food safety system. Building blocks for the infrastructure are in place: increased and targeted surveillance through FoodNet and PulseNet; coordination of Federal, State and local responses to outbreaks by the Foodborne Outbreak Response Coordinating Group (FORCG); expanded reliance on preventive controls (such as the Hazard Analysis and Critical Control Points (HACCP) based inspection systems for meat, poultry and seafood, and Good Agricultural and Good Manufacturing Practices guidance for produce); coordination of Federal food safety research; cooperation on risk assessment through the interagency Risk Assessment Consortium; leveraging inspection resources; and innovative public/private education partnerships. These efforts provide a common ground for moving forward.

In the May 1997 report, the food safety agencies made a commitment to prepare a 5-year comprehensive strategic plan, with the participation of all concerned parties. The President recently issued an Executive Order establishing a President's Food Safety Council which will now be responsible for development of a comprehensive strategic Federal food safety plan. A coordinated food safety strategic planning effort is needed to build on the common ground, and to tackle some of the difficult public health, resource, and management questions facing Federal food safety agencies. The strategic plan will focus on not just microbial contamination, but the full range of issues and actions necessary to ensure the safety of the food and water Americans use and consume. The charge is to develop a strategic long-range plan that can be used to help set priorities, improve coordination and efficiency, identify gaps in the current system and how to fill those gaps, enhance and strengthen prevention and intervention strategies, and identify measures to show progress. In developing the plan, the agencies will consider the conclusions and recommendations of the National Academy of Sciences' report on "Ensuring Safe Food from Production to Consumption" and the review of Federal food safety research and the research plan currently being developed by an interagency working group under the auspices of the National Science and Technology Council.

The food safety agencies have already taken the first steps to lay the groundwork for development of the strategic plan, which the Council will now develop, by participating in interagency strategic planning sessions. The result is the following draft statement encompassing the agencies' vision for the U.S. food safety system and the roles of all those involved in food safety.

Consumers can be confident that food is safe, healthy, and affordable. We work within a seamless food safety system that uses farm-to-table preventive strategies and integrated research, surveillance, inspection, and enforcement. We are vigilant to new and emergent threats and consider the needs of vulnerable populations. We use science- and risk-based approaches along with public/private partnerships. Food is safe because everyone understands and accepts their responsibilities.

The next step is to engage consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process, beginning with a discussion of the draft vision statement and how to structure a strategic planning process that involves all interested parties and best addresses the important food safety challenges and makes the best use of the agencies' limited resources. This October 2nd meeting is the first of several public meetings to assist with development of a long-term strategic plan. Additional public meetings will be announced in the **Federal Register** prior to the date of each meeting.

The purpose of the October 2nd meeting is to obtain the public's view on a long-term vision for food safety in the U.S. and to identify a strategic planning process, goals, and critical steps as well as potential barriers to achieving that vision. The Council is interested in comments on the draft vision statement and suggestions for goals and how they might be achieved. Some questions to help frame the discussion follow.

1. Does the vision statement accurately depict an achievable food safety system vision? What modifications, if any, would you make?
2. What are the barriers to pursuing this vision? What gaps currently exist in the food safety system that impede achievement of this vision?
3. To make the vision a reality, what changes are needed for: (a) government agencies at the Federal, State, and local level; (b) industry; (c) public health professionals; (d) consumers; and (e) others?
4. What should be the short-term goals and critical steps to realize this vision? What should be the long-term goals and steps?
5. What is the best way to involve the public in development of a long-term food safety strategic plan? What additional steps besides public meetings would be beneficial?

## **II. Public Dockets and Submission of Comments**

The agencies are announcing the establishment of public dockets about the Food Safety Initiative Strategic Plan. Comments submitted to the dockets are to be identified with the appropriate docket number. For those comments directed to USDA, use Docket No. 98-045N, and for comments directed to FDA, use Docket No. 97N-0074. Commenters are encouraged to submit a disk along with their written comments in Wordperfect 5.1/6.1 or ASCII file format. Submit written comments (in triplicate) to:

### *USDA/FSIS*

USDA/FSIS Hearing Clerk, 300 12th St., SW., Rm. 102 Cotton Annex,  
Washington, DC 20250-3700

### *FDA*

Dockets Management Branch (HFA-305), Food and Drug Administration,  
12420 Parklawn Drive, Rm. 1-23, Rockville, MD 20857

### *Electronic Comments*

Comments may also be submitted electronically to:  
[oppts.homepage@epa.gov](mailto:oppts.homepage@epa.gov). All comments and data in electronic form must be identified by the docket number "OPP-00550." Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

*Transcripts*

Transcripts of the public meetings may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, Rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcripts of the public meetings will be available for public examination at the FDA Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, excluding legal holidays. Transcripts of the meetings will also be available on the internet at: <http://www.fda.gov/ohrms/dockets/default.htm> and <http://www.epa.gov/opptsfrs/home/nfssuppt.htm>.

*Electronic Docket*

The public docket in its entirety will be available on the internet at: <http://www.epa.gov/opptsfrs/home/rules.htm#docket>.

**List of Subjects**

Environmental protection, Food safety.

Dated: \_\_\_\_\_

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**Catherine E. Woteki,**  
*Undersecretary for Food Safety, United States Department of Agriculture.*

Dated: \_\_\_\_\_

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**James O'Hara,**  
*Deputy Assistant Secretary for Health, Department of Health and Human Services.*

Dated: \_\_\_\_\_

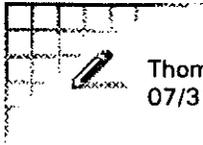
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**Lynn R. Goldman,**  
*Assistant Administrator for Prevention, Pesticides and Toxic Substances, Environmental Protection Agency.*

[FR Doc. 98-???? Filed ?-?-98; 8:45 am]

**BILLING CODE 6560-50-F**

class pres - food safety -  
single agency



Thomas L. Freedman  
07/31/98 01:12:52 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Michelle Crisci/WHO/EOP  
cc: Laura Emmett/WHO/EOP, Mary L. Smith/OPD/EOP  
Subject: NAS report on single food agency and Exec. Order



**FOODSAFE.7** Attached is a draft executive order establishing a Food Safety Council. The Council consists of the Secretaries of USDA, HHS, the DPC, and OSTP. HHS and USDA co-chair and they would appoint an exec. director. It is charged with developing a unified food safety budget, a unified food safety strategy, reviewing the NAS report and making recommendations, and overseeing the research institute. We have discussed this concept (but not the actual paper) with USDA and FDA, some people in each agency have reservations about it, and would likely prefer not to preempt NAS, but to instead wait and see what it says and what reaction it gets. OMB will also have concerns and will want time to vet it. If you are interested in circulating it, I have some thoughts on how to process it.

#### Other Information

The NAS report: According to sources, it is still on target for release August 17. It is still said to be critical of the current structure of food safety and includes criticism of food safety planning, budget and standard setting. It reportedly suggests action on dietary supplements, critiques current epidemiology, and criticizes the mixing of missions of promoting food and regulating it. It also cites specific recent examples including Guatemalan raspberries and the salmonella in cereal.

#### Other Steps.

We've asked the agencies to come up with other steps that could be announced independently or in conjunction with the above announcement. Here is what they suggest.

1. Eggs. The agencies say they could be ready to announce the shifting of responsibility for eggs to USDA, previously it was split between FDA and USDA.
2. Achievements. The agencies have prepared a list of areas in which they do cooperate successfully.
3. Vision statement and public hearings. The agencies have a shared "vision statement" on creating a "seamless food safety system" that they would put in the federal register and hold public hearings on.

(I'll be at the sports medicine doctor for part of this afternoon, but back later).

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**QUESTIONS AND ANSWERS ON NATIONAL  
ACADEMY OF SCIENCES STUDY  
August 20, 1998**

**Q: What Does the NAS report say?**

**A:** The National Academy of Sciences report, "Ensuring Safe Food From Production to Consumption," makes three basic conclusions: (1) an effective and efficient food safety system must be based on science; (2) the current statutes governing food safety should be revised in order to achieve a food safety system based on science; and (3) Congress should enact legislation to establish a unified and central framework for managing federal food safety programs, which should be headed by a single official with responsibility for all federal food safety activities.

**Q: Does the Administration agree with the NAS report?**

**A:** The Administration welcomes the opportunity to review the NAS report and believes that the report will play an important role in leading to further improvements. The Administration is encouraged that the NAS report supports many current Administration initiatives such as:

- new science-based systems to prevent contamination, including the Hazard Analysis and Critical Control Points (HACCP) system for inspections of meat, poultry, and seafood;
- a new science-based early warning system to help detect and respond to outbreaks of foodborne illness; and
- proposed legislation to ensure that the FDA halts imports of fruits, vegetables, and other food products that do not meet U.S. food safety requirements or come from countries that do not provide the same level of protection as is required for U.S. products.

The NAS report also highlights the role of Congress in ensuring food safety, and the Administration urges Congress to pass its FDA import legislation, to pass additional legislation to permit USDA to mandate recalls of meat and poultry, and to provide full funding for the Administration's Food Safety Initiative.

**Q: Does the Administration agree with the NAS recommendation that there be a single official who has responsibility and control of resources for all federal food safety activities?**

**A:** The Administration certainly agrees that there should be greater coordination of federal food safety activities, and has made several significant steps toward this coordination. While continuing these efforts at greater

coordination consistent with the current statutory scheme, the Administration will ensure full consideration of the NAS's proposal for legislation to give a single official responsibility for all food safety activities.

**Q: The NAS report focuses on the coordination of food safety activities. How does the federal government already coordinate its food safety activities?**

**A:** In less than two years, the Clinton Administration has taken significant strides toward building a coordinated food safety system. Most recently, the President announced the creation of the Joint Institute for Food Safety Research that will develop a strategic plan for coordinating government and private food safety research activities. In addition, the Administration announced the Foodborne Outbreak Response Coordinating Group (FORC-G) which brings together federal, state, and local agencies to develop a comprehensive, coordinated, national foodborne illness response system.

The Administration also has provided for increased and targeted surveillance of foodborne illness through PulseNet and FoodNet. PulseNet is a national network of public health laboratories that perform DNA "fingerprinting" on foodborne pathogens and compares these patterns through an electronic database at the Centers for Disease Control and Prevention. FoodNet is a collaborative effort between USDA, FDA, CDC and seven selected sites throughout the United States to track major pathogens that cause sporadic illness, and to explore what associations may exist between cases and the types of food products consumed.

**Q: What about the NAS report's recommendation regarding a National Food Safety Plan?**

**A:** The Administration already has efforts underway to develop a comprehensive strategic Federal food safety plan with the cooperation of consumers, producers, industry, food service providers, retailers, health professionals, state and local governments, tribes, academia, and the public. The strategic plan will focus not only on microbial contamination, but on the full range of issues and actions necessary to ensure the safety of the food Americans eat. The plan will be used to set priorities, improve coordination and efficiency, identify gaps in the current system, and enhance and strengthen prevention strategies.

### **Food Safety Budget**

**Q: What did the President ask for in the FY 1999 Budget request with respect to food safety?**

**A:** The FY 1999 Budget included a \$101 million increase over the FY 1998 level for the Administration's inter-agency food safety initiative. Of this total amount, \$25 million would finance FDA's improved capability to ensure the safety of imported foods. Another \$24 million of the Initiative would go towards: developing rapid tests for the detection of pathogens; improving slaughter and processing systems to avoid contamination of food products; and establishing baseline data to better assess the risk of contamination in the US food supply. In addition, \$7.8 million would be used to expand consumer education initiatives, especially for high risk populations (the elderly and children).

**Q:** What is the status of the Food Safety Initiative in the FY 1999 Appropriation bills?

**A:** So far, Congress has failed to provide full funding of the Administration's food safety initiative. The Senate Appropriations Committee provided only about \$3 million for these efforts, but the full Senate voted by a large bipartisan majority for an amendment offered by Senator Harkin to provide an additional \$66 million. Senator Harkin's amendment required USDA's tobacco program administrative costs to be partially funded by the tobacco industry, and used the savings as the major offset for the cost of expanded food safety programs for both USDA and FDA. The House-passed Agriculture Appropriations bill would provide only \$16.8 million of the requested increase: \$7 million for FDA imported food safety and \$9.8 million for USDA activities. The Administration will continue to work with the conference committee members to urge them to provide full funding for the food safety initiative.

**Q:** Is all of the \$101 million that the President asked for necessary for food safety?

**A:** Without additional funding for the Food Safety Initiative, the federal food safety agencies will not be able fully to develop appropriate response, prevention, and control strategies for reducing the level of food-borne illness in the United States.

In addition to the funding requested to strengthen FDA's import inspection and expand USDA's and FDA's research and education activities, funding is requested to continue to improve FDA's food safety infrastructure, as started in the FY 1998 Food Safety Initiative. Also, significant resources are targeted to strengthening both USDA's and FDA's risk assessment capabilities. Risk assessment is important in helping to identify foods and processes that are most likely to lead to foodborne illness. Finally, funding is requested to expand the USDA's and HHS's ability to identify and track

food-borne illnesses.

### **Legislative Proposals**

**Q: What is the Administration's FDA import legislation?**

**A:** This legislation, introduced by Senators Milkulski and Kennedy and Reps. Eshoo and Pallone, gives the FDA greater authority over imported foods. This legislation will ensure that the FDA halts imports of fruits, vegetables, and other food products that do not meet U.S. food safety requirements or that come from countries that do not provide the same level of protection as is required for U.S. products. The legislation also enables the FDA to halt imports from a country or facility that refuses to allow FDA inspections. This legislation gives FDA authority that is similar to USDA's existing authority to prevent the importation of unsafe meat and poultry.

**Q: What is the Administration's USDA mandatory recall/civil penalties legislation?**

**A:** The Administration urges passage of the Food Safety Enforcement Enhancement Act, sponsored by Senators Harkin, Daschle, Johnson, and Leahy, which gives USDA the ability to assess civil fines and to order mandatory recalls of unsafe meat and poultry products. Currently, the USDA can respond to food safety violations only by bringing criminal actions or withdrawing inspections; all recalls are done on a voluntary basis and no civil penalties are available. This new legislation will give USDA additional enforcement tools to prevent consumers from ingesting and becoming ill from dangerous meat and poultry.

**Q: Aren't these legislative proposals essentially dead? Has Congress moved on them at all?**

**A:** These proposals are not dead. The Administration is working with members to try to get these vital pieces of legislation passed and expects the Congressional sponsors of these measures to raise the bills on the House and Senate floors. We hope that the NAS report provides an additional spur to Congressional action.

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## Executive Summary

Adequate, nutritious, safe food is essential to human survival, but food can also cause or convey risks to health and even life itself. Although estimates vary widely, there is agreement that foodborne illness is a serious problem. In the United States, as many as 81 million illnesses (Archer and Kvenberg, 1985) and up to 9,000 deaths (CAST, 1994) per year have been attributed to food related hazards. Estimates of the annual cost of medical treatment and lost productivity vary widely, from \$6.6 billion to \$37.1 billion from seven major foodborne pathogens (Buzby and Roberts, 1997).

The nation's agriculture and food marketing systems have evolved to provide food to a growing and increasingly sophisticated population. Complex processes built on advances in science and technology have been developed to evaluate and manage the risks associated with the changing nature of the food supply. Well-established systems control many food risks, but serious hazards to public health remain.

### PURPOSE AND SCOPE OF THE STUDY

As a result of the continuing concern about the food safety system in the United States, Congress commissioned the National Academy of Sciences, through the Agricultural Research Service of the US Department of Agriculture (USDA), to undertake the study that resulted in this report. The charge to the committee was twofold. The committee was asked to (1) assess the effectiveness of the current system to ensure safe food, and (2) provide recommendations on scientific and organizational changes needed to increase the effectiveness of the

food safety system. Over a 6 month period, the committee held three meetings as well as two open forums where agency representatives and relevant stakeholders discussed the food safety system. The committee reviewed many documents, including reports on how other countries are reshaping their systems.

This report summarizes the committee's review of food safety in the United States by (1) describing the current US system for food safety and the changing nature of concerns which it encounters, (2) outlining an effective food safety system, (3) identifying the ways in which the current food safety system is inadequate, and (4) providing recommendations to move toward the scientific foundation and organizational structure of a more effective food safety system.

Protecting the safety of food requires attention to a wide range of potential hazards. Food safety is not limited to concerns related to foodborne pathogens, toxicity of chemical substances, or physical hazards, but may also include issues such as nutrition, food quality, labeling, and education. While the scope of this study includes all of these components, this committee's immediate concern focuses on food related hazards.

### 1. The Current US Food Safety System

The US food supply is abundant and affordable and is judged by many to present an acceptable level of risk to health. The system has evolved from one that provided consumers with minimally processed basic commodities that were predominantly for home preparation to today's system of highly processed products designed either to be ready-to-eat or to require minimal preparation in the home. As a result of many technological advances, the food system has progressed dramatically from traditional food preservation processes such as salting and curing to today's marketplace with frozen ready-to-eat meals and take-out foods. Likewise, distribution systems for foods have changed greatly.

While these developments have provided the American consumer with a wide array of food products with a high degree of safety, a more diverse food supply carries additional risks as well as benefits. The availability of new food choices such as "minimally processed" vegetable products (for example, prebagged and chopped leaf lettuce mixes) presents new risks for microbial contamination. The globalization of the food system brings food from all parts of the world into the US marketplace, and with it the potential for foodborne infection or other hazards not normally found in the United States.

The current US food safety system has many of the attributes of an effective system. The nature of food safety concerns has changed due to past successful efforts to control the use of unidentified or misrepresented food ingredients and problems with the appearance and wholesomeness of food products; microbiological and chemical hazards now present new and in some cases increasingly serious challenges which cannot be detected using traditional inspection methods. The introduction of Hazard Analysis Critical Control Point (HACCP) monitoring systems in meat, poultry, and seafood products is an

example of the introduction of science-based process control methodology into food safety regulation and enforcement.

Many Americans now eat in ways that increase risk, including consuming more raw or minimally processed fruits and vegetables and eating fewer home-prepared meals. A smaller number of food processing and preparation facilities provide food to increasingly larger numbers of US consumers, enhancing the extent of harm that can arise from any one incident. Simultaneously, increasing numbers of Americans have compromised immune systems because of age, illness, or medical treatment. The development of genetically modified foods and modified macronutrients are two examples of new products or technologies that require new ways of evaluating the safety of substances added to the food supply.

The federal government has usually addressed these developments by adding new structures and processes or adjusting old ones. These incremental adjustments have created a number of inefficiencies and apparent conflicts within the system. Some have been addressed (for example, pesticides have been exempted from the Delaney clause's ban on carcinogens), but others remain. USDA is obligated by statute to maintain the system of continuous on-site factory inspection by government inspectors that has been the hallmark of meat and poultry regulation. The Food and Drug Administration (FDA), meanwhile, with a more varied industry to regulate, has relied on selective monitoring, in which far fewer inspectors periodically visit settings where food is produced, processed, or stored to verify compliance with or to uncover violations of its requirements. A result is that in some cases inspectors from these two agencies oversee food processing in the same processing facility at the same time due to the different enabling statutes. Agencies are at times precluded by statute from implementing monitoring or enforcement practices that are based in science.

The size and complexity of the US food system require significant involvement of government at all levels—federal, state, and local; of the food industry—ranging from the producer to food server; of universities; of the news media; and, most importantly, of the consumer, to address adequately the multitude of issues that arise in ensuring safe food. At the federal level, the efforts are currently fragmented, with at least 12 agencies<sup>1</sup> involved in the key functions of safety: monitoring, surveillance, inspection, enforcement, outbreak management, research, and education. Efforts to coordinate federal activities have intensified over the last two years with the National Food Safety Initiative. There are over 50 memoranda of agreement between various agencies related to food safety. The recent proposal to create a Joint Food Safety Research Institute

<sup>1</sup>The major federal agencies involved include: the Agricultural Marketing Service, the Animal and Plant Health Inspection Service, the Agricultural Research Service, the Cooperative State Research, Education and Extension Service, the Economic Research Service, the Food Safety and Inspection Service, and the Grain Inspection, Packers and Stockyards Administration of the United States Department of Agriculture; the Centers for Disease Control and Prevention, the Food and Drug Administration, and the National Institutes of Health of the Department of Health and Human Services; the National Marine Fisheries Service of the Department of Commerce; and the Environmental Protection Agency.

between USDA and FDA is an obvious outgrowth of such efforts. Notwithstanding these relatively recent activities, however, there still exist significant barriers to full integration.

### Summary Findings: The Current US System for Food Safety

- has many of the attributes of an effective system;
- is a complex, inter-related activity involving government at all levels, the food industry from farm and sea to table, universities, the media, and the consumer;
- is moving toward a more science-based approach with HACCP and with risk based assessment;
- is limited by statute in implementing practices and enforcement that are based in science;
- is fragmented by having 12 primary federal agencies involved in key functions of safety: monitoring, surveillance, inspection, enforcement, outbreak management, research, and education; and
- is facing tremendous pressures with regard to:
  - emerging pathogens and ability to detect them;
  - maintaining adequate inspection and monitoring of the increasing volume of imported foods, especially fruits and vegetables;
  - maintaining adequate inspection of commercial food services and the increasing number of larger food processing plants; and
  - the growing number of people at high risk for foodborne illnesses.

## 2. An Effective Food Safety System

### Mission

The committee defines safe food as food that is wholesome, that does not exceed an acceptable level of risk associated with pathogenic organisms or chemical and physical hazards, and whose supply is the result of the combined activities of Congress, regulatory agencies, multiple industries, universities, private organizations, and consumers. The mission of a food safety system should be stated as an operational charge that uses and reflects that definition. After reviewing the missions presented by some of the lead federal agencies involved in the US food safety system, the committee defined an overall mission as follows:

*The mission of an effective food safety system is to protect and improve the public health by ensuring that foods meet science-based safety standards through the integrated activities of the public and private sectors.*

## Attributes of an Effective Food Safety System

The attributes of a model food safety system can be summarized in five major components. First, it should be science-based, with a strong emphasis on risk analysis, thus allowing the greatest priority in terms of resources and activity to be placed on the risks deemed to have the greatest potential impact (see Box ES-1). Adjusting effort to risk depends on being able to identify hazards, evaluate the dose-response characteristics of the hazards, estimate or measure exposures, and then determine the likely frequency and severity of effects on health resulting from estimated exposure. Hazards are properties of substances that can cause adverse consequences. Hazards associated with food include microbiological pathogens, naturally occurring toxins, allergens, intentional and unintentional additives, modified food components, agricultural chemicals, environmental contaminants, animal drug residues, and excessive consumption of some dietary supplements. In addition, improper methods of food handling and preparation in the home can contribute to increases in other hazards.

The limited resources available to address food safety issues direct that regulatory priorities be based on risk analysis, which includes evaluation of prevention strategies where possible. This approach enables regulators to estimate the probability that various categories of susceptible persons (for example, the elderly, or nursing mothers) might acquire illness from eating specific foods and thereby allows regulators to place greater emphasis and direct resources on those foods or hazards with the highest risk of causing human illness. Risk analysis provides a science-based approach to address food safety issues. Comprehensive human and animal disease surveillance must be an integral part of any risk analysis in order to estimate exposure.

The second component in a model system is to have a national food law that is clear, rational, and comprehensive, as well as scientifically based on risk. Scientific understanding of risks changes, so federal food safety efforts must be carried out within a flexible framework. US regulatory agencies are moving toward science-based HACCP programs<sup>2</sup>. This is a major step toward a science-based system, but other steps remain critical. An ideal system would be preventive and anticipatory in nature, and thus designed with integrated national surveillance and monitoring along with education and research required to support these activities woven into the fabric of the system. A reliable and accurate system of data collection, processing, evaluation, and transfer is the foundation for scientific risk analysis. Research should have both applied and basic components and be targeted at the needs of producers, processors, consumers, and regulatory decision-makers and other scientists.

<sup>2</sup> The implementation of the science-based HACCP strategy is perhaps the most notable recent advance. In contrast to the traditional reactive food safety strategies, the HACCP system focuses on preventing hazards that could cause foodborne illness by applying science-based control processes at each step, from raw material to finished product.

**Box ES-1. What is the Meaning of Science-Based?**

A science base for ensuring safe food encompasses many elements. When utilized, these elements improve the ability to identify, reduce, and manage risks; minimize occurrence of foodborne hazards; gather and utilize information; enhance knowledge; and improve overall food safety. Several examples of science-based actions that have been implemented in the US food safety system that are readily recognized as positive elements of the system include:

- implementation of low-acid canned food processing technology, which reduces the risk of botulism;
- implementation of HACCP systems and risk assessment in decision-making;
- approval of irradiation technology for use in spices, pork, beef, poultry, fruits and vegetables;
- prohibition of the use of lead-based paints on utensils that come in contact with food;
- estimation of maximum allowable exposure levels to pesticides;
- development of standards for allowable practices associated with transport of foods following transport of pesticides in the same containers;
- use of labeling as a device to warn consumers who are sensitive to potential food allergens of the content of the allergen, and
- requirements that meat and poultry products at the retail level carry consumer information related to safe food handling practices.

While the approaches above are important successful science-based tools in food production and processing, these are only examples of implementation of the scientific basis for food safety. An effective food safety system also integrates science and risk analysis at all levels of the system, including food safety research, information and technology transfer, and consumer education.

Third, a model food safety system should also have a unified mission and a single official who is responsible for food safety at the federal level and who has the authority and the resources to implement science-based policy in all federal activities related to food safety. This would allow for effective and consistent regulation and enforcement. Similar risks require similar planning, action, and response. Thus the intensity, nature, and frequency of inspection should be similar for foods posing similar risks. A central voice is critical to effective marshaling of all aspects of the food safety system to create a coordinated response to foodborne disease outbreaks. Control of resources is also critical in order to encourage movement toward science-based food safety provisions and

to ensure that research and education are targeted toward efforts that will produce the greatest benefit for a given cost of improving food safety.

The fourth essential feature of an ideal federal food safety system is that it be organized to be responsive to and work in true partnership with nonfederal partners. These include state and local governments, the food industry, and consumers. The food safety system must function as an integrated enterprise. It must be agile, fluid, connected, integrated, and transparent, with well defined accountability and responsibility for each partner in the system. It must frame approaches to risk management that recognize the importance of public perception of risks as well as assessments conducted by experts.

Finally, an effective food safety system must be supported by funding adequate to carry out its major functions and mission—to promote the public's health and safety. Moving toward science-based risk analysis as the underpinning of the system should allow reallocation of resources to areas identified as critical to an integrated, focused effort to ensure safe food.

**Summary Findings: An Effective Food Safety System**

- should be science-based with a strong emphasis on risk analysis and prevention thus allowing the greatest priority in terms of resources and activity to be placed on the risks deemed to have the greatest potential impact;
- is based on a national food law that is clear, rational, and scientifically based on risk;
- includes comprehensive surveillance and monitoring activities which serve as a basis for risk analysis;
- has one central voice at the federal level which is responsible for food safety and has the authority and resources to implement science-based policy in all federal activities related to food safety;
- recognizes the responsibilities and central role played by the non-federal partners (state, local, industry, consumers) in the food safety system; and
- receives adequate funding to carry out major functions required.

**3. Where Current US Food Safety Activities Fall Short**

Statutory revision is essential to the development and implementation of an effective and efficient science-based food safety system. Major aspects of the current system are in critical need of attention in order to move toward a more effective food safety system. Food safety in the United States lacks integrated Congressional oversight, allocation of funding based on science, and sustained political support. Statutory impediments interfere with implementation of a more effective food safety system. More than 35 primary statutes regulate food safety. Statutory revision is essential to the development and implementation of an effective and efficient science-based food safety system. The meat and poultry inspection laws mandate a form of compliance monitoring that is largely

unrelated to the magnitude or the types of risks that are now posed by those foods. This diverts efforts and perhaps resources from actual risks and other hazards. Inconsistent food statutes often inhibit the use of science-based decision making in activities related to food safety, including lack of jurisdiction to evaluate food handling practices in countries of origin for some types of imported foods.

The federal government response to food safety issues is too often crisis-driven. Management decisions, emphasis, and agency culture are driven by the primary concerns of each agency and special initiatives. One result is fragmentation, which causes a lack of coordination and consistency among agencies in mission, food safety policies, regulation, and enforcement. The fact that some agencies have dual responsibilities (regulation of the quality of food products while marketing them via promotional activities) makes their actions more vulnerable to criticism regarding possible conflicts of interest and may bias their approach to food safety.

In addition to fragmented and overlapping authorities, federal activities are not well integrated with state and local activities. This results in overlapping responsibilities, gaps in responsibilities, and inefficiencies. Although FDA recommended minimum food handling standards in a Food Code issued in 1993, the Code has not been adopted in its entirety by most state and local authorities. Surveillance efforts currently in place (such as FoodNet) have been designed to provide data representative of national trends with regard to seven indicator foodborne pathogens yet are not designed to identify trends within smaller geographic areas or communities. Similarly, there are conflicts between US requirements and those of other nations and international bodies. These inadequacies have serious implications for both food imports and food exports.

The multi-faceted federal framework of the US food safety system lacks direction from a single leader who can speak for the government when confronting food safety issues and providing answers to the public. There is no single voice in the government to communicate with stakeholders regarding food safety issues. The lack of clear leadership at the federal level impedes the federal role in the management of food safety. Leadership is needed to set priorities, deploy resources, and integrate a consistent policy into all levels of the system.

A significant impediment to moving toward a science-based food safety system is the lack of adequate emphasis on and integration of surveillance activities that provide timely information on current and potential foodborne disease and related hazards. This timely information is critical if the food safety system is to move from a mode of reaction to prevention. FDA's lack of resources to maintain adequate inspection and monitoring of commercial food facilities and of fresh fruits and vegetables, both domestic and imported, using statute-driven methods of monitoring and enforcement, increases the threat of foodborne disease and related hazards in the food supply.

The committee found that the resource base for research and surveillance was not adequate to achieve the goals identified as necessary for an effective system. Furthermore, there is not an adequately coordinated effort on the scale

required to analyze risk and respond to the challenges of the changing nature of American food hazards related to increases in consumption of imported foods and of food eaten outside the home.

With respect to consumer education, the committee found two major problems: in some instances, consumer knowledge is inadequate or erroneous; and even where knowledge is adequate, it often fails to influence behavior.

#### Summary Findings: Where the US Food Safety System Falls Short

- inconsistent, uneven and at times archaic food statutes that inhibit use of science-based decision making in activities related to food safety, including imported foods;
- a lack of adequate integration among the 12 primary agencies that are involved in implementing the 35 primary statutes that regulate food safety;
- inadequate integration of federal programs and activities with state and local activities;
- absence of focused leadership: no single federal entity is both responsible for the government's efforts and given the authority to implement policy and designate resources toward food safety activities;
- lack of similar missions with regard to food safety of the various agencies reviewed;
- inadequate emphasis on surveillance necessary to provide timely information on current and potential foodborne hazards;
- resources currently identified for research and surveillance inadequate to support science-based system;
- limited consumer knowledge, which does not appear to have much impact on food handling behavior; and
- lack of nationwide adherence to appropriate minimum standards.

#### 4. Conclusions and Recommendations Needed to Improve the US Food Safety System

Given the concerns outlined above, the committee came to three primary conclusions:

- I. An effective and efficient food safety system must be based on science.
- II. To achieve a food safety system based on science, current statutes governing food safety regulation and management must be revised.
- III. To implement a science-based system, reorganization of federal food safety efforts is required.

To accomplish these objectives, the committee recommends that the following measures be taken regarding the scientific and organizational changes needed to improve the US food safety system:

**Recommendation I:**

**Base the food safety system on science.**

The United States has enjoyed notable successes in improving food safety. One example is the joint government-industry development of low-acid canned food regulations, based on contingency microbiology and food engineering principles, that has almost eliminated botulism resulting from improperly processed commercial food. Similarly, the passage of the 1958 Food Additives Amendment to the Food, Drug, and Cosmetic Act of 1938 was a "technology forcing" event that improved the evaluation of the safety of added and natural substances and reduced the risks associated with the use of food additives. In a like manner, the Delaney clause of that amendment resulted in increased attention to carcinogenic substances in the food supply. With increasing knowledge, many rational, science-based regulatory philosophies have been adopted, some of which rely on quantitative risk assessment. Adoption of such a science-based regulatory philosophy has been uneven and difficult to ensure given the fragmentation of food safety activities, and the differing missions of the various agencies responsible for specific components of food safety. This philosophy must be integrated into all aspects of the food safety system, from federal to state and local.

**Recommendation IIa:**

**Congress should change federal statutes so that inspection, enforcement, and research efforts can be based on scientifically supportable assessments of risks to public health.**

Limitations on the resources available to address food safety issues require that food safety activities operate with maximal efficiency within these limits. This does not require full-scale, cost-benefit analysis of each issue, but it does require that costs, risks, and benefits be known with some precision. Thus, where feasible, regulatory priorities should be based on risk analysis which includes evaluation of prevention strategies where possible. The greatest strides in ensuring food safety from production to consumption can be made through a science-based system that ensures that surveillance, regulatory, and research resources are allocated to maximize effectiveness. This will require identification of the greatest public health needs through surveillance and risk analysis, and evaluation of prevention strategies. The state of knowledge and technology

defines what is achievable through the application of current science. Public resources can have the greatest favorable effect on public health if they are allocated in accordance with the combined analysis of risk assessment and technical feasibility. However, limiting allocation of resources to *only* those areas where high priority hazards are known can create a significant problem: other hazards with somewhat lower priority but with a much greater probability of reduction or elimination might not be addressed due to limited resources. Thus both the marginal risks and marginal benefits must also be considered in allocating resources.

Not all agencies responsible for monitoring the safety of imported food are authorized to enter into agreements with the governments of exporting countries in order to reciprocally recognize food safety standards or inspection results. Uniform or harmonized food safety standards and practices should be established, and officials allowed to undertake research, monitoring, surveillance, and inspection activities within other countries. This should permit inspection and monitoring efforts to be allocated in accordance with science-based assessments of risk and benefit. Changes in federal statute that would foster and enhance science-based strategies are shown in Box ES-2.

**Box ES-2. Changes in Federal Statute that Would Foster and Enhance Science-based Strategies:**

- eliminate continuous inspection system for meat and poultry and replace with a science-based approach which is capable of detecting hazards of concern;
- mandate a single set of science-based inspection regulations for all foods; and
- mandate that all imported foods come from only countries with food safety standards deemed equivalent to US standards.

**Recommendation IIb:**

**Congress and the administration should require development of a comprehensive national food safety plan. Funds appropriated for food safety programs (including research and education programs) should be allocated in accordance with science-based assessments of risk and potential benefit.**

Changes in statutes or organization should be based on a rational, well-developed national food safety plan formulated by current federal agencies charged with food safety efforts and with representation from the many stakeholders involved in ensuring safe food. Such a plan, as shown in Box ES-3, should serve as the blueprint for strategies designed to determine priorities for

funding, to determine what the needs are, and to ensure that they are incorporated into activities and outcome evaluation.

**Box ES-3. The National Food Safety Plan should:**

- include a unified, science-based food safety mission;
- integrate federal, state, and local food safety activities;
- allocate funding for food safety in accordance with science-based assessments of risk and potential benefit;
- provide adequate and identifiable support for the research and surveillance needed to:
  - monitor changes in risk or potential hazards created by changes in food supply or consumption patterns; and
  - improve the capability to predict and avoid new hazards;
- increase monitoring and surveillance efforts to improve knowledge of the incidence, seriousness, and cause-effect relationships of foodborne diseases and related hazards;
- address the additional and distinctive efforts required to ensure the safety of imported foods;
- recognize the burdens imposed on state and local authorities that have primary front-line responsibility for regulation of food service establishments; and
- include a plan to address consumers' behaviors related to safe food-handling practices.

**Recommendation IIIa:**

To implement a science-based system, Congress should establish, by statute, a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.

The committee was asked to consider organizational changes that would improve the safety of food in the United States. During the 6 months of active review of information and deliberation, the committee identified characteristics needed in an organizational structure that would provide for an improved focus for food safety in the United States. The committee found that the current fragmented regulatory structure is not well equipped to meet the current challenges. The key recommendation in this regard is that in order for there to be successful structure, one official should be responsible for federal efforts in food safety and have control of resources allocated to food safety.

This recommendation envisions an identifiable, high-ranking, presidentially-appointed head, who would direct and coordinate federal activities and speak to the nation, giving federal food safety efforts a single voice. The structure created, and the person heading it, should have control over the resources Congress allocates to the food safety effort; the structure should also have a firm foundation in statute and thus not be temporary and easily changed by political agendas or executive directives. It is also important that the person heading the structure should be accountable to an official no lower than a cabinet secretary and, ultimately, to the President.

Many members of the committee are of the view that the most viable means of achieving these goals would be to create a single, unified agency headed by a single administrator—an agency that would incorporate the several relevant functions now dispersed, and in many instances separately organized, among three departments and a department-level agency. However, designing the precise structure and assessing the associated costs involved are not possible in the time frame given the committee, nor were they included in its charge. The committee did discuss other possible structures; while it ruled out some, it certainly did not examine all possible configurations and thus the examples provided in Box ES-4 are only illustrative of possible overall structures that could be considered.

**Box ES-4. Some Examples of Possible Organizational Structures to Create a Single Federal Voice for Food Safety:**

- a Food Safety Council with representatives from the agencies with a central chair appointed by the President, reporting to Congress and having control of resources;
- designating one current agency as the lead agency and having the head of that agency be the responsible individual;
- a single agency reporting to one current cabinet-level secretary; and
- an independent single agency at cabinet level.

Note: These examples are provided for illustrative purposes and many other configurations are possible. It is strongly recommended that future activities be directed toward identifying a feasible structure that meets the criteria outlined.

The committee does not believe that the type of centralized focus envisioned can be achieved through appointment of an individual with formal coordinating responsibility but without legal authority or budgetary control for food safety, a model similar to a White House-based 'czar'. Nor, in the committee's view, can this goal be achieved through a coordinating committee similar to that currently provided via the National Food Safety Initiative. In evaluating possible structures, the committee realized that past experience with other structures or

reorganizations, including the creation of new agencies, such as the Environmental Protection Agency (EPA), should inform any final judgment. Further, it is quite possible that other models may now exist in government that can serve as templates for structural reform. Whether or not a single agency emerges, the ultimate structure must provide for not just delegated responsibility, but also for control of resources and authority over food safety activities in the federal government.

#### Recommendation IIIb:

**Congress should provide the agency responsible for food safety at the federal level with the tools necessary to integrate and unify the efforts of authorities at the state and local levels to enhance food safety.**

This report specifically addresses the federal role in the food safety system, but the roles of state and local government entities are equally critical. For integrated operation of a food safety system, officials at all levels of government must work together in support of common goals of a science-based system. The federal government must be able to ensure nationwide adherence to minimal standards when it is deemed appropriate. The work of the states and localities in support of the federal mission deserves improved formal recognition and appropriate financial support. Statutory tools required to integrate state and local activities regarding food safety into an effective national system are shown in Box ES-5.

#### **Box ES-5. The Statutory Tools Required to Integrate Local and State Activities Regarding Food Safety into an Effective National System:**

- authority to mandate adherence to minimal federal standards for products or processes,
- continued authority to deputize state and local officials to serve as enforcers of federal law,
- funding to support, in whole or in part, activities of state and local officials that are judged necessary or appropriate to enhance the safety of food,
- authority given to the federal official responsible for food safety to direct action by other agencies with assessment and monitoring capabilities, and
- authority to convene working groups, create partnerships, and direct other forms and means of collaboration to achieve integrated protection of the food supply.

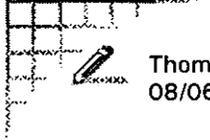
### MOVING TOWARD A MODEL SYSTEM

It is recognized that these recommendations will need significant review and discussion. The committee focused on the need for a centrally managed federal system to ensure coordination and direction in food safety programs and policy, and to serve as a single voice with authority and resources to suggest and implement legislation. It had insufficient time to review all the possible organizational structures that could accomplish this goal. A successor study could focus on this. Of critical importance, though, are the first two recommendations: the first, to base the system on science, and the second, that of rewriting the current patchwork of federal food statutes that in many cases do not serve to ensure a scientifically supportable and risk-based food safety system, and certainly prevent it from being more cost effective.

Regardless of the organizational structure chosen, a revamped federal food statute is critical to being able to reallocate resources toward risks that have or will have the greatest significance to the public's health. Implementation of these recommendations should not be looked at as a cost-cutting measure, but rather as a way to design a well-defined integrated system to ensure safe food. This system may well be able to demonstrate effectively a need for additional resources to address important and specific problems. Although the National Food Safety Initiative properly seeks to alleviate problems inherent in the present decentralized structure, experience indicates that any ad hoc administrative adjustments and commitments to coordination will not suffice to bring about the vast cultural changes and collaborative efforts needed to create an integrated system.

Changing hazards associated with food and changing degrees of acceptance of risk are factors that impact the nation's ability to protect public health and ensure safe food. Risk acceptance and foodborne hazards will continue to change and evolve with new technologies and consumer demands. Federal food safety efforts must be designed to deal with those changes. This report is not a comprehensive and all-inclusive discussion of these issues. Adoption of the recommendations in this report will not end the effort to make food safer. They should, however, contribute to ensuring the safety of our food while providing a blueprint for a truly integrated system.

dispute - food safety -  
single agency



Thomas L. Freedman  
08/06/98 08:44:21 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP  
cc: Laura Emmett/WHO/EOP, Mary L. Smith/OPD/EOP  
Subject: Food Safety Talking Points



FOODSAFE.7

#### What the EO is

I've attached the draft of the EO that we gave out to the agencies. Briefly put, it establishes a food safety council co-chaired by secretaries of USDA, HHS, and either DPC or VP. It is charged with reviewing and making recommendations on the NAS report, presenting a unified food safety budget, and formulating a food safety plan.

#### What Glickman/Frazier may say and some Answers.

**USDA:** We should wait for the NAS report to come out, review it, and respond with what is right.

A. Three part answer (not artfully constructed but you will weave it together somehow)

1. Yes we agree. We should review the NAS in a thoughtful way and only do what makes sense from a food safety perspective. One of the most important things the EO does is set up a process to review NAS in a coherent way and report back to the President. It provides a structure to think long-term about what is the right thing to do on food safety.
2. But this is a good step even w/o the NAS report. We don't need the NAS report to know that we should have better coordination on food safety. We should be working off a unified food safety plan each year, and we should have a food safety budget that helps fulfill that plan. This year, HHS came to us and said they were thinking of not participating in a unified budget with USDA at all. That should not be up in the air each year. This is an interim step, but a useful one.
3. It also doesn't make sense to wait. For one thing, we have always been working ahead on food safety doing what we think should be done, not waiting for criticism that we know will come and then responding. Like the GAO report on nursing homes, it is better to be welcoming reform and instituting it rather than responding to a NYT story.

By waiting we will be inevitably in the position of having outside folks say whether we have gone far enough or not. The NAS is expected to recommend four options: a food czar, a new agency, designating one agency as lead, or making one agency totally responsible for food safety. USDA would probably dislike each of their recommendations more than the Council, but if we wait we will be faced with the argument that whatever we do, we haven't done what they asked. The consumer groups that asked for this study want a single food agency with a food czar. Once the report is out, you give them that as the measuring rod.

It is also very likely that NAS will ask for more money to do a second report finishing up its recommendations on what to do. The same argument could be made that we should then wait for their second report.

**USDA: This report is coming out on August 17th and will get lost.**

A. Well, we should do what is right on the merits and the Council is the right thing to do even if the NAS does get no press. In addition, the report is now moved back to August 20th for release so the chance for press is increased. And any decent reporter will know how to play this -- there is a good chance it will get play.

**USDA: This is a FDA power grab.**

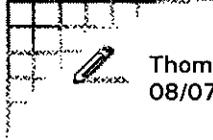
A. We don't see this as a way for FDA to get its hands on USDA money. We don't want that and don't want to go along with it.

{ You could note we have three co-chairs (DPC is one). We could argue we favor putting in an executive director who we thought should be Eric Olsen or someone who gets that this is about moving forward, not about reallocating resources. }

**USDA: We don't think it will be that critical.**

A. It may or may not get played as critical. But there will be plenty there. We've heard the NAS report right now says we need: a national food safety plan; a new budgeting system; a universally adopted food code; and there is not enough research; not enough standards (like milk); our epidemiological system is insufficient; statutory changes need to be made to harmonize regulations; USDA should involve more science; there should not be a mixing of food promotion and regulation within agencies; and a concern about dietary supplements. It will suggest potentially four options: including a food czar, an EPA like organization; letting either HHS or USDA be the lead agency or sole agency. It is the fodder for something critical.

Chis pro - food safety -  
single agency



Thomas L. Freedman  
08/07/98 10:15:00 AM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP  
cc: Laura Emmett/WHO/EOP, Mary L. Smith/OPD/EOP  
Subject: more food safety

Other points they may make:

**USDA: we are already doing this, we have a budget.**

A. There is no harm to institutionalizing it. We understand that right now there is a good deal of hemming and hawing -- FDA hasn't even shared its proposed budget with USDA yet. That should not be a subject of debate and this will make it less of an ad hoc process.

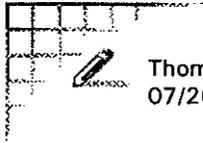
**USDA: This is too sudden, it is sprung on us.**

A. We have been doing regular meetings for months chaired by NPR and DPC, asking the agencies for examples of new coordination mechanisms we could promote. We finally suggested this one weeks ago. This timing and the idea of it are not new.

**Other:**

According to OMB, we probably will need to make this a Directive not an Order because Orders they give the agencies a week to vet. You might offer that as a "concession" to the agencies who wanted to soft pedal the council.

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Thomas L. Freedman  
07/26/98 05:46:56 PM

Record Type: Record

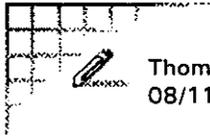
To: Elena Kagan/OPD/EOP, Bruce N. Reed/OPD/EOP  
cc: Laura Emmett/WHO/EOP, Mary L. Smith/OPD/EOP  
Subject: Food Safety and NAS report

I agree that the upcoming NAS report on single food agency is a potential problem (we don't know how much attention it will get) but it also may be a good opportunity to move the agencies into bolder than usual action. Here is my preliminary list of options for preempting/responding to the report:

1. Create a Joint Food Safety Council. Currently, there is a joint food safety budget but it comes about basically by combining the budget requests of the relevant agencies. By EO, the President could appoint the relevant agency heads to a council to annually produce a unified budget and strategic plan. One of the major criticisms is the disparate resources the different agencies have (USDA 5,000 inspectors, FDA 300). The Council could be charged with creating a plan to properly allocate resources and authority.
2. Follow-up the NAS report by appointing a panel to see how it should be implemented. This is the informal recommendation of the food safety advocates at CSPI. They would like to see the Mike Taylors, the Kesslers, etc. appointed to a panel to recommend what the next step should be in coordinating and creating a single food agency.
3. Public hearings with interested parties. The agencies have drafted a plan for this for the federal register. The hearings would center on a 'mission statement' they wrote which I'll give you at the Team leaders meeting. I think the hearings are worthwhile, I don't think the mission statement stands up to scrutiny.
4. Endorse all or part of the Pallone bill. Pallone has a bill that would require all non-registering plants to register with FDA (currently meat register with USDA). It also requires quarterly inspections and works to even out the inspectors problems. The farm community has big problems with this bill, but I'm trying to get USDA to break out parts that would be done by EO or reform the bill into one we could push for.

I like the first idea the most. It is a tangible step towards unifying food safety planning. We should also try and combine it with some EO that actually does something, like from the Pallone bill.

Cusipw - food safety -  
single agency



Thomas L. Freedman  
08/11/98 10:10:14 AM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Mary L. Smith/OPD/EOP  
cc: Laura Emmett/WHO/EOP  
Subject: Food Safety



FOOD.81 Attached is the draft EO for a food safety council. We've received comment from OMB, USDA, OSTP. The major issues are: including the vision statement, sunseting the council, and the scope of the budget that gets submitted by the council. Changes from the original draft are in bold, and I've briefly summarized the changes below. O'hara at HHS called Monday after returning from vacation and said he would like to submit as well.

We've discussed trying to have this ready for the 8- 19/20 when NAS comes out. The other big issue we need to resolve is whether the VP wants to be the third co-chair. (I think he preserves his ability to intervene selectively by not being on the council.)

1. Introduction: We added the "vision statement" as preamble. USDA, NPR (Jean), and EPA all mentioned that they would like to do this independantly as a FR notice with hearings on the vision statement topic. I think we should either combine it into the EO or wait and do this at some other later time.

Also, OSTP suggested this science-based language in the introduction.

2. Sections I(a)(b): we added a third joint chair (TBD), and put EPA and OMB on the council. Also a provision suggested by OSTP to provide staff as necessary.

3. Section 2, Purpose: OSTP suggested making it less a review of NAS and more towards developing a long-range plan taking into consideration the NAS report. We added preparing an annual budget as one of the purposes.

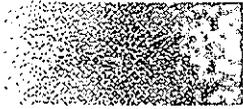
4. Section 3: OSTP suggested a deadline for developing the food safety plan. I've added space for a due date.

section (c): OSTP wanted the council to "establish" the research institute, we changed it back to "oversee" as it already is supposed to being established under previous presidential action. we did add their lanaguage about working with NSTC

5. Section 4: USDA wanted the section to include states.

6. Section 5: There was a general request for a sunset in this section. I didn't add it because i felt that the council should go out of business when it recommended a better coordinating mechanism -- but that in the absence of a better way, we shouldn't mandate its demise.

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single agency



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Jerold R. Mande

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08/13/98 03:45:02 PM

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Record Type: Record

To: Ron Klain/OVP @ OVP

cc: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Morley A. Winograd/OVP @ OVP, David W. Beier/OVP @ OVP

Subject: Food safety council

I am writing to recommend that the VP lead the proposed President's Council for Food Safety. While I recognize that this subject can be fraught with political danger, particularly from some farm and other agribusiness constituencies, the issue is nevertheless important enough to require Vice Presidential leadership. I am confident that with the proper staff support from Morley and Elena this can be a "win-win" for the VP and affected communities. I am concerned that without the VP's leadership the very serious problems with the current system will not be fixed and a dangerous time bomb will be left ticking.

As you know, the National Academy of Science's will shortly issue a Congressionally mandated review of the structure of the nation's food safety system. While we won't know what is in the report until we are briefed next week, it is likely to be quite critical of the structure of the current system, but complimentary of the Administration's efforts to improve food safety. If this is the report's conclusion, we should endorse the findings and lead the next step -- developing the solution.

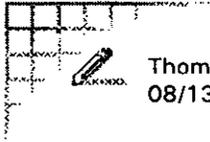
The VP has led the Administration's effort to improve food safety. Beginning with his 1993 reinventing report recommending a single food agency, to his behind the scenes placing of Mike Taylor to reform USDA's food safety program, to his release of the May 1997 President's Food Safety Initiative report, the VP has compiled an impressive record on this issue that is understood by experts in the food safety field. It would be jarring and troubling to anyone following this debate to see this next important phase go forward without the VP in charge.

It is extremely important to the producer community -- particularly beef and pork -- to have a dependable food safety system that maintains public confidence domestically and provides the platform for building international markets. Producers see the cracks in the current system, understand that their markets are being put at risk, and will support change that provides a secure foundation for the future. Done properly, a VP led Council would result in a grateful industry.

If you have other specific concerns I am eager to hear them and to respond. Thanks.

Ron; No.

ews pro - food safety -  
single agency



Thomas L. Freedman  
08/13/98 01:06:31 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Mary L. Smith/OPD/EOP

cc: Laura Emmett/WHO/EOP

Subject: Food safety



FOODEOX.8 Attached is the current draft of EO. Other updates: 1. I've now spoken in general terms to two of the three leading advocates, they like our concept (one said "great"); 2. Bill Schultz said he had "given off the record" talks to Elena and I and he wanted to call back to say he thought the EO was a better idea than he had said to us previously. 3. Getting USDA on with some enthusiasm is important to making this not be the subject of retribution on the Hill, the agency seems discontented still. Eric thought giving it more time might help the agency placate opposition.

Mary and I would like to come over before I leave at 3 pm today to walk through the likely future disputes and what is in the EO. Maybe around 2ish?

*Cons pro - food safety - single agency*

Food Safety, HFR, 310  
For Release noon EDT

WASHINGTON (AP) The nation needs a presidentially appointed "food czar" to oversee the patchwork of food safety regulations, a governmental advisory group said today.

Although the U.S. food supply is considered the world's safest, up to 9,000 Americans still die every year from food poisoning, and millions are sickened. The Clinton administration is seeking \$100 million for a new plan to strengthen food safety.

Congress asked the independent Institute of Medicine, which advises the government, whether the system needs fixing. The institute's report says it works well most of the time.

But the report calls federal food safety oversight "fragmented" and underfunded, and recommends a comprehensive food policy led by one official responsible for setting safety standards and fighting disease outbreaks.

Today, 12 agencies oversee various food-safety questions. Most are handled by the Agriculture Department, which is in charge of meat and poultry and certain fresh produce issues, and the Food and Drug Administration, which oversees most other foods.

Some consumer advocates and lawmakers are pushing for a single food-safety agency. The institute wasn't asked to evaluate that plan, but some committee members reported favoring it. But the report also suggests a "food safety council" made up of FDA, USDA and other safety groups that would report to the president and Congress.

The Clinton administration's top health experts will study the recommendations, but one official noted that the White House already is working toward greater food-safety coordination.

The consumer advocacy Center for Science in the Public Interest called a food czar "a good first step," while the National Food Processors Association called it an unneeded new bureaucrat.

AP-NY-08-20-98 0136EDT

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Received by NewsEDGE/LAN: 8/20/98 1:42 AM

OPTIONAL FORM 69 (7-90)

FAX TRANSMITTAL

# of pages 1

To <i>MARY SMITH</i>	From <i>ANDY SOLOMON</i>
Dep/Agency <i>DPC</i>	Phone #
Fax # <i>456-7431</i>	Fax #

NSN 7540-01-317-7388

5000-101

GENERAL SERVICES ADMINISTRATION

caus pro - food safety -  
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## Issues for the EO on Food Safety

### TO DO

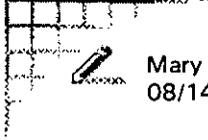
1. DRAFT OK'd by BR, EK, VP
2. OMB circulates
4. Advocacy Groups -- us (2 down)
5. Hill -- usda
6. Industry -- usda
7. Timing -- we should wait till principals
8. Paper Weekly, q/a/, one pager (list of contacts)

### THE EO Balance

1. Vision
2. BR as third chair
3. Break out two reports -- 180 days to comment on NAS, open ended for full plan
- \*4. Budget language involves council at two points: 1. Setting priorities, 2. Reviewing what agencies come back with. Query before or after OMB, query, are secretaries subject to council?
5. Include research, yes.
- \*6. Sunset -- still no, but they fear the evil secretary. Maybe yes.

*Jilly*

Cms pro - food safety -  
single agency



Mary L. Smith  
08/14/98 05:43:33 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Thomas L. Freedman/OPD/EOP

cc:

Subject: Update on the Food Council Executive Order

I've talked to USDA, HHS, and OMB, and we are making progress. We've got some budget language that USDA could live with. HHS, however, does not want to use the word "budget", but wants to use the term "food safety resource plan."

In addition, the following major issues remain:

1. HHS (per Jim O'Hara) doesn't want DPC, NPR, and OSTP as members of the Council. O'Hara says HHS only wants those agencies with "line authority" for food safety to be members of the council. HHS says the Council could consult with the DPC, NPR, and OSTP like the Council will consult with state and local governments and private entities. The reasoning for this is basically the "Evil President" theory. Along those lines, they don't want DPC to be the third co-chair. HHS is not opposed to a third co-chair, but would want it to be an agency like EPA, not a WH agency. This seems to be HHS's way of getting around the sunset provision.
2. However, OMB and EPA are still pushing sunsetting.

Chris go - food safety -  
single agency

 Mary L. Smith  
08/19/98 01:28:46 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Thomas L. Freedman/OPD/EOP  
cc: Laura Emmett/WHO/EOP  
Subject: NAS Briefing

The following are the main points from the NAS briefing.

Their conclusions were:

1. That our food safety system must be based on science
2. That the statutes governing the food safety need to be revised because these statutes are not always framed so that the statute is science-based
  - As part of the No. 2, we should develop a comprehensive national food safety plan
  - they emphasized repeatedly that we should coordinate more with states and local governments in doing this planning process (which we are going to do in the executive order)
3. That Congress should establish, by statute, a "unified and central framework for managing federal food safety programs, one that is headed by a single official" who has both responsibility for the planning and the accompanying resources
  - the NAS made clear that No. 3 is not recommending a single food agency
  - in the report the NAS didn't lay out how this "central framework" would look like
  - However, they were very adamant that there be only one individual with responsibility for food safety. They were quick to point out that they were not recommending a "czar." They had defined czar as someone who is appointed by the President and who does not have authority over budget resources. They said that this single person should be authorized by statute so that this person would be less influenced by political pressure and that the person must have, as they put it, the authority, the responsibility, and the resources

The NAS also made clear that they did not point out specifically how budget resources should be allocated, but only pointed out where there are gaps in the current system are.

The next steps for the NAS are to wait to hear back from Congress as to whether Congress wants them to do a second phase of the study. This study grew out of last year's Ag appropriations bill, and if Congress wants followup, they would probably decide that in this year's Ag appropriations conference.

I will get some Q&A to you later in the afternoon. Also -- is this going to be the radio address --if so, we should get the executive order in the OMB process today. Thanks, Mary

Cow pro - food safety -  
single agency

## NATIONAL ACADEMY OF SCIENCES

2101 Constitution Avenue, N.W. Washington, D.C. 20418

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**Embargoed; Not for public release until**  
**Thursday, August 20, 1998, 12:00 Noon EDT**

### **ENSURING SAFE FOOD**

#### **From Production to Consumption**

Committee to Ensure Safe Food from Production to Consumption

#### **Conclusions:**

- I. An effective and efficient food safety system must be based in science.**
- II. To achieve a food safety system based on science, current statutes governing food safety regulation and management must be revised.**
- III. To implement a science-based system, reorganization of federal food safety efforts is required.**

#### **Recommendations:**

- I. Base the food safety system on science.**
- IIa. Congress should change federal statutes so that inspection, enforcement, and research efforts can be based on scientifically supportable assessments of risks to public health.**

Changes in federal statute that would foster and enhance science-based strategies:

- eliminate continuous inspection system for meat and poultry and replace with a science-based approach which is capable of detecting hazards of concern;
  - mandate a single set of science-based inspection regulations for all foods;
  - mandate that all imported foods come from only countries with food safety standards deemed equivalent to US standards.
- IIb: Congress and the administration should require development of a comprehensive national food safety plan. Funds appropriated for food safety programs (including research and education programs) should be allocated in accordance with science-based assessments of risk and potential benefit.**

The National Food Safety Plan should:

- include a unified, science-based food safety mission;
- integrate federal, state, and local food safety activities;
- allocate funding for food safety in accordance with science-based assessments of risk and potential benefit;  
provide adequate and identifiable support for the research and surveillance needed to:
  - monitor changes in risk or potential hazards created by changes in food supply or consumption patterns, and
  - improve the capability to predict and avoid new hazards;
- increase monitoring and surveillance efforts to improve knowledge of the incidence, seriousness, and cause-effect relationships of foodborne diseases and related hazards;
- address the additional and distinctive efforts required to ensure the safety of imported foods;
- recognize the burdens imposed on state and local authorities that have primary front-line responsibility for regulation of food service establishments; and
- include a plan to address consumers' behaviors related to safe food-handling practices.

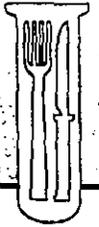
**IIIa: To implement a science-based system, Congress should establish, by statute, a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.**

**IIIb: Congress should provide the agency responsible for food safety at the federal level with the tools necessary to integrate and unify the efforts of authorities at the state and local levels to enhance food safety.**

The statutory tools required to integrate local and state activities regarding food safety into an effective national system:

- authority to mandate adherence to minimal federal standards for products or processes,
- continued authority to deputize state and local officials to serve as enforcers of federal law,
- funding to support, in whole or in part, activities of state and local officials that are judged necessary or appropriate to enhance the safety of food,
- authority given to the federal official responsible for food safety to direct action by other agencies with assessment and monitoring capabilities, and
- authority to convene working groups, create partnerships, and direct other forms and means of collaboration to achieve integrated protection of the food supply.

Aug 17, 1998



# FOOD CHEMICAL NEWS

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## White House drafts food safety executive order to preempt NAS report

In anticipation of a National Academy of Sciences report that will call for better coordination among food safety agencies, the White House has drafted an executive order that would create a presidential food safety council charged with harmonizing food safety programs and spending.

The latest draft of the executive order, obtained by *Food Chemical News*, would establish a President's Council on Food Safety made up of cabinet and other high-level officials: the Agriculture Secretary, Health and Human Services Secretary, Assistant to the President for Domestic Policy, the Senior Policy Advisor for the Vice President and the Director of the Office of Science and Technology Policy. There was speculation last week that former FDA and USDA official Michael Taylor, a King & Spaulding attorney, would head the council.

The council's purpose would be to review reports from NAS and other organizations on the effectiveness of the current food safety system with an eye toward developing a comprehensive, science-based food safety strategy. That plan would include both interim and long-term food safety issues, including new and emergent threats and the needs of vulnerable populations.

"The council shall build upon the President's Interagency Food Safety Initiative and shall consult extensively with all concerned parties, including consumers, producers, industry, academia, and state and local governments," said the draft order. This would include continuing an emphasis on public-private partnerships. Specifically, the council would develop a "unified food safety budget" that would include money for surveillance, inspection, risk assessment, education and research. The council also would oversee the Joint Institute on Food Safety Research to ensure high-priority research is incorporated into the unified food safety plan.

The new council is just part of the streamlining reforms that will be announced by the Clinton administration. According to a draft "announcement package," the administration plans to cite gains made through the Food Safety Initiative and list "streamlining actions" aimed at better coordinating the federal food safety system.

(See *NAS report, Page 21*)

important to note that when the Florida Department of Citrus conducted tests on citrus, it had to artificially introduce pathogens because citrus found in the field does not bear the very microbes that FDA seeks to control. Even when the test fruit is contaminated in this manner, a 5-log reduction cannot be achieved," the congressmen maintained. (8FCN 2607, 2 pages, \$5)

— Allison Wright

### **(NAS report, continued from Page 3)**

Many of the initiatives are not new, will require legislative authority to accomplish and appear to hand FDA more jurisdiction over food safety, said a Capitol Hill staffer. One clear goal of the initiative is to consolidate food safety programs at FDA, which is expected to be hardest hit in the NAS report, which could be released as soon as this week. One source said the NAS report, requested by Congress last year, is "fairly negative" on FDA programs.

Under streamlining actions, the White House is considering consolidating egg regulatory programs at either the USDA or FDA. Removing the egg program from USDA would require legislation, said a Hill staffer. Other actions include moving USDA's food additive program to FDA, moving the FDA game meats program to USDA, moving the NMFS seafood program to FDA, consolidating animal pharmaceuticals at FDA, moving FDA bottled water regulation and all pesticide programs to the Environmental Protection Agency, and moving "all food transportation safety programs somewhere."

Under the umbrella of "efficiency-enhancing actions," FDA plans to contract with USDA's Foreign Agricultural Service, the Defense Department and USDA's Food Safety and Inspection Service to conduct foreign investigations, and partner with non-FDA federal personnel to conduct FDA domestic inspections. FDA would form an integrated food safety system with the states to conduct inspection activities, including the creation of a common database, uniform standards and training, and "across the board acceptance of state inspections by FDA, industry, and by foreign trade partners," said the draft document.

Finally, the administration plans to announce a National Food Safety Training Center, which will

train food handlers on uniform, multi-agency standards and protocols. This center could build on an existing FSIS training center in Texas and through the JIFSAN center in College Park, Md.

### **NAS panel not expected to recommend single food safety agency**

The NAS panel is not expected to recommend a single food safety agency, the National Food Processors Association and other sources told *Food Chemical News*.

The panel's report is, however, expected to recommend some improvements in coordinating food safety policy and more cooperation among the federal agencies that have some jurisdiction over food safety issues, including FDA, USDA and EPA. NFPA's Rhona Applebaum said the trade association's sources are confident that the panel is not recommending a single, omnibus agency or one like the Canadian food safety agency.

The panel's report, which has been held tightly by panel members while being independently reviewed, was due in Congress' hands on August 15. But NAS officials predict that the report won't be available until some time this week. Apparently, the reviewers made extensive comments that may take a few more days to incorporate into the final report.

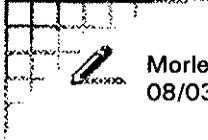
— Joan Murphy

### **No legal basis for imposing HACCP on processors of pasteurized juices, associations tell FDA**

FDA's proposal to mandate HACCP for processors of juice is factually, scientifically and legally unsupportable, according to two major food trade associations. It also "falls far short" of an adequate regulatory response to the demonstrated safety risks attributable to unpasteurized fruit and vegetable juices, according to the National Food Processors Association.

NFPA advised FDA in an Aug. 7 letter to revise the proposal and "promptly" impose a "universal thermal process or equivalent treatment requirement" for all juices that would destroy microorganisms of public health significance. NFPA also urged FDA to withdraw the juice HACCP proposal as unnecessary and unduly intrusive. Imposing HACCP procedures on companies

Food safety - single agency



Morley A. Winograd @ OVP  
08/03/98 10:58:27 AM

Record Type: Record

To: Thomas L. Freedman/OPD/EOP  
cc: Bruce N. Reed/OPD/EOP  
Subject: FW: Response to NAS report

Tom:

Here is one more perspective on what we might want to do on food safety. Don't know if you are familiar with how the possibility of a single food agency, etc. will play into the appropriations controversy next month.

You asked where I am on all this. I am in favor of creating a single food agency. I think the work that Jean has done in getting folks to a single vision and a comfort level with each other is an absolutely critical first step to getting to that goal. I am not clear in my own mind if we need to make the next step an interagency council with co-chairs and a clear mission to develop a single plan and budget for improving the safety of our food supply, but it sounds like the right next step, short of having a new agency. If I thought the timing was right for skipping that step and going directly to a new single agency I would be for that. My impression is that we are better off saving that one for the next Congress.

But if we do this interim thing, it should be with the clear understanding that our goal is seamless provision of food safety and that any organizational obstacles that are thrown up in the way of producing a single strategy and a single budgetary approach will be used as evidence on the need to move MORE quickly to a single food agency.

One last thought, while making Shalala and Glickman the co-chairs is probably the right solution, an alternative would be a Food Czar who they both agree on and who thereby gets a head start on becoming the agency head.

I think the people addressed on this message should meet this week with you and Jean Logan to make the call and get ready for next week.

Morley

----- Forwarded by Morley A. Winograd/OVP on 08/03/98 11:09 AM -----



Morley.Winograd @ npr.gov  
08/01/98 03:47:11 PM

Record Type: Record

To: Morley A. Winograd/OVP  
cc:  
Subject: FW: Response to NAS report

---

> -----Original Message-----

> From: Jean Logan  
> Sent: Friday, July 31, 1998 2:32 PM  
> To: Morley Winograd; Morley Winograd @OVP  
> Cc: Sarah Krissoff  
> Subject: FW: Response to NAS report

>

> Hi Morley

>

> See below. Cliff Gabriel is from OSTP, and I think leads their work  
> on food safety/food science. He's arguing for something similar to  
> what I was arguing for in my email from earlier today-that the  
> President ask his best science advisors to review the work of the NAS.  
> Thought you might be interested in his take.

>

> Have a great weekend.

>

> Jean

>

> -----Original Message-----

> From: Wendy\_A.\_Taylor@oa.eop.gov [SMTP:Wendy\_A.\_Taylor@oa.eop.gov]  
> <mailto:[SMTP:Wendy\_A.\_Taylor@oa.eop.gov]>  
> Sent: Friday, July 31, 1998 5:23 PM  
> To: Jean.Logan@npr.gov  
> Subject: Response to NAS report

>

> Message Creation Date was at 31-JUL-1998 17:23:00

> ----- Forwarded by Wendy A. Taylor/OMB/EOP on

> 07/31/98 05:22 PM

> -----

>

>

>

>

>

> Clifford J. Gabriel

> 07/31/98 05:22:43 PM

> Record Type: Record

> To: Thomas L. Freedman/OPD/EOP@EOP, Wendy A. Taylor/OMB/EOP@EOP,

> Dana L. Flower

> Lake/OMB/EOP@EOP, Jerold R. Mande/OSTP/EOP@EOP

> cc:

> Subject: Response to NAS report

>

> Just wanted to bounce some ideas of you for what we might want to do

> in

> response to the release of the NAS report. I think it would be very

> premature

> to announce any major new initiative that appears to be a knee-jerk

> reaction to

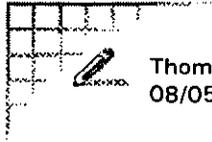
> outside criticism. All I think we need at the time of release is a

> well

> coordinated press package with Qs and As. We might also want to issue

- > a
- > Presidential Review Directive under the authority of the NSTC or DPC
- > to
- > consider the input from the Academy and develop a long-range plan that
- > includes
- > some of the tougher policy questions that have been difficult to focus
- > on to
- > date. This would initiate a thoughtful deliberative process, rather
- > than a
- > reactive one, that might get us where we want to go Remember we have
- > USDA/FDA
- > appropriations conference after the August recess, so we certainly
- > don't want
- > to announce anything that would jeopardize those negotiations. Cliff
- >
- >
- >

Food safety - simple agency



Thomas L. Freedman  
08/05/98 11:34:49 AM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc: Laura Emmett/WHO/EOP, Mary L. Smith/OPD/EOP

Subject: food notes



FOOD.08 FOODSAFE.7 Elena, here are some suggested talking points and Q and As for today's meeting, and a draft EO. I haven't shown the EO to anyone (although Eric confidentially helped draft it). I'd suggest that if you think it is ok, you be the one to send it to Morely, and if that you and he talk before the meeting. I talked to his secretary who is identifying the meeting as DPC/NPR when she calls.

If the EO looks ok, we should make copies to hand out.

## **Talking Points for Food Safety**

- \* The NAS report on single food agency is due out sometime around August 17th, the agencies are supposed to get to review it a couple days before it is released.
- \* We all have heard rumors about what is in the report. The report will obviously focus on structural shortcomings, it may or may not be seen as particularly critical by the media.
- \* We want to take advantage of the ideas in the report and the chance to keep looking at the way things are organized in the food safety area.
- \* One idea is for the President, before the report is released, to designate a group chaired by the Secretaries of USDA and HHS and with DPC, NPR and OSTP, to be designated to review the NAS report and report back and what steps we should take next. Perhaps he could do it in the radio address next week.
- \* We would also ask the group to formalize the current process and present a unified food safety budget based upon a unified food safety plan. If the group recommends another process in the future, we could move on from there.
- \* We've drafted something in the form of an executive order, it would be something weighty, but we wanted to get your reactions to this.
- \* I know you have done a lot of other work, I don't think this precludes the idea of something on eggs, I think it would compliment it.
- \* I also know you've put together a vision statement for the federal register on a seamless food agency and to hold public hearings, the process we're suggesting is similar -- we want the public hearings, we just want to take this next step now.

## Q and A

Q. Won't you be preempting NAS?

A. No, this is setting up a process for reviewing NAS and taking an incremental step on the budget that makes sense.

Q. Don't we already do a unified budget?

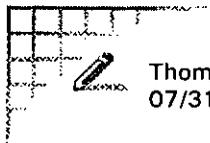
A. Yes, this does institutionalize that. Tom notes that this year there was some discussion whether to even do one. We want to make sure it happens.

Q. We don't know what the NAS report will say, do we want to get out there prematurely?

A. Well, this sets the stage to review NAS without being defensive. Everything we've heard is NAS will go further than what we propose, that it will recommend four options; including a food czar, putting one agency in charge, designating a lead agency, or creating an EPA like new agency. Maybe none of those options will make sense, in that case, suggesting this interim step at a later time may make even less sense -- we will look like we are doing too little too late.

Q. Will this unified budget cover everything that possible touches food safety or just issues in the initiative?

A. **(I would throw this open to discussion, the agencies have strong feelings about scope, and can perhaps hammer out the details of what should or should not be included.)**



Thomas L. Freedman  
07/31/98 01:12:52 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Michelle Crisci/WHO/EOP  
cc: Laura Emmett/WHO/EOP, Mary L. Smith/OPD/EOP  
Subject: NAS report on single food agency and Exec. Order



**FOODSAFE.7** Attached is a draft executive order establishing a Food Safety Council. The Council consists of the Secretaries of USDA, HHS, the DPC, and OSTP. HHS and USDA co-chair and they would appoint an exec. director. It is charged with developing a unified food safety budget, a unified food safety strategy, reviewing the NAS report and making recommendations, and overseeing the research institute. We have discussed this concept (but not the actual paper) with USDA and FDA, some people in each agency have reservations about it, and would likely prefer not to preempt NAS, but to instead wait and see what it says and what reaction it gets. OMB will also have concerns and will want time to vet it. If you are interested in circulating it, I have some thoughts on how to process it.

#### Other Information

The NAS report: According to sources, it is still on target for release August 17. It is still said to be critical of the current structure of food safety and includes criticism of food safety planning, budget and standard setting. It reportedly suggests action on dietary supplements, critiques current epidemiology, and criticizes the mixing of missions of promoting food and regulating it. It also cites specific recent examples including Guatemalan raspberries and the salmonella in cereal.

#### Other Steps.

We've asked the agencies to come up with other steps that could be announced independently or in conjunction with the above announcement. Here is what they suggest.

1. Eggs. The agencies say they could be ready to announce the shifting of responsibility for eggs to USDA, previously it was split between FDA and USDA.
2. Achievements. The agencies have prepared a list of areas in which they do cooperate successfully.
3. Vision statement and public hearings. The agencies have a shared "vision statement" on creating a "seamless food safety system" that they would put in the federal register and hold public hearings on.

(I'll be at the sports medicine doctor for part of this afternoon, but back later).

## **EXECUTIVE ORDER**

### **PRESIDENT'S COUNCIL ON FOOD SAFETY**

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to strengthen efforts to improve food safety for American consumers by establishing a President's Council on Food Safety, it is hereby ordered as follows:

#### **Section 1. Establishment of President's Council on Food Safety.**

(a) There is established the President's Council on Food Safety (Council). The Council shall comprise the Secretary of Agriculture, the Secretary of Health and Human Services, the Assistant to the President for Domestic Policy, the Senior Policy Advisor for the Vice President, and the Director of the Office of Science and Technology Policy. The Council shall consult with the Office of Management and Budget, the Environmental Protection Agency, the Department of Defense, the Commerce Department, and such other senior executive branch officials as the Council determines.

(b) The Secretaries of Agriculture and Health and Human Services shall serve as Co-Chairs of the Council. In consultation with other Council members, the Secretaries shall jointly designate an Executive Director for the Council. Council members may designate senior executive branch officials as their representatives.

#### **Section 2. Purpose.**

The purpose of the Council shall be to review the National Academy of Sciences report, "Ensuring Safe Food from Production to Consumption", and other reports on the effectiveness of the current food safety system, to review and improve ongoing efforts to develop and implement a science-based comprehensive strategy to improve the safety of the food supply, and work towards enhanced coordination among Federal agencies and with State, local governments and the private sector. The Council shall build upon the President's Interagency Food Safety Initiative and shall consult extensively with all concerned parties, including consumers, producers, industry, academia, and State and local governments.

#### **Section 3. Specific Activities and Functions.**

(a) The Council shall annually develop a unified food safety budget to eliminate duplication and ensure the most effective use of resources. This unified food safety budget shall include food safety surveillance, inspection, risk assessment, education, and research.

(b) The Council shall work to develop a science-based, unified plan for improving food safety from the farm to the table. The fundamental goal of the plan should be the establishment of a seamless food safety system, including the steps necessary to achieve this goal, and should consider key public-health, resource, and management questions facing Federal food safety

agencies. The plan should consider both interim and long term food safety issues, including new and emergent threats and the needs of vulnerable populations. The plan should include education, inspection, research, surveillance, and should also ensure effective coordination of Federal, State, local, and private resources to improve food safety, including public-private partnerships, where appropriate

(c) The Council shall oversee the operation of the Joint Institute on Food Safety Research, and shall ensure that the Institute focuses on addressing the high priority research needs identified in the unified food safety plan. The Council shall also ensure that the Institute issues a report annually and holds regular public conferences and meetings regarding food safety research developments and findings, including research conducted by the private sector and academia.

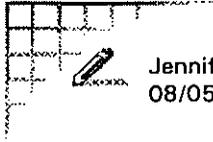
(d) The Council shall review the National Academy of Sciences report, "Ensuring Safe Food from Production to Consumption", and other reports on the effectiveness of the current food safety system. After providing opportunity for public comment, including public meetings, the Council shall report to the President with recommendations for appropriate additional actions to improve food safety. Any such recommendations should be in the context of the strategic planning effort of the President's Interagency Food Safety Initiatives.

#### Section 4. Cooperation.

All actions taken by the Council shall, as appropriate, further partnerships and cooperation with other public and private sector efforts wherever such partnerships and cooperation are possible and would further improve the safety of the food supply.

#### Section 5. Judicial Review.

This order does not create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.



Jennifer R. Muller @ OVP  
08/05/98 01:43:24 PM

Record Type: Record

To: Laura Emmett/WHO/EOP

cc:

Subject: Food Safety Meeting

The 2pm food safety meeting will include:

William Hubbard  
Dr. Michael Freedman (FDA)  
Cathy Woteki (USDA)  
Caren Wilcox (USDA)  
Eileene Kennedy (USDA)  
Lynn Goldman  
Judith Nelson  
Bruce Morehead  
Josh Gotbaum (OMB)  
TJ Glautier  
Dan Mendleson  
Morley Winograd  
Elena Kagen

Let me know if you need anything else. -JEN

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© The Council shall oversee the operation of the Joint Institute on Food Safety Research, and shall ensure that the Institute focuses on addressing the high priority research needs identified in the unified food safety plan. The Council shall also ensure that the Institute issues a report annually and holds regular public conferences and meetings regarding food safety research developments and findings, including research conducted by the private sector and academia.

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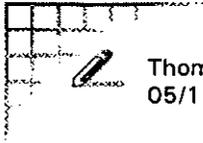
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#### Section 5. Judicial Review.

This order does not create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.

Can pro - food safety -  
single agency



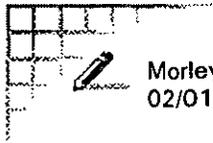
Thomas L. Freedman  
05/11/98 08:33:47 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP  
cc: Laura Emmett/WHO/EOP, Mary L. Smith/OPD/EOP  
Subject: Single Food Agency Issues

1. Issue: the prestigious National Academy of Science will likely release a first phase of its report on the single food agency in August. It is likely to list problems with the current food safety system.
2. Problem: We should try to be in a position so we don't have to just take the punch in August, but to agree with the findings and be on the side of reform when the report comes out. However, the cabinet secretaries have told the VP/Morely they would disagree strongly with a single food agency (unless it is in their department.)
3. What we've done so far: We've started a process with NPR, and joined by USDA, FDA, EPA, Commerce, OSTP and OMB to complete the following: list the areas we are likely to be criticized in, find what steps we have taken or could take to better coordinate federal policy, list the areas where we have on-going efforts at coordination, and complete a policy planning strategy statement that was promised in the May report of last year. The goal is to have at least a "virtual" food safety agency plan in place for each important area -- research, surveillance, emergency outbreaks, education, and by products where there is joint jurisdiction (eggs). The idea would be to have joint/coordinated plans made in every important area. We already do this for some problems (budget for example). I also thought we might formally designate a group to consider the NAS findings and recommendations and discuss how they could be implemented.  
It is the best plan we could come up with. Thoughts?

CMU pro -  
food safety -  
single agency



Morley A. Winograd @ OVP  
02/01/98 07:09:06 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:

Subject: Re: food safety

Elena:

We have a lot of catching up to do. I talked to Glickman and Shalala per VP's request and we also vetted idea with key cong. types. I have made a recommendation on how to proceed to VP, but do not have sign off on it from him or my staff. I promise to bring you back in the loop if you promise to tell me what is going on with INS reform. How about a quick conversation after Tuesday's COS meeting (I won't be there on Monday) and then lets proceed from there. In the meanwhile, I will send you for your eyes only what I recommended to VP.

Morley

EK--

Attached is the draft breakout of what would be in a single food agency. There was general agreement at the meeting today with OMB, OSTP, Cabinet Affairs, that this made sense. Sylvia sent a representative. The scope of the agency is food safety, farm to table, with emphasis on table, thus we avoid doing general pesticide regulation that EPA does as they study the whole chemical interaction with the environment, but we should include the USDA office that determines pesticide residue levels in food in the new agency.

It seems clear that on a good government level, the idea of a single food agency makes sense. But on the political level, OMB seems to want to make this an efficiency argument. I think it has to satisfy two constituencies-- consumers and farmers. We may need to think of how this increases resources or outputs related to food safety. In addition, to think about farmer groups I think we should add OPL at some point.

A handwritten signature in black ink, consisting of the letters 'FOM' in a stylized, cursive font. The 'F' is connected to the 'O', and the 'M' has a long, sweeping tail that extends to the right.

**Federal Food Safety Agency: Agencies Currently with Food Safety Activities**

Agency	Current Food Safety Responsibility	Authorizing Statute/ Relevant Cmtes.	FY 1998 Budget ( in millions)	Recommendation	Rationale
<p><b>HHS/FDA: Center for Food Safety and Applied Nutrition (CFSAN)</b></p>	<p>Regulates all food (except meat, poultry, and egg products) to ensure that it is wholesome, unadulterated, and properly labeled.</p> <p>Also responsible for the safety and proper labeling of cosmetics.</p>	<p><i>Statute:</i> Food, Drug, and Cosmetic Act</p> <p><i>House:</i> Commerce</p> <p><i>Senate:</i> Labor and Human Resources, Agriculture Appropriations Committees</p>	<p>\$220 M in appropriated BA and 2,342 FTEs.</p> <p>\$3.6 M in user fees for the certification of color additives.</p> <p>Note: Total FDA appropriated BA is \$925 M and 8,503 FTEs. Total program level is \$1,038 M and 9,288 FTEs which includes \$113 M in user fees.</p>	<p>Include as part of a new food safety agency.</p>	<p>The agency's primary responsibility is food safety inspections, food research and risk assessment, and education. These activities, along with the safety standards and inspections of meat and poultry, would comprise the core of any food safety agency.</p>
<p><b>HHS/FDA: Center for Veterinary Medicine (CVM)</b></p>	<p>Regulates the manufacture and distribution of drugs and feed additives intended for animals.</p>	<p><i>Statute:</i> Food, Drug, and Cosmetic Act</p> <p><i>House:</i> Commerce</p> <p><i>Senate:</i> Labor and Human Resources, Agriculture Appropriations Committees</p>	<p>\$44 M in appropriated BA</p> <p>403 FTEs.</p>	<p>Include as part of a new food safety agency.</p>	<p>The agency's primary responsibility is the approval of animal drugs and feeds, a major component of food safety.</p>

\* GAO also includes activities of the Treasury's Bureau of Alcohol, Tobacco, and Firearms, Treasury's Customs Service, and the Federal Trade Commission in their list of Federal food safety agencies.

**Federal Food Safety Agency: Agencies Currently with Food Safety Activities**

Agency	Current Food Safety Responsibility	Authorizing Statute/ Relevant Cmtes.	FY 1998 Budget ( in millions)	Recommendation	Rationale
<p><b>USDA: Food Safety Inspection Service (FSIS)</b></p>	<p>Regulates meat, poultry, and egg products to ensure that they are wholesome, unadulterated, and properly labeled</p>	<p><i>Statutes:</i> Federal Meat Inspection Act, Poultry Products Inspection Act, Egg Products Inspection Act</p> <p><i>House/Senate:</i> Agriculture</p> <p>Agriculture Appropriations Committees</p>	<p>\$589 M in appropriated BA</p> <p>\$94 M in user fees</p> <p>9,895 FTEs</p>	<p>Include as part of a new food safety agency</p>	<p>Setting standards and performing food safety inspections are the agency's primary responsibility.</p>
<p><b>USDA: Agricultural Research Service (ARS)</b></p>	<p>Performs food safety research, such as developing ways to detect and control bacterial contamination of foods</p>	<p><i>Statute:</i> Organic Act of 1862, Research and Marketing Act of 1946</p> <p><i>House/Senate:</i> Agriculture</p> <p>Agriculture Appropriations Committees</p>	<p>approx. \$50 M in appropriated BA</p> <p>150 FTEs</p>	<p>Include as part of a new food safety agency</p>	<p>This funding, in addition to the research funding provided through FDA's programs, would support the pre- and post-harvest research necessary to support the agency's regulatory and education activities.</p>
<p><b>Commerce: National Oceanic and Atmospheric Admin. (NOAA)</b></p>	<p>Provides voluntary inspection and certification services for fish and fishery products on a fee-for-service basis. Services address safety, wholesomeness, quality, and proper labelling of fishery products. Inspected products can carry a DOC mark indicating compliance with Federal standards.</p>	<p><i>Statute:</i> Agricultural Marketing Act</p> <p><i>House:</i> Resources</p> <p><i>Senate:</i> Commerce</p> <p>Commerce Appropriations</p>	<p>\$700,000 in appropriated BA</p> <p>\$13M in user fees</p> <p>190 FTE</p>	<p>Include as part of a new food safety agency</p>	<p>The agency contains the seafood inspection/products expertise that FDA needs to meet HACCP requirements. In order to gain efficiencies, NOAA and FDA are currently developing a legislative proposal to transfer NOAA'S National Marine Fisheries Service (NMFS) to FDA (as a PBO). The voluntary inspection program would continue, but NMFS inspectors would also be available for use by FDA to conduct inspections within its mandatory/regulatory program. NMFS' seafood expertise would be important to a new food safety agency, and inclusion in the new agency would avoid duplicative programs on labelling, wholesomeness, etc.</p>

**Federal Food Safety Agency: Agencies Currently with Food Safety Activities**

Agency	Current Food Safety Responsibility	Authorizing Statute/ Relevant Cmtes.	FY 1998 Budget ( in millions)	Recommendation	Rationale
<p align="center"><b>EPA – Drinking Water</b></p>	<p>Regulates drinking water to ensure that it is safe to drink. Conducts research to support standards.</p> <p>Regulates injection of contaminated water into underground wells to protect drinking water wells.</p> <p>Provides Drinking Water State Revolving Funds (DW SRFs) capitalization grants to states for infrastructure upgrades and state programs.</p>	<p><i>Statute:</i> Safe Drinking Water Act</p> <p><i>House:</i> Commerce, Science and Transportation (partial), Infrastructure (partial)</p> <p><i>Senate:</i> Environment, Public Works</p> <p>VA/HUD Appropriations subcommittees</p>	<p>\$149 M in BA for regulation, research and enforcement, \$105 M of which goes to States as grants to run drinking water and related programs. \$725 M for DW SRF capitalization grants.</p> <p>941 FTE</p>	<p>Do not include as part of a new food safety agency</p>	<p>The Administration and Congress just reformed this program, with passage of the 1996 SDWA Amendments, and the reforms seem to be working. Program implementation is very different from the other programs under consideration because the drinking water program is primarily implemented by the States with EPA grant money. There is also a large Federal assistance component in the DW SRF. EPA would lose significant economies of scale in the administration of the Drinking Water and Clean Water SRFs if they were separated. At the same time, the DW SRF needs input from the drinking water program on project prioritization based on public health goals. Protection of drinking water sources is an environmental issue and has synergies with EPA's Clean Water Act programs.</p>
<p align="center"><b>EPA – Pesticides</b></p>	<p>Evaluates the risks to public health and the environment from pesticide active and inert ingredients.</p> <p>Sets the terms and conditions for the sale, use, and labeling procedures for food/feed-use and nonfood-use pesticides.</p> <p>Sets pesticide worker protection standards, provides certification and training, works with USDA, FDA, and pesticide users to reduce pesticide risk and use, and promotes international harmonization and regulatory coordination.</p>	<p><i>Statute:</i> Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Federal Drug, and Cosmetic Act. (FFDCA), and Food Quality Protection Act of 1996 (FQPA) amending FIFRA and FFDCA.</p> <p><i>House:</i> Agriculture, Commerce</p> <p><i>Senate:</i> Agriculture, Labor and Human Resources</p> <p>VA/HUD and Agriculture Appropriations Committees</p>	<p>\$118 M (Total for all pesticide program activities)</p>	<p>Do not include as part of a new food safety agency.</p>	<p>It would be difficult to separate EPA's tolerance setting activities for food-use active ingredients from other registration, reregistration, and cross-cutting activities. EPA is currently implementing the requirements of the new law.</p>

**Federal Food Safety Agency: Agencies Currently with Food Safety Activities**

Agency	Current Food Safety Responsibility	Authorizing Statute/ Relevant Cmtes.	FY 1998 Budget ( in millions)	Recommendation	Rationale
<p><b>HHS: Center for Disease Control and Prevention (CDC)</b></p>	<p>Gives grants to State and Local Health Departments to conduct surveillance and investigate causes of human foodborne disease.</p> <p>Funds help link 8 "FoodNet" state laboratories via computer technology with CDC labs to conduct "digitized" fingerprinting of foodborne pathogens.</p> <p>Conducts research, trains epidemiologists and coordinates investigations of disease outbreaks.</p>	<p><i>Statute:</i> Public Health Service Act</p> <p><i>House:</i> Commerce</p> <p><i>Senate:</i> Labor and Human Resources</p> <p>L/HHS Appropriations Subcommittees.</p>	<p>Of the \$115 million appropriated for infectious disease activities, \$15 million is designated for <b>Foodborne Disease</b> activities.</p>	<p>Do not include as part of a new food safety agency.</p>	<p>As part of its overall infectious disease program activities, CDC awards grants to States to conduct surveillance and epidemiology of a variety of diseases including foodborne diseases, emerging infections and waterborne diseases. States conduct foodborne disease surveillance in concert with these other related surveillance activities. We recommend maintaining these functions within CDC given this structure and its longstanding relationship with State and local health departments.</p>
<p><b>USDA: Agricultural Marketing Service (AMS)</b></p>	<p>Pesticide data program (PDP) determines residue levels in food</p>	<p><i>Statute:</i> Agricultural Marketing Act of 1946</p> <p><i>House/Senate:</i> Agriculture</p> <p>Agriculture Appropriations Committees</p>	<p>PDP: \$10M in appropriated BA</p>	<p>Do not include as part of a new food safety agency</p>	<p>Pesticide programs are not recommended for inclusion in new agency</p>
<p><b>USDA: Grain Inspection</b></p>	<p>Determines levels of aflatoxin and vomitoxin as part of inspection process</p>	<p><i>Statute:</i> Agricultural Marketing Act of 1946, U.S. Grain Standards Act</p> <p><i>House/Senate:</i> Agriculture</p> <p>Agriculture Appropriations Committees</p>	<p>Aflatoxin and vomitoxin testing is funded through user fees, as one of several charges to users</p>	<p>Do not include as part of a new food safety agency</p>	<p>This is an integral part of the overall activities of this agency, and is only one of many tests that are given.</p>

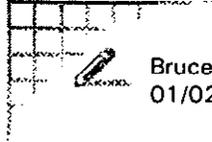
**Federal Food Safety Agency: Agencies Currently with Food Safety Activities**

Agency	Current Food Safety Responsibility	Authorizing Statute/ Relevant Cmtes.	FY 1998 Budget ( in millions)	Recommendation	Rationale
<b>USDA: Animal and Plant Health Inspection Service (APHIS)</b>	Ensures safety of animal and plant resources from infestations	<i>Statute:</i> many, including the Organic Act of 1944 and the 1990 Farm Bill  <i>House/Senate:</i> Agriculture  Agriculture Appropriations Committees	\$0 for direct food safety activities	Do not include as part of a new food safety agency	There is no immediate direct connection with food safety.

## Clinton Administration Food Safety Accomplishments

- 1993 USDA proposes **Safe Food Handling Labels** for meat and poultry products.
- 1993 Administration announces **Safe Drinking Water Act** reauthorization principles.
- 1993 **NPR recommends creating a single food safety agency**
- 1994 Administration proposes **Pesticide Reform Act of 1994**. This reform initiative was developed collaboratively by an interagency policy group including EPA, USDA, FDA, and other stakeholders to address the Delany Clause problem and the recommendations of the 1993 National Academy of Sciences report on procedures to improve pesticide regulation to better assure that children are fully protected from pesticide risk.
- 1994 USDA proposes **Pathogen Reduction Act**, which includes authority for mandatory recall, traceback, civil penalties, and the designation of foods not handled in a way to destroy pathogens as adulterated.
- 1995 **EPA reinvents Drinking Water Program** to reorient to the highest public health risks, using administrative authorities and renegotiating consent decrees.
- 1995 **FDA Seafood HACCP** final rule is published.
- 1996 Administration and Congress reauthorize the **Safe Drinking Water Act**. The new law includes most of the Administration's principles and reinvention activities to address highest risks.
- 1996 **The Food Quality Protection Act of 1996 (FQPA)**, unanimously passed by Congress, is signed.
- 1996 **USDA Meat and Poultry HACCP program** final rule is published.
- 1997 **President's Food Safety Initiative** is announced. USDA, HHS, and EPA draft a report to the President with a plan to improve food safety that includes budget, regulatory and legislative proposals.
- 1997 FDA publishes **Substances Prohibited from Use in Animal Feed, Animal Proteins Prohibited in Ruminant Feed (Mad Cow Disease Rule)**; final rule.
- 1997 FDA publishes the **Fruit and Vegetable Juice Beverages HACCP program**, Interim Warning Statement, and Educational Program; notice.
- 1997 USDA proposes "**The Food Safety Enforcement Enhancement Act of 1997**" to strengthen its enforcement authority by allowing for mandatory recalls and civil penalties in response to the voluntary recall of 25 million pounds of hamburger.
- 1997 President announces new **initiative to enhance FDA oversight over imported foods** and develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

Cms pro-food safety -  
single agency



Bruce N. Reed  
01/02/98 04:36:52 PM

Record Type: Record

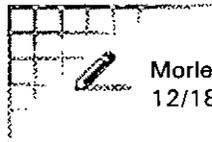
To: Elena Kagan/OPD/EOP

cc:

Subject: Status of pure food agency proposal

Any news on this front?

----- Forwarded by Bruce N. Reed/OPD/EOP on 01/02/98 04:36 PM -----



Morley A. Winograd @ OVP  
12/18/97 07:53:49 PM

Record Type: Record

To: Paul E. Begala/WHO/EOP, Rahm I. Emanuel/WHO/EOP

cc: Bruce N. Reed/OPD/EOP

Subject: Status of pure food agency proposal

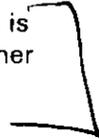
Per both of your requests for status and offers to help, here is what happened at first planning meeting on the issue today, chaired by Elena.

Sally Katzen presented OMB's arguments for single agency and why we should do this in terms of policy benefits and government efficiency. NPR supported recommendation as we have since 1993. We agreed that OMB's idea for single agency is an even better idea and might help with the meat and poultry producers who wanted no part of being regulated by HHS the last time.

Decision was made to run this one by Secretaries Glickman and Shalala before proceeding. Bruce Reed was to do that. If either of you want to help Bruce, talk to him about it. There does appear to be a legislative vehicle already out there that might be used for this. Hilley was to check out its status.

Question was asked as to depth of VP's support. Since I wasn't there, NPR repeated that this is one of those recommendations that we have never backed off of or abandoned. I will get further reading from VP ASAP and let you know if there is any reason for concern there.

Morley



Private convs w/ Schalala/Slickman

Jethro/Kennedy/Harkin/Lugar  
Schalala/Smith

- Senate } need control by  
strategies

Hit members; not staff  
(Work w/ Drubon/Fazio)

Keep in same approps conf

Kennedy on labor side -

try to get him involved in beginning

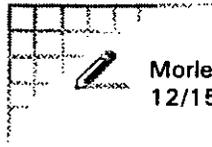
Summer groups - get support  
but they'll not be discrete -  
timing is key.

Big cos - major players in food industry

Look at straw man - which ~~issues~~ <sup>issues</sup> do we want to  
pick up? Policy vehicle group - should set up  
1:00 - Sally mtg.

See if Hiller  
Thinks were  
wets.

Cms pro - food safety - single agency



Morley A. Winograd @ OVP  
12/15/97 06:29:18 PM

Record Type: Record

To: Elena Kagan/OPD/EOP  
cc:  
Subject: Food safety continued

Elena:

Here is first thoughts on possible opposition to the idea from constituents. But keep in mind we WANT to do this.

Morley

----- Forwarded by Morley A. Winograd/OVP on 12/15/97 06:37 PM -----



Jean.Logan @ npr.gsa.gov  
12/15/97 05:51:00 PM

Record Type: Record

To: Morley A. Winograd @ OVP@EOP  
cc:  
Subject: Food safety continued

Off the top of my head, and without having been personally involved in the work on food safety to any great extent, here is what I know:

Food safety responsibilities are scattered, so there will be serious federal territory issues, as there was in 1993 when we proposed that food safety be consolidated in FDA. The turmoil that recommendation caused is one of the main reasons that the HHS accompanying report, which contained the recommendation, never came out.

The 2 proposals being considered call for either a stand alone agency, or a new agency under the HHS umbrella. OMB is not considering consolidation in USDA.

The big player is the meat and poultry industry and they would strongly oppose any consolidation into HHS--they've grown comfortable with the USDA oversight, and would expect massive change in the inspection system if food safety was under the HHS umbrella.

Therefore I would expect that USDA would find it more palatable to have food safety relocated into a stand alone agency, rather than in either an existing or new agency under HHS.

Consumer groups would applaud the single food agency concept, wherever it was placed.

While some may say this is an example of government growing, it's really not--it's a consolidation of existing functions; nothing is being expanded, there's really nothing new here.

I'll keep poking around and keep you posted.

*Case no - food safety - single agency*

**SUBJECT: CREATING A SINGLE FOOD SAFETY AGENCY**

The current food safety system is criticized for its fragmentation, lack of coordination, inconsistencies in inspection coverage, non-uniform enforcement authorities, and inefficient distribution of resources. A single agency that combined the food safety programs of USDA, HHS/FDA, and the seafood inspection activities of the Department of Commerce could address these concerns. A single food safety agency would:

- Eliminate many unnecessary activities, such as overlapping research and duplicate inspection of establishments that produce products regulated by different agencies;
- Improve the coordination of Federal responses to foodborne illness outbreaks by eliminating gaps in regulatory coverage, avoiding conflicting actions, and ensuring a comprehensive Federal response; and
- Allow for better allocation of scarce Federal food safety resources based on the risk that different commodities pose to public health (e.g., over twice as much is spent on meat and poultry inspection as on inspection for all other foods), and better responses to changing consumption patterns and emerging food safety issues.

This single food safety agency could be either: (1) a new, stand-alone food safety agency, or (2) under the auspices of an existing department. Given the need for this agency to have a clear public health mission, if placed in an existing department, HHS would be the most appropriate home. USDA's mission is broader than HHS' and encompasses an industry promotion responsibility, which could conflict with a food safety agency's regulatory responsibilities. ] ✓

**Option 1: Create a new stand-alone agency**

- Would highlight food safety issues; food safety issues would be the agency's top priority.
- Would limit interest group opposition. The meat and poultry industry, and therefore the Agriculture Committees, strongly oppose moving food safety activities into HHS because they fear this might result in undesirable changes or rapid streamlining of the inspection system and because they believe USDA is better positioned to take a "farm-to-table" approach to food safety. (Note: USDA and FDA share the same appropriations subcommittee.)
- Would limit Federal agency opposition. USDA opposed a proposal included in the first National Performance Review (NPR) report to consolidate the food safety functions within FDA; HHS would likely oppose a similar consolidation of food safety activities within USDA.
- Is consistent with a recent legislative proposal of Senators Durbin and Torricelli and Representatives Fazio and Pallone.

**Option 2: Consolidate food safety programs within HHS**

- May appear to reduce the Federal bureaucracy rather than enlarge it.
- May allow for better coordination and the leveraging of resources among all agencies with public health mandates.
- Would have direct cabinet access through the HHS Secretary.
- Is consistent with the 1993 NPR proposal to form a single food safety agency.
- May have lower administrative costs than creating a new, independent agency because it would be able to share the overhead resources of HHS.

cons pro - food safety - single agency



EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF MANAGEMENT AND BUDGET  
WASHINGTON, D.C. 20503

EK -  
They say they  
haven't shared  
this w/ the agencies.  
The chert at the  
back is useful.  
Tom

November 20, 1997

MEMORANDUM FOR THE DIRECTOR

THROUGH:

T.J. GLAUTHIER  
JOSH GOTBAUM  
SALLY KATZEN

*[Handwritten initials: JG, SK, JE]*

FROM:

Adrienne Erbach/Jim Esquea/Wendy Taylor/Lisa Grove/David  
Rowe/Greg White/Pam Barr/Gillian Foster/Sarah Laskin/Margaret  
Malanoski

*[Handwritten initials: AE, JE, WT, JL, DR, GR, PB, GB, GF, SL, MM]*

SUBJECT: Creation of a Single Food Safety Agency (DECISION)

This responds to your request at the November 5th USDA budget review for a memorandum on the pros and cons of creating a single food safety agency.

**ISSUE:** Can the current fragmented Federal food safety system be improved to better address the risks of foodborne illness, and to clarify and simplify Federal agencies accountability on food safety-related issues? The current organizational structure of food safety agencies is arbitrary and fragmented; it impedes coordination and Federal response to crises; it permits an inefficient distribution of food safety resources among agencies; and it inhibits the allocation of resources based on risk and cost effectiveness. Inconsistent approaches and the lack of uniform enforcement authorities also undermine the system's effectiveness (e.g., foods posing similar health risks, such as seafood, meat, and poultry are treated differently). Creation of an appropriately uniform, risk-based system under a single food safety agency should help to address these problems.

**BACKGROUND:** Federal food safety activities are divided among 12 different federal agencies, six of which have major roles. (See the attached table of the major food safety agencies.) This division of responsibilities was not deliberately designed, but rather evolved as Congress passed laws to address particular food safety concerns, beginning at the turn of the century.

The Clinton Administration has actively worked to improve the Federal food safety system. Since the January 1993 outbreak of foodborne illness arising from Jack-In-The-Box hamburgers in Washington State, the Administration has proposed new regulations and legislative changes, and has taken administrative steps to make the Federal inspection systems more science-based and focused on microbiological pathogens (e.g., bacteria, viruses, and parasites). (See the attached list of the Administration's food safety accomplishments.)

However, food safety efforts to date do not address the fundamental problem that the Federal government's food safety activities remain highly fragmented. Over the past few years, there have been numerous calls to consolidate Federal food safety activities into one agency. In 1993, the first National Performance Review report proposed creating a single food safety agency within FDA. As far back as May 1994 and as recently as October 1997, GAO recommended the creation of a single agency. In the FY 1998 Agriculture Appropriations Bill, Congress funded a study to be conducted by the National Academy of Sciences to look at the need for and feasibility of creating a single food safety agency. The study is due by August 15, 1998. Most recently, on November 4th, Senators Durbin and Torricelli and Representatives Fazio and Pallone introduced the "Safe Food Act of 1997," which would establish an independent food safety agency.

The creation of a single food safety agency has failed largely because of interest group and bureaucratic opposition. Bureaucratic opposition is largely the result of agencies protecting their turf. For instance, USDA opposed the NPR's proposal to move all food safety activities into FDA; as a result, the Administration never developed legislation to implement this change. HHS would likely oppose a similar consolidation of food safety activities into USDA. Consumer groups oppose moving all food safety activities under USDA because they believe it would cause a conflict of interest between the Department's food industry promotion and food safety regulation activities. The meat and poultry industry, and therefore the Agriculture Committees, strongly oppose moving food safety activities into HHS because they fear this might result in changes or streamlining of the inspection system and because they believe USDA is better positioned to take a "farm-to-table" approach to food safety.

## **ANALYSIS:**

**Issue 1:**     Should food safety programs be consolidated into one agency?

### **Pros:**

- Consolidation will help in the development of a comprehensive, focused Federal food safety policy for meat, poultry, fruits, vegetables, seafood, and all other foods.
- Scarce Federal food safety resources could be better allocated based on the risk that different commodities pose to public health, and could more easily respond to changing consumption patterns and emerging food safety issues.
- It would eliminate many duplicative activities, such as the duplicate inspection of establishments that produce products regulated by the different agencies (e.g., FDA inspects frozen cheese pizzas while USDA inspects frozen pepperoni pizzas), and duplicative, overlapping research.
- It would improve the coordination of Federal responses to foodborne illness outbreaks by eliminating gaps in regulatory coverage, avoiding conflicting actions, and ensuring a comprehensive Federal response.
- It would combine the strengths of FDA and USDA (e.g., the science and risk-based approach of FDA with the funding and staff of USDA) and thus strengthen Federal regulation of all foods.

**Cons:**

- It could be viewed as “moving the boxes around” rather than addressing substantive food safety issues. Consolidation is only the first step toward consistency in inspection requirements for different food products; other significant statutory changes would be needed in the future (e.g., the meat and poultry acts currently require “continuous inspection” which limits USDA’s ability to target its inspections, while FDA conducts periodic, random inspection of all other food processing plants.)
- The likelihood that a proposed consolidation will not be implemented is high, given the history of consolidation efforts.
- The inspection forces of FDA and USDA differ in average salary/grade, training, and education requirements. USDA’s inspectors’ union has actively opposed previous proposals they believed would reduce the number of inspectors.

**Issue 2:**      Should the new agency be a stand-alone (vs. located within an existing agency)?

**Pros:**

- A stand-alone agency would limit interest group opposition.
- The agency could promote a public health focus without the perception that it also has industry promotion responsibilities.

**Cons:**

- The agency would be relatively small, with a program level of \$1 billion and a staff of 12,980 FTEs.
- There may be higher administrative costs associated with creating a new, independent agency because it would not be able to share the resources of an existing agency.

**Issue 3:**      Which programs should be combined?

To improve the chances of successful implementation, we recommend that this new food safety agency have a narrow focus, with a primary mission of food safety inspection, research, and education. Out of the 12 Federal agencies with food safety activities, we recommend including only four: (1) USDA's Food Safety Inspection Service (FSIS); (2) the risk assessment and research activities of USDA's Agricultural Research Service (ARS); (3) HHS/FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Center of Veterinary Medicine (CVM); and (4) the fish inspection activities of Commerce's National Oceanic and Atmospheric Administration (NOAA). The attached table explains in detail why we recommend including these agencies and excluding others.

Some groups have recommended that the drinking water and pesticide activities of the Environmental Protection Agency (EPA) should also be part of a single food safety agency. However, including this part of EPA would broaden the focus of a new food safety agency too much, and it is not clear what gain would come from including this program in a new food safety agency. See the attached table for a detailed explanation of our rationale.

**NEXT STEPS / IMPLEMENTATION ISSUES:** Finally, given the agencies reactions in the past, it is likely that neither FDA nor USDA will be willing to work hard to get a bill enacted that creates a single food safety agency. *White House approval and strong Cabinet-level support, as well as an implementation strategy that recognizes historical consolidation pitfalls, will be needed to move this proposal.* This issue should be discussed among senior White House officials, and an implementation/roll-out strategy should be developed, prior to consulting with the affected agencies.

**RECOMMENDATION:**

Issue 1: Propose in the Budget to create a single food safety agency.

Agree \_\_\_\_\_ Disagree \_\_\_\_\_ Let's discuss \_\_\_\_\_

Issue 2: Propose that it be a stand-alone agency, not housed within an existing department.

Agree \_\_\_\_\_ Disagree \_\_\_\_\_ Let's discuss \_\_\_\_\_

Issue 3: Include the FSIS, the food safety and animal drug activities of FDA, the seafood inspectors from NOAA, and USDA's food safety research, education, and risk assessment activities, but not EPA's drinking water and pesticides programs.

Agree \_\_\_\_\_ Disagree \_\_\_\_\_ Let's discuss \_\_\_\_\_

Attachments

Federal Food Safety Agency: Agencies Currently with Food Safety Activities					
Agency	Current Food Safety Responsibility	Authorizing Statute/ Relevant Cmtes.	FY 1998 Budget ( in millions)	Recommendation	Rationale
<b>HHS/FDA: Center for Food Safety and Applied Nutrition (CFSAN)</b>	Regulates all food (except meat, poultry, and egg products) to ensure that it is wholesome, unadulterated, and properly labeled.  Also responsible for the safety and proper labeling of cosmetics.	<i>Statute:</i> Food, Drug, and Cosmetic Act  <i>House:</i> Commerce  <i>Senate:</i> Labor and Human Resources,  Agriculture Appropriations Committees	\$220 M in appropriated BA and 2,342 FTEs.  \$3.6 M in user fees for the certification of color additives.  Note: Total FDA appropriated BA is \$925 M and 8,503 FTEs. Total program level is \$1,038 M and 9,288 FTEs which includes \$113 M in user fees.	Include as part of a new food safety agency.	The agency's primary responsibility is food safety inspections, food research and risk assessment, and education. These activities, along with the safety standards and inspections of meat and poultry, would comprise the core of any food safety agency.
<b>HHS/FDA: Center for Veterinary Medicine (CVM)</b>	Regulates the manufacture and distribution of drugs and feed additives intended for animals.	<i>Statute:</i> Food, Drug, and Cosmetic Act  <i>House:</i> Commerce  <i>Senate:</i> Labor and Human Resources,  Agriculture Appropriations Committees	\$44 M in appropriated BA  403 FTEs.	Include as part of a new food safety agency.	The agency's primary responsibility is the approval of animal drugs and feeds, a major component of food safety.

\* GAO also includes activities of the Treasury's Bureau of Alcohol, Tobacco, and Firearms, Treasury's Customs Service, and the Federal Trade Commission in their list of Federal food safety agencies.

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<p><b>USDA: Food Safety Inspection Service (FSIS)</b></p>	<p>Regulates meat, poultry, and egg products to ensure that they are wholesome, unadulterated, and properly labeled</p>	<p><i>Statutes:</i> Federal Meat Inspection Act, Poultry Products Inspection Act, Egg Products Inspection Act</p> <p><i>House/Senate:</i> Agriculture</p> <p>Agriculture Appropriations Committees</p>	<p>\$589 M in appropriated BA</p> <p>\$94 M in user fees</p> <p>9,895 FTEs</p>	<p>Include as part of a new food safety agency</p>	<p>Setting standards and performing food safety inspections are the agency's primary responsibility.</p>
<p><b>USDA: Agricultural Research Service (ARS)</b></p>	<p>Performs food safety research, such as developing ways to detect and control bacterial contamination of foods</p>	<p><i>Statute:</i> Organic Act of 1862, Research and Marketing Act of 1946</p> <p><i>House/Senate:</i> Agriculture</p> <p>Agriculture Appropriations Committees</p>	<p>approx. \$50 M in appropriated BA</p> <p>150 FTEs</p>	<p>Include as part of a new food safety agency</p>	<p>This funding, in addition to the research funding provided through FDA's programs, would support the pre- and post-harvest research necessary to support the agency's regulatory and education activities.</p>
<p><b>Commerce: National Oceanic and Atmospheric Admin. (NOAA)</b></p>	<p>Provides voluntary inspection and certification services for fish and fishery products on a fee-for-service basis. Services address safety, wholesomeness, quality, and proper labelling of fishery products. Inspected products can carry a DOC mark indicating compliance with Federal standards.</p>	<p><i>Statute:</i> Agricultural Marketing Act</p> <p><i>House:</i> Resources</p> <p><i>Senate:</i> Commerce</p> <p>Commerce Appropriations</p>	<p>\$700,000 in appropriated BA</p> <p>\$13M in user fees</p> <p>190 FTE</p>	<p>Include as part of a new food safety agency</p>	<p>The agency contains the seafood inspection/products expertise that FDA needs to meet HACCP requirements. In order to gain efficiencies, NOAA and FDA are currently developing a legislative proposal to transfer NOAA'S National Marine Fisheries Service (NMFS) to FDA (as a PBO). The voluntary inspection program would continue, but NMFS inspectors would also be available for use by FDA to conduct inspections within its mandatory/regulatory program. NMFS' seafood expertise would be important to a new food safety agency, and inclusion in the new agency would avoid duplicative programs on labelling, wholesomeness, etc.</p>

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**Federal Food Safety Agency: Agencies Currently with Food Safety Activities**

Agency	Current Food Safety Responsibility	Authorizing Statute/ Relevant Cmtes.	FY 1998 Budget ( in millions)	Recommendation	Rationale
EPA -- Drinking Water	<p>Regulates drinking water to ensure that it is safe to drink. Conducts research to support standards.</p> <p>Regulates injection of contaminated water into underground wells to protect drinking water wells.</p> <p>Provides Drinking Water State Revolving Funds (DW SRFs) capitalization grants to states for infrastructure upgrades and state programs.</p>	<p><i>Statute:</i> Safe Drinking Water Act</p> <p><i>House:</i> Commerce, Science and Transportation (partial), Infrastructure (partial)</p> <p><i>Senate:</i> Environment, Public Works</p> <p>VA/HUD Appropriations subcommittees</p>	<p>\$149 M in BA for regulation, research and enforcement, \$105 M of which goes to States as grants to run drinking water and related programs.</p> <p>\$725 M for DW SRF capitalization grants.</p> <p>941 FTE</p>	<p>Do not include as part of a new food safety agency</p>	<p>The Administration and Congress just reformed this program, with passage of the 1996 SDWA Amendments, and the reforms seem to be working. Program implementation is very different from the other programs under consideration because the drinking water program is primarily implemented by the States with EPA grant money. There is also a large Federal assistance component in the DW SRF. EPA would lose significant economies of scale in the administration of the Drinking Water and Clean Water SRFs if they were separated. At the same time, the DW SRF needs input from the drinking water program on project prioritization based on public health goals. Protection of drinking water sources is an environmental issue and has synergies with EPA's Clean Water Act programs.</p>
EPA -- Pesticides	<p>Evaluates the risks to public health and the environment from pesticide active and inert ingredients.</p> <p>Sets the terms and conditions for the sale, use, and labeling procedures for food/feed-use and nonfood-use pesticides.</p> <p>Sets pesticide worker protection standards, provides certification and training, works with USDA, FDA, and pesticide users to reduce pesticide risk and use, and promotes international harmonization and regulatory coordination.</p>	<p><i>Statute:</i> Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Federal Drug, and Cosmetic Act. (FFDCA), and Food Quality Protection Act of 1996 (FQPA) amending FIFRA and FFDCA.</p> <p><i>House:</i> Agriculture, Commerce</p> <p><i>Senate:</i> Agriculture, Labor and Human Resources</p> <p>VA/HUD and Agriculture Appropriations Committees</p>	<p>\$118 M (Total for all pesticide program activities)</p>	<p>Do not include as part of a new food safety agency.</p>	<p>It would be difficult to separate EPA's tolerance setting activities for food-use active ingredients from other registration, reregistration, and cross-cutting activities. EPA is currently implementing the requirements of the new law.</p>

**Federal Food Safety Agency: Agencies Currently with Food Safety Activities**

Agency	Current Food Safety Responsibility	Authorizing Statute/ Relevant Cmtes.	FY 1998 Budget ( in millions)	Recommendation	Rationale
<p><b>HHS: Center for Disease Control and Prevention (CDC)</b></p>	<p>Gives grants to State and Local Health Departments to conduct surveillance and investigate causes of human foodborne disease.</p> <p>Funds help link 8 "FoodNet" state laboratories via computer technology with CDC labs to conduct "digitized" fingerprinting of foodborne pathogens.</p> <p>Conducts research, trains epidemiologists and coordinates investigations of disease outbreaks.</p>	<p><i>Statute:</i> Public Health Service Act</p> <p><i>House:</i> Commerce</p> <p><i>Senate:</i> Labor and Human Resources</p> <p>L/HHS Appropriations Subcommittees.</p>	<p>Of the \$115 million appropriated for infectious disease activities, \$15 million is designated for Foodborne Disease activities.</p>	<p>Do not include as part of a new food safety agency.</p>	<p>As part of its overall infectious disease program activities, CDC awards grants to States to conduct surveillance and epidemiology of a variety of diseases including foodborne diseases, emerging infections and waterborne diseases. States conduct foodborne disease surveillance in concert with these other related surveillance activities. We recommend maintaining these functions within CDC given this structure and its longstanding relationship with State and local health departments.</p>
<p><b>USDA: Agricultural Marketing Service (AMS)</b></p>	<p>Pesticide data program (PDP) determines residue levels in food</p>	<p><i>Statute:</i> Agricultural Marketing Act of 1946</p> <p><i>House/Senate:</i> Agriculture</p> <p>Agriculture Appropriations Committees</p>	<p>PDP: \$10M in appropriated BA</p>	<p>Do not include as part of a new food safety agency</p>	<p>Pesticide programs are not recommended for inclusion in new agency</p>
<p><b>USDA: Grain Inspection</b></p>	<p>Determines levels of aflatoxin and vomitoxin as part of inspection process</p>	<p><i>Statute:</i> Agricultural Marketing Act of 1946, U.S. Grain Standards Act</p> <p><i>House/Senate:</i> Agriculture</p> <p>Agriculture Appropriations Committees</p>	<p>Aflatoxin and vomitoxin testing is funded through user fees, as one of several charges to users</p>	<p>Do not include as part of a new food safety agency</p>	<p>This is an integral part of the overall activities of this agency, and is only one of many tests that are given.</p>

Federal Food Safety Agency: Agencies Currently with Food Safety Activities					
Agency	Current Food Safety Responsibility	Authorizing Statute/ Relevant Cmtes.	FY 1998 Budget ( in millions)	Recommendation	Rationale
<b>USDA: Animal and Plant Health Inspection Service (APHIS)</b>	Ensures safety of animal and plant resources from infestations	<i>Statute:</i> many, including the Organic Act of 1944 and the 1990 Farm Bill  <i>House/Senate:</i> Agriculture  Agriculture Appropriations Committees	\$0 for direct food safety activities	Do not include as part of a new food safety agency	There is no immediate direct connection with food safety.

## Clinton Administration Food Safety Accomplishments

- 1993 **USDA proposes Safe Food Handling Labels** for meat and poultry products.
- 1993 **Administration announces Safe Drinking Water Act** reauthorization principles.
- 1993 **NPR recommends creating a single food safety agency**
- 1994 **Administration proposes Pesticide Reform Act of 1994.** This reform initiative was developed collaboratively by an interagency policy group including EPA, USDA, FDA, and other stakeholders to address the Delany Clause problem and the recommendations of the 1993 National Academy of Sciences report on procedures to improve pesticide regulation to better assure that children are fully protected from pesticide risk.
- 1994 **USDA proposes Pathogen Reduction Act,** which includes authority for mandatory recall, traceback, civil penalties, and the designation of foods not handled in a way to destroy pathogens as adulterated.
- 1995 **EPA reinvents Drinking Water Program** to reorient to the highest public health risks, using administrative authorities and renegotiating consent decrees.
- 1995 **FDA Seafood HACCP** final rule is published.
- 1996 **Administration and Congress reauthorize the Safe Drinking Water Act.** The new law includes most of the Administration's principles and reinvention activities to address highest risks.
- 1996 **The Food Quality Protection Act of 1996 (FQPA),** unanimously passed by Congress, is signed.
- 1996 **USDA Meat and Poultry HACCP program** final rule is published.
- 1997 **President's Food Safety Initiative** is announced. USDA, HHS, and EPA draft a report to the President with a plan to improve food safety that includes budget, regulatory and legislative proposals.
- 1997 **FDA publishes Substances Prohibited from Use in Animal Feed, Animal Proteins Prohibited in Ruminant Feed (Mad Cow Disease Rule);** final rule.
- 1997 **FDA publishes the Fruit and Vegetable Juice Beverages HACCP program,** Interim Warning Statement, and Educational Program; notice.
- 1997 **USDA proposes "The Food Safety Enforcement Enhancement Act of 1997"** to strengthen its enforcement authority by allowing for mandatory recalls and civil penalties in response to the voluntary recall of 25 million pounds of hamburger.
- 1997 **President announces new initiative to enhance FDA oversight over imported foods and** develop guidance on good agricultural and manufacturing practices for fruits and vegetables.