

Food Safety

APPENDIX

These are the organizational options contained in the current draft of the Council's strategic plan.

I. Coordinated Federal Food Safety System

This option would provide centralized executive leadership (including a "single voice" for food safety), and improved coordination to facilitate achievement of food safety and public health goals. There are alternative ways to accomplish this. The alternatives differ in terms of the nature of the executive leadership as well as whether there is coordination and oversight of not only planning, budgeting and research, but also policy and/or operations. There would be no organizational changes with this option. It could be implemented alone or in combination with Option II, some Lead Agency alternatives under Option III, or the less expansive forms of a consolidated agency in Options IV and V.

- A. Modified President's Council on Food Safety: This sub-option would modify the current Council structure for coordination and leadership. Specifically, the President's Council would be modified by designating a single chair appointed by the President, establishing a small dedicated staff, and/or broadening the Council's members to include representatives from the Federal Trade Commission (FTC), the Department of Treasury (DOT), and the Department of Defense (DOD).
- B. Joint Chiefs of Staff: In this sub-option, a Board of Directors or Joint Chiefs of Staff would be established with a neutral Chairman appointed by the President and representatives from all the food safety regulatory agencies. Each agency would retain its core mission, but would be obliged to plan and coordinate in areas where their missions coincide.

II. Specific Consolidations of Food Safety Functions

This option would consist of streamlining or consolidating specific federal food safety functions, particularly those where there are jurisdictional overlap, perceived duplication, or public confusion, in order to more efficiently achieve the goals of the Strategic Plan. In this option, full responsibility for certain food products or for specific points in the farm-to-table chain would be housed in one place within an existing organization.

Examples of areas which might be examined for the possibility of streamlining or consolidation include:

- A. Certain Food Products: game meats and USDA-regulated meats; pizza (cheese and pepperoni); and sandwiches (open-faced and closed-faced).
- B. Specific Points in Farm-To-Table Continuum: food production on farms; egg safety; and federal guidance for retail establishments.

- C. Functional Overlaps: inspections at jointly-regulated facilities; pre-market approval of antimicrobials; animal drugs and biologics; and food safety labeling.

An in-depth analysis could result in specific areas being consolidated (e.g., oversight of all meats with USDA; all federal guidance for retail food operations with DHHS), or food safety responsibilities for certain points in the farm-to-table chain being placed with one agency (such as discussed in the Egg Action Plan regarding packer/distributors).

III. Lead Agency Approach

As in Option I, the Lead Agency Approach provides centralized executive leadership and a "single voice" for all or discrete parts of the food safety system. It differs from Option I in that one agency becomes the lead for all or for specific food safety functions rather than vesting the "single voice" for food safety in a Council or Joint Chiefs. This option could be implemented in combination with Option II and the Canadian Model might also be combined with Option I.

- A. Single Lead Agency: Designate one agency as the lead agency (USDA or DHHS) and have the head of that agency be responsible for achieving food safety goals, including determining the strategic direction of federal food safety planning, budgeting, and policy.
- B. Canadian Model: This option would establish two lead agencies, and each would have specific areas of responsibility under all the food safety laws for achievement of the Strategic Plan goals. For example, one agency could be responsible for monitoring, inspection, recall, enforcement and outbreak response for all foods and components of food (e.g., food additives, pesticides). Another agency could be responsible for research, risk assessment, surveillance, standards and regulations for all food products (meat, poultry, eggs, and other foods). EPA would continue to register and set tolerances for pesticides. This would be similar, but not identical, to the recently reorganized Canadian food safety system.

IV. Consolidated Agency within Existing Department/Organization

This option would consolidate most food safety regulatory functions--i.e., policy, guidance, standard setting, inspection, enforcement, and education--in one agency reporting to either a current Cabinet Secretary, or the management of an existing independent agency.

- A. Under HHS: Combine food safety responsibilities within HHS, headed by a Presidential-appointed, sub-Cabinet level official, such as the Commissioner for Food and Drugs. This sub-option is similar, but not identical, to Great Britain's consolidation.
- B. Under USDA: Combine food safety responsibilities within USDA, headed by a

Presidential-appointed sub-Cabinet level official, such as the Under Secretary for Food Safety.

- C. Under EPA: Consolidate food safety regulatory responsibilities with EPA, forming the Food and Environmental Protection Agency. This organization would continue to be an independent agency managed by a Presidential-appointed Cabinet-level official.
- D. Under an Existing Commission (e.g., CPSC) Consolidate food safety regulatory responsibilities in an existing Commission, such as the Consumer Product Safety Commission (CPSC).

V. New Consolidated, Stand Alone Food Safety Agency

Different from Option IV which consolidates food safety functions within an existing organization, this option would create a new stand alone Cabinet-level food safety agency to facilitate achievement of food safety and public health goals. It would create an agency with its own executive leader or Cabinet-level Administrator (analogous to EPA or FEMA). Alternatively, the new agency could be managed by a five or seven member Presidential-appointed, Senate-confirmed Commission, with a Chairman who manages the day-to-day business of the Agency.

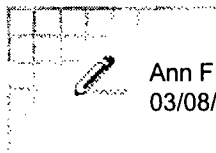
There are many ways to design a new stand-alone food safety agency. The following alternatives for a separate, stand alone agency take a functional approach. The first sub-option reflects an agency focused on a single function (inspections). With each subsequent sub-option, additional functions are added until all functions related to food safety are consolidated within one agency.

- A. Consolidate food safety inspections: Consolidate the food safety inspection functions of USDA/FSIS, DOC/NMFS, and parts of FDA's Office of Regulatory Affairs (ORA) into a new stand-alone agency.
- B. Consolidate food safety regulatory functions (Sub-Option A above plus standards, labeling, and education): Combine the "core" standard-setting, food safety labeling, education, inspection, and enforcement functions for meat, poultry, eggs, seafood and other FDA-regulated foods and animal feed.
- C. Consolidate food safety regulatory and research functions (Sub-Option B above plus research): Combine the functions outlined in Sub-option B above with food safety research.
- D. Consolidate food safety regulatory functions including pesticides (Sub-Option B above plus pesticides): Combine policy-setting and operational food safety functions for all food products and substances in food (Sub-option B above plus pesticides) into a separate, stand alone agency.

FDA's into inspections and other regulatory efforts. Under this option, the President could propose legislation permitting FDA to commission other Federal officials. The idea here is that other officials could help FDA enforce its laws while carrying out their own. For instance, USDA's Animal and Plant Inspection Service (APHIS) plant and animal inspectors at the border could look at the fruit for both contamination as well as fruit flies; FSIS inspectors could inspect the non-meat portions of a food plant as well as the meat sections (pizza, soup, dinners, etc); Commerce seafood inspectors could do both the fee-for-service inspection they do and the FDA inspection, thus accomplishing in another way the proposal that's in the President's budget to merge those programs; and Agricultural Marketing Service (AMS) graders at USDA could look at both the size of the apple as well as its safety. The advantage for FDA would be an extension of its coverage, for USDA the ability to show added value to the consumer, and for the public the knowledge that their tax dollars were being maximally utilized.

In order for this to work, however, careful attention would need to be paid to training. Currently, the majority of inspectors is not prepared to deal with multiple inspection responsibilities. This would require extensive cross training and upgrading of the inspection workforce.

This option might face some opposition from the Hill because it could be seen as a way to usurp the appropriations process. There might also be some opposition from the USDA inspectors' union. The consumer groups would likely support it because it would be a way to increase inspections for foods other than meat and poultry.



Ann F. Lewis
03/08/2000 05:14:49 PM

April
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Record Type: Record

To: Stephanie S. Streett/WHO/EOP@EOP
cc: Aprill N. Springfield/WHO/EOP@EOP, Deborah B. Mohile/WHO/EOP@EOP, Maureen T. Shea/WHO/EOP@EOP, Patricia Solis-Doyle/WHO/EOP@EOP
Subject: April 30

I think the invitation from Robert Morgenthau and Benjamin Meed to attend Holocaust ceremonies in New York

on April 30 looks very good:

-- This will be the first Holocaust memorial (Yom Ha-Shoah) in the new millennium, so it is a significant opportunity to speak on a subject important to the President personally, and in terms of his leadership;

- Robert Morgenthau is a leading figure in law and politics in New York and has been helpful to us;
- The President's participation will make this a national event; otherwise it is likely to be dominated by NY officeholders.

Remember that Yitz Greenberg, who has been announced (or officially leaked ?) as Chair of the Holocaust Commission is from New York .

Don

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

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.

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(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.

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Food Safety Council

**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.

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

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*Single copy
Food Safety Council*



NEWS RELEASE

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Remarks

OF
AGRICULTURE SECRETARY DAN GLICKMAN
BRIEFING ON CREATION OF PRESIDENT'S COUNCIL ON FOOD SAFETY
WASHINGTON, D.C. -- AUGUST 25, 1998

Food Safety Council

"Good morning. Thank you all for joining us. As you know, President Clinton has signed an Executive Order creating a President's Council on Food Safety to be co-chaired by the secretaries of agriculture and health and human services, as well as the head of the White House Office of Science and Technology Policy. We are here today to give you a little background on what all this means in terms of this Administration's broader food safety strategy.

"In many ways, this is a classic Washington versus the real world issue: Ask a food safety expert here in town: who inspects poultry? Who inspects fruits and vegetables? Who inspects hamburger? They'd tell you: USDA inspects poultry. FDA inspects fruits and vegetables. USDA inspects hamburger. Ask people out in the countryside, and they'd have a different answer. But their answer would be right, too: My government is responsible for inspecting my food.

"In the larger scheme of their daily lives, folks could care less if it's HHS or USDA. They just want to know that when they sit down at their dinner table after a hard day's work, the food they feed their families is safe. They want to know that their government -- not just HHS or USDA or the Food and Drug Administration or the Food Safety and Inspection Service -- but their government is doing everything it can to give them peace of mind.

"That's what President Clinton is getting at with this order. Today's action doesn't reflect a change in policy. Rather it is the next step in a process begun when this Administration first took office. From day one, we have set out to ensure that there is one high standard of food safety in this country. Today's announcement is a significant step in that direction.

"Basically, the President has ordered:

"1) That we move toward a seamless government-wide strategy that cuts through bureaucratic barriers to improving public health, and abides by what the best science tells us is in the best interest of America's families.

"2) That our various food safety budgets reflect this more coordinated approach; that we work closely together to strengthen existing efforts while also ensuring that federal resources target areas of highest priority.

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“And, 3) That we work together to advance national research priorities by using the best minds and resources that each government agency and the academic and private worlds have to offer. President Clinton wants us to avoid the ‘turf trap’ of stovepiped or duplicative efforts and move boldly and strategically into the next frontier of food safety which is science and technology.

“Given President Clinton’s active role in championing food safety, it should be no surprise that he has already put this new council to work. He has ordered us in the next 180 days to come back to him with a unified response to the National Academy of Sciences’ report on food safety. As all our food safety policy actions do, this response will incorporate an open process, involving the insights of industry, consumer groups, public health officials and more.

“In closing, I want to thank President Clinton for pushing us toward a more coordinated approach to food safety in this country. As a result, our nation will benefit from a more strategic public health vision, safer food, and healthier families in the 21st century.”

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NOTE: USDA news releases and media advisories are available on the Internet. Access the USDA Home Page on the World Wide Web at <http://www.usda.gov>

THE WHITE HOUSE

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

*Food
Safety
Council*

For Immediate Release

August 25, 1998

August 25, 1998

MEMORANDUM FOR THE PRESIDENT'S COUNCIL ON FOOD SAFETY

SUBJECT: National Academy of Sciences Report

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system, including through reform of current food safety legislation.

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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

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FOR RELEASE UPON DELIVERY
TUESDAY, AUGUST 25, 1998

*Food Safe
Council*

*REMARKS BY

DONNA E. SHALALA

U.S. SECRETARY OF HEALTH AND HUMAN SERVICES

ANNOUNCING THE PRESIDENT'S COUNCIL ON FOOD SAFETY

U.S. DEPARTMENT OF AGRICULTURE

WASHINGTON, D.C.

*THIS TEXT IS THE BASIS OF SECRETARY SHALALA'S ORAL REMARKS. IT SHOULD BE USED WITH THE UNDERSTANDING THAT SOME MATERIAL MAY BE ADDED OR OMITTED DURING PRESENTATION.

Mark Twain once said, "part of the secret of success in life is to eat what you like and let the food fight it out inside." Our job is to make sure that fight is always healthy -- and never harmful.

Today, without question, our nation has one of the safest food supplies in the world. That's because we have the best food safety agencies in the world. We have the highest standards, the toughest inspections, and the best research, science and methodology. And we are constantly seizing on new technology and techniques to reach new frontiers in food safety. Because in this Administration, when it comes to food safety, good enough is never enough.

The President's executive order today will help create a seamless food safety net that's anchored in science. Now Congress must do its part.

First, Congress needs to support the President's Food Safety Initiative by fully funding the budget request.

Second, Congress needs to pass the President's food safety legislation. It gives the FDA greater authority over imported foods, including the power to halt imports of fruit, vegetables and other food products that fail our standards.

Third, as Secretary Glickman mentioned, Congress needs to pass the Food Safety Enforcement Act, which gives the USDA greater enforcement powers over unsafe meats and poultry products.

Finally, the US Senate must give the FDA the strong Commissioner it needs by taking action on the confirmation of the President's nominee, Dr. Jane Henney. Dr. Henney is the right choice to lead the FDA into the new millennium. She is a nationally recognized leader in public health, a skilled manager, a dedicated reformer, a natural consensus builder and a respected scientist. As a former FDA Deputy Commissioner, Dr. Henney helped to modernize the FDA and cut red tape. In the process, she's built a reputation for working closely with consumers, physicians and industry to protect public health. All of my predecessors in the Bush and Reagan administrations have endorsed Dr. Henney. They should know -- she worked for them. It's time for the US Senate to take action on Dr. Henney's confirmation without delay.

Food Safety Council

Clinton creates safety panel to cut food-caused fatalities

Appoints Glickman, Shalala, technology director Lane

REUTERS NEWS AGENCY

President Clinton yesterday set up a food safety council aimed at drastically reducing food-borne illnesses in the United States that kill an estimated 9,000 people every year and make up to 81 million others sick.

"My administration is committed to ensuring that the American people enjoy the safest food possible," Mr. Clinton said in a statement from Martha's Vineyard in Massachusetts, where he is vacationing.

The President's Council of Food Safety will be headed by Agriculture Secretary Dan Glickman, Health and Human Services Secretary Donna E. Shalala and White House Office of Science and Technology Policy Director Dr. Neal Lane.

The formation of the council comes on the heels of last week's report by National Academy of Sciences experts recommending that the United States appoint a powerful food safety chief who would have budget and staff control over all U.S. food safety operations.

It also recommended establishing a science-based regime that would identify and prevent the ma-

jor food risks, such as chemical or microbial contamination.

Currently, more than 12 federal agencies have some role in protecting the nation's food supply with many jurisdictions overlapping. For example, the manufacturing of frozen cheese pizza is regulated by the Food and Drug Administration, but a frozen pizza with pepperoni or other kinds of meat falls under Agriculture Department jurisdiction.

Many on the NAS panel supported the creation of a single food safety agency, an idea that has been opposed by industry.

The first job of the president's council is to analyze the NAS recommendations and report back to the White House in 180 days, Mr. Clinton said. However, the chiefs of the council said consolidating food safety may not be the best alternative.

"We need to be outcomes-oriented rather than organization-oriented," Mr. Glickman said at a news conference.

Some government watchdogs said the administration's decision to appoint a council may lead to the continuation of the current confusing patchwork of food safety policies.

"We think the NAS calls for much greater action," Caroline Smith deWaal, head of food safety at the Center for Science in the Public Interest, said. "This is a case where three voices may not be as good as one."

But others said they thought it was better for the government to move slowly on changing the food safety system and the council was likely to take some bureaucracy out of major decisions.

"It does place the horse in front of the cart," Brian Sansoni, spokesman for the Grocery Manufacturers of America, said. "They are not willy-nilly changing all rules and regulations."

Interest in food safety has been accelerated since the record recall of more than 25 million pounds of tainted ground beef a year ago and a series of high-profile food poisoning cases.

Democrats have introduced a bill to create a new food safety agency, but the bill's sponsor, Sen. Richard J. Durbin of Illinois, acknowledged the legislation had little chance of being passed.

Miss Shalala and Mr. Glickman pressed for Congress to approve the administration's request to boost food safety spending.

Defeat of the killer tomatoes

NT 8/26

Good news, consumers. According to trade press accounts, the Centers for Disease Control is on the verge of reducing sharply the number of deaths it attributes to food-borne illness. Rather than the oft-cited estimate of 9,000 deaths a year resulting from tainted food, the agency now puts the figure at somewhere between 2,000 and 3,000, Food Chemical News reports.

Interestingly, the story goes on to report health officials are preparing for a backlash once the new numbers appear. Backlash? Against good news? Well, good news about food safety is bad news for persons who believe that only expanded federal bureaucracy can do the job: Why spend more money to fix what may not really be broken?

Undeterred by these happy tidings, President Clinton has taken a break from his vacation to sign an executive order creating a government panel to oversee food safety. The President's Council on Food Safety would comprise the secretaries of Agriculture, Health and Human Services, and Commerce, along with the heads of the Office of Management and Budget, Environmental Protection Agency and the National Partnership for Reinventing Government. Make that Re-enlarging Government.

Now on the face of it, the naming of another bureaucratic acronym with the laudable task of overseeing food safety is commendable. Presidential spokesman Rahm Emmanuel said the group would help modernize a food-safety system that Teddy Roosevelt put in place. And the National Academy of Sciences did just release a report calling, among other things, for the naming of a food czar with sweeping powers to reorganize and streamline existing regulatory supervision of the food supply. Right now, there are 12 agencies using 35 statutes doing the job. Rearranging the regulatory furniture seems in order.

But right at the top of the report's executive sum-

mary, the NAS cites the estimate of 9,000 deaths related to food-borne illness, which may give people a misleading idea of what's really at stake here. The CDC began using that figure about 10 years ago, say officials at the Georgetown Center for Food and Nutrition, but other federal food-safety experts played it down as an estimate or extrapolation. These qualifiers magically disappeared when regulators got hold of it, and the 9,000 deaths became official.

Says the center, the figure "is given a lot of credit for fueling the President's Food Safety Initiative and assorted other programs. It also became a clarion cry for many well-meaning people who conscientiously demanded food safety reform without knowing the history of the figure. And the figure became irresistible to those who have orchestrated the politicization of food safety." CDC officials could not be reached for comment.

Lost in all this is the apparent success of other, earlier initiatives in promoting food safety: the implementation of new meat, poultry and seafood monitoring systems, for example, the approval of irradiation technology for food products or the provision of information related to safe food handling practices. If anything, food safety seems better than ever.

Sure it's a good thing to cut back the bureaucratic and statutory dead wood, eliminate overlapping jurisdictions and coordinate responsibilities of government at all levels. And maybe the creation of one more government council will really do that.

But perhaps the most important recommendation in the NAS report is its emphasis on using strong, science-based risk analysis to deal first with the biggest risks facing consumers today. The good news, as mentioned above, is that when scientists determine what those risks are, food safety is likely to be a tiny one.

*Food Safety Council***The Washington Times**

PAGE A18 / FRIDAY, AUGUST 28, 1998 ★

Letters

A roadblock in the movement toward a single food safety agency

I am writing in regard to the Aug. 26 article "Clinton creates safety panel to cut food-caused fatalities." The article does not fully explain the Center for Science in the Public Interest's position on the President's Food Safety Council.

The council represents an important improvement over the existing food safety system, in which 12 agencies independently implement more than 35 separate laws. The council represents the logical next

step for the Clinton administration, which has an excellent record of food safety accomplishments already.

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. This step would require action by both the president and Congress.

The Food Safety 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 does not simply rubber-stamp the current ineffective system.

CAROLINE SMITH DE WAAL
Director of Food Safety
Center for Science in the Public Interest
Washington

No Harm to Children Seen in Low-Mercury Ocean Fish

Children whose mothers ate lots of ocean fish containing low levels of mercury while they were pregnant suffered no ill effects in a study conducted in the Indian Ocean country of Seychelles. At elevated levels, mercury can be dangerous for humans and can cause severe neurological damage in unborn children.

Fish are contaminated with mercury to different degrees throughout the world. In the Seychelles, where 85 percent of

the population eats fish every day, mercury contamination levels are comparable to those in the U.S. market.

In the new study, published in today's *Journal of the American Medical Association*, researchers tested the pregnant women for mercury levels in their bodies, then followed the development of 711 children until age 5½.

No adverse effects were found in a battery of tests in such areas as language, reading, arithmetic, spatial skills and social abilities.

An Environmental Protection Agency study last year also found no reason to fear mercury in commercially bought

fish in the United States.

Both the EPA and the researchers in the Seychelles study pointed out, however, that freshwater fish in this country are a different story. Many of these fish are much more highly contaminated with mercury and PCBs.

Drug Shows Promise in Treating Extreme Anxiety

A debilitating form of anxiety that makes people into extreme introverts can be controlled at least for the short term with an antidepressant, a study found.

Paroxetine, marketed as Paxil, was given

to people with a disorder known as generalized social phobia. The disorder, which afflicts millions of Americans, can produce fears so agonizing that victims avoid people and develop few friendships, have trouble dating, drop out of school and refuse promotions at work.

Fifty-five percent of the 91 people treated with paroxetine reported feeling much improved or very much improved at the end of the 12-week study, compared with 24 percent of those receiving a placebo.

An estimated 4.5 percent of the population suffers from the disorder, Murray B. Stein of the University of California at San Diego wrote in today's *Journal of the*

Food Safety Council Set

Panel Is to Coordinate Federal Role

By RICK WEISS

Washington Post Staff Writer

President Clinton yesterday signed an executive order calling for the creation of a new interagency council to coordinate the dozen or so federal offices that share responsibility for assuring the safety of the nation's food supply.

The move came less than a week after the release of a National Academy of Sciences report that criticized the patchwork nature of the current federal food safety system. That report called for the creation of a single, powerful food safety authority—either an individual person or a new agency—to oversee food safety in this country.

While many food safety advocates had applauded the call for a centralized authority, they also expressed doubts that such a change would win the congressional approval that would be necessary, given the food industry's opposition to the plan and Congress's inaction on other food safety initiatives already before it.

The president's decision to create a Council on Food Safety represents about as much as he could do on his own without congressional action, observers said. Several representatives of food safety groups said they supported the approach, as long as it ultimately reduces, rather than increases, bureaucratic inefficiencies.

"It will be helpful if it's one step in the journey to a more rational food safety system," said Caroline Smith DeWaal, director of food safety at the Center for Science in the Public Interest. "But if it's used as a roadblock by agencies that don't want to progress, then it could be detrimental."

The council is to be jointly chaired by Dan Glickman and Donna E. Shalala, the secretaries of Agriculture and Health and Human Services, along with the head of the White House Office of Science and Technology Policy, Neal Lane. Its mission is to develop a "comprehensive strategic plan" for federal food safety activities, taking into account the recommendations of the academy report and input from food producers, processors, retailers and the public. The council is to present its findings and recommendations to the president in six months.

At a minimum, experts said, the council may facilitate better budgetary coordination among the vari-

ous agencies that deal with food safety. By eliminating overlapping budget requests and regulatory gaps, they said, those agencies should be able to present to the Office of Management and Budget a more convincing case for food safety funding.

Indeed, one of the prime functions of the council, according to the president's executive order, is to present to the OMB an annual unified budget for the funding of the president's Food Safety Initiative. Congress so far has been less than enamored by that initiative, which aims to develop and implement new, science-based food inspection systems. The president requested \$101 million for the initiative for fiscal 1999, but legislators have so far indicated they are willing to budget just a fraction of that amount—in part because of their apparent dismay over the lack of coordination among the agencies that would spend it.

"If this council could have an impact on how OMB allocates budgets between FDA food safety and USDA food safety, that alone would be a huge improvement," said Carol Tucker Foreman, who coordinates the Safe Food Coalition, a District-based advocacy group, and was USDA assistant secretary for food and consumer services from 1977 to 1981.

Agriculture Secretary Dan Glickman said in an interview that the council had great potential to speed implementation of the many food safety initiatives already launched by the Clinton administration. "We're just getting these meat packing plants in order and inspectors up to speed," Glickman said, referring to new federal inspection procedures required since January. Although the council may conclude that bigger changes are needed, he said, "to totally reorganize our food safety system and move to a single agency right now would wreak havoc" with these positive changes.

In addition to Shalala, Glickman and Lane, the new food safety council will include the secretary of commerce, director of the OMB, administrator of the Environmental Protection Agency, assistant to the president for domestic policy, and the director of the National Partnership for Reinventing Government. The council's first public meeting will be held in Arlington on Oct. 2.

—Compiled from reports by the Associated Press

American Medical Association. The study found no serious side effects with the drug, unlike other substances used to treat generalized social phobia. The researchers said the effectiveness of the drug beyond 12 weeks is not known. The research was paid for by Smith-Kline Beecham Pharmaceuticals, which markets Paxil. Three years ago, paroxetine became the first nonaddictive drug to win government approval for treating panic disorder.

The Washington Post

WEDNESDAY, AUGUST 26, 1998

Majority backs public money for private schools

By Tamara Henry
USA TODAY

WASHINGTON — For the first time, a majority of U.S. adults would support partial government payment of tuition at private and parochial schools, says a Gallup Poll out Tuesday.

The poll, an annual survey for the Phi Delta Kappa professional education fraternity, found 51% of the public favors allowing parents to send their children to any public, private or church-related school if the "government pays all or part of the tuition"; 45% oppose the idea.

This is a reversal from 1996, when 43% favored the idea and 56% opposed it. Opinion was evenly divided in 1997, with 49% in favor and 48% opposed. More than 1,150 randomly selected adults responded to the poll, conducted by telephone. It has a 4-percentage-point margin of error.

The survey is the latest indication of shrinking public opposition to spending public dollars on private or parochial schools. The idea is even becoming popular in some segments of low-income communities, particularly among urban blacks whose faith in public schools' ability to educate them out of poverty is quickly waning.

Using taxpayer money for nonpublic schools is popularly known as awarding vouchers. But the word "voucher" is a political hot potato. When the

word "voucher" is used, responses are not as positive: 48% favor and 46% oppose vouchers covering all of the tuition at nonpublic schools; 52% favor a voucher for partial tuition, and 41% oppose it.

When asked about tuition "tax credits" — tax breaks for education costs — respondents also preferred a partial payment: 56% favor tax credits covering all tuition paid, and 42% oppose it; 66% favor partial payments, and 30% oppose them.

"The findings appear to guarantee that the issue of public funding for church-related schools will be a battleground for the foreseeable future," say authors Lowell C. Rose of Phi Delta Kappa International and Alec M. Gallup, co-chairman of the Gallup Organization.

Reaction to the survey underscores the divisiveness of the issue. Education Secretary Richard Riley says, "Vouchers drain taxpayer resources from the public schools that educate 90% of America's children."

Riley points to other results in the poll that show 75% think schools accepting such payment should be accountable to the state in the same way public schools are, and 70% say they should accept students from a wider range of backgrounds.

Bob Chase, president of the National Education Association, says it's impossible to demand accountability for public education dollars "if we give public tax dollars to private and religious schools."

Federal panel formed to protect food supply

By Anita Manning
USA TODAY

President Clinton, by executive order, created an eight-member federal council Tuesday charged with improving the safety of the national food supply.

The announcement, which followed by five days a report from the National Academy of Sciences (NAS) suggesting ways to streamline federal food-safety activities, got thumbs-up from consumer and industry groups.

The joint chairs of the President's Council on Food Safety will be Agriculture Secretary Dan Glickman, Health and Human Services Secretary Donna Shalala, and Neal Lane, assistant to the president for science and technology.

Its task will be to come up with a plan that incorporates recommendations from the NAS and others, coordinates food-safety budgets and targets federal research.

The president "wants us to avoid the turf trap of stovepiped or duplicative efforts," Glickman said, "and move boldly and strategically into the next frontier of food safety, which is science and technology."

Caroline Smith DeWaal of the Center for Science in the Public Interest, which favors establishment of a separate food-safety agency, said the action to set up the council "is the logical next step for the administration" after the NAS report, "but this should be a temporary measure, a first step on the road to a much more unified food-safety structure."



By Ric Fed. AP

Glickman: Heading 'into the next frontier of food safety'

Blacks lag at Southern colleges

By Mary Beth Marklein
USA TODAY

WASHINGTON — Higher education in the South is nearly as segregated as it was two decades ago, says a report out Tuesday that blames misguided financial aid, lack of leadership and hostile courts.

Moreover, "the gap between opportunity and achievement between whites and blacks may be widening," says Eldridge McMillan, president of the Atlanta-based Southern Education Foundation, a public charity.

The report focuses on 16 Southern states and three other states. Together, they enroll nearly three-fourths of the nation's black first-year students in

public universities. All of those states once segregated black and white students into two systems of higher education, but a 1992 U.S. Supreme Court ruling said they must eliminate all vestiges of segregation.

The report says its findings suggest little improvement: The proportion of blacks receiving bachelor's degrees has risen only 1.8% since the 1970s. And in 1996, blacks accounted for 20% of the 18-to-24-year-old population but only 8.6% of first-year students at the flagship schools.

Despite evidence of "good intentions," the report faults policymakers and education leaders for failing to enact reforms to benefit all students.

Clinton creates safety panel to cut food-caused fatalities

Appoints Glickman, Shalala, technology director Lane

REUTERS NEWS AGENCY

President Clinton yesterday set up a food safety council aimed at drastically reducing food-borne illnesses in the United States that kill an estimated 9,000 people every year and make up to 81 million others sick.

"My administration is committed to ensuring that the American people enjoy the safest food possible," Mr. Clinton said in a statement from Martha's Vineyard in Massachusetts, where he is vacationing.

The President's Council of Food Safety will be headed by Agriculture Secretary Dan Glickman, Health and Human Services Secretary Donna E. Shalala and White House Office of Science and Technology Policy Director Dr. Neal Lane.

The formation of the council comes on the heels of last week's report by National Academy of Sciences experts recommending that the United States appoint a powerful food safety chief who would have budget and staff control over all U.S. food safety operations.

It also recommended establishing a science-based regime that would identify and prevent the ma-

jor food risks, such as chemical or microbial contamination.

Currently, more than 12 federal agencies have some role in protecting the nation's food supply with many jurisdictions overlapping. For example, the manufacturing of frozen cheese pizza is regulated by the Food and Drug Administration, but a frozen pizza with pepperoni or other kinds of meat falls under Agriculture Department jurisdiction.

Many on the NAS panel supported the creation of a single food safety agency, an idea that has been opposed by industry.

The first job of the president's council is to analyze the NAS recommendations and report back to the White House in 180 days, Mr. Clinton said. However, the chiefs of the council said consolidating food safety may not be the best alternative.

"We need to be outcomes-oriented rather than organization-oriented," Mr. Glickman said at a news conference.

Some government watchdogs said the administration's decision to appoint a council may lead to the continuation of the current confusing patchwork of food safety policies.

"We think the NAS calls for much greater action," Caroline Smith deWaal, head of food safety at the Center for Science in the Public Interest, said. "This is a case where three voices may not be as good as one."

But others said they thought it was better for the government to move slowly on changing the food safety system and the council was likely to take some bureaucracy out of major decisions.

"It does place the horse in front of the cart," Brian Sansoni, spokesman for the Grocery Manufacturers of America, said. "They are not willy-nilly changing all rules and regulations."

Interest in food safety has been accelerated since the record recall of more than 25 million pounds of tainted ground beef a year ago and a series of high-profile food poisoning cases.

Democrats have introduced a bill to create a new food safety agency, but the bill's sponsor, Sen. Richard J. Durbin of Illinois, acknowledged the legislation had little chance of being passed.

Miss Shalala and Mr. Glickman pressed for Congress to approve the administration's request to boost food safety spending.



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www.gmafood.org

September 1, 1998

Mr. Bruce N. Reed
Assistant to the President for Domestic Policy
Executive Office of the President
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500-0000

TOM

Council
on
Food
Safety

Dear Mr. Reed:

I would like to convey GMA's strong support for the President's action in appointing you and other key Cabinet members to serve on a new Council on Food Safety. We applaud efforts such as this to improve the coordination and communication among agencies involved in food safety and to ensure effective use of resources and consistent, science-based regulation.

Led by a board of 44 Chief Executive Officers, GMA is the world's largest association of food, beverage and consumer product companies. GMA speaks for food manufacturers at the state, federal and international levels on vital food, nutrition and public policy issues affecting the industry.

GMA has organized an industry-wide task force of fifteen GMA member company representatives and fifteen food trade associations to assess food safety efforts. The task force presented its findings to the National Academy of Sciences and to the Congress. (See attached) The task force recommendations to date have emphasized improved coordination and communication, better prioritization and management of existing resources and science-based decision-making, and have cautioned against any unnecessary or disruptive restructuring of the federal bureaucracy.

On behalf of GMA and the Food Industry Task Force on Food Safety, I welcome the opportunity to work together and provide you and your colleagues any assistance or perspective based on the knowledge and expertise of our staff and that of our member companies. The food industry has invested significant resources to ensure that our nation has the safest food supply in the world and will continue to do so. We look forward to continuing our partnership with the federal government to ensure America's food supply remains the safest and most abundant in the world.

Sincerely,

C. Manly Molpus
President and Chief Executive Officer

GMA Food Safety/Independent Food Agency Task Force

News Release

Chairman

Calvin Collier,
Senior Vice President/General
Counsel, Corporate Affairs
Kraft Foods

Trade Association Participants

American Bakers Association
American Frozen Food Institute
American Meat Institute
Chocolate Manufacturers
Association
Food Distributors International
Food Marketing Institute
International Dairy Foods
Association
National Broiler Council
National Food Processors
Association
National Grocers Association
National Restaurant
Association
National Soft Drink Association
Snack Food Association
United Fresh Fruit and
Vegetable Association

GMA Member Company Participants

Bestfoods
Campbell Soup Company
The Coca-Cola Company
ConAgra, Inc.
Del Monte Foods
General Mills
Hershey Foods Corporation
Kraft Foods
Nabisco, Inc.
Nestlé USA
Ocean Spray Cranberries, Inc.
PepsiCo, Inc.
The Pillsbury Company
The Procter & Gamble
Company
Unilever United States, Inc.

EMBARGOED FOR RELEASE UNTIL NOON THURSDAY, AUGUST 20th

CONTACT: Gene Grabowski
(202) 337-9400 or www.gmabrands.com

U.S. FOOD INDUSTRY APPLAUDS NAS FOR INCLUDING SCIENCE-BASED APPROACH FOR FOOD SAFETY

Task Force Cautions Against Disruptive Agency Reorganization

WASHINGTON, DC, August 20, 1998 – The U.S. food industry applauded the National Academy of Sciences today for incorporating the industry's recommendation for a more effective, science-based approach to food safety efforts, but strongly cautioned against disruptive restructuring of the federal food safety system, as also suggested by the NAS.

The Food Safety/Independent Food Agency Task Force representing 15 allied trade associations, food company representatives, and experts in the technical, regulatory, legal, and government affairs arenas, recommended federal agencies improve their approaches to food safety rather than create a new federal bureaucracy.

"As an industry, we applaud the NAS for calling attention to the importance of science-based food safety policies just as we outlined in our testimony earlier this year," said Task Force Chairman Cal Collier, Senior Vice President and General Counsel, Kraft Foods, Inc. "Calling for a wholesale reorganization of federal bureaucracies in Washington will not do anything to ensure the safety of our food supply. Our focus as an industry is on providing safe, wholesome food for America's consumers."

The industry task force conducted extensive research into the best ways to enhance food safety and presented its findings in testimony before the NAS on April 29. The task force specifically analyzed current food safety policies and the feasibility of a single, independent federal food agency.

Task Force recommendations include:

- Identifying and fighting the true causes of foodborne illnesses with the appropriate scientific weapons created through an emphasis on more research.
- Educating consumers, food manufacturers, retailers and farmers about the proper handling of food products.
- Ensuring the existing federal food safety system has the necessary resources, scientists and researchers to effectively do the job of protecting our food supply.

(more)

PAGE 2 – U.S. FOOD INDUSTRY APPLAUDS SCIENCE-BASED APPROACH

- Ensuring the existing federal food safety system has the necessary resources, including scientists and researchers, to do the job of protecting our food supply effectively.
- Focusing on real food risk areas. Shifting to more of an emphasis on microbiology and research rather than merely hiring more inspectors who are likely to miss the unseen microbiological sources of food contamination.

"We in the food industry are advocating a change of focus in the world's most successful food safety program, not a change in its structure," Collier said. "A stronger science-based food safety strategy, strengthened by our federal food system, would further enhance the research efforts our industry conducts every day to protect the food Americans eat. Congress should resist overreacting to calls for costly legislation that is likely to be highly disruptive but does nothing to improve food safety. The industry will continue to work as we always have to ensure our food supply is the safest in the world."

Following a request from Congress, the NAS, through the Institute of Medicine's Food and Nutrition Board and the National Research Council's Board on Agriculture, conducted a \$420,000 study on "Ensuring Safe Food from Production to Consumption." The purpose of the study was to determine ways the federal food safety system could be improved.

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S.T.O.P. - Safe Tables Our Priority

335 Court Street Suite 100 Brooklyn, NY 11231

Phone (718) 246-2739 Fax (718) 624-4267 Victim Hotline (800) 350-STOP

TO: Mary Smith
FROM: Heather Klinkhamer
DATE: August 26, 1998
PAGE(S): 2

Too
Sub
Law

S.T.O.P. - Safe Tables Our Priority

335 Court Street Suite 100 Brooklyn, NY 11231

Phone (718) 246-2739 Fax (718) 624-4267 Victim Hotline (800) 350-STOP

DATE: August 25, 1998

CONTACT: Heather Klinkhamer

S.T.O.P. Supports President's Creation of Food Safety Council, Blasts Congress for Not Fully Funding Food Safety Initiative

S.T.O.P. -- Safe Tables Our Priority considers President Clinton's creation of a Council on Food Safety a significant step forward in efforts to coordinate a cohesive, national food safety program. S.T.O.P. has consistently urged government to replace the current patchwork regulatory food safety systems with one that would coordinate food safety efforts among regulating agencies. The Council on Food Safety puts in place a strategic planning committee that will coordinate efforts and determine priorities among the various food safety agencies. A strategic planning body should help to eliminate duplication of food safety efforts, thereby maximizing resources for improving food safety.

"It makes sense for the various federal food agencies to huddle and follow a single game plan," said Nancy Donley, president of S.T.O.P. whose son died of E. coli O157:H7 poisoning in 1993. "The next play is Congress". It's time for elected officials to stop simply talking about being concerned about food safety and start acting on it by putting our tax dollars towards funding food safety initiatives. It's outrageous that full funding of food safety is even up for debate."

Food safety is a serious and growing concern. Pathogens such as E. coli O157:H7 cause severe illnesses and deaths at low doses. Also of rising concern is the growing proportion of the U.S. population most vulnerable to foodborne illness: the elderly, children, pregnant women, and others with weakened immune systems. Approximately 20% of the U.S. population falls into these categories.

"While S.T.O.P. continues to support the establishment of a single food safety agency as the ideal system to address food safety in the U.S." said S.T.O.P. program director, Heather Klinkhamer, "the Council on Food Safety is the next best thing."

-END-

S.T.O.P. -- Safe Tables Our Priority is an independent, national, non-profit, grassroots organization devoted to victim assistance, public education, and policy advocacy for safe food and public health. Our membership has grown to include victims of pathogenic bacteria from a variety of foods, and their family members, consumers, and concerned members of the public health and public interest communities.

CSPI

Center for
Science in the
Public
Interest

Publisher of

Nutrition Action HealthletterDate: 8/26/98Time: 3:15 pm

FAX COVER SHEET

Food
Safety
Council

TO: Thomas FreedmanCompany: White House Domestic Policy CouncilFax Number: 456 7431 Phone Number: _____Total Number of pages INCLUDING this cover sheet: 3SENDER: Zoe Enga for Caroline Smith DeWaalSENDER'S Phone Number: X364

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SUBJECT: Letter to Washington Times

COMMENTS:

NEWS RELEASE

For Immediate Release:
August 20, 1998

Contact: Caroline Smith DeWaal; (202) 332-9110, ext. 366
Zoe Enga; (202) 332-9110, ext. 364

NAS CONFIRMS FDA AND FSIS NOT EQUIPPED TO MEET FOOD-SAFETY CHALLENGES OF THE FUTURE Calls for Single Person to be in Charge of Federal Food-Safety Efforts

In a report released today, the National Academy of Sciences (NAS) documented that, short of the President of the United States, no one person is really in charge of the safety of the nation's food supply. Today, food-safety responsibilities are spread between numerous Federal agencies with conflicting missions and responsibilities, resulting in uneven coverage and enforcement, according to the Academy.

While the Academy's Committee did not come to a full consensus on the need for a single food-safety agency to replace the current antiquated system, the Committee report said, "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." Currently, at least 12 Federal agencies implement 35 food-safety statutes.

The Committee did call for the appointment of 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." However, the report said that it is critical the person should have both legal authority and budgetary control for food safety, and therefore it did not back the creation of a White House-based food-safety 'czar.'

"The National Academy of Sciences has provided the strongest evidence yet of the weakness of the current food-safety system," said Caroline Smith DeWaal, CSPI's food safety director. "With new food-safety hazards on the horizon, it is urgent that the White House and Congress move quickly to implement the recommendations in the report and to fully fund the agencies currently responsible for food safety."

The National Academy of Sciences stressed the need for better science and clearer statutory mandates in conjunction with a more streamlined system to correct the current deficiencies. The report said that the current legal structure for food safety is based on laws that

Publisher of ***Nutrition Action Healthletter***

August 26, 1998

Letters to the Editor
The Washington Times
3600 New York Avenue, N.E.
Washington, D.C. 20002
Attn: Mr. Sam Ryan, Letters Editor
Via Fax: (202)832-2982

Dear Editor:

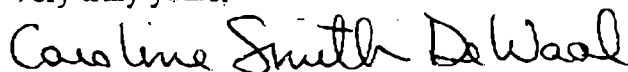
I am writing in regards to an article published on August 25, 1998 called, "Clinton creates safety panel to cut food-caused fatalities." [Editors note: This article was supplied to you by the Reuters News Service.] The article did not fully explain the Center for Science in the Public Interest's position on the President's Food Safety Council.

The President's Council represents an important improvement of the existing food safety system where 12 agencies independently implement over 35 separate laws. It represents the logical next step for the Clinton administration, which has an excellent record of food safety accomplishments already.

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. This step would require action by both the President and Congress.

The Food Safety 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.

Very truly yours,



Caroline Smith DeWaal
Director of Food Safety
Work Ph: (202) 332-9110, x 366
Home Ph: (301) 588-0711

Food Supply Cord

To Smith

Didn't get much
space, but here it
is - (L)

a judge... contaminants at his transmission service.

After watching the Circuit Judge Stephen A. Schiller handed a rather dull... call Monday—the first day of his sentence—Fijal said he was impressed. "It's interesting," Fijal said at the Daley Center. "One lawyer argues against another lawyer, and the judge has to figure out who's lying."

Court veterans predicted the novelty would soon wear off.

"Maybe he should bring a pillow," said one, in reference to the hard wooden spectator benches that seem designed to keep people awake. "Did he bring doughnuts?"

The sensory deprivation that can set in during long bouts of courtroom jousting over mortgage foreclosures and liquor licenses didn't seem to faze Fijal. This despite Schiller uttering sentences like: "The equities don't support the relief that you're seeking in the form of an injunction at this point because you had the means to expedite the termination of the second charge which for all I know could have effectively produced the termination."

Then there is the visual stimulation. Long expanses of bare white walls are broken up only by a clock and

"If I'm in jail, it would be... on the other... I, you don't make any money sitting in a courtroom."

He was found guilty in July, 1996, and ordered to clean up and pay a \$4,900 civil fine, said Assistant State's Attorney Mark Pera.

"Yeah, I did kind of put it off and put it off and put it off, but like I'm saying, I've been doing it myself," Fijal said. Fijal said oil and contaminants couldn't have seeped far because the ground has an old asphalt parking lot underneath. He also questions whether he is entirely responsible for the cleanup because he rents the property.

When Fijal missed a court date in August, "He wore out the judge's patience," said his attorney, Frank M. Howard. "His time clock is a little bit different than others."

Fijal returned to court Aug. 19. "He sentenced me and it was my birthday," Fijal said. "Happy birthday."

Schiller issued a creative sentence to communicate that court orders are to be respected and to save taxpayers jail costs, Pera and Howard said.

U.S. to get food safety panel

BY LYNN SWEET
SOMETIMES WASHINGTON BUREAU

WASHINGTON—To strengthen the nation's fight against food-borne illness, President Clinton today will create a Council on Food Safety, the Chicago Sun-Times has learned.

The idea behind the council is to "ensure better coordination between the sometimes-fragmented food safety system," a White House source said.

Food safety has been a priority for the Clinton administration.

The presidential food safety council will be co-chaired by the two Cabinet members whose agencies share much of the responsibility for making sure food consumed in the United States is safe.

Those Cabinet members are Agriculture Secretary Daniel Glickman and Health and Human Services Secretary Donna Shalala.

They will be joined by fellow co-chair Neal Lane, the White House's top science and technology adviser.

Clinton also will ask the council to consider whether a single indi-

vidual should be in charge of all food safety activities.

Sen. Dick Durbin (D-Ill.) has proposed uniting all food safety activities under a single agency.

For example, two federal agencies are involved in ensuring the safety of a pepperoni pizza.

The Agriculture Department is primarily responsible for meat, poultry and some egg products.

The Food and Drug Administration, part of the Health and Human Services Department, handles all other foods.

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FY 2000
budget

August 14, 1998

MEMORANDUM FOR GENE SPERLING

FROM: JON ORSZAG
CECILIA ROUSE

SUBJECT: Preliminary Compilation of Potential "New Ideas" for FY2000 Budget

This book is an initial compilation of potential "new ideas" for the FY2000 budget. When we return from vacation -- on August 24th -- we will continue to compile and develop new policies for the fall. Many of the proposals in this book come from interest groups, etc. and have not been vetted with any of the economic agencies.

The proposals are categorized into six areas: Education and Training, Community Empowerment, Homeownership, Tax Cuts/Simplification, Financial, and Other. Here is a summary of the proposals:

Education and Training.

- **Tax Credits for Summer School and Tutoring.** Research indicates that students forget a great deal during the summer months. Therefore, Alan Krueger recommends that we propose a refundable tax credit of \$150 per student per year to help parents send their kids to summer school. *\$150 - food, transportation, book school - \$650 mill.* *4/1/01*
- **Higher Education Proposals.** Tom Kane has four proposals: (1) a demonstration to test how much grants, loans, work-study, etc. affect college enrollment; (2) limit Pell Grant eligibility to the first two years of college and simultaneously increase the maximum grant size; (3) simplify the need analysis for financial aid which is currently so complicated that it likely serves as a disincentive for some folks to take advantage of the programs; and (4) since minorities are more likely to drop-out of college than whites, create program to provide incentives to colleges to retain minority students better. *Training*
- **Education Proposals from Shireman.** Shireman provides eight potential proposals, including an English-Plus Agenda -- an initiative that would invest in the foundation skill of English, then branch out to embrace more foreign language learning (especially in the elementary grades) and international education (in college and graduate school); a School-to-Work II proposal; a National Service II proposal; expanded youth training programs; a truly major Pell Grant increase; a State High Hopes or Pre-K-to-16 Pipeline-to-College initiative; an initiative to get the best and the brightest into teaching; and some kind of proposal on school finance equity. *0.4/1/01*
- **Tax Relief for AmeriCorps Awards.** Individuals who receive an AmeriCorps education award must pay tax on that award. We could provide a tax exemption for the award, which would cost about \$14-\$20 million per year.

- **INTERNAL Department of Labor Training Memo.** This is an internal Department of Labor memo and we are "not supposed to have it." Ray Uhalde¹ lays out a number of proposals. The most interesting may be to establish a \$200 million a year program to provide grants to local areas suffering from skills shortages. The problem with this approach would be that it would go against our efforts of consolidation. G.I.
V. W. C.
- **Community Workforce Partnerships.** A similar proposal to Regional Skills Alliances.
- **Community Education Centers.** This idea -- from a White House Fellow -- would create public schools into Community Education Centers (CECs), where after-school programs would be administered; Head Start and child care would be available; evening classes for adults would be provided; and on weekends, CECs could function as a "one-stop shop" for health and government services that are currently difficult to access.
- **INTERNAL Department of Labor Memo on FY2000 Budget Themes.** This is an internal Department of Labor memo and we are "not supposed to have it." Geri Palast lays out a number of potential themes for the Administration's and the Department's FY2000 budget. The proposed theme for the Administration is an "Out-of-School Youth" effort.
- **Super Small Business Section 127 Tax Credit.** In 1996, we proposed a "super" Section 127 tax credit for small businesses. Under our plan, employers with average receipts over the prior three years of \$10 million or less would be allowed a 10 percent non-refundable income tax credit with respect to amounts paid to third parties for employee education and training under a Section 127 plan. The employer's deduction for education expenses would be reduced by the amount of the credit.

Community Empowerment.

- **Local Infrastructural Improvement and Economic Revitalization Fund.** Emil forwarded you this idea to establish a Federal grant program to fund local infrastructural improvements. This would spark revitalization of declining or stagnant low-income areas by providing funds to upgrade local infrastructure. These Federal dollars could leverage State, local, and private funds for such infrastructural efforts.
- **Environmental Activity Bonds.** Just as we proposed to provide tax credits for the interest of school construction bonds, Weinstein and Orszag propose that we do the same to help urban (and rural) areas clean up waterways. (J)
- **Asset Development for Section 8 Voucher Recipients.** Currently, an individual still sees the size of their subsidy reduced for each extra dollar he/she earns. This new idea from Liebman and Orszag would roll-over any savings -- or a part of the savings -- from an individual earning more money into an Individual Development Account (IDA). That is, if the size of a person's Section 8 voucher is reduced by about 30 cents for each extra dollar he/she earns, we could put this savings -- up to 30 cents -- in an IDA.

- **Brownfields Meets Community Development.** Under this proposal, we would push banks to invest in brownfields as part of their CRA commitments.
- **Electronic Funds Transfer and IDAs.** Mike Stegman proposes that we use EFT '99 to help increase savings among low-income Americans. We could use our ability to electronically transfer money to efficiently establish IDAs for more Americans.
- **Community Development Corporation Tax Credit.** In 1993, we put in place a demonstration tax credit for investors in 20 CDCs. According to this report for Bruce Katz' shop at Brookings, this program has been effective. We could propose expanding this CDC tax credit to more areas. The author of this report also proposes some changes to make the tax credit more effective.
- **CDFI Tax Credit.** In 1996, we proposed a tax credit for investors in CDFIs. We could re-propose this \$100 million non-refundable tax credit. The maximum amount of credit allocable to a particular investment would be 25 percent of the amount invested. 5M
- **Community Revitalization Tax Credit.** LISC proposes a Community Revitalization Tax Credit (CRTC) -- similar to the Low-Income Housing Tax Credit -- to help stimulate private-sector investment in commercial property in underserved neighborhoods. (7)

Homeownership.

- **Low-Income Homeownership Tax Credit.** Self-Help -- a community group in North Carolina -- proposes a tax credit for investors who provide second mortgages to low-income families. This could significantly reduce the barriers to homeownership among low-income families, who do not really benefit from the home mortgage interest deduction. BR 4
- **Increase Allocation of Mortgage Revenue Bonds.** Each state receives a supply of tax-exempt mortgage revenue bonds. These bonds help low-income families become homeowners and help develop affordable rental housing. There are currently 53 co-sponsors of legislation in the Senate and 316 co-sponsors of legislation in the House to increase the allocation of mortgage revenue bonds by slightly more than 50 percent and then index it to the rate of inflation.
- **Expand Use of Mortgage Credit Certificates.** Mortgage Credit Certificates (MCCs) are credits against federal income tax equal to between 10 and 50 percent of mortgage interest (to a limit of \$2,000 per homeowner) issued by state governments. MCCs count against state's ability to issue mortgage revenue bonds. We could propose to expand the MCC program to allow the limit to be \$4,000 for homeowners in EZs or ECs. We could also propose allowing states to not have to count MCCs against their mortgage revenue bond base.

- **First-Time Homebuyer Tax Credit.** The 1997 tax law put in place a \$5,000 tax credit for first-time homebuyers in the District of Columbia. To boost homeownership in Empowerment Zones, we could propose allowing any first-time homebuyer in an EZ to take advantage of this tax provision.
- **Historic Homeownership Assistance Tax Credit.** The National Trust for Historic Preservation proposes a 20-percent tax credit to homeowners who rehabilitate or purchase a newly rehabilitated historic home and occupy it as a principal residence.

Tax Cuts/Simplification.

- **H&R Block Tax Simplification Proposals.** H&R Block make 10 proposals to simplify the tax code. The proposals include: (1) simplifying interest and dividend reporting; (2) simplify definitions; (3) simplify forms; (4) simplify child tax credit calculations; (5) simplify education loan interest deductions; (6) simplify home refinancing; (7) simplify deductions used in residential rentals; (8) simplify deductions for software; (9) simplify retirement plan rollovers and penalties; and (10) simplify or eliminate AMT.
- **Marriage Penalty Proposals.** This Treasury document walks through the various marriage penalty proposals.

Financial Matters.

- **ATM Proposal.** Weinstein proposes that Treasury publish an annual report on consumer financial issues, including ATM fees. In each report, Treasury would provide a list of insured financial institutions based on geographic divisions and by size. Treasury would report on the following categories: (1) Fees charged to depositors at ATMs at their home branches; (2) Fees charged by institutions to depositors using other banks ATMs; (3) Fees charged by ATM networks; (4) ATM fees charged to non-member depositors by institutions; (5) Minimum deposit requirements for checking and savings accounts; (6) Fees for overdrafts; and (7) Checking account fees. Fees and charges for checking accounts often depend on what packet of services are offered when you opened account and how much money is in the account. We will need to develop categories which underscore the differences in types of accounts. If we just list checking account fees, the fees that aren't reported would increase.
- **"Debt for Development" Assistance.** Bruce McNamer's proposal for the White House Fellow program.
- **Micro-Enterprise Proposals.** Cliff Kellogg memo outlining existing programs on micro-enterprise loans and on the Kennedy-Domenici PRIME bill.

Other Proposals.

- **Auto Insurance Fraud.** Auto insurance fraud is a \$13 billion-a-year problem in America. We could propose significant funding for a Justice Department anti-auto insurance fraud. Since an estimated 13 percent of auto-insurance premiums go to pay for fraud, we could claim that this effort will help drive down auto-insurance premiums.
- **Department of Labor Memo on Pensions.** This memo lays out 20 potential pension proposals. Emil has a copy and will be reviewing these options with the pension group. *→ more pens*
- **Research and Development Collaboration.** PPI proposes that we expand the R&E tax credit to provide a flat 20-percent credit for industry expenditures in research consortia and partnerships between industry and universities or federal laboratories. They also propose that we establish an Industry Research Alliance Challenge Grant to help develop stronger links between government and industry research.
- **Child Support Reform for Low-Income Families.** Sara McLanahan proposes that we provide some kind of incentive for low-income fathers to meet their child support obligations.

Frank
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United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

SUBJECT: President's Council on Food Safety Clearance Documents

TO: See Distribution List

FROM: Joan Mondshein
Confidential Assistant to the Administrator
Food Safety and Inspection Service

20 NOV 1998

Charles Danner
Director, Planning Staff
Food Safety and Inspection Service

Attached for your final review are the most recent charter and decision memoranda (4) drafts which, when finalized, will be discussed by the President's Council on Food Safety at its first meeting in early December.

The final charter will provide general direction to the Council. Comments received on the earlier draft of this document have been incorporated in the attached version.

The decision memoranda define important food safety issues that were addressed in the President's Executive Order establishing the Council. Discussion of the issues contained in the papers and approval of the charter will form the major portion of the agenda for the first meeting.

Please review the attached documents and forward your comments to Charles Danner by COB Monday, November 30, 1998. You may telephone, fax or email your comments to:

Phone: 202-720-4745

Fax: 202-690-1742

Email: charles.danner@usda.gov

Attachments

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(Draft 11/2)

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

Article I: Purpose.

On August 25, 1998, the President, by Executive Order, No. 13100, established the President's Council on Food Safety ("Council") to improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs. The purpose of the Council is to develop and update periodically a comprehensive strategic plan for Federal food safety activities, to make recommendations to the President on how to implement the comprehensive strategy and enhance coordination among Federal agencies, State, local and tribal governments, and the private sector, to advise Federal agencies in setting priority areas for investment in food safety, to oversee research efforts of the Joint Institute for Food Safety Research, and to evaluate and make recommendations to the President on the proposals contained in the National Academy of Sciences report on food safety.

This Charter provides the basis for collaboration among the members of the Council in carrying out the responsibilities of the Council as set forth in the Executive Order.

Article II: Membership

Council membership shall comprise:

1. Secretary of Agriculture,
2. Secretary of Commerce,
3. Secretary of Health and Human Services,
4. Administrator of the Environmental Protection Agency,
5. Director of the Office of Management and Budget,
6. Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy,
7. Assistant to the President for Domestic Policy, and
8. Director of the National Partnership for Reinventing Government.

Each member may designate a senior Federal employee, subject to the approval of the co-chairs, to serve as an alternate representative to perform the duties of the Council member.

Article III: Co-Chairs

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, or their designated alternates, shall serve as co-chairs of the Council.

The co-chairs shall provide leadership and direction to the Council, and coordinate the formation and schedule of standing committees. Each meeting will be led by one co-chair and this responsibility shall rotate quarterly among the co-chairs.

Article IV: Staff Support Services

Staff support services for the activities of the Council will be provided by the Co-Chairs through a Secretariat, which will consist of a senior Federal employee from each of the following: the Department of Agriculture, Department of Health and Human Services, and the Office of Science and Technology. Other members may provide additional staff support services, as necessary. The Secretariat will facilitate planning, coordination, and communication among Council members.

Article V: Meetings

The Council shall meet on a quarterly basis at a time and location chosen by the co-chairs. Additional meetings may be held at the call of the co-chairs or at the request of a majority of the members.

A majority of the Council membership shall constitute a quorum for the transaction of business. All decisions made by the Council at the meetings shall be by general agreement.

The Secretariat will prepare a summary report of each meeting of the Council for distribution to the membership and make each report available for public inspection and copying and on the Council Internet web site.

The Council may prepare a report for submission to the President on October 1 of each year. The report will contain, at a minimum, a description of the Council's activities and accomplishments during the preceding fiscal year and a description of the planned activities for the coming year, and a review of strategic planning objectives and progress made toward accomplishing those objectives.

Article VI: Duties and Responsibilities

The specific responsibilities of the Council are to:

1. Develop and update periodically a comprehensive strategic Federal food safety plan ("plan") to reduce the annual incidence of acute and chronic foodborne illness by further enhancing the safety of the nation's food supply. The plan will address public health, resource, and management questions facing Federal food safety agencies and will focus on the full range of food safety issues, including the needs of regulatory agencies, and the actions necessary to ensure the safety of the food Americans use and consume. The planning process will consider both

short-term and long-term issues including new and emerging threats to the nation's food supply and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council will take into consideration the findings and recommendations of the National Academy of Sciences report "Ensuring Safe Food from Production to Consumption" and the review of Federal food safety research by the interagency working group under the auspices of the National Science and Technology Group.

The final plan will help set priorities, improve coordination and efficiency, identify gaps in the current system and ways to fill those gaps, enhance and strengthen prevention and intervention strategies, and identify reliable measures to indicate progress.

The Council will conduct public meetings 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.

2. Advise Federal agencies of priority areas for investment in food safety and ensure that the member agencies develop annual coordinated food safety budgets for submission to the Office of Management and Budget (OMB) to sustain and strengthen priority activities on food safety, eliminate duplication, and ensure the most effective use of resources for achieving the goals of the plan.

3. Oversee the Joint Institute for Food Safety Research (JIFSR). The Council will evaluate the reports from JIFSR on food safety research activities and give direction to JIFSR on research needed to establish the most effective possible food safety system.

4. Evaluate and report to the President on 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, by February 21, 1999, report to the President on the Council's response to and recommendations concerning the NAS report and appropriate additional actions to improve food safety.

Article VII: Committees

The co-chairs, after consultation with Council members, may establish committees of Council members, their alternates, or other Federal employees, as they deem necessary, to facilitate and carry out effectively the responsibilities of the Council. Such committees shall report to the Council.

The following committees shall be established by the co-chairs:

1. Strategic Planning Committee

The Committee shall develop a comprehensive strategic Federal food safety plan ("plan") that will review public health, resource and management issues facing Federal food safety agencies and will focus on the full range of issues and the actions necessary to ensure the safety of the

food Americans use and consume. The Committee will conduct public meetings 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. The plan will include a comprehensive strategy for the enhancement of coordination among Federal agencies, State, local and tribal governments, and the private sector on food safety issues.

The Committee will provide the plan to the Council that will help set priorities, improve coordination and efficiency, identify gaps in the current system including legal authorities, and ways to fill those gaps, and enhance and strengthen prevention and intervention techniques.

2. Budget Committee

The Committee will examine all Federal food safety related budgets to identify priority areas for investment in food safety and ensure that resources are used effectively and to eliminate duplication.

3. JIFSR Executive Research Committee

The Committee will evaluate the reports from the JIFSR on its efforts to coordinate food safety research and make recommendations to the Council regarding research needed to establish the most effective possible food safety system.

4. NAS Report Review Committee

The Committee shall prepare a response to the NAS report, after providing for public comment, and shall submit the report to the Council by January 21, 1999.

Article VIII: Web Site

The Council shall establish an Internet web site. The Department of Agriculture shall be the system owner of the web site and shall be responsible for maintaining it. The Council website will provide links to websites of federal agencies having food safety responsibilities.

Article IX: Effective Date

This Charter shall become effective on the latest date affixed below and may be modified with supplemental agreements signed by the members of the Council.

Secretary of Agriculture

Secretary of Commerce

Secretary of Health
and Human Services

Administrator of Environmental
Protection Agency

Director of Office
of Management and Budget

Assistant to the President for Science
and Technology/Director of the
Office of Science and Technology
Policy

Assistant to the President
for Domestic Policy

Director of the National Partnership
for Reinventing Government

November 16, 1998

MEMORANDUM FOR THE PRESIDENT'S COUNCIL ON FOOD SAFETY

FROM: INTERAGENCY FOOD SAFETY WORKING GROUP

SUBJECT: Assessment of NAS Report "Ensuring Safe Food from Production to Consumption"

ACTION: Approval of plan to provide the President with an assessment of the NAS Report "Ensuring Safe Food from Production to Consumption."

BACKGROUND: In the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1998, funds were provided to the Agricultural Research Service to support the NAS to "1) determine the scientific basis of an effective food safety system, 2) assess the effectiveness of the current food safety system in the United States, 3) identify scientific needs and gaps within the current system, and 4) provide recommendations on the scientific and organizational changes in federal food safety activity needed to ensure an effective science-based food safety system."

The NAS established their study committee under the auspices of both the Institute of Medicine and the National Research Council and held three meetings (from March through June 1998) obtaining input from Federal agencies and other stakeholders of the Federal food safety system. The NAS issued their report on August 20, 1998. Attached is a summary of its findings and recommendations.

Congress viewed this study as part one of a possible two-part process. Should the NAS recommend that a single Federal food safety agency is required to achieve adequate performance and levels of public health protection, Congress planned to appropriate additional funds to support a second NAS study, which would focus on how such an agency should function. The NAS Committee did not explicitly recommend the establishment of a single Federal food safety agency, and funds for part two were not appropriated for fiscal year 1999.

On August 25, 1998, the President issued a directive tasking the Council on Food Safety to provide him with an assessment of the NAS report in 180 days (by February 21, 1999). Specifically, the President directed:

"...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 its report, the council should take into account the comprehensive strategic Federal food safety plan that it will be developing."

Four public meeting have been scheduled to solicit stakeholder input (October 2, in Arlington, VA; October 20, in Sacramento, CA; November 10, in Chicago, IL; and December 8 in Dallas, TX).

RECOMMENDATION: The Interagency Food Safety Working Group recommends that the Council establish a task force consisting of one representative from each of the following agencies: OSTP, HHS, USDA, EPA, and DOC. This 5 person task force will systematically assess the NAS report by providing 1) an analysis of the report's findings, including whether we agree or disagree with the findings and why; 2) an assessment of the strengths and weaknesses of each recommendation as they relate to the findings that are determined to have merit; and 3) recommendations on whether to incorporate particular elements of the NAS report into the Council's comprehensive strategic plan. If appropriate, the task force should identify barriers (e.g., legal) to implementation and recommend ways to overcome them. Each task force representative will be responsible for coordinating input from within his or her own agency. The task force will be chaired by OSTP and provide a draft report to the Council by February 5, 1999. Once the report is submitted to the President by February 21, 1999, the Council will seek additional public input on its assessment of the NAS report's recommendations.

MEMORANDUM FOR THE PRESIDENT'S COUNCIL ON FOOD SAFETY**FROM; INTERAGENCY FOOD SAFETY WORKING GROUP****SUBJECT: Process for developing a Food Safety Strategic Plan for all Federal food safety agencies****ACTION: Approval of a process for preparing a food safety strategic plan**

BACKGROUND: On January 25, 1997, the President announced a new food safety initiative. He directed the Secretaries of Agriculture and Health and Human Services and the Administrator of the Environmental Protection Agency to identify specific steps to improve food safety. Those agencies held public meetings with consumers, producers, industry, states, universities, and the public, and reported back to the President. The Report, issued in May 1997, was entitled *Food Safety from Farm to Table, A National Food-Safety Initiative*. In that report, the Federal agencies involved in food safety recommended a longer-term strategic planning effort to consider how to best address important challenges and make the best use of the agencies' limited resources. The agencies made a commitment to involve all public and private stakeholders in the process.

The President's Council on Food Safety will be responsible for development of a 5-year Federal food safety strategic plan. A coordinated food safety strategic planning effort is needed to build on 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 that are discussed in the scope of food safety decision paper. It will also identify actions necessary to ensure the safety of the food Americans consume. The charge is to develop a comprehensive strategic long-range plan that addresses the steps necessary to achieve a seamless food safety system including key public health, resource, and management issues regarding food safety. The plan will be used to help set priorities, improve coordination and efficiency, identify gaps in the current system and mechanisms to fill those gaps, continue to enhance and strengthen prevention and intervention strategies, and develop performance measures to show progress. Each agency will incorporate the relevant parts of the strategic plan into its Government Performance and Results Act (GPRA) strategic plan, commensurate with its budget.

The food safety agencies have already taken the first steps in developing the food safety strategic plan, by participating in interagency strategic planning sessions and developing a draft vision statement for the U.S. food safety system and the roles of all those involved in food safety. The vision statement establishes the essential characteristics of an effective food safety system:

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-based and risk-based approaches along with public/private partnerships. Food is safe because everyone understands and accepts their responsibilities.

During early 1997, the federal food safety agencies engaged a wide range of stakeholders in discussions about food safety issues through a series of public meetings and through written comments to public dockets. At four additional meetings, held between October and December 1998, the food safety agencies engaged consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process. Participants commented on the draft vision statement as well as the strategic planning process. They were also asked to discuss goals and critical steps and to identify potential barriers to achieving those goals.

Additionally, at the request of Congress, the National Academy of Sciences (NAS) conducted a study of the current food safety system to: (1) determine the scientific basis of an effective food safety system; (2) assess the effectiveness of the current system; (3) identify scientific and organizational needs and gaps at the federal level; and (4) provide recommendations. The NAS released its findings, conclusions, and recommendations in an August 20th report, *Ensuring Safe Food from Production to Consumption*. The report stated that "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."

RECOMMENDATION: The Interagency Food Safety Working Group recommends that the President's Food Safety Council convene a task force to develop a comprehensive food safety strategic plan based on the recommendations and comment received from its various constituencies. The task force will consist of representatives from each of the following agencies: HHS (CFSAN, CVM, NIH, CDC), USDA (FSIS, ARS, CSREES, ORACBA), and EPA.

The task force will first conduct a content analysis of the transcripts and dockets of the 1998 meetings and the input received through the notice and comment process to determine the major themes, issues, and subject areas that emerged during the public outreach phase. This will identify what stakeholders want in a food safety strategic plan. The task force will also consider the conclusions and recommendations of:

The National Academy of Sciences' report on *Ensuring Safe Food from Production to Consumption*,

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,

Input from the 50-State meeting on state/local issues and recommendations, and

Input from the agencies involved.

The task force will then develop a proposed set of strategic goals and objectives and present a draft strategic plan to the President's Food Safety Council. Following Council review, the draft food safety strategic plan will then be presented to the public for review.

After a suitable period of further public comment, the task force will prepare a final draft of the strategic plan with specific recommendations on needed changes and steps to achieve a seamless food safety system including resource needs, roles, and barriers to implementation, and submit it to the Council for approval.

Discussion Paper: Coordinated Food Safety Budget Process

For Consideration by the President's Council on Food Safety

Action Required: Approval of a process to develop coordinated food safety budgets and a unified food safety initiative budget submission.

Background

Executive Order 13100 established the President's Council on Food Safety, to "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 Office of Management and Budget (OMB) that sustain and strengthen existing capacities, eliminates duplication, and ensure the most effective use of resources for improving food safety." The President further directed the Council to "ensure that the Federal agencies annually develop a unified budget for submission to OMB for the President's Food Safety Initiative and such other Food Safety issues as the Council determines appropriate."

Timetable for the Federal Budget Process

The Federal agency budget process begins no later than the spring of each year, at least 9 months before the budget is transmitted to Congress. In the spring and summer, the process focuses on the review of program performance, as well as ways to ensure efficient Government resources and successful implementation of programs and policies. Beginning in early fall, Executive branch departments and agencies submit initial materials to OMB in accordance with a schedule developed by OMB. Initial due dates for submitting material may differ between agencies, but final OMB action on budget decisionmaking is the same. OMB reviews agency budget requests, based on Presidential priorities, program performance, and budget constraints. A complete set of budget proposals is presented to the President by early December for approval. After this process is complete, agencies revise their budget requests to bring them into accord with the President's decisions. Under current law, the budget must be submitted to Congress no later than the first Monday in February.

The Federal Budget Process

The budget process is governed by OMB Circular No. A-11, "Preparation and Submission of Budget Estimates," which provides detailed instructions and guidance on the preparation and submission of agency budget requests and related materials, including the development of strategic plans and annual performance plans. Policy guidance is given to agencies for the upcoming budget year and out-years to provide initial guidelines for preparation of agency budget requests. OMB works with agencies to identify major issues for the upcoming budget; undertakes the analysis

necessary to provide the context for decisionmaking; identifies major options; and develops and implements plans for analysis of future issues.

During the OMB review process, major issues and options are prepared for consideration by the President, organized around major Administration themes and cross-cutting issues. The A-11 requires data for cross-cutting issues in addition to agency budget submissions to analyze individual agency budgets, make Government-wide resource allocation decisions, and prepare unified budget presentations. Contributing agencies submit detailed budget schedules and narrative information that describes agency functions and provides budget justifications. The narrative justifications include evidence of cooperative development of complementary requests among the major agencies involved. OMB utilizes the information to make crosscutting comparisons between agencies and to make Government-wide resource allocation decisions.

One example of a cross-cutting activity is for research and development. Agencies are required to report cross-cutting data for the specific areas of research identified by the National Science and Technology Council (NSTC). Prior to the beginning of the budget process, NSTC identifies a set of research and development areas that are important national efforts requiring coordinated investments across several agencies. These priorities, and other guidance, are provided to participating agencies to consider during the development of agency budgets. The agencies utilize this information to justify proposed changes in research and development activities addressed by NSTC. The A-11 also identifies other cross-cutting areas such as drug control programs and violent crime control programs.

Current Interagency Budget Planning Process

Currently, a formal process for coordinating the budget for food safety functions has not been established as it has been for other cross-cutting functions. In the absence of specific guidance, the Department of Health and Human Services (HHS), and the Department of Agriculture (USDA) have coordinated a multi-agency effort to present a unified budget for the President's Food Safety Initiative. This process began with and is based on the May 1997 report to the President, entitled, *Food Safety from Farm-to-Table: A National Food Safety Initiative*. The report recognized microbial foodborne illness as an emerging public health hazard that requires aggressive government action. The report recognizes that only through joint planning can Federal resources be maximized and the greatest improvements in food safety be achieved. The farm-to-table strategy developed in the May 1997 report identifies critical gaps in the food safety system for controlling or eliminating foodborne pathogens from the food supply and proposes a strategy for closing those gaps.

The involved agencies have worked collaboratively to present a unified food safety initiative budget to OMB and the Congress for 1998 and 1999. However, the process for coordination and joint planning has not been initiated until the completion of individual agency budget decisionmaking. The result is inclusion of food safety initiative budget requests in individual agency budget submissions to OMB and preparation of a unified budget submission "after the fact".

The Council's Role in Food Safety Budget Planning

A primary responsibility of the Council is the development of a comprehensive Federal food safety strategic plan with the goal of a "seamless," science-based food safety system (e.g., a system that is an integrated Federal, State, and local system). The plan will contain specific recommendations on needed changes, including measurable outcome goals, steps necessary to achieve the goal, and key food safety public health, resource, and management issues. In developing the strategic plan, the Council will consult with all interested parties and will 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.

The strategic plan will provide a solid basis for coordinated food safety budget planning and resource requests. The Council will also ensure that the agencies submit a unified food safety initiative budget that includes other food safety issues, as determined appropriate by the Council.

Preparation of a Coordinated Food Safety Budget Planning Process

Developing a coordinated budget process for food safety activities includes a number of key factors. The first key factor is the development of guidance by the Council for food safety agencies to consider during the preparation of their budgets. In order for this guidance to be most useful, the Council should make it available to the agencies by late February to coincide with the beginning of the budget planning process of the involved agencies. A second major factor is the collection of budget data necessary for coordinating food safety budgets and recommending government-wide resource allocations. A third factor is establishing a process for agencies to submit relevant budget information to the Council and OMB for use in evaluating agency budget submissions.

Recommendation: Form a task force composed of representatives from the budget and program planning staffs of HHS, USDA, and EPA to work with the Council to develop a coordinated budget process for food safety activities similar to other cross-cutting issues. The team will work throughout the budget process to assure coordination of activities and resource requests. The task force should conduct the following functions:

- Review the strategic plan and Council budget guidance to identify budget data and other information that will be necessary to plan and evaluate agency budget submissions;
- Design a uniform format for presenting food safety initiative budget components for use in both agency and the unified budget submissions;
- Develop necessary guidance to facilitate submission of a unified food safety initiative budget and any other agencies deemed appropriate by the Council;
- Develop a timetable for submitting information to the Council that accommodates the various agencies budget processes.

DRAFT - 11/20/98

MEMORANDUM TO PRESIDENT'S COUNCIL ON FOOD SAFETY**FROM:** Interagency Food Safety Working Group**SUBJECT:** Scope of the Council's Comprehensive Strategic Food Safety Plan**ACTION:** Decision on the scope -- what's in and what's out -- of the Council's initial actions and comprehensive strategic Federal food safety plan.

BACKGROUND: On January 25, 1997, the President issued a directive to the Secretaries of USDA and HAS and the Administrator of EPA to work with stakeholders and the public to identify ways to further improve the safety of the food supply, and to report back to him in 90 days. The Federal food safety agencies (HAS, USDA and EPA) initially focused on the goal of reducing illnesses caused by microbial contamination of food and water. 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"(FBI).

To implement the plan, USDA and HAS submitted joint budget requests for pathogen research, surveillance, risk assessment, inspection and education for F, F, and F. Microbial contamination of water and biomedical research are included within the scope of the FBI, and NH and EPA participated in the Initiative; however, support for NH and EPA programs have not been included in the joint budget submissions.

The May, 1997 report made a commitment to prepare a comprehensive 5-year strategic plan, with the participation of all concerned parties. The President's Council on Food Safety was established in August, 1998 under E.G. 13100 and is now responsible for development of this strategic food safety plan. The first steps to lay the groundwork for development of the strategic plan have already been taken by drafting a vision statement for the U.S. food safety system along with a series of questions designed to elicit the public's view on the vision, goals and critical steps as well as potential barriers to achieving that vision. In developing the vision, the agencies assumed that the scope of the strategic plan would be broadened beyond the FBI to include chemical hazards in the food supply.

Independently, the National Academy of Sciences (AS) was charged by Congress with: 1) determining the scientific basis of an effective food safety system; 2) assessing the effectiveness of the current food safety system; 3) identifying scientific needs and gaps; and 4) providing recommendations on the scientific and organizational changes needed to ensure an effective system. The AS released its findings and recommendations in August, 1998 in "Ensuring Safe Food from Production to Consumption". In the report, AS broadly defined food safety as "not only the avoidance of foodborne pathogens, chemical toxicants, and physical hazards, but also issues such as nutrition, food quality, labeling, and education". While the scope of the study included all these components, the report focused primarily on microbial, chemical and physical hazards from "substances that can cause adverse consequences" in domestically-produced and imported foods, including additives, agricultural chemicals and animal drug residues.

For the Council's purposes in defining "food safety" and determining the scope of the strategic plan, this paper identifies two categories of activities: "core food safety activities" and "collateral" or related activities. "Core food safety activities" includes programs or activities that enhance the safety of the nation's food supply and protect public health by reducing the annual incidence of acute and chronic foodborne illness. "Collateral activities" are related to and have implications for food safety but are undertaken to serve another primary purpose or mission, such as insuring fishable, swimmable waters. Specific food safety research or regulatory actions may need to be coordinated with these collateral activities, and vice versa, but they will not be included in the initial strategic plan. Collateral activities will be identified as appropriate for coordination or integration, and could be brought in the future within the scope of the strategic plan and the Council's work.

This framework is designed to allow the Council to focus on the important, "core" activities that directly impact food safety. Once developed, the strategic plan should assist the agencies to address the important food safety challenges by identifying priorities and making the best use of limited resources. This paper does not, therefore, determine priorities within the initial scope for Federal attention and resources, but rather leaves those decisions to the strategic planning process. Further, activities within the scope may not all be addressed in the same depth or at the same time depending on our assessment of the public health risks and potential benefits of action.

RECOMMENDATION: It is recommended that the Council and the strategic plan focus first on "core food safety activities" defined as microbial hazards, physical hazards, and chemical substances. Other "collateral activities" that are less directly related to the safety of the food supply will be considered for collaborative efforts or enhanced coordination on a specific, targeted basis as needed. Included in this second category are: miscellaneous food constituents, the nutrition programs, and waterborne hazards. *[Note: USDA and FDA recommended water be in the core.]*

Table 1: Recommended Scope of Food Safety Strategic Plan

	Core	Collateral
Microbial Hazards	X	
Chemical Substances	X	
Misc. Food Constituents		X
Nutrition Programs		X
Physical Hazards	X	
Waterborne Hazards		X

The remainder of this paper defines the categories above and examines the pros and cons for inclusion of each category within the scope of the Council's comprehensive food safety strategic plan. Table 2 (attached) provides information on "core" and "collateral activities" at the food

safety agencies.

OPTIONS: Building federal capacity to prevent, reduce and respond to microbial hazards in the food supply will continue to be a priority issue addressed by the Council and in the strategic plan. This includes not only known and emerging problems due to human pathogens in imported and domestic food (from farm to table) and antibiotic resistance in pathogens, but also some naturally-occurring toxicants (e.g., mycotoxins). Federal programs for microbial research, monitoring, surveillance, regulation and prevention (including irradiation of food), voluntary and mandatory certification and inspection, and enforcement as well as labeling and education (e.g., Fight BAC) that encourage proper food handling to avoid microbial contamination will be part within the scope of the plan.

This paper examines options for expanding the scope of the strategic plan beyond pathogens. Several categories of work have been identified which, separately or in combination, would broaden the scope and make the plan more comprehensive:

- Option 1: Chemical Substances
- Option 2: Miscellaneous Food Constituents
- Option 3: Nutrition Programs
- Option 4: Physical Hazards
- Option 5: Waterborne Hazards

Option 1: Chemical Substances *[Note: This section is still under discussion, and may be revised.]* Food itself is a complex collection of "naturally-occurring" and added (inadvertently or for a specific purpose) chemicals with nutritive and other properties. "Added chemicals", including synthetic chemicals and metals, are sometimes inadvertently introduced into foods (e.g., industrial contaminants) and/or are present at unauthorized levels, while others are intentionally added and present in food, in most cases, at or below legal and "safe" levels.

The category includes a diverse set of substances: environmental contaminants (e.g., methyl mercury in fish, lead in baby food); industrial contamination (e.g., dioxin in chicken feed, polybrominated biphenyls in animal feed); pesticides (both residues in/on food and antimicrobials used to control pathogens); sanitizers; components of packaging materials (e.g., fungicide treated fruit and vegetable wraps); animal drugs (including residues in meat and/or milk); byproducts of manufacturing and process-induced components of foods (e.g., nitrosamines and pyrolysis products). Among the chemical substances of concern are naturally-occurring and added substances in dietary supplements (particularly herbals and botanicals, such as ephedrine alkaloids in ma huang and *Digitalis lanata* in a plantain-containing supplement). Similarly, nutrients present in either low or high levels may pose health risks to vulnerable populations in products specifically designed to meet their needs (e.g., infant formula, medical foods, and foods for special dietary purposes). Another area of concern included in the category are genetically modified plants and products used in food or animal production. This category also includes food and feed additives (e.g., coloring agents, preservatives, food packaging waxes), flavors, enzymes, and vitamins and minerals (including high levels of substances such as Selenium and Vitamin D). Because of broad public concern about the risks posed by chemicals, they have

historically been the subject of Federal attention and regulation.

Under this option, all FDA, USDA, EPA and CDC chemical-related food safety responsibilities, including those aimed at ensuring "safe" and lawful levels of chemicals in food, would be considered in the strategic plan. The plan would address chemical/pesticide research (including research on preventive controls and intervention strategies), monitoring/surveillance (food and human diseases), regulation and related voluntary programs, inspection, enforcement, education and outreach.

There are several reasons to include chemical substances as "core food safety activities" in the comprehensive strategic plan.

- Food safety involves protecting consumers from a wide range of potential hazards including the risks posed by chemicals.
- Significant Federal programs/resources at HAS, EPA and USDA are devoted to protecting the public's health from chemical hazards in food; since the mission of these programs is to ensure safe food, they should be part of the food safety strategic plan.
- Some resource efficiencies in surveillance and enforcement efforts could likely be achieved by integrating work on pathogens and chemicals.
- There is broad public concern about the safety of pesticide residues, food additives, and other chemical hazards in food.
- The plan will be perceived by the public as deficient if chemical substances are left out.
- The AS report specifically cited the need to include chemical hazards in any discussion of food safety and called for development of a comprehensive strategic plan for food safety; there would be a significant gap if chemical hazards were not considered in developing the plan.
- Some chemical substances present new and important challenges for the food safety system (e.g., endocrine disruption, protections for vulnerable populations) that should be considered in the strategic plan.
- There is a direct link between certain chemicals and our ability to control microbial contamination. For example, antimicrobials, pesticides and food additives play a role in controlling microbial contamination of food.
- There is growing interest in dietary supplements; some supplements, including herbal products, may pose a risk of adverse health effects because they contain a toxic constituent. The Dietary Supplements Health and Education Act exempted dietary supplements from Federal premarket approval of their safety, so effective post-market approaches are needed.
- There is public concern about the safety of products from genetically modified plants and animals.
- Including chemicals broadens the spectrum of programs included in the Initiative and the stakeholders, and should bring additional opportunities for improvements to the food safety system.

On the other hand, there are some reasons to exclude chemical substances from the "core".

- Some may argue that the urgency of the problem with pathogens warrants a focus on

microbial contamination alone.

- There are legal, scientific, regulatory and organizational distinctions that make chemical issues different from microbes; it may be an awkward blend and create challenges in terms of balancing competing priorities.
- The potential risks associated with this diverse group of substances varies widely in scope and severity. Some believe that including all chemical hazards may broaden the scope of the strategic plan beyond what is manageable.
- Some chemicals may not be priorities, and thus may not need to be included initially. For example, there are classes of pesticides (e.g., plant growth regulators with no toxic mode of action) that are addressed differently from those with a toxic mode of action. Similarly, risks posed by regulated food/feed additives are generally well characterized and addressed in terms of science and regulation.
- Pesticide residues are being extensively addressed due to the recent legislation, and these activities can be supported through other mechanisms.

Recommendation: All chemical substances in food should be included within the scope of the Council's efforts and its strategic plan, and potentially the annual coordinated budgets. This does not mean, however, that because these substances are in the same category for purposes of this paper that they pose public health risks of the same magnitude, or that they will all be a priority in the strategic plan or for budget initiatives; their inclusion does provide opportunities for better coordination, integration, and resource efficiencies. Further, continued progress on goals and objectives for microbial hazards can be ensured by adding chemical hazard activities slowly on a priority basis to the budget, so that they can be absorbed into the overall FBI work in an orderly fashion (exact timing for budget inclusion to be determined by the Budget Task Force).

Option 2: Miscellaneous Food Constituents There are a number of miscellaneous constituents such as artificial sweeteners, fat substitutes, and other "naturally occurring" substances that serve various functions when added to food. These constituents are not typically considered "chemical hazards", but as components of food products are a candidate for inclusion within the scope.

Reasons to include these miscellaneous food constituents within the "core activities" of the strategic plan are provided below.

- Food processors are examining "new" sources of ingredients (e.g., gums and fibers) for more conventional functional properties and adding them to food; the use of these ingredients raises safety questions.
- Food processors are utilizing macronutrient substitutes (e.g., non-nutritive sweeteners and fat substitutes); since quantities of these substitutes in the diet may be larger than traditional food additives, there are questions about the effect of their use on the quality of the American diet.

Reasons to exclude these miscellaneous constituents from the "core activities" are the following.

- Some may argue that the urgency of the problems with pathogens and chemicals warrants a focus on those hazards; inclusion of these miscellaneous constituents would broaden the scope beyond what may be practical.

- These areas are not likely to be priorities in the plan, and may not need to be addressed at this time.
- Although there are concerns about the effect of these constituents in the American diet, the primary purpose of programs dealing with them is not to reduce foodborne illnesses.

Recommendation: Include this category in the "collateral activities", but do not consider it in developing the strategic plan (and budget) at this time. Although related to food safety, Federal programs dealing with these constituents are not focused on reducing the incidence of acute or chronic foodborne illness due to these products in the food supply. The issue can always be revisited if significant food safety issues arise.

Option 3: Nutrition Programs There are several HAS and USDA programs as well as public-private partnerships designed to define and educate the American people on the benefits of a healthy, nutritious diet. USDA and FDA have developed the food pyramid, which recommends daily quantities of fruits, vegetables, meat and grains. Both agencies also have labeling programs designed to inform the public on the caloric and nutritional content of food. These programs are important in encouraging the consumption of a healthy, nutritious diet which can help to reduce the incidence of both acute and chronic disease.

Some feel that these nutrition programs are aligned with food safety and should be part of the "core activities" for the following reasons.

- The Federal government cannot ensure a healthy and affordable food supply, as outlined in the vision, without consideration of the nutrition programs.
- This would provide an opportunity to develop public health messages about both the nutritional benefits and the infectious/toxicologic hazards associated with various foods.
- Nutrition information could send a positive, constructive message to the American people, making food safety about more than just food contamination and poisoning. Food safety could also be about eating a wholesome, balanced diet to reduce the risk of disease, particularly chronic diseases (e.g., some cancers), and malnutrition.

On the other hand, the nutrition programs might not be considered "core activities" for several reasons.

- Some would argue that the urgency of the problems with pathogens and chemicals warrants a focus on these hazards; consideration of the nutrition programs would broaden the scope beyond what is practical and include areas that do not need attention or funding.
- Inclusion of the nutrition programs could dilute FBI efforts on infectious and toxicologic hazards to the point of ineffectiveness.
- The intent of these programs is to promote healthy eating habits by the American people and reduce the incidence of chronic disease; their primary purpose is not to enhance the safety of the food supply.

Recommendation: Federal programs to define and promote a healthy diet should be considered "collateral activities". They can support and help to implement the vision of a safe, healthy and affordable food supply, but are not designed to ensure food safety.

Option 4: Physical Hazards This includes a diverse set of "foreign" physical hazards in food that can cause serious harm if consumed, including stones, bones, metal chips or parts, and glass. Included also in this category are insect and rodent infestations (e.g., insects in flour, rat droppings). For purposes of this paper, tampering is included here although it is recognized that tampering may include the addition of biological and microbiological agents, as well as chemical or other agents, to foods to intentionally harm the consumer. This category was included in AS' definition of food safety concerns, but received little attention in the report.

Incidents of contamination of food with physical hazards can have significant adverse consequences. Reasons for inclusion in the "core food safety activities" include the following.

- Some physical hazards can result in significant harm to individuals.
- The public perceives contamination with physical hazards as part of the food safety issue.
- USDA and FDA legislation covers control and prevention of physical hazards, and USDA has substantial resources devoted to inspecting for physical hazards.
- These hazards are relatively easy to detect and may be easy to mitigate with limited Federal attention and/or resources.

Reasons to not include physical hazards in the "core activities" are as follows.

- Some may argue that the urgency of the problem with pathogens and chemicals warrants a focus on them.
- Food processors and handlers have numerous safeguards in place to protect against physical hazards and tampering in order to avoid liability and other costs as well as the harmful publicity associated with incidents of easily-detected physical materials in food.
- Partly for the reason cited above and because these hazards generally do not pose a widespread threat to public health, some food safety agencies have paid less attention to these hazards. Expanding the scope to include them seems unnecessary and would divert Federal resources from more significant public health problems.
- The food safety system for controlling these hazards is perceived by some to not be broken, with the exception of dealing with tampering and bioterrorism, and thus does not warrant increased attention at this time.

Recommendation: Physical hazards should be included in the "core food safety activities", and addressed in the strategic plan.

Option 5: Waterborne Hazards Water is an essential component of food production, processing and preparation; food production and processing are also a significant source of contamination to the nation's waters. Public water suppliers provide a majority of the drinking water used for washing and final preparation of food, including for use in reconstituted food products available in restaurants and the home. Waterborne hazards include: pathogens in irrigation and other waters used on farms and ranches and that can contaminate food -- sometimes as a result of poor farming practices, in particular mismanagement of animal wastes; pathogens and chemicals in surface or groundwater from point and non-point sources that can contaminate food; microbes and chemicals in public and private water supplies used for food processing and preparation; as well as chemicals and especially pathogens in drinking water

consumed by the public (*Cryptosporidium* in Milwaukee; *E Coli* in Alpine, Wyoming).

There are several reasons to include waterborne hazards as "core" activities in the strategic plan.

- Drinking water is part of the diet and an important component of many final food products (6 of the top 10 foods consumed by Americans are mixed with water before consumption *Is this correct?*).
- Water is used in most food production and manufacturing processes and drinking water is used in food preparation and consumption; use of potable water is a fundamental requirement of all regulations and guidance (GMPs, GAP/GMP guidance for produce, HACCP regulations, and recommended codes -- e.g., Pasteurized Grade A milk code, Food Code).
- Some programs to reduce pathogen contamination of water are already included in the President's Food Safety Initiative, and EPA's research on pathogens to support its water program is in the OSTP research Inventory -- i.e., microbial contamination of water is already in the FBI.
- Inclusion within the scope would provide attention to the important role of irrigation and processing water in food safety.
- There may be public health benefits that can be achieved by inclusion of EPA's water programs within the "core" scope, since:
 - There is a need to coordinate across the government on research on emerging pathogens in order to ensure efficiency and non-duplication of Federal research (e.g., the agencies share mutual objectives in the areas of risk assessment, health effects, dose response, and analytical methods for pathogens whether in food or water);
 - Irrigation water and animal manures can be a pathway for contamination of food by pathogens; several acute disease outbreaks have occurred from this route (e.g., *Cryptosporidium* in apple juice), and there is a need for coordination of surveillance and inspections; and
 - Several commonly waterborne pathogens are sometimes transmitted by the foodborne route.
- EPA develops fish advisories for locally-caught fish, while FDA develops action levels for commercial seafood; inconsistencies in the action levels/fish advisories might be addressed through these joint efforts.
- Water, whether for consumption by humans or animals, is considered "food" under the Federal Food, Drug, and Cosmetic Act.

However, there are also significant reasons why waterborne hazards should not be included in the "core" activities.

- The purpose of EPA's water programs is to insure fishable, swimmable surface waters and safe tap water for drinking, and not to enhance food safety by reducing acute or chronic illnesses.
- Inclusion of these programs in the food safety initiative could divert EPA from its primary responsibilities under SDWA and CWA, including meeting statutory and judicial deadlines, and may expand the scope beyond what is manageable.

- Tap water that is safe for drinking is also safe for food production, processing and consumption.
- EPA does not regulate water in food production, processing, preparation and consumption, and it has not been a primary concern for EPA.
- The issues related to animal manures and irrigation water would not only bring into the strategic plan a large range of EPA activities but also a suite of programs managed by USDA and the Department of Interior.
- We already coordinate on regulatory issues via the President's Clean Water Action Plan and via the Animal Feeding Operation Strategy; duplicative coordination is inefficient.
- It will be extremely difficult, if not impossible, to separate EPA's regulation/enforcement water program budget for food safety from the budget for the entire water program.

Recommendation: Water safety should be considered a "collateral activity" which is related to food safety but whose primary mission is not to reduce foodborne illnesses. Collaboration to avoid duplication of research efforts and ensure adequate EPA input into development of FDA and USDA guidelines (e.g., Good Agricultural Practices, Good Manufacturing Practices and the Food Code) is critical but can be accomplished without water being a part of the initial strategic plan.

TABLE 2
FEDERAL ACTIVITIES RELATING TO FOOD SAFETY

Federal Agency	Other Agencies Involved	Activity	Type of Activity	Issues Addressed	Core or Collateral Activity
U.S. Department of Agriculture					
Food Safety & Inspection Service	FDA EPA CDC	Sets standards for meat, poultry and egg shells shipped interstate; inspects domestic and imported meat and poultry and enforces standards; recalls adulterated products.	Regulation, Inspection, & Enforcement	Pathogens Chemical residues Physical hazards Food quality	Core
Agricultural Marketing Service	EPA	Pesticide data program to monitor and collect pesticide residue information for EPA risk assessment; microbial data program surveillance and monitoring; manages voluntary quality certification program.	Regulatory Support, Monitoring, & Risk Assessment	Pesticides Pathogens Food quality	Core
Agricultural Research Service	EPA FDA	Research (basic) on elimination, mitigation and detection of hazards	Research, & Regulatory Support	Pathogens Chemicals	Core
Cooperative State Research, Education & Extension Service	EPA FDA	Research (applied), outreach, and education on elimination, mitigation, and detection of hazards.	Research, & Regulatory Support	Pathogens Chemicals	Core
Animal & Plant Health Inspection Service	EPA FDA	Regulation of biotechnology and irradiation, methods.	Regulation, Inspection, & Enforcement	Biotechnology Irradiation	Core
Economic Research Service	EPA FDA	Data Interpretation.	Regulatory Support, Guidance, & Risk Assessment	Pesticide uses Chemicals	Core
National Agricultural Statistical Service	EPA FDA	Data collection and monitoring	Regulatory Support, & Risk Assessment		Core

Federal Agency	Other Agencies Involved	Activity	Type of Activity	Issues Addressed	Core or Collateral Activity
Grain Inspection, Packers & Stockyards Administration		Inspect for toxins (e.g., aflatoxin)	Inspection	Toxins	
Office of Risk Assessment & Cost Benefit Analysis	EPA FDA	Data interpretation, guidance, and risk assessment	Regulatory Support, & Guidance		Core
Office of Pest Management Policy	EPA FDA	Data collection, interpretation, guidance, and risk assessment	Regulatory Support, & Guidance	Pesticides	Core
Food & Drug Administration					
Center for Food Safety & Applied Nutrition	USDA EPA CDC		Regulation, Inspection, Enforcement	Pathogens Chemicals Nutrition	Core
Center for Veterinary Drugs	USDA CDC			Animal Drugs	Core
Centers for Disease Control & Prevention					
Centers for Disease Control & Prevention	USDA FDA EPA	Investigates outbreaks of foodborne illness; monitors and collects information on food- and waterborne illnesses; conducts nationwide surveillance for food- and waterborne diseases; designs and implements surveillance systems; performs research on diagnostic and subtyping methods; and training and education.	Surveillance, Monitoring, Research, Training, & Education	Food- and waterborne pathogens FoodNet and PulseNet Infectious disease outbreaks Chemical hazards	Core
U.S. Environmental Protection Agency					

Federal Agency	Other Agencies Involved	Activity	Type of Activity	Issues Addressed	Core or Collateral Activity
Office of Prevention, Pesticides & Toxic Substances	USDA FDA CDC	Regulation of pesticide uses, residues in/on food and antimicrobials for control of pathogens. Supports investigations of certain chemical contamination incidents and regulates chemicals.	Regulation, & Risk Assessment	Pesticides Chemicals	Core
Office of Water	USDA CDC FDA	Regulates drinking water quality and biosolids; establishes discharge standards for facilities. Provides criteria for ambient water contamination, watershed controls, and other pathogen elimination/protection authorities.	Regulation, Guidance, Research & Risk Assessment	Pathogens in water Chemicals in water Animal wastes Other agricultural wastes	Collateral
Office of Research & Development	OSTP USDA FDA	Responsible for research on pesticide testing methods, chemical monitoring methods development, and risk assessment issues; provides technical and scientific advice on risk assessment, and testing and monitoring methods.	Research, Guidance, & Risk Assessment	Chemicals Pesticides Pathogens?	Core (pesticides)
Office of Enforcement & Compliance Assurance	FDA USDA	Ensures that pesticides used on crops/food are registered, are not adulterated, and are used correctly. Ensures that data used to support pesticides registration is not fraudulent. Referrals for possible illegal residues. Collects pesticide production information.	Inspections, Enforcement, Referrals, Regulation, & Risk Assessment Support	Product inspections Use inspections Lab Inspections Pesticide misuse Recalls	Core (pesticides)
Department of Commerce					
National Marine Fisheries Service	FDA	Voluntary inspection program for seafood quality.	Inspection		



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*Food
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- link*

FAX TRANSMITTAL SHEET

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NUMBER OF PAGES (INCLUDING COVER SHEET): *3*

Draft Press Plan for FDA/FSIS memo.

Please get me your comments ASAP.

*Thanks
Cliff*

PROPOSED PRESS PLAN

FSIS/FDA MEMORANDUM OF UNDERSTANDING
ON THE FOOD SAFETY INITIATIVE
January 12, 1999

Plan of Action:

-- FDA and USDA's Food Safety and Inspection Service will issue a joint press release on the MOU.

-- The following mainstream media print outlets will be individually contacted:

AP	Washington Post
UPI	New York Times
Bloomberg News Wire	Wall Street Journal
Dow Jones News Wire	USA Today
Reuters	Knight Ridder

-- We will also notify the network television outlets, CNN and MSNBC, Conus etc.

-- While generating interest in the mainstream media may be difficult, we anticipate that trade press publications will be interested and we will contact the following outlets:

Food Chemical News	Food Protection Report
Food Regulation Weekly	The Tan Sheet
FDA Week	Dickinson's FDA

-- Additionally, FDA will contact the following trade associations considered multipliers since they issue their own press releases:

National Food Processors Assn.
Grocery Manufacturers Assn.
United Fresh Fruit and Vegetable Assn.
International Food Information Council

-- Spokespeople: Joseph Levitt, Director, FDA's Center for Food Safety and Applied Nutrition. Tom Billy, Administrator, FSIS

Message:

-- Making sure the food Americans put on their tables is a top priority of the Clinton Administration. This new memorandum paves the way for greater collaboration and cooperation between the agencies responsible for ensuring a safe food supply.

Highlights from the MOU:

--In the May 1997 Report to the President entitled "Food Safety From Farm to Table - A National Food-Safety Initiative," several recommendations addressed the issue of increasing cooperation among agencies, specifically FSIS and FDA, to avoid duplication of efforts. This MOU defines those issues in the following ways:

- * Both agencies agree to develop, maintain and annually update lists of their district offices and contacts, and food establishments that are regulated dually by FDA and FSIS.

- * Actions such as outbreaks of foodborne illnesses, recalls, regulatory actions and tampering that involve the jurisdiction of both agencies should be reported to counterparts and follow up action accomplished.

- * Information for enforcement purposes should be shared.

- * Training opportunities should be developed and evaluated so that each agency appropriately understands the workings of its counterpart agency.