



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

Food
Safety

DEC 13 1996

MEMORANDUM FOR THE PRESIDENT

SUBJECT: New Initiative to Protect Americans' Food Supply

PURPOSE

We wanted to let you know about a joint initiative we are proposing, to reduce death and disease caused by food poisoning. This food safety initiative, which is now under consideration as part of the FY 1998 budget process, would affect every American but would involve only a modest amount of new funding (about \$100 million).

BACKGROUND

Last month's outbreak of E. coli-contaminated apple juice sickened dozens and killed one child. There was a similar outbreak involving hamburger in the northwest during the early days of your Administration. Although those outbreaks received nationwide publicity, the reality is that every year millions of Americans are sickened, and an estimated 9,000 die, from E. coli, Salmonella, Cryptosporidium and other foodborne "pathogens."

Hospitalization costs alone for these illnesses are over \$3 billion a year, and costs for lost productivity have been estimated to range, for seven specific pathogens, between \$6 and \$9 billion; total costs for all food poisonings are likely to be much higher. In August, you announced that USDA was adopting modern requirements to make meat and poultry safer. Last year, HHS adopted similar requirements for seafood. This initiative would strengthen those programs and implement important measures to make the rest of the food supply safer.

Today, our understanding of many pathogens is limited; for some, we do not even know how much must be present in food to cause illness. The public health system has limited means to identify and track the causes of foodborne illness; and Federal, State, and local food safety agencies need to improve coordination for more effective response to outbreaks of illness. Years go by before most non-meat plants receive an FDA or State inspection, and increasing quantities of imported foods flow into this country daily with little scrutiny by FDA inspectors. And food processors, restaurateurs, supermarket managers, and consumers often lack basic understanding of the threat of foodborne contaminants and how to protect against them.

During the past three months, experts at our two departments and the EPA have worked intensively to develop a highly targeted initiative to address this issue; a summary has been shared with your staff. OSTP and State health officials have also been involved in the development of this plan, which addresses one of the initiatives identified in your recent report, "Meeting the Challenge: A Research Agenda for America's Health, Safety, and Food (1996)."

PROPOSAL

The good news is that we have the scientific talent and wherewithal to reduce the number of illnesses that do occur and to ensure that the United States will have a safer food supply. We believe that this Administration should launch a major new initiative next year that will positively affect the lives of all Americans. We would work through this initiative to reinvent the currently inadequate system devised by Theodore Roosevelt at the turn of the century into one that incorporates the science and technology of the 21st Century. Moreover, these gains can be achieved with a relatively small investment in new resources--around \$100 million--that can yield enormous benefits in health and public confidence in the food supply. Indeed, it is estimated that we can prevent 2 to 9 million illnesses, head-off up to 3,000 deaths, and save society billions of dollars in preventable health care costs each year.

The proposed interagency food safety initiative includes the following actions:

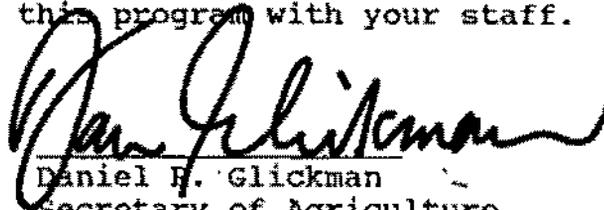
- o Build up the "early warning" and surveillance systems for foodborne illnesses and track them to their cause.
- o Increase FDA's inspections of food processors and imported foods, and improve collaboration with States in that area.
- o Better coordinate when disease outbreaks occur, including electronic communication among Federal, State, and local health authorities.
- o Expand education of food processors, retailers, restauranteurs, and consumers about the latest safe food processing, storage, and handling techniques.
- o Improve risk assessment for food pathogens, so that regulators can make the most cost-effective decisions.
- o Expand and better coordinate Federal research efforts on pathogens that pose the highest risk to the public.

In addition, we recognize that fundamental change of the food safety system is necessary, and we propose the development of a comprehensive, strategic plan to improve the food safety infrastructure through broad-based discussions involving all stakeholders.

A number of industry, academic, and other reports, such as those of GAO and NAS, have indicated that such reforms are necessary. We believe, therefore, that this initiative will be well received by the food industry and the general public. This interagency food safety initiative can be a significant feature of your domestic agenda for the coming year, and will accomplish an historic advance in public health. If you concur, we will coordinate further preparation of this program with your staff.



Donna E. Shalala
Secretary of
Health and Human Services



Daniel F. Glickman
Secretary of Agriculture

MEMORANDUM

TO: BRUCE REED, ELENA KAGAN

FROM: TOM FREEDMAN, MARY L. SMITH

RE: BACKGROUND FOR MEETING WITH NEAL LANE ON FOOD SAFETY COUNCIL

DATE: SEPTEMBER 24, 1998

This memorandum provides points for discussion for your meeting with Neal Lane on the goals, both short-term and long-term, for the President's Council on Food Safety. We have discussed this with Cliff Gabriel, Neal Lane's deputy. In addition, the following attachments are included: (1) draft charter for President's Council on Food Safety; (2) draft agenda for public meeting for the strategic planning process on October 2; (3) draft remarks of Neal Lane to open October 2 public meeting; (4) draft report on the Joint Institute on Food Safety Research; (5) a USA Today article dated September 16 which describes PulseNet, a database that permits states to compare quickly the genetic fingerprints of bacteria responsible for outbreaks; and (6) the executive order establishing President's Council on Food Safety.

I. FOCUS OF THE COUNCIL

A. What should the Council accomplish?

- The Council should establish a seamless, science-based food safety system. In doing this, the Council should have an overarching framework that incorporates the following principles:
 - the improvement of food safety
 - efficiency
 - cooperation and coordination with states and localities as well as within the federal government. We already are cooperating with states through the states through the PulseNet system, which tracks the genetic fingerprints of bacteria in outbreaks (see attached article).
 - prevention
 - measurable outcome goals
- Concurrently with developing the overarching framework in order to develop a seamless food safety system, the Council should tackle specific issues including prevention, inspections, streamlining within the federal government, and coordinating with states. For instance, there has been some discussion about consolidating responsibility for eggs in one federal food safety agency. Currently, USDA and FDA both have responsibility for different aspects of eggs.

B. Scope of Council (issues we need to focus on and have answers for October 2 meeting)

1. Does the Council deal with more than microbial --yes
2. Does it include pesticides -- need to discuss
3. What is going on with research -- Neal will give update in his opening remarks.

II. Short-Term Goals

- A. Respond to the NAS study-- within 180 days from August 25 --so it will be February 21
- B. FY2000 budget -- unified budget for the food safety initiative for the FY2000 budget, we will do the "coordinated budgets" for the entire food safety activities starting in FY2001
- C. Joint Institute for Food Safety Research -- has to report back by October 3 (the day after the October 2 meeting) (see attachment)

III. Long-Term Goals

- A. Strategic plan to be prepared by the Council (see attached charter for process)

IV. Miscellaneous Issues

- A. Procedures of the Council -- How often will the Council meet, etc. See attached draft charter.
- B. How the Council will obtain public input. There will be three additional public meeting to obtain input for the strategic planning process
 - October 20, 1998 in Sacramento, California
 - November 10, 1998 in Schaumburg, Illinois
 - December 8, 1998 in Dallas, Texas

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

Article I: Purpose.

On August 25, 1998, the President, by Executive Order, No. 13,100, 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 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 National Institute for Food Safety Research, and to evaluate and make recommendations to the President on the proposals contained in the National Academy of Sciences (NAS) report on food safety.

This Charter provides the basis for the 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: Officers

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: 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 consensus or general agreement. If a consensus or general agreement cannot be reached, a final decision will be made by a consensus of the co-chairs.

A summary report of each meeting of the Council shall be prepared for distribution to the membership and shall be made available for public inspection and copying and on the Council Internet web site.

The Council shall prepare a report for submission to the President not later than 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 V: Duties and Responsibilities

The specific responsibilities of the Council are to:

1. Develop a comprehensive strategic Federal food safety plan ("plan") to reduce the annual incidence of acute and chronic foodborne and waterborne illness by further enhancing the safety of the nation's food supply. The plan will address the public health, resource, and management questions facing Federal food safety agencies and will focus on the full range of food safety issues and the actions necessary to ensure the safety of the food and water Americans

use and consume. The planning process will consider both short and long term issues including new and emerging threats to food safety 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 research plan currently being developed 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 collegially develop annual coordinated food safety budgets for submission to 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 National Institute for Food Safety Research (NIFSR). The Council will evaluate the reports from NIFSR on food safety research activities and give direction to NIFSR 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, within 180 days of the Executive Order, report to the President on the Council's response to and recommendations concerning the NAS report and appropriate additional actions to improve food safety including proposals for legislative reform of the food safety laws and regulatory structures.

Article VI: Committees

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

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

1. Strategic Plan 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 actions necessary to ensure the safety of the food and water 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, within 12 months of the effective date of this Charter, 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. NIFSR Oversight Committee

The Committee will evaluate the reports from the NIFSR 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. Ad Hoc NAS Report Review Committee

The committee shall review and report to the Council on the NAS report after providing for public comment and will, by January 1, 1999, provide a report to the Council containing a proposed Council's response to the NAS report.

Article VII: 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. The Secretariat will facilitate planning, coordination, and communication among Council members.

Article VIII: Web Site

The Council shall establish an Internet web site and the Department of Agriculture shall maintain and will be the system owner of the web site. 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.

CALENDAR

(DRAFT)

August 25, 1998	Announcement of Executive Order. Directive to review NAS report, and hold public meetings.
by	Determine how Council will operate, staff, schedule first meeting, consider how to accomplish the following:
September 30, 1998	<ol style="list-style-type: none"> 1. Plan for review of NAS report – due February 1999 2. Plan for strategic plan 3. Review of agency FY 2000 budget requests and President's Food Safety Initiative budget 4. Plan for FY2001 budget (can be delayed until later) 5. Approve plan for NIFSR
September 18, 1998	Principals' Meeting to consider FY2000 budget and NIFSR report.
October 1, 1998	NIFSR report sent to President.
October 1, 1998	FY 2000 Initiative Budget to OMB.
October 2, 1998	First public meeting on strategic plan, NAS report. Arlington, Virginia
October 20, 1998	Second public meeting on strategic plan, NAS report. Sacramento, California
October 1998	Publish NIFSR report in Federal Register comment.
November 10, 1998	Third public meeting on strategic plan, NAS report. Chicago, Illinois
November 12-13, 1998	Research, Education and Economics Food Safety Conference
December 8, 1998	Fourth public meeting on strategic plan, NAS report. Dallas, Texas
January 1999	Comment period closes for NIFSR Federal Register. Analyze comments and develop a more detailed "straw proposal" for Institute.
January 1999	Discussion draft of report to President on NAS report recommendations.
January 25, 1999	HACCP Implementation - Small Plants
by	Report to President on response to NAS report.
February 21, 1998	

March 1999	Publish straw proposal for NIFSR in Federal Register for comment.
April 1999	Third public meeting on NIFSR.
May 1999	Publish "final" report on NIFSR in Federal Register.
August 1999	President appoints Advisory Committee for NIFSR.
August 31, 1999	Council delivers strategic plan to President.
October 1, 1999	NIFSR begins operations.

AGENDA

President's Council on Food Safety Public Meeting on Food Safety Strategic Plan October 2, 1998 Arlington, Virginia DRAFT for internal use only

- 8:30-9:30 **Registration**
- 9:30-9:40 **Welcoming Remarks:** Neal Lane, Assistant to the President for Science and Technology, Office of Science Technology Policy (includes Executive Order 13100 establishing the Council, introducing the Secretaries (Co-Chairs), Council tasked with strategic planning & reporting to President on NAS recommendations in 180 days. Brief discussion of the Research Institute, the Agenda, what to expect, ground rules-3 min. rule so everyone has a voice, purpose of today's meeting is to listen to your ideas.-we are here with an open mind.)

9:40-9:50 **The Importance of Food Safety, Accomplishments to Date and Success Stories.**

9:40-9:45 **Donna Shalala, Secretary of Health and Human Services**
 9:45-9:50 **Richard Rominger, Deputy Secretary of Agriculture,**

9:50-9:55 **Introduce Agency Representatives for Strategic Plan Discussion: Neal Lane**

Dr. Catherine E. Woteki, Under Secretary for Food Safety, USDA
James A. O'Hara, Deputy Assistant Secretary for Health, HHS
Dr. Lynn R. Goldman, Assistant Administrator for Prevention, Pesticides and Toxic Substances, Environmental Protection Agency
Thomas J. Billy, Administrator, Food Safety and Inspection Service, USDA
Joseph Levitt, Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, HHS
Dr. Morris Potter, Assistant Director for Foodborne Diseases, Centers for Disease Control and Prevention, HHS

9:55-10:10 **The Agencies' Vision: Panel briefly describes themes contained in the vision statement: 1) A Safe & Affordable Food Supply (L. Goldman), 2) Assuring Food Safety Requires Everyone to Play a Role (J. O'Hara), and 3) Protecting the Food Supply Must Be Grounded in Sound Science (C.Woteki).**

9:55-10:00 **Dr. Lynn R. Goldman**
 10:00-10:05 **James A. O'Hara**
 10:05-10:10 **Dr. Catherine E. Woteki**

10:10-10:25 **Break**

OPTIONAL FORM NO. 10 (7-90)

FAX TRANSMITTAL # of pages: 2

To: <u>Juan</u>	From: <u>Torru</u>
Dept./Agency:	Phone #:
Fax #:	Fax #:
<u>690-0550</u>	

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10:25 - 11:45 Facilitated Discussion of the Vision/Strategic Plan (based on questions in FR)

10:25-10:45 #1. Does the vision statement accurately depict an achievable food safety system vision? What modifications, if any, would you make?

10:45-11:45 #2. What are the barriers to pursuing this vision? What gaps currently exist in the food safety system that impede achievement of this vision?

#3. To Make the vision a reality, what changes are needed for: a) government agencies at the Federal, State, and local level; b) industry; c) public health professionals; d) consumers; and e) others?

11:45-12:30 Lunch

12:30-2:30 Facilitated Discussion of the Vision (can't)

12:30-1:15 #4. What should be the short-term goals and critical steps to realize this vision? What should be the long-term goals and steps?

1:15-1:30 #5. What is the best way to involve the public in development of a long-term food safety strategic plan? What additional steps besides public meetings would be beneficial?

1:30-2:30 #6. What are your comments on the conclusions and recommendations of the National Academy of Sciences' report, "Ensuring Safe Food From Production to Consumption"?

2:30-2:45 Break

2:45-3:45 Prepared Remarks: (max. of 5 minutes per person)

3:45-4:00 Closing: Dr. Catherine E. Woteki, James A. O'Hara, Dr. Lynn R. Goldman

ãD?sôæ½@@.F-□Neal Lane's Opening Remarks for Food Safety Meeting
October 2, 1998
Arlington, VA

I am privileged to welcome you to this first meeting hosted by the President's Council on Food Safety. I think it's most appropriate that the President's Council is starting its deliberative process by seeking public input today. This means that we will not only welcome but we will seek input from all stakeholder—consumers, public health officials, representatives from State and local governments and food producers, processors, and distributors. Transparent decision-making will be one of the underlying operational principles of the Council's work. All Americans have a stake in the safety of our food supply. And while we can rightfully take pride in the fact that Americans do have one of the safest food supplies in the world, we know we can do better.

America's food habits are changing. Consider the foods we eat today—the manner in which they are prepared and the consumers' expectations of quality and wholesomeness all are vastly different from when our food safety system was established at the turn of the century.

The composition of our population is changing also; we are graying and becoming more ethnically diverse. By the year 2010, X percent of our population will be over the age of 65 compared to X percent in the early 1900s. By the year 2010, approximately half of our school age population will be from minority groups. How should our food safety system reflect these dramatic changes?

Our food safety system must take into consideration not only the growing diversity of our citizenry, but also the growing diversity of our food sources. Since 1985, food imports have tripled. The expansion of global markets requires us to rethink our regulatory approach for imported as well as domestically produced food.

Since the beginning of his first term, President Clinton has demonstrated vision and leadership in his efforts to improve the safety of America's food supply. Faced with the tragic E. coli O157:H7 outbreak on the West Coast in 1993, the Administration quickly understood the need to improve the safety of our food supply, and acted just as quickly. Starting with the Vice President's 1993 call for more emphasis on prevention, to the issuing HACCP regulation to the creation of the Food Safety Council, this Administration has been out in front on this issue. But much remains to be done.

We are fortunate today to have with us Morley Winograd, Senior Policy Advisor for the Vice President, and Bruce Reed, the Assistant to the President for Domestic Policy. Their attendance today is a clear indication of the importance the President places on this issue.

The President signed Executive Order 13100 establishing his Council on Food Safety on August 25, 1998. The Council was given the clear purpose of "improving the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs." Specifically, the Council will develop a comprehensive strategic plan that integrates Federal efforts into those of State and local governments and the private sector. For the first time, a comprehensive cross agency plan will be tied to the budget process.

The Council will also oversee food safety research activities across the Federal government. This process was initiated last year through the National Science and Technology Council and further advanced by the President's directive to create a Joint Institute for Food Safety Research. The function of the institute will be to develop an interagency food safety research plan and appropriate outreach to the private sector and universities.

Sound science must underpin all our food safety efforts. Even though most of us in this room take this basic premise for granted, it is so central to improving our food safety system that it bears repeating—again and again. From regulation to education, we need the best science possible to direct our actions. We must tighten the links between our regulatory agencies and science agencies. We must make sure consumers and producers have the very best information available to prevent the occurrence

of food borne illnesses. We must provide our researchers with the resources they need so they can generate the knowledge that will protect us from food-borne illnesses. But resources are limited, so we need to target them wisely.

In this regard, we need to make better use of risk analysis. What do we know about specific risks associated with the farm-to-table pathway? What research is needed to help us identify and better understand those risks and how to manage them? Risk analysis is a planning tool we need to refine. We must make sure we have data to support the development of sound quantitative approaches to risk analysis.

The President has also asked the Council to provide him with our assessment of the Academy report "Ensuring the Safe Food from Production to Consumption." The Academy has done an excellent job in laying out many of the issues that the Council must address over the next several months. Their report, and our assessment of it, will give the Council a jumpstart to our planning process.

This is an important meeting that starts us down the road that leads us to a safer food supply. While there have been numerous public meetings in the past on any number of food safety issues, this is the first one specifically designed to solicit input on our overall approach to food safety. Where do you think we should be going? Specifically, we look forward to hearing your views on the NAS report and on our proposed vision statement.

After brief remarks from my fellow Council co-chairs, Secretary Shalala and Deputy Secretary Rominger, who is representing Secretary Glickman, senior agency officials will facilitate a discussion on the 6 questions contained in the Federal Register notice. This discussion will take us through the rest of the morning. There will be a break for lunch and the discussion will resume until 2:30 p.m. At 2:45 p.m., there will be time for many of you to give prepared statements. Since time is limited, brevity is much appreciated. Please keep your remarks to less than 5 minutes. We encourage you to provide written remarks, which will be carefully studied and factored into our planning process.

Let me reiterate; this is an open process. We have open minds. If we are to find success, we must first hear from you. Our plan must reflect the needs of the stakeholders, not just the needs of the agencies. Our Federal programs must be designed not only for compliance with existing statutes, but also for improved efficiency and coordination with other programs—so that the whole is greater than the sum of its parts. We are looking for your advice and guidance on how we can achieve the President's goal of a safer food supply. We are here to listen and learn.

It is a pleasure for me to welcome my fellow Council co-chair, Health and Human Services Secretary Donna Shalala.

9-22-98

The Honorable William Jefferson Clinton
The White House
Washington, DC 20500

Dear Mr. President:

Attached is our report, as requested in your July 3, 1998, Memorandum, regarding the creation of a National Institute for Food Safety Research. The report articulates the concept of the Institute and provides a proposed structure, operating principles, goals and outcomes, and an implementation schedule for the Institute.

The report reflects our consultation with the Domestic Policy Council, the Office of Management and Budget, the Office of Science and Technology Policy, the National Partnership for Reinventing Government, and the Environmental Protection Agency. After your review and approval of the report, our next step will be to publish this proposal for public comment and hold a public meeting in the next few months to further consult with State and local governments, consumers, producers, industry, and academia.

We are confident our proposal will further the goals of your National Food Safety Initiative as well as more efficiently coordinate the Nation's Federal food safety research among Federal agencies and academia to meet the needs of regulatory agencies and the private sector.

Sincerely,

Donna B. Shalala
Secretary of Health and Human Services

Dan Glickman
Secretary of Agriculture

Enclosure

DRAFT 2, September 22, 1998 (without DHHS comments)

National Institute for Food Safety Research

Report to the President

October 1, 1998

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Appendices

- A. President Clinton's Memorandum for the Secretary of Health and Human Services and the Secretary of Agriculture, July 3, 1998**
- B. Executive Summary, President Clinton's National Food Safety Initiative, May, 1997**
- C. Executive Order: President's Council on Food Safety, August 25, 1998**
- D. Federal agencies with research and risk assessment responsibilities**
- E. Glossary of acronyms**

EXECUTIVE SUMMARY

On July 3, 1998 President Clinton directed the Department of Health and Human Services (DHHS) and the Department of Agriculture (USDA) to report back within 90 days with a plan to create a Joint Institute for Food Safety Research ("the Institute"). The Institute is to (1) coordinate planning and priority setting for food safety research among the two Departments, other government agencies, and the private sector and (2) foster effective translation of research results into practice along the farm-to-table continuum. Enhanced and more efficient national investment in food safety research will do much to lower incidence of foodborne illness in the United States.

DHHS and USDA will have joint leadership of the Institute and will use existing resources to support it. This acknowledgement of the critical need to expand and coordinate food safety research also emphasizes the companion needs to expand and strengthen public-private partnerships and to augment collaboration among state, local, and other Federal agencies, thereby providing effectively the scientific information required to help achieve public health goals.

This document articulates the concept of the Institute, describes goals and the administrative principles underlying its organization, presents a proposed structure for the Institute, and a draft timeline for its implementation. Appendices A through E provide, respectively, the Presidential Directive for the Institute, the Executive Summary from the May 1997 Food Safety Initiative Report to the President, the Executive Order creating the President's Council on Food Safety, a listing of the twelve Federal agencies involved in food safety, and a glossary of acronyms. These materials will help define the history of Executive Branch Directives on food safety and the interagency consultative efforts that have contributed to the establishment of the Institute.

The ultimate goal of the Institute is to coordinate food safety research, such that the incidence of foodborne illness is reduced to the greatest extent feasible.

I. INTRODUCTION

On July 3, 1998, President Clinton directed the Secretary of Health and Human Services and the Secretary of Agriculture to report back to him within 90 days on the creation of a Joint Institute for Food Safety Research (*Institute*). The Institute will:

- *(1) develop a strategic plan for conducting food safety research activities consistent with [the President's National] Food Safety Initiative; and
- (2) efficiently coordinate all Federal food safety research, including with the private sector and academia.*

As the President's memorandum directed, the Secretary of Health and Human Services and the Secretary of Agriculture will jointly lead the Institute, which will cooperate and consult with all interested parties, including other Federal agencies and offices -- such as the Environmental Protection Agency, the National Partnership for Reinventing Government, and the Office of Science and Technology Policy -- as well as State and local agencies focusing on research and public health, and consumers, producers, industry, and academia. The Institute will make efforts to build on ongoing private sector research, through the use of public-private partnerships and other appropriate mechanisms.

This document articulates the concept of the Institute and provides a proposed structure, operating principles, goals and outcomes, and an implementation schedule for the Institute.

The ultimate goal of the Institute's research agenda is to reduce the incidence of adverse human health effects associated with the consumption of food. The objective of creating the Institute--and all other Administration food safety activities -- is to reduce the incidence of foodborne illness to the greatest extent feasible. Scientific information about prevention of foodborne illness and detection of organisms that may cause it is critical to further reduce the incidence of foodborne illness.

This report will serve as a starting rather than ending point for development of the Institute. The report will be published in the Federal Register for comment during October-November of 1998 with a public meeting in November/December of 1998. A draft proposal, based on the public comments received, will be announced in the Federal Register in February/March of 1999, with a public meeting in March/April of 1999. The final proposal will be submitted to the National Science and Technology Council of the Office of Science and Technology Policy (NSTC/OSTP) in June, 1999 for final review. A final report, which will serve as the detailed blueprint for the Institute, will be announced in the Federal Register in July of 1999. The Institute will officially begin its operations on October 1, 1999.

September 22, 1998 DRAFT #6B (without DHHS comments)

II. BACKGROUND

A. The National Food Safety Initiative

In his January 25, 1997 radio address, President Clinton announced he would request \$43.2 million in his 1998 budget to fund a nationwide early-warning system for foodborne illness, increase seafood safety inspections, and expand food safety research, training, and education. The President directed three Cabinet members--the Secretary of Health and Human Services, the Secretary of Agriculture, and the Administrator of the Environmental Protection Agency (EPA)--to identify specific actions to improve the safety of the food supply. He further directed them to consult with stakeholders (consumers, producers, industry, states, universities, and the public) and to report back to him in 90 days. The President emphasized the need to explore opportunities for public-private partnerships to improve food safety, particularly in the areas of surveillance, inspections, research, risk assessment, education, and coordination among local, state, and Federal health authorities. Through a series of interagency and stakeholder meetings and consultations, the May 1997 Report to the President entitled "Food Safety from Farm to Table: A National Food Safety Initiative" was developed and issued. (See Appendix B).

While the American food supply is the safest in the world, the Administration directed the National Food Safety Initiative (FSI) because there are still millions of Americans stricken by illness every year caused by the food they eat. The FSI recognized that research provides new information and technologies essential to successful implementation of six key activities: standard setting and rulemaking, inspection and compliance, education, surveillance, and risk assessment. To ensure that current research investments are adequately supporting the six key activities identified by the FSI, Federal research agencies are working on a coordinated, interagency research plan. Federal agencies that conduct food safety research have recently completed a major step in the development of this plan by creating a Federal inventory of food safety research projects, active or planned, for Fiscal Year 1998, including the scientific and fiscal resources that supported the research. DHHS and USDA, in collaboration with NSTC/OSTP, will use this information to identify additional priority food safety research areas that are not currently addressed in the FSI and will develop future food safety initiatives and their budgetary requirements. The Institute will become the vehicle for coordinating these activities to create a seamless, interagency food safety research planning, budgeting, and prioritization mechanism.

The FSI identified five broad areas in which significant knowledge gaps require a concerted interagency research effort:

- Improving detection methods
- Understanding microbial resistance to traditional preservation technologies
- Understanding antibiotic drug resistance
- Developing prevention techniques for pathogen avoidance, reduction, and elimination
- Understanding the contribution of food handling, distribution, and storage to pathogen contamination of food and developing preventions

The FSI also identified the research goal to develop methods and scientific data that would enhance the ability of Federal agencies to conduct microbial risk assessments. Two additional research areas, critical for addressing this goal, are:

- Developing and validating microbial exposure models, based on probabilistic methodology
- Developing and validating dose-response assessment models for use in risk assessment

When the FSI was developed in 1997, these immediate needs were given priority within the research and risk assessment agenda because microbial contamination of foods by pathogens has increasingly been linked to increasing incidence of foodborne illness and to high rates of morbidity and mortality. As these research and risk assessment activities progress and improvements in preventative measures are developed, the Institute will provide leadership for identification of other research and risk assessment priorities, which will receive increased attention from Federal food safety research agencies in future years.

III. NAME AND STRUCTURE OF INSTITUTE

The Secretary of Health and Human Services and the Secretary of Agriculture propose that the official name of the Institute be the "National Institute for Food Safety Research (NIFSR)."¹

¹The Food and Drug Administration of the Department of Health and Human Services (DHHS) already has a research facility and program which is named the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). Several prominent universities also have food safety institutes as part of their research programs. To avoid confusion, DHHS and the Department of Agriculture (USDA) have proposed a new name, the "National Institute for Food Safety Research".

The Institute will report to The President's Council on Food Safety (see Appendix C), which is chaired by the Secretaries of Agriculture and Health and Human Services and the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy. The Institute will be led by an Executive Director, who will be a highly recognized food scientist, jointly recruited, appointed, and supported by the USDA and DHHS. The Executive Director will supervise a small, permanent Institute staff of no more than 10 employees, and existing staff resources of USDA and DHHS will support the Institute and its operations.

The Executive Director will report to an Executive Research Committee and be advised by a Federal policy and budget committee and the National Institute for Food Safety Research Advisory Committee. The Executive Research Committee will comprise one senior research official appointed by each of the co-chairs of the President's Council on Food Safety. The Executive Research Committee will report to the President's Council on Food Safety.

The Federal policy and budget committee will be comprised of Federal food safety policy officials and agency heads, representing both research agencies and regulatory agencies. This committee will serve as a mechanism by which the government's chief scientific and public health experts can interact with the Institute Director and the Executive Research Committee to ensure the goals of the Institute are achieved. This committee will also be the vehicle for consultation and coordination across all Federal food safety agencies, and its membership will represent agencies of the USDA, DHHS, the Environmental Protection Agency, the National Science Foundation, and other relevant federal agencies.

The National Institute for Food Safety Research Advisory Committee will have 16 stakeholder members, with 6 members appointed by the Secretary of Agriculture, 6 members appointed by the Secretary of Health and Human Services, and 4 members appointed by OSTP/NSTC. Members of this committee may be chosen from existing advisory committees to the USDA, DHHS, and OSTP/NSTC. USDA, DHHS, and OSTP/NSTC will jointly support the Advisory Committee.

The work of the Institute will be accomplished through temporary interagency task forces that form and close as specific issues are resolved and through a small, permanent Institute staff, which will provide technical, administrative, clerical and computer support. The Institute will focus initially on microbial pathogens, in keeping with the President's National Food Safety Initiative. In future years, based on the direction of the President's Food Safety Council, advice of the National Institute for Food Safety Research Advisory Committee, and on other public input, the Institute may expand its scope progressively to include other known or potential contributors to foodborne illness and/or food safety, such as chemical contaminants, natural toxins, pesticide residues, animal drug residues, food additives, and

nutritional safety and health. All of these topics already are foci for important food safety research activities that warrant coordination by the Institute. With an expanded scope, the Institute would develop broad-based strategic planning with input from stakeholders and coordinate the resources administered by the numerous Federal agencies that participate in food safety research. (See Appendix D).

IV. ORGANIZING PRINCIPLES

The DHHS and USDA have developed the following principles as the foundation for establishing and operating the Institute.

A. Optimize Current Investment and Infrastructure

The Institute's mission includes optimizing the effectiveness of current food safety research investments and infrastructure to maximize funds going to conduct research, rather than for construction or maintenance of additional research facilities. For this reason, the President's directive is not intended to result in construction of new research or administrative facilities. The Institute will be "virtual," *i.e.*, it will focus on coordinated planning for research programs and budgets and on enhanced communications among existing organizational entities working within existing facilities. The Institute will be supported by a small staff and will draw on current resources within the responsible food safety agencies. The Institute will assist in fulfilling the Administration's farm-to-table strategy by relying on access to existing Federal research laboratories throughout the country.

B. Provide Centralized Communication with Stakeholders

Effective communication between the Federal food safety research providers and the users of the knowledge gained is critical to establishing priority-based research programs that are responsive to national needs. More than a dozen Federal agencies actively contribute to food safety research efforts. Food safety researchers have numerous critical constituencies: (1) regulatory agencies that rely on scientific information for the protection of public health; (2) industry and producers, including retailers, who design and implement effective food safety programs; and (3) consumers. While each agency makes a critical contribution, providing their unique expertise, perspective, and infrastructure, this array of activities can be daunting to stakeholders. Effective interchange--not only among Federal laboratories and the managers of Federally supported extramural research programs, but also their counterparts in industry and academia--is critical to developing cost-effective programs that maximize the benefits to

public health. Therefore, the Institute will serve as a centralized focal point for communication between stakeholders and the appropriate members of the Federal research community by facilitating public input into priorities through public meetings and advice from the National Institute for Food Safety Research Advisory Committee.

C. Use Current Intramural and Extramural Research Programs in Innovative Ways

Leveraging Federal research dollars for maximum public health benefit is critical to effective implementation of the FSI farm-to-table strategy. To better leverage current and future funds, the Institute will foster development of joint program announcements involving multiple Federal research programs and multi-center trials to demonstrate the cost-effectiveness of prevention strategies and technologies. Particular emphasis will be placed on "on-farm" research for the development of new technologies and tools to prevent microbial contamination of raw foods.

D. Mobilize Resources to Minimize the Impact of Current and Emerging Food Safety Problems

Food safety concerns are usually complex, involving the interaction of factors associated with agricultural productivity, public health, food processing and distribution practices, market economies and international trade, and consumer preferences and perceptions. The research needed to solve food safety problems is equally complex, requiring contributions from both basic and applied researchers in physical and biological sciences, and equally important advances in economic and behavioral research, and food technology and engineering. The impact that new food safety problems have, both in relation to threats to public health and the economic well-being of industry, is often dependent on how rapidly research resources can be mobilized. In the absence of a centralized coordinating mechanism to provide leadership, such as the Institute, the timely mobilization of resources among diverse groups of scientific disciplines has historically been a barrier to effective problem identification and resolution. The Institute, through advanced communications and coordination systems, will realize increased efficiencies in bringing to bear research resources when they are needed to minimize the impact of current and emerging food safety problems.

E. Increase Accountability for Federal Research Priorities and Implementation of Strategies to the Public

One of the Administration's highest priorities has been to make Federal agencies more responsive to the needs of the nation through transparent decision-making. To effectively

encompass the nation's food safety research needs, the Administration to date has focused on joint research planning and prioritization, with the participation of numerous Federal agencies. Establishment of the Institute will build on this planning process, thereby increasing the transparency of federal food safety research efforts, to better assure the public that Federal investments are strategic and not redundant.

V. GOALS/OUTCOMES OF THE INSTITUTE

A. Coordination in Research Planning, Budgeting, and Prioritization

The ultimate goal of the Institute's research agenda is to reduce the incidence of adverse human health effects associated with the consumption of food. Research planning, budgeting, and prioritization will be a consultative process among food safety research and regulatory agencies, with a primary purpose being to fulfill the informational needs of food safety regulatory agencies. As stated above, DHHS and USDA will cooperate to lead this effort, in consultation with the National Science and Technology Council of the Office of Science and Technology Policy (NSTC/OSTP). The goals of this effort are: (1) to maximize the public health benefit to the American people for resources devoted to basic and applied research, by assuring that the information acquired is applicable to the development of effective food safety guidance, policy, and regulation; (2) to maximize the return-on-investment to producers, processors, and the public for resources devoted to research by developing cost-effective prevention technologies; (3) to effectively communicate and operate together with Federal, state, and local public health, agriculture and research agencies and government partners; and (4) to develop partnerships among the Federal, state, and local governments and industry or academe to identify and solve, scientifically, food safety issues. The Institute will also coordinate and monitor activities that agencies undertake to further these goals and to provide periodic assessments of research accomplishments.

B. Scientific Support of Food Safety Regulation

The Nation's collective food safety research capabilities must be responsive to the risk-based public health priorities of the food safety regulatory agencies. Science and technology are required to develop effective food safety guidance, policy, and regulation. The Institute will identify research needs to (1) achieve public health goals; (2) support guidance, pathogen reduction regulation, and hazard analysis and critical control points (HACCP) systems approaches to regulation (e.g., meat, poultry, seafood, fresh juice); and (3) shift research orientation to a risk-based approach. Through the Federal policy and budget committee, which advises the Institute Director, food safety regulatory agencies will play an integral role in the Institute's operation and its development of research strategies to foster public health goals.

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C. Communication/Links with Other Food Safety Agencies

Through participation in the Institute, all Federal food safety research agencies will coordinate, complement, and bolster research efforts on related and multifaceted food safety issues. The Institute will coordinate the use of existing mechanisms, such as interagency agreements, contracts, and the development of scientific conferences, and the development of new mechanisms, such as jointly funded program announcements and other innovative approaches to further the achievement of the Institute's goals.

D. Communication/Links with Industry and Academic Partners

The Institute will encourage the development of public-private partnerships with industry and academia to efficiently develop and transfer new information and technologies. Technology transfer mechanisms for cooperation between Federal agencies and industry exist through the Cooperative Research and Development Agreement (CRADA) process. This mechanism protects the intellectual property rights of the parties involved and is designed to avoid conflicts of interest, which are of particular concern within regulatory agencies. The Institute will foster and build on existing technology transfer mechanisms.

Several food safety research consortia, which include Federal, state, academic, and industry partners, already exist and are supported in part through competitively awarded Federal extramural research grants. These institutes can optimize and combine resources to perform stronger and more cost-effective research programs in food safety than can a single university. The USDA and DHHS research agencies will continue to use grants, contracts, and cooperative agreements in partnership with academia.

VI. IMPLEMENTATION SCHEDULE

<u>Oct. 1, 1998</u>	Present report to the President
October/November 1998	Announce report in Federal Register for comment and notice of public meeting
November/December 1998	Host public meeting
January 1999	Analyze comments and develop a more detailed draft proposal for the Institute
March/April 1999	Announce draft proposal in Federal Register for comment
April/May 1999	Host public meeting
June 1999	Submit final proposal to National Science and Technology Council for review
July 1999	Announce final report in the Federal Register
August 1999	National Institute for Food Safety Research Advisory Committee Members are appointed by Secretary of Health and Human Services and Secretary of Agriculture and Office of Science and Technology Policy
October 1, 1999	Institute begins operation

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Appendix A

THE WHITE HOUSE
WASHINGTON

July 3, 1998

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES
THE SECRETARY OF AGRICULTURE

SUBJECT: Joint Institute for Food Safety Research

Americans enjoy the most bountiful and safe food supply in the world. My Administration has made substantial improvements in the food safety system, from modernizing meat, seafood, and poultry inspections to creating a high-tech early warning system to detect and control outbreaks of foodborne illness.

Our success has been built on two guiding principles: (1) engaging all concerned parties including consumers, farmers, industry, and academia, in an open and far-ranging dialogue about improving food safety; and (2) grounding our efforts in the best science available. We have made progress, but more can be done to prevent the many foodborne illnesses that still occur in our country.

As we look to the future of food safety, science and technology will play an increasingly central role. An expanded food safety research agenda is essential to continued improvements in the safety of America's food. We need new tools to detect more quickly dangerous pathogens, like *E. coli* O157:H7 and campylobacter, and we need better interventions that reduce the risk of contamination during food production.

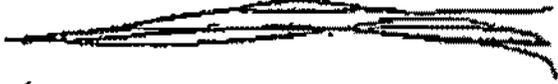
Food safety research is a critical piece of my Fiscal Year 1999 food safety initiative; and I have urged the Congress to revise the appropriations bills it currently is considering to provide full funding for this initiative. I also have urged the Congress to pass two critical pieces of legislation to bring our food safety system into the 21st century: (1) legislation ensuring that the Food and Drug Administration halts imports of fruits, vegetables, and other food products that come from countries that do not meet U.S. food safety requirements or that do not provide the same level of protection as is required for U.S. products; and (2) legislation giving the Department of Agriculture the authority to impose civil penalties for violations of meat and poultry regulations and to issue mandatory recalls to remove unsafe meat and poultry from the marketplace.

At the same time, we need to make every effort to maximize our current resources and authorities. One very important way to achieve this objective is to improve and coordinate food safety research activities across the Federal Government, with State and local governments, and the private sector. Solid research can and will help us to identify foodborne hazards more rapidly and accurately, and to develop more effective intervention mechanisms to prevent food contamination.

I therefore direct you to report back to me within 90 days on the creation of a Joint Institute for Food Safety Research that will: (1) develop a strategic plan for conducting food safety research activities consistent with my Food Safety Initiative; and (2) efficiently coordinate all Federal food safety research, including with the private sector and academia. This Institute, which will operate under your joint leadership, should cooperate and consult with all interested parties, including other Federal agencies and offices -- particularly, the Environmental Protection Agency, the National Partnership for Reinventing Government, and the Office of Science and Technology Policy -- State and local agencies focusing on research and public health, and on consumers, producers, industry, and academia. The Institute should make special efforts to build on efforts of the private sector, through the use of public-private partnerships or other appropriate mechanisms.

These steps, taken together and in coordination with our pending legislation, will ensure to the fullest extent possible the safety of food for all of America's families.

William J. Clinton



APPENDIX B
FOOD SAFETY FROM FARM TO TABLE:
A NATIONAL FOOD SAFETY INITIATIVE
REPORT TO THE PRESIDENT

MAY 1997

EXECUTIVE SUMMARY

While the American food supply is among the safest in the world, there are still millions of Americans stricken by illness every year caused by the food they consume, and some 9,000 a year--mostly the very young and elderly--die as a result. The threats are numerous and varied, ranging from *Escherichia coli* (*E. coli*) O157:H7 in meat and apple juice, to *Salmonella* in eggs and on vegetables, to *Cyclospora* on fruit, to *Cryptosporidium* in drinking water--and most recently, to hepatitis A virus in frozen strawberries.

In his January 25, 1997 radio address, President Clinton announced he would request \$43.2 million in his 1998 budget to fund a nationwide early-warning system for foodborne illness, increase seafood safety inspections, and expand food-safety research, training, and education. The President also directed three Cabinet members--the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency--to identify specific steps to improve the safety of the food supply. He directed them to consult with consumers, producers, industry, states, universities, and the public, and to report back to him in 90 days. This report responds to the President's request and outlines a comprehensive new initiative to improve the safety of the nation's food supply.

The goal of this initiative is to further reduce the incidence of foodborne illness to the greatest extent feasible. The recommendations presented in this report are based on the public-health principles that the public and private sectors should identify and take preventive measures to reduce risk of illness, should focus our efforts on hazards that present the greatest risk, and should make the best use of public and private resources. The initiative also seeks to further collaboration between public and private organizations and to improve coordination within the government as we work toward our common goal of improving the safety of the nation's food supply.

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Six agencies in the federal government have primary responsibility for food safety: two agencies under the Department of Health and Human Services (HHS)--the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC); three agencies under the Department of Agriculture (USDA)--the Food Safety and Inspection Service (FSIS), the Agricultural Research Service (ARS), and the Cooperative State Research, Education, and Extension Service (CSREES); and the Environmental Protection Agency (EPA). Over the last 90 days, these agencies have worked with the many constituencies interested in food safety to identify the greatest public-health risks and design strategies to reduce these risks. USDA, FDA, CDC, and EPA have worked to build consensus and to identify opportunities to better use their collective resources and expertise, and to strengthen partnerships with private organizations. As directed by the President, the agencies have explored ways to strengthen systems of coordination, surveillance, inspections, research, risk assessment, and education.

This report presents the results of that consultative process. It outlines steps USDA, HHS, and EPA will take this year to reduce foodborne illness, and spells out in greater detail how agencies will use the \$43.2 million in new funds requested for fiscal year 1998. It also identifies issues the agencies plan to consider further through a public planning process.

The actions in this report build on previous Administration steps to modernize our food-safety programs and respond to emerging challenges. As part of the Vice President's National Performance Review (NPR), the agencies have encouraged the widespread adoption of preventive controls. Specifically, the NPR report urged implementation of Hazard Analysis and Critical Control Point (HACCP) systems to ensure food manufacturers identify points where contamination is likely to occur and implement process controls to prevent it. Under HACCP-based regulatory programs there is a clear delineation of responsibilities between industry and regulatory agencies: Industry has the primary responsibility for the safety of the food it produces and distributes; the government's principle role is to verify that industry is carrying out its responsibility, and to initiate appropriate regulatory action if necessary.

The Administration has put in place science-based HACCP regulatory programs for seafood, meat, and poultry. In late 1995, the Administration issued new rules to ensure seafood safety. In July 1996, President Clinton announced new regulations to modernize the nation's meat and poultry inspection system. The Early-Warning System the President announced in January will gather critical scientific data to further improve these prevention systems. Additional actions outlined in this report will encourage the use of HACCP principles throughout the food industry.

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The need for further action is clear. Our understanding of many pathogens and how they contaminate food is limited; for some contaminants, we do not know how much must be present in food for there to be a risk of illness; for others, we do not have the ability to detect their presence in foods. The public-health system in this country has had a limited ability to identify and track the causes of foodborne illness; and federal, state, and local food-safety agencies need to improve coordination for more efficient and effective response to outbreaks of illness. Resource constraints increasingly limit the ability of federal and state agencies to inspect food processing facilities (e.g., years can go by before some plants receive a federal inspection.) Increasing quantities of imported foods flow into this country daily with limited scrutiny. Some food processors, restaurateurs, food-service workers, supermarket managers, and consumers are unaware of how to protect food from the threat of foodborne contaminants. These and other deficiencies will be addressed by key Administration actions outlined in this report and described below.

Enhance Surveillance and Build an Early-Warning System

As the President announced in January, the Administration will build a new national early-warning system to help detect and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks. For example, with FY98 funds, the Administration will:

Enhance Surveillance. The Administration will expand from five to eight the number of FoodNet active surveillance sentinel sites. Personnel at these sentinel sites actively look for foodborne diseases. Existing sites are in Oregon, Northern California, Minnesota, Connecticut, and metropolitan Atlanta. New sites will be in New York and in Maryland, with an eighth site to be identified. CDC will also increase surveillance activities for certain specific diseases. For example, CDC will begin a case-control study of hepatitis A to determine the proportion of cases due to food contamination, FDA will strengthen surveillance for *Vibrio* in Gulf Coast oysters; and CDC will strengthen surveillance for *Vibrio* in people.

Equip FoodNet sites and other state health departments with state-of-the-art technology, including DNA fingerprinting, to identify the source of infectious agents and with additional epidemiologists and food-safety scientists to trace outbreaks to their source.

Create a national electronic network for rapid fingerprint comparison. CDC will equip the sentinel sites and other state health departments with DNA fingerprinting technology, and will link states together to allow the rapid sharing of information and to quickly determine whether outbreaks in different states have a common source.

Improve Responses to Foodborne Outbreaks

At the federal level, four agencies are charged with responding to outbreaks of foodborne and waterborne illness: CDC, FDA, FSIS, and EPA. States and many local governments with widely varying expertise and resources also share responsibility for outbreak response. The current system does not assure a well-coordinated, rapid response to interstate outbreaks. To ensure a rapid and appropriate response, with FY98 funds, agencies will:

Establish an intergovernmental Foodborne Outbreak Response

Coordinating Group. Federal agencies will form an intergovernmental group, the Foodborne Outbreak Response Coordinating Group, to improve the approach to interstate outbreaks of foodborne illness. This group will provide for appropriate participation by representatives of state and local agencies charged with responding to outbreaks of foodborne illness. It will also review ways to more effectively involve the appropriate state agencies when there is a foodborne outbreak.

Strengthen the infrastructure for surveillance and coordination at state health departments. CDC, EPA, FDA, and FSIS will assess and catalogue available state resources, provide financial and technical support for foodborne-disease-surveillance programs, and other assistance to better investigate foodborne-disease outbreaks.

Improve Risk Assessment

Risk assessment is the process of determining the likelihood that exposure to a hazard, such as a foodborne pathogen, will result in harm or disease. Risk-assessment methods help characterize the nature and size of risks to human health associated with foodborne hazards and assist regulators in making decisions about where in the food chain to allocate resources to control those hazards. To improve risk-assessment capabilities, with FY98 funds, the agencies will:

Establish an interagency risk assessment consortium to coordinate and guide overarching federal risk-assessment research related to food safety.

Develop better data and modeling techniques to assess exposure to microbial contaminants, and simulate microbial variability from farm to table. Such techniques will help scientists estimate, for example, how many bacteria are likely to be present on a food at the point that it is eaten (the end of the food chain), given an initial level of bacteria on that food as it entered the food chain.

Develop New Research Methods

Today, many pathogens in food or animal feed cannot be identified. Other pathogens have

developed resistance to time-tested controls such as heat and refrigeration. With FY98 funds, the agencies will focus research immediately to:

Develop rapid, cost-effective tests for the presence in foods of pathogens such as Salmonella, Cryptosporidium, E. coli O157:H7, and hepatitis A virus in a variety of foods, especially foods already associated with foodborne illness.

Enhance understanding of how pathogens become resistant to food-preservation techniques and antibiotics.

Develop technologies for prevention and control of pathogens, such as by developing new methods of decontamination of meat, poultry, seafood, fresh produce, and eggs.

Improve Inspections and Compliance

With FY98 funds, the agencies will pursue several strategies to increase inspections for higher-risk foods; the agencies will, among other things:

Implement seafood HACCP. FDA will add seafood inspectors to implement new seafood HACCP regulations, and will work with the Commerce Department to integrate Commerce's voluntary seafood-inspection program with FDA's program.

Propose preventive measures for fresh fruit and vegetable juices. Based on the best science available, FDA will propose appropriate regulatory and non-regulatory options, including HACCP, for the manufacture of fruit and vegetable juice products.

Propose preventive measures for egg products. Based on the best science available, FSIS will propose appropriate regulatory and non-regulatory options, including HACCP, for egg products.

Identify preventive measures to address public-health problems associated with produce such as those recently associated with hepatitis A virus in frozen strawberries and E. coli O157:H7 on lettuce. These measures will be identified through a comprehensive review of current production and food-safety programs including inspection, sampling, and analytical methods.

Improve coverage of imported foods. FDA will develop additional mutual recognition agreements (MRAs) with trading partners, initiate a federal-state communication system covering imported foods, and FDA and FSIS will provide technical assistance to countries whose products are implicated in a foodborne illness.

Further Food-Safety Education

Foodborne illness remains prevalent throughout the United States, in part because food preparers and handlers at each point of the food chain are not fully informed of risks and related safe-handling practices. Understanding and practicing proper food-safety techniques, such as thoroughly washing hands and cooking foods to proper temperatures, could significantly reduce foodborne illness. The Administration--working in partnership with the private sector--will use FY98 funds to, among other things:

Establish a Public-Private Partnership for Food-Safety Education. FDA, USDA, CDC, and the Department of Education will work with the food industry, consumer groups and the states to launch a food-safety public awareness and education campaign. The Partnership will develop, disseminate, and evaluate a single food-safety slogan and several standard messages. Industry has pledged \$500,000 to date to support the partnership's activities and plans to raise additional funds.

Educate professionals and high-risk groups. Agencies will better educate physicians to diagnose and treat foodborne illness; strengthen efforts to educate producers, veterinarians, and state and local regulators about proper animal drug use and HACCP principles; and work with the Partnership to better train retail- and food-service workers in safe handling practices and to inform high-risk groups about how to avoid foodborne illness, e.g., in people with liver disease, illness that may be caused by consuming raw oysters containing *Vibrio vulnificus*.

Enhance federal-state inspection partnerships. New federal-state partnerships focused on coordinating inspection coverage (particularly between FDA and the states) will be undertaken, in an important step towards ensuring the effectiveness of HACCP and ensuring that the highest-risk food plants are inspected at least once per year.

Continue the Long-Range Planning Process

Through this initiative, and through previous activities, HHS, USDA, and EPA have laid the groundwork for a strategic planning effort. There is a broad recognition of the need to carefully implement the initiative's programs, and to consider how to apply preventive

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measures in other areas of concern. A strategic-planning effort is needed to build on this common ground, and to tackle some of the difficult public-health, resource, and management questions facing federal food-safety agencies. The federal food-safety agencies are committed to continuing to meet with stakeholders, ultimately to produce a strategic plan for improving the food-safety system.

September 22, 1998 DRAFT #6E (without DHHS comments)



August 25, 1998

Placeholder until official version is available

EXECUTIVE ORDER

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.

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

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

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

WILLIAM J. CLINTON

THE WHITE HOUSE,
August 25, 1998.

APPENDIX D

Federal Food Safety Agencies

Twelve Federal agencies have food safety responsibilities:

Agricultural Marketing Service, (AMS), U.S. Department of Agriculture (USDA)
Animal and Plant Health Inspection Service, (APHIS), USDA
Agricultural Research Service (ARS), USDA
Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS)
Cooperative State Research, Education, and Extension Service (CSREES), USDA
Economic Research Service, (ERS), USDA
Environmental Protection Agency, (EPA)
Food and Drug Administration, (FDA), DHHS
Food Safety and Inspection Service, (FSIS), USDA
Grain Inspection, Packers and Stockyards Administration, (GIPSA), USDA
National Institutes of Health, (NIH), DHHS
National Marine Fisheries Service (NMFS), Department of Commerce

APPENDIX E

Glossary of Acronyms

AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
CDC	Centers for Disease Control and Prevention
CRADA	Cooperative Research and Development Agreement
CSREES	Cooperative State Research, Education, and Extension Service
DHHS	Department of Health and Human Services
EPA	Environmental Protection Agency
ERS	Economic Research Service
FDA	Food and Drug Administration
FSI	National Food Safety Initiative
FSIS	Food Safety and Inspection Service
GAPs	Good Agricultural Practices
GIPSA	Grain Inspection, Packers and Stockyards Administration
GMPs	Good Manufacturing Practices
HACCP	Hazard Analysis Critical Control Point
JIFSAN	Joint Institute for Food Safety and Applied Nutrition
NIFSR	National Institute for Food Safety Research
NIH	National Institutes of Health
NMFS	National Marine Fisheries Service
NPR	National Performance Review
NSTC/OSTP	National Science and Technology Council/Office of Science and Technology
USDA	U.S. Department of Agriculture

CDC system allows officials to track dangerous bacteria

By Fred Bayles
USA TODAY

BOSTON — The disease detectives at Massachusetts' Department of Health wouldn't have seen a pattern among the scattered cases they were investigating earlier this summer if they had been using their old methods.

They wouldn't have known that five Keene, N.H., residents and a few people in Maine and Connecticut were hit by the same intestinal malady that had cropped up in Massachusetts.

Instead, in less than a week, the disparate cases were linked to a batch of hamburger meat contaminated with a potent strain of E. coli bacteria. The tainted meat was quickly removed from stores throughout the Northeast.

"Normally we would have had no clue that all these cases had a common source," says Bela Mayas, Massachusetts' head epidemiologist. "We would have spent weeks trying to figure out why our folks were getting sick."

The difference was PulseNet, a system developed by the Centers for Disease Control and Prevention.

It allows Massachusetts and a growing number of states to compare quickly the genetic fingerprints of the bacteria responsible for the rising number of food-borne illnesses. Just as police find suspects by using all-points bulletins, mug shots and fingerprints, state health officials can now track bacterial quarry by issuing a nationwide alert via computer.

"It's like a criminal investigation, only the bacteria are the crooks," says Sue Hunter, a CDC microbiologist who is compiling a computerized rogues' gallery for investigators to match bacteria against. "It offers the power to share information across states instantaneously," says Michael Osterholm, Minnesota's state epidemiologist and a member of a U.S. Department of Agriculture advisory committee on food safety. "It's like moving from the telegraph to the telephone."

Northwest outbreak

PulseNet's origins go back to 1993, when 500 people were stricken and four children died in the Northwest after eating hamburgers contaminated by the same strain of E. coli bacteria that showed up in Massachusetts this year.

CDC scientists were able to identify it as E. coli O157:H7 by using a DNA fingerprinting method called pulsed-field gel electrophoresis, or PFGE.

The process starts with a bacterial culture. The bacteria's DNA is chemically stripped away in a gelatin-like substance that is placed in a machine that resembles a record turntable.

An electric current taps the gel, separating bands of DNA by molecular weight. The result is a pattern resembling a supermarket bar code. Because bacteria that cause an outbreak share a specific DNA pattern, samples from patients and suspected foods can be compared. "It is one of the best ways to identify a contaminated food source," and prevent other people from eating it, says Bela Swaminathan, head of the CDC's food-borne disease laboratories.

Traditionally, epidemiologists interview victims to see what they ate and where they ate it. Their answers are then compared to find a common source. Often, there's no easy — or quick — conclusion. Narrowing the search takes valuable time.

"PulseNet technology helps trigger the realization of relationships that would take a while to figure out. It allows you to ask how does this cluster in Georgia relate to a small outbreak in Idaho," says Laurence Slutsker, a CDC epidemiologist.

PFGE was used in last summer's recall of tons of hamburger after the meat, produced by Hudson Foods, caused widespread sickness. Soon the CDC lab in Atlanta was being inundated with state requests to match scores of samples taken from stricken residents.

After that experience, which took quite a bit of time to sort out, Swaminathan and his staff decided critical time could be saved if states could do their own PFGE work.

Then compare samples through a nationwide database. That's happening now.

"As other labs come on line, the work moves much faster — from three or four days to 24 hours or less," says Tim Barrett, a CDC microbiologist who runs the program. "That's critical in cases where tainted food is still out there."

Presently, 14 states and the cities of Los Angeles, New York and Washington are part of the system. Another 13 states are expected to be on line next year.

Eventually all states will be able to send PFGE patterns directly to a CDC computer that matches DNA fingerprints against a growing database of culprits. If a match is made, the computer sends e-mail warnings to states with cases that share a pattern.

"When there's a widespread outbreak, the system gives us a chance to coordinate with other states," says Steve Dietrich, a Michigan biologist who was in Atlanta recently to train on the system.

Record of success

While the interlinking system is still being built, the fingerprinting technique already has had a number of successes:

► In 1995, outbreaks in Illinois and Connecticut seemed unrelated. Some victims were stricken after eating at a restaurant; others ate at home. PFGE tests found the common source, mesclun lettuce grown on a California farm.

► An E. coli outbreak in Michigan last summer was traced to alfalfa sprouts believed to be contaminated at a local health food firm. Then an outbreak in Virginia produced the same DNA pattern. The source was tracked to a Kentucky seed company where 6,000 pounds of contaminated seeds were discovered.

► This summer, CDC epidemiologists struggled to determine the cause of an outbreak around Alpine, Wyo. When matching PFGE patterns came in from 17 other states, scientists traced the source to the town's water supply, which had been used by residents and by tourists.

PulseNet has been introduced at a time when reports of food-borne illnesses are on the increase. Experts estimate there are now as many as 81 million illnesses and 9,000 deaths a year.

Earlier this summer, the Institute of Medicine and the National Research Council called for better coordination within the maze of agencies charged with preventing contamination and tracking down outbreaks.

The institute released a report that the system was being taxed by virulent new bacterial forms, and by an increasingly global food distribution system that sends processed products and raw produce around the country and around the world.

"That's why PulseNet is so important," says Osterholm, who took part in the study. "It used to be a case where you'd have a dozen people get ill by eating grandma's potato salad. Now the source can be a mass produced product that can show up in seven different states."

USA TODAY WEDNESDAY, SEPTEMBER 16, 1998

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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(OVER)

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

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

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WILLIAM J. CLINTON

THE WHITE HOUSE,
August 25, 1998.

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ACTIVITIES OF THE COUNCIL (with reference to executive order)

- A. Comprehensive strategic plan. This plan is referenced in two sections of the executive order.
1. Section 2 states: "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."
 2. Section 3(a) states in pertinent part: "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."
- B. Budget Activities. The Council will help coordinate the budget for food safety activities in two respects: (1) coordinated food safety budgets; and (2) a unified budget for the President's Food Safety Initiative.
1. Section 3(b) states in pertinent part: "[T]he 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."
 2. The Council is also tasked with developing a unified budget for the President's Food Safety Initiative, which is a subset of all the food safety activities that are performed by the agencies.

THE WHITE HOUSE

WASHINGTON

August 25, 1998

MEMORANDUM FOR THE PRESIDENT'S COUNCIL ON FOOD SAFETY

SUBJECT: National Academy of Sciences Report

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

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

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

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

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

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

William J. Clinton

THE WHITE HOUSE

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

For Immediate Release

August 25, 1998

EXECUTIVE ORDER

PRESIDENT'S COUNCIL ON FOOD SAFETY

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(OVER)

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WILLIAM J. CLINTON

THE WHITE HOUSE,
August 25, 1998.

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THE WHITE HOUSE

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

For Immediate Release

August 25, 1998

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MEMORANDUM FOR THE PRESIDENT'S COUNCIL ON FOOD SAFETY

SUBJECT: National Academy of Sciences Report

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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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THE WHITE HOUSE
WASHINGTON

May 11, 1998

*Bruce
FYI
These are the final
letters that were
sent to the
Hill on the
GAO food
safety report
May*

Dear Mr. Speaker:

The report to be released today by the General Accounting Office (GAO) calls on Congress to give the Food and Drug Administration (FDA) the authority to ensure that food eligible for import to the United States is produced under food safety systems that will provide the same level of protection as the safety systems in place in the United States. This report is further confirmation of the need for Congress to pass the Safety of Imported Food Act, which I called for in October 1997, which Senators Mikulski and Kennedy, and Representatives Eshoo and Pallone have introduced.

This important legislation will do what the GAO says is necessary: it will ensure that the FDA denies the entry of imports of fruits, vegetables, or other food from a foreign country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required in the United States. It will give FDA the authority it urgently needs, comparable to the Department of Agriculture's existing authority to prevent the importation of unsafe meat and poultry, to protect the safety of the food Americans eat.

I have taken several further steps to begin implementing standards to ensure the safety of imported food. My FY '99 budget committed approximately \$25 million to enabling the FDA to dramatically expand its international food inspection force in order to implement the pending legislation. In March of this year, I released a report on how the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture, and in cooperation with the agricultural community, will develop guidance on good agricultural and manufacturing practices that will apply to both domestic and foreign producers.

There is no more important task our government faces than ensuring the safety of the American food supply. That is why last year Vice President Gore and I announced my comprehensive new initiative, "Food Safety from Farm to Table" -- which detailed a comprehensive program including surveillance, outbreak response,

The Honorable Newt Gingrich
Page Two

education and research. The Safety of Imported Food Act is another vital step in protecting the safety of all the food Americans eat, and I urge you to pass it promptly.

Sincerely,

Ben Clinton

The Honorable Newt Gingrich
Speaker of the
House of Representatives
Washington, D.C. 20515

THE WHITE HOUSE

WASHINGTON

May 11, 1998

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The Honorable Thomas A. Daschle
Page Two

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Sincerely,

Tom

The Honorable Thomas A. Daschle
Democratic Leader
United States Senate
Washington, D.C. 20510

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WASHINGTON

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The Honorable Trent Lott
Page Two

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Sincerely,

Bill Clinton

The Honorable Trent Lott
Majority Leader
United States Senate
Washington, D.C. 20510

THE WHITE HOUSE

WASHINGTON

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The Honorable Richard A. Gephardt
Page Two

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Sincerely,

Bin

The Honorable Richard A. Gephardt
Democratic Leader
House of Representatives
Washington, D.C. 20515

May 6, 1998

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: ELENA KAGAN
SALLY KATZEN

SUBJECT: USDA's Proposed Organic Rule

In 1990, Congress passed the Organic Food Production Act, which required the Department of Agriculture (USDA) to establish a government certification program and national standard defining the use of the term "organic" for use on food products. The legislation was strongly supported by the organic industry which sought to involve the federal government in creating a unified organic standard, rather than the myriad of private and state-endorsed definitions.

In December 1997, USDA published a proposed regulation to establish a national organic standard. It has been the USDA position that the standard is solely a marketing description. The Secretary has emphasized that the organic designation is not intended to convey information about the safety, nutritional value, or environmental benefits of organic products and practices. In some tension with this approach, the Administration has long promoted food safety and there is a serious question whether an organic label will be construed as an indication of the improved safety of the product.

Since the publication of the proposed rule, it has been the subject of extensive criticism. USDA has received almost 200,000 comments regarding the proposed rule, the most ever received for a USDA rulemaking. The rule has also been the subject of unfavorable editorials in many newspapers including the New York Times, the Washington Post, the Chicago Tribune, and the Los Angeles Times. Finally, 47 members of the House and 31 Senators have signed letters to Secretary Glickman expressing concern about the proposed rule. The primary complaint has been that the proposed rule does not explicitly prohibit the use of genetically modified organisms, irradiation, and biosolids (sludge) in food that could be labeled "organic." In the preamble to its proposal, USDA had requested comments on these products and practices because of their possible safety benefits and consistency with Administration policy.

Current Status

Secretary Glickman plans to issue a press release this Friday, (attached), indicating that USDA will repropose the rule and "make fundamental changes in the new proposed rule on organic standards." Specifically, the statement would indicate that biotechnology, irradiation, and biosolids "will not be included in our revised proposal, and food produced with these products and practices will not be allowed to bear the organic label." Articles last week in USA

TODAY and the Washington Post have indicated that USDA is preparing such a statement.

Representatives of OMB (Don Arbuckle), NEC (Sally Katzen), and DPC (Elena Kagan) have been concerned about USDA's approach to this issue. OMB has argued that consumers will likely view a product labeled as organic as safe, even though there is no evidence to demonstrate that organic food is any safer than non-organic food, or that genetically modified, irradiated, or food grown using sludge is unsafe. To the extent that consumers read an organic label as demonstrating safety, they may be misled. OMB points out that organic material might be even worse than non-organic food in terms of some microbiological hazards. Organic foods fertilized with manure have been and may in the future be linked to illnesses such as occurred in the Odwalla juice outbreak. By contrast, foods using the three disputed techniques (e.g., irradiation) may have actual safety benefits. OMB and NEC therefore have suggested that USDA consider modifying the organic label to include a provision stating something along the lines of "organic food may be no more or less safe than non-organic food" or that USDA continue its comment review process and not prematurely prohibit using the term organic for food using any of the three disputed techniques.

USDA felt strongly that the label should not be modified and that a statement announcing a reproposal needs to be made promptly. USDA states that the organic label is not intended to signify the overall safety of the food, only the methods by which the food was produced, and that it will not advertise the label as having anything to do with safety. USDA notes that the disputed techniques are clearly not in keeping with the public's expectation of what constitutes organic. The Food and Drug Administration has expressed general support for USDA's position.

Recommendation

We recognize the need for USDA to clarify its position on organics, and recommend that Secretary Glickman issue a statement indicating that biotechnology, irradiation, and sludge will not be part of the revised proposal. We are still discussing with Secretary Glickman's office the precise language of this statement, but think we can work out this issue. In addition, after discussions with OMB, OSTP, FDA and USDA we have agreed upon two additional measures that could ameliorate some concerns over safety. These include (1) having USDA and FDA conduct a survey on consumer attitudes towards organic food to determine whether consumers purchase organic products on the basis of unproven safety claims, and (2) having USDA insert in the preamble of its new rule language indicating that the National Organic Standard Board should report regularly to the Secretary on possible uses of new technologies and whether they might meet an organic standard.



THE SECRETARY OF AGRICULTURE
WASHINGTON, D.C.
20250-0100

Ek/Tam -
Pls advise.

BR

MEMORANDUM TO BRUCE REED AND GENE SPERLING

From: Secretary Dan Glickman

Subject: National Organic Standards Regulation

Over the past few months, the Department of Agriculture (USDA) has received extensive criticism in the national media regarding USDA's proposed rule establishing a national organic food standard, several examples of which I am attaching for your review. There is also a widespread national grassroots campaign against the proposed rule which has generated over 130,000 comments to date, nearly all of which are negative. The public comment generated by this rule has exceeded any that USDA has received on any rule for decades. There has also been significant bipartisan congressional concern raised about this proposal.

With 44 different State and private standards in place, the organic industry wants to establish a uniform national standard to ensure consistency as well as to promote international trade in organic food products. In 1990, Congress passed the Organic Food Production Act (OFPA), which requires the Department of Agriculture (USDA) to establish a national standard defining the use of the term organic on food products.

USDA began the process of drafting rules and held extensive consultations regarding the content of the proposed national organic standard with the National Organic Standards Board, an advisory committee comprised of representatives of organic producers, processors, and consumers. On December 16, 1997, USDA published a proposed regulation to establish a national organic standard.

Much of the criticism is focused on the fact that the proposal does not explicitly prohibit the use of genetically modified organisms, irradiation, and biosolids (sludge) in organic production. While these three issues have received the bulk of the attention, a number of other substantive concerns with the proposal have been raised, such as the use of antibiotics in livestock. Another fundamental issue to be resolved is whether the final rule should be a highly detailed, prescriptive regulation, which the organic industry seems to support strongly, or whether it should merely provide flexible performance standards along the lines of the proposed rule, which the Office of Management and Budget has in general advocated.

In essence, the organic industry views the proposal as weakening or undermining existing standards in a way that threatens the meaning of the organic label, thereby endangering the viability of organic production and the profitability of their markets. Perhaps even more significant, however, is that the organic community also views the proposal as a breach of trust

by USDA and the Administration.

The comment period closes on April 30, 1998. In response to the requests of commenters, USDA intends to develop a new proposed rule for public comment. The process of evaluating the public comments and then redrafting and obtaining clearance of the entire regulation is likely to take several months.

I have publicly stated on many occasions that our organic standards will reflect changes based on public comment and that USDA's goal is to issue a final rule that organic growers and consumers will embrace. However, I am convinced that USDA needs to send a clear, specific message to the public and the organic community that we intend to make fundamental changes in the proposed rule, and I believe we need to send this message soon. To do otherwise risks further erosion of public confidence in the responsiveness and good faith of the Administration's efforts during the lengthy process of developing a new proposal.

I intend to issue the attached press release the week of May 4, 1998. My office has submitted the release for interagency clearance, and it is quite possible that there will be issues that may require the careful attention of the Administration.

I will call you soon to discuss this issue, and I will keep you posted on our progress.

cc: Jack Lew
Sylvia Matthews
Larry Stein

Attachments

DRAFT -- NOT FOR DISTRIBUTION -- DOES NOT REPRESENT USDA POLICY

USDA To Make Fundamental Changes in New Proposed Rule On Organic Standards

Washington, May X, 1998 -- Secretary of Agriculture Dan Glickman announced today that the Department of Agriculture (USDA) will make fundamental revisions to its proposed national organic standards as a result of the [170,000] comments USDA received on the initial proposal.

"USDA is committed to developing national organic standards that organic farmers and consumers will embrace," Glickman said. "Thousands of commenters requested that USDA issue new proposed standards, and we intend to do so. Most importantly, the new proposal will contain fundamental changes from our initial draft."

The earlier draft, published on December 16, 1997, proposed standards for growing, processing, labeling, importing, and certifying organically grown food. But it did not take a position on certain controversial issues; instead, the proposal asked for public comment on these items. The bulk of the extraordinary number of comments opposed including the products of biotechnology, the use of irradiation in food processing, and the application of biosolids (municipal sludge) in organic food production.

"Biotechnology, irradiation, and biosolids are safe and have important roles to play in agriculture. However, they neither fit current organic practices nor meet current consumer expectations about organics, as the comments made clear," said Glickman. "Therefore, these three issues are being taken off the table and will not be included in our new proposal."

Similarly, many of the [170,000] comments asserted that national organic standards must be rigorous and credible. Otherwise, consumers will lose faith in the organic label.

"If organic farmers and consumers reject our national standards, we have failed. Our task is to stimulate the growth of organic agriculture, ensure that consumers have confidence in the products that bear the organic label, and develop export markets for this growing industry," said Glickman.

Before publishing the new proposal, USDA will evaluate the comments submitted in response to the December 1997, proposal. This record will guide the drafting of the new proposal, which USDA will issue later this year and which will also be available for public comment. "This additional opportunity for public comment will assist us in crafting a rigorous, credible national standards for organic farming and handling that organic farmers and consumers can support," declared Glickman.

(121)

Organic Politics

WHAT IS IT with celebrities and food safety issues? First it was Meryl Streep testifying before Congress on Alar, stoking an apple-safety panic and the wave of weird "veggie libel" laws that have caused such trouble for Oprah Winfrey. Now the Agriculture Department reports that the singers Willie Nelson, Neil Young and John Mellencamp are among 115,000 people who have written or faxed comments complaining about the proposed definition of "organic" food in recently issued regulations. The rule, Agriculture Secretary Dan Glickman told the Associated Press, has drawn "more comments ... than on any rule in the history of the Department of Agriculture in modern times."

Country music stars may have little useful to say about the fine points of what foods should be permitted to be labeled "organic," but their presence does serve as index for an issue that has achieved what marketers call "breakout." The organic labeling fight has drawn a startling amount of attention, with denunciations in many media of a rule that, in this draft at least, would have allowed foods to be labeled organic even if they were genetically engineered or irradiated. The label also could be

used for foods grown in "sludge," which, to be sure, sounds less organic than "fertilizer," though that's basically what it is.

The agriculture department is caught in its customary bind between regulating the labeling of food products and representing the interests of the agriculture industry, which includes many large growers and packagers that engage in these practices and want a piece of the "organic" market. Its initial solution, to define the word loosely enough so that the big companies could use it too despite differences between their method and the competing ones, fell flat with an audience of Americans who manifestly want to know *exactly* what they are eating.

The point here is not whether genetic engineering, irradiation or the use of "sludge" is good or bad for you, nor whether the boutique all-natural or free-range foods actually are enough superior to warrant their higher cost (the very cost the big companies keep low by the use of chemicals and other less "natural" methods). The issue at this stage is merely whether people are being told what they want to know about the food they buy and eat. So far, it looks as if they aren't.

W. Post Editor 4/28/98 A16

Revisiting the Rules on Organic Food (128)

In mid-December, the Department of Agriculture published its National Organic Program regulations, a set of proposed rules for production of organic food that would be the basis for a national organic certification program. The department also invited public comment until April 30. Reaction has been sharply critical, particularly from those most directly affected, like organic growers, organic processors and consumers who prefer organic food.

For decades, organic growers have endured virtual neglect by the Agriculture Department. That pattern remains unchanged. The new rules make it plain that the department listened harder to the voice of agribusiness, which has always derided organic agriculture, than it did to the people who have proved its incontestable worth.

If the rules enter law as they stand now, it will be a major setback for the organic community. Growers who try to distinguish their organic products from products grown under a less stringent,

but nationally certified standard will be prevented from using the word "organic" — a word whose meaning has been defined by their practices. Consumers will find that "organic" has come to mean something quite different from what they thought. The rules allow practices that no one calls organic, including irradiation, the use of sewage sludge as fertilizer and genetically engineered crops.

There is nothing wrong with a national organic certification program. But with these rules, there is plenty wrong. Over the last 50 years, the Agriculture Department, in tandem with agribusiness, has been nudging American farmers toward a set of agricultural practices that are as uniform as the plants in a field of soybeans. But a cardinal tenet of organic farming is that diversity is as essential to biological health as it is to cultural health. If the organic rules are passed as they stand, organic farming will certainly go on, but under a different name and with renewed bitterness.

NY Times Editorial 4/13/98 A30

Editorial

The New York Times
ON THE WEB

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December 16, 1997

Reading the Organic Rules

Yesterday the Department of Agriculture announced a proposed set of Federal standards for organic food production and processing. Organic food has become big business in the last few years, but the definition of what "organic" means has been erratic. Some states, like California, have strict certification procedures for organic farmers. Others have none. The new National Organic Program will now provide a single set of rules, following guidelines developed over seven years by the National Organic Standards Board in consultation with organic farmers and the public.

Consumers commonly assume that the word "organic" describes a product -- a spear of organic asparagus, for instance, or a peck of organic Winesap apples. But the word actually describes a system of agriculture, a set of practices that is roughly outlined by the U.S.D.A.'s new National Organic Program regulations. Organic agriculture excludes the use of synthetic fertilizers and pesticides. More important, it strives for low environmental impact and enlists the interdependence of natural biological systems -- using cover crops, for instance, to increase soil fertility. The supermarket is full of foods whose labels tell the consumer almost nothing about the way they were produced. A food labeled "organic" under the National Organic Program rules will assure consumers that it was produced under a stringent set of guidelines. The very purpose of the label is to inform consumers about agricultural practice.

But the organic standard is only as good as the regulations that define it. In the National Organic Program's proposed rule, there are some troubling signs of vacillation and, perhaps, of industry or political pressure. The Agriculture Department, calling for further public commentary, has put off a final decision on several practices that the National Organic Standards Board had rejected after extensive public consultation. These include irradiation, the use of sewage sludge as fertilizer and the use of genetically engineered crops. Whatever the value of these technologies and practices may be, none are part of accepted organic practice, and each offers a beachhead within the program for major non-organic agricultural corporations.

Even the potential acceptance of these practices within the National Organic Program threatens to vitiate what is otherwise a commendable proposal. That would be a shame, for the Agriculture Department's new recognition of organic practices is indeed historic.

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EDIC

The Packer

Page 8A

Feb 16, 1998

EDITORIALS

Bowing to pressure

More comment sought on organic rules

The U.S. Department of Agriculture's proposed rules for organic foods so far have drawn 6,000 public comments, many of them negative. In fact, the reaction has been so heavy that the agency has extended the comment period until the end of April. *Story, 3A*

The proposal, which will set national standards for organics and establish a regulatory framework, is in trouble. None of the organic organizations seems to like it. They are deeply troubled by the fact that the USDA, and specifically the Agricultural Marketing Service, wants to allow irradiation, genetically engineered plants and products, and municipal sewage sludge to be used in organic production.

Many in the organic community feel betrayed by this. They believe these processes and products are "foreign" to organic principles and will turn off consumers.

They may be right. While genetically engineered produce, and even irradiation, have become a part of the "conventional" food industry, the organic industry's whole reason for being has been based on low technology, environmental friendliness and an image of "purity" and simplicity. It doesn't take much imagination to understand consumers could be alienated if the "organic" produce has been grown with sewer residue, altered with "alien" genes and then zapped with radiation.

Some of these technologies will be a part of conventional agriculture. But the USDA ought to look closely at its organic proposals and modify them in light of strong opposition. Why approve final regulations that are unpopular with those being regulated?

Trade Press

OPINION

 startribune.com Opinion

Published Monday, April 27, 1998

Revise organic label proposals

The organic food movement has roots in both philosophy and science, and especially in the zone of belief where these agree. Philosophy holds that food produced without synthetic additives is preferable; science shows that many man-made fertilizers and pesticides pose risks to human health and the environment.

But philosophy and food science can also diverge, and in the fight over new national standards for what may be called organic, they sometimes do.

The debate goes beyond food quality. The organic market has tripled in size since 1990 and is now attracting the interest of large corporations; new rules will shape the future of competition in the industry. Producing an organic potato is no longer simple.

The national standards, being prepared by the U.S. Department of Agriculture, are intended to replace the current system in which organic foods are certified by any of 33 industry groups and 11 states (not including Minnesota), each using different definitions. The argument for a national approach is persuasive: Consumers are entitled to a uniform, reliable assurance of what they're getting when they buy "organic" food.

As a first step in preparing its rules, USDA took recommendations from a national panel of industry representatives, scientists and consumers. As a second step, it proposed major departures, prompting a storm of protest.

Some in the industry are calling for USDA to start over, even abandon the effort entirely. This would be a regrettable and wasteful outcome. The rules are not wholly wrongheaded, but they do need significant revision to ensure that in updating and broadening the standards for organic food, USDA does no harm to essential principles.

The foremost of those principles -- no synthetic additives -- is threatened by potential redefinition of permissible agricultural chemicals and residues, by a loosening of the rules for livestock feed and by a more tolerant approach to pesticide "drift" from nearby nonorganic farms. Similarly, USDA takes the wrong approach in proposing to change the safety standard on certain farming practices -- permitting them until shown to be harmful, rather than prohibiting them until shown to be safe.

Of the four major areas in which USDA has reserved judgment, two are especially troublesome. Fertilization with sewage sludge of unknown chemical content is plainly offensive to the notion of organically grown food; so is a liberalized rule for nonmedical use of drugs in livestock.

But in the other two areas -- genetic engineering and irradiation -- organic purists are relying more on philosophy than science, and their arguments are unconvincing. Irradiation has been shown to be a safe and effective, if "unnatural," tool for preserving food. And genetic manipulation of food is arguably an extension of such centuries-old techniques as selective propagation, hybridization and grafting.



Of course, some shoppers may prefer to avoid irradiated or genetically engineered food, and **USDA** should not interfere with that choice. Nothing in the new national standard should prevent food producers from adhering to still stricter principles, and labeling their products accordingly.

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Irradiated, sure, but organic

Melostar Tribune Commentary

Proposed rules
would have made
word meaningless

By Ellen Goodman 4/21/98
Boston Globe

(24) A13

BOSTON — This is not your everyday political event. How often does a grass-roots movement ask the government to regulate its own enterprise? When was the last time small operators rose up to bitterly complain that government rules and regulations weren't strict enough?

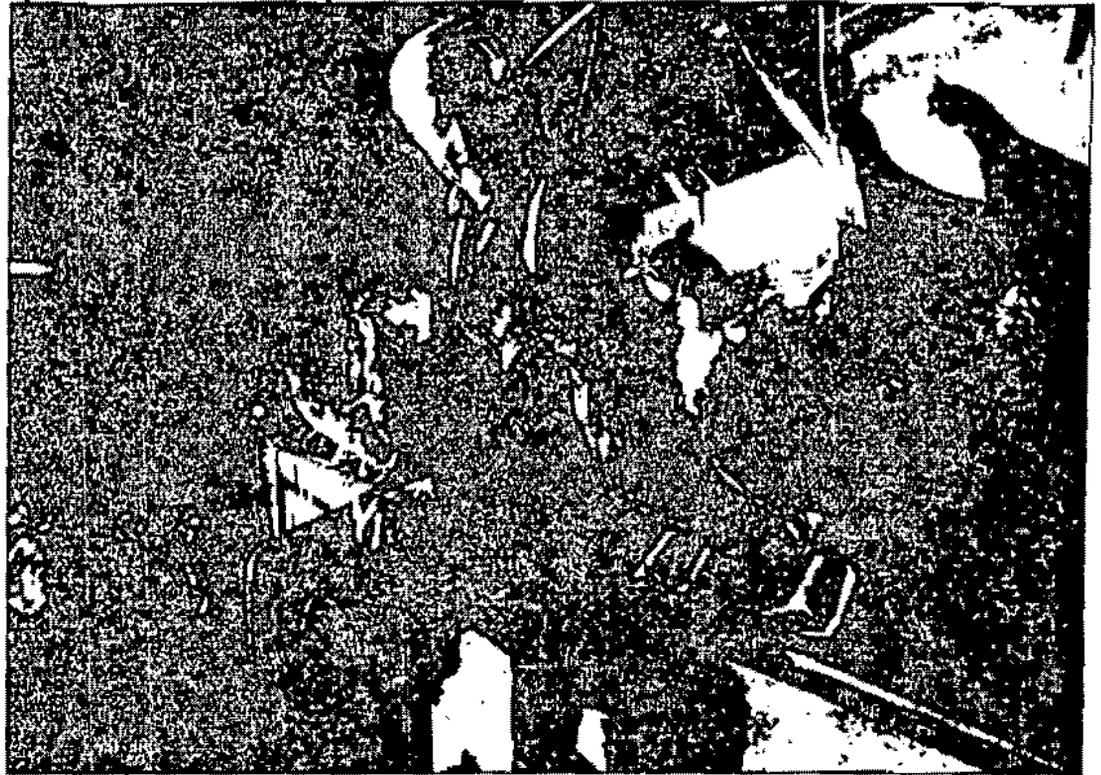
But this is the upside-down nature of a food fight that has erupted between the U.S. Department of Agriculture and the organic farming community.

Ever since December when the USDA released the first-ever proposals for minimum standards for organic foods, a full-scale debate has been raging about the meaning of the "O" word. Now, an astonishing 101,000 farmers and chefs, and consumers and environmentalists have developed an appetite for protest. In the face of an April 30 deadline for comments, they have registered deep disapproval of the agency's taste.

This story of "O" began, in the best biblical tradition, with an apple. In the alar scare of 1989-90, people became alarmed about chemicals. Suddenly, a bumper crop of apples appeared on the market bearing the label "organic."

Organic farming, which once exuded the aura of a hippie enterprise with lethargic and overpriced vegetables, was just becoming a full-fledged alternative. The apples of dubious "organic" origin convinced many in the disparate community that they needed a national standard to prevent fraud, and maintain consumer confidence.

These farmers were always wary of involving the USDA, an agency which, to put it gently, has been a bastion of conven-



New York Times

Organic farmer George Bass, of Hubbardston, Mass., in the barn with his Rhode Island Red chickens.

tional farming and a buddy of agribusiness. But with the help of Vermont's Sen. Patrick Leahy, the Organic Foods Production Act was passed in 1990 to determine minimum standards. Farmers, consumers, scientists and environmentalists spent four years working out an agreement on the definition of organic.

Then the USDA stepped in, to fulfill their worst fears. In the tradition of the "fox guarding the henhouse," the agency proposed to lower these standards.

The USDA rules would, for example, allow lettuce fertilized with sewage sludge, genetically engineered pigs and irradiated radicchio to carry the label "organic." They would allow a chicken that had never seen the light of day, let alone a free range, to carry an "organic" tag.

These giant loopholes in the "O" are big enough to drive a truck through. "We'd have Tyson's Organic Chickens before you could blink an eye," says Margaret Mellon of the Union of Concerned Scientists. "It

would doom the word organic."

If the Department of Agriculture is surprised by the huge outrage, that in itself is not surprising. The department's bias toward conventional farming is long and deep. Organic farming is now a \$4 billion business growing by 20 percent a year. But its success is taken as a rebuke to the factory-farming, supermarket-to-the-world agribusiness that is now the rule.

It is widely believed that the folks marketing sludge, promoting genetic engineering or irradiation got the USDA's ear because they want to piggyback onto the good name of "organic" to mute controversies here and abroad.

We can debate the safety of genetic engineering till the cloned cows come home, but it fits no image of organic farming. This food fight is not just about safety of the product. It's about the process of farming.

As Kathleen Merrigan of the National Organic Standards Board puts it, "We want a label

that connects people to how their food is produced. We want to give people a way to be sure their food was produced by people who are walking lightly on the earth."

Americans have a nostalgic and primal relationship to the farm. But now agriculture, like so many other parts of the economy, is going in two directions.

The larger trend is to consolidate farmland as if it were a megabank. It's to industrialize farming, and mass produce identical products on a land factory. The sturdy but smaller trend is toward diversity, toward sustaining the land.

Today organic farms are not just food boutiques, trendy little supply centers for people who are willing to pay more for mesclun greens. They are the labs, the models, the alternatives.

The USDA has done little to promote organic farms. But if these proposals are put into law, organic will have lost any meaning. The "O" in the O-word will stand for Zero.

State of New York
Legislative Resolution

Assembly No 1838



BY: M. of A. Gromack, Farmer, Pfeiffer, Christensen, Hochberg and Prentiss

CALLING upon the Secretary of the United States Department of Agriculture to rework the proposed rules for the National Organic Program to meet the needs and interests of New York State consumers, organic farmers and food businesses

WHEREAS, This Assembled Body calls upon the Secretary of the United States Department of Agriculture (USDA) to rework the proposed rules for the National Organic Program to meet the needs and interests of New York State consumers, organic farmers and food businesses; and

WHEREAS, Consumers choose organic foods because of their heightened concerns about food, the environment and health; the current proposed federal organic food rules would allow soil application of sewage sludge, irradiation, genetically modified organisms, and other products and processes that are unacceptable to the majority of both consumers and producers of organic food in the State of New York; and

WHEREAS, The USDA proposal would also impose significant fees on New York organic certifying organizations and small growers that could seriously damage this expanding segment of the New York agriculture and food industry; the standards put forth in the USDA rules would not meet most international requirements and therefore limit export opportunities for organic food businesses; and

WHEREAS, The standards originally developed by the USDA National Organic Standards Board, which was formed as part of the 1990 Organic Foods Production Act, are largely acceptable to the organic community and the Secretary of the United States Department of Agriculture should consider using them for the final rules; and

WHEREAS, If the federal standards are not changed to meet the New York organic community's recommendations, this Assembled Body requests that the final federal rules allow for the establishment of a state organic program that will be acceptable; and

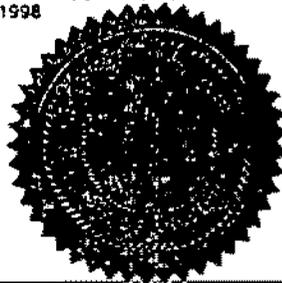
WHEREAS, Organic food sales are the fastest growing segment of the food industry and there is a need for standardization to allow consumers to make informed choices; however, organic food consumers, experienced growers and organizations representing consumers and growers should have the most significant input into federal guidelines that will determine the meaning of organic for years to come; now, therefore, be it

RESOLVED, That this Legislative Body pause in its deliberations to urge the Secretary of the United States Department of Agriculture to rework the proposed rules for the National Organic Program to meet the needs and interests of New York State consumers, organic farmers and food businesses; and be it further

RESOLVED, That a copy of this Resolution, suitably engrossed, be transmitted to the Secretary of the United States Department of Agriculture

ADOPTED IN ASSEMBLY ON
April 1, 1998

By order of the Assembly,



Francine M. Misasi
Francine M. Misasi, Clerk

Business GO Site Index GO

Los Angeles Times BUSINESS & TECHNOLOGY HELP


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Friday, April 17, 1998

HEARD ON THE BEAT / FARMING AND FOOD

A Growing Controversy

• Organic Food Folks Fight Federal Plan

By **MARTHA GROVES**, Times Staff Writer

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The verdict is in, and the state's farmers and environmentalists have found the U.S. Department of Agriculture guilty. Guilty, that is, of proposing regulations for the nation's organic food business that ignore the industry's practices, philosophy and desires.

At a rally Thursday in Sacramento, leaders of the state's organic farming and food community railed against the proposed rules, demanding that the USDA go back to the drawing board. Otherwise, they said, the federal government risks undermining California's 8-year-old organic farming law, one of the nation's strongest.

"We don't want them to amend this proposal," said Joan Clayburgh, a spokeswoman for Californians for Pesticide Reform, a San Francisco organization that espouses organic farming methods. "We want them to throw it out."

Organic activists in California aren't alone in their opposition. The USDA has been swamped with more than 100,000 letters, postcards and e-mails, most of them highly critical of the rules. The agency appears to be getting the message. For several weeks, U.S. Agriculture Secretary Dan Glickman has been reassuring grower groups that changes will be made.

The USDA published its proposal in December after seven years of haggling and information-gathering. The outpouring of opinion prompted the agency to extend the public-comment period for the rules to April 30.

About 70,000 of the responses are form letters, including 16,000 from readers of Organic Gardening magazine and 34,000 from customers of Working Assets, a San Francisco company that sells long-distance phone service and gives part of its revenue to socially responsible groups.

The agency has also heard from leading organic food companies, including Pavich Family Farms, growers of organic grapes, raisins and nuts, based in Terra Bella; Horizon Organic

Dairy in Boulder, Colo.; and Cascadian Farm, a producer of frozen desserts, vegetables and other items, based in Sedro-Woolley, Wash.

And it has gotten an earful from the growing ranks of customers of natural food chains such as Wild Oats and Whole Foods Market (www.wholefoods.com), which have distributed pamphlets to mobilize grass-roots support.

In particular, food processors and retailers are critical of what they see as three key stumbling blocks: irradiation, biotechnology and the use of sewage sludge as fertilizer. As the proposal stands, those three processes would not be outlawed--contrary to the vociferously stated wishes of the industry. Activists have charged that the rules were designed to accommodate agribusiness concerns, which see the \$3.5-billion organic food industry as a hot growth area.

Industry leaders say the agency could save itself time and trouble by adopting the recommendations of the National Organic Standards Board, a panel established by law in 1990 to advise the USDA. In preparing its proposal, the agency largely ignored the board's suggestions.

In a letter to Glickman early this week, California Agriculture Secretary Ann M. Veneman said the state Department of Food and Agriculture would be submitting records from four public hearings held on the issue throughout the state in January, February and March. She urged the agency to "revise the rule to ensure a strong organic program."

Mail-Order Wine

California wine retailers are puzzling over the latest wrinkle in a long-running battle over direct-mail wine sales.

Earlier this month, the U.S. Supreme Court chose not to take up a legal battle between mail-order "wine clubs" and states over the regulation of alcoholic beverage sales. Without comment, the court let stand rulings that rejected Florida's effort to sue in federal court to stop what state officials call "illegal interstate bootlegging."

At least one Southern California wine retailer was hopeful that the action would make it legal to ship wine to Florida customers.

Not so. It simply means that the high court is leaving the matter up to the states. Florida still has a law making it a felony for wineries or retailers to ship wine directly to customers in the state.

"We'll continue to have to fight them," said Ron Louterback, proprietor of three Wine Club retail shops in California.

Florida had sued Wine Club (which is a retailer, not a wine club per se) and three other vendors over direct shipments, saying they failed to pay various state taxes and fees. A federal judge

221

Organic is as organic says

1-12
9/27/98
CH1 TR18

Now that organic farming has mushroomed from a hippy-dippy diversion into a giant industry with annual sales exceeding \$4 billion, conventional food processors also want a slice of the market. They should be welcome to it—but not at the cost of diluting proposed government guidelines defining the term "organic" and its legitimate use on foodstuffs.

Organic food regulations were first proposed by the industry itself in 1986. Four years later, Congress passed the Organic Foods Production Act, which in turn created the National Organic Standards Board (NOSB) and assigned to it the task of drawing up guidelines to govern the production, handling and marketing of organic foods.

It's an important mission: As the market has grown, so has the promiscuous use of "natural," "organic" and other New Age mumbo-jumbo and advertising gimmicks. Even the most discerning consumers are baffled, a situation complicated by conflicting standards and definitions established by different states and local organizations.

Meanwhile, the organic market is growing like kudzu. For the past seven years it has posted sales growth of 20 percent or greater, according to the Organic Trade Association. Clear, nationally recognized standards are essential for domestic consumers as well as the export market, particularly since the European Union adopted its own organic food guide-

lines in 1992.

In 1996, the NOSB proposed a set of definitions and standards. But late last year—under pressure from conventional food processors and agricultural interests—the U.S. Department of Agriculture proposed considerably looser regulations.

Consumers have until April 30 to comment on the revised guidelines; they should urge the USDA to stick with the previous, more stringent rules.

The disagreements generally revolve around the use of genetically engineered hormones and other organisms, food irradiation, municipal sewer sludge for fertilizer and synthetic antibiotics in farm animals. The NOSB banned them; the USDA proposes to allow them.

Consumer safety is not the main point here. There is, for example, no scientific evidence that irradiated food is harmful or unsafe. But is it "organic"?

What's at stake instead is the integrity of a set of regulations drawn up by experts and representatives of the organic food industry after lengthy discussion. It's most unusual, in fact, for an industry to impose such stringent standards upon itself.

If the term "organic" is to mean anything at the supermarket to the rapidly growing number of consumers, the USDA should abide by the recommendations of a board of experts that was, after all, created by the federal government.

THE WHITE HOUSE

WASHINGTON

March 3, 1998

FOOD SAFETY EVENT

DATE: March 4, 1998
LOCATION: Roosevelt Room
BRIEFING TIME: 1:30 pm - 1:20 pm
EVENT TIME: 1:45 pm - 2:45 pm
FROM: Bruce Reed

I. PURPOSE

To highlight the introduction of legislation in the Senate that you proposed to ensure the safety of imported fruits and vegetables, and to receive a progress report from USDA and HHS on the development of guidance on good agricultural and manufacturing practises.

II. BACKGROUND

You will be speaking to an audience of approximately 40 consumer advocates, food industry representatives, families, and Members of Congress.

You will be making the following announcements:

Challenge to Congress to Enhance FDA Oversight for Imported Foods. You will challenge Congress to pass the food safety legislation to be introduced by Senators Mikulski and Kennedy to require the FDA to halt imports of fruits, vegetables, and other food products from any foreign country with food safety systems and standards that are not equivalent to those of the United States. The legislation also will require the FDA to halt imports from countries or facilities that do not allow FDA inspections to occur. This legislation, which you proposed last fall, was previously introduced in the U.S. House of Representatives by Reps. Eshoo and Pallone. You have committed to providing approximately \$27 million in your Fiscal Year 1999 budget to enable the FDA to dramatically expand its international food inspection force.

Agency Report on Guidance on Good Agricultural and Manufacturing Practices. You will announce that you have received a report from Secretaries Shalala and Glickman on the progress they have made in providing guidance on Good Agricultural and Manufacturing Practices to domestic and international growers, harvesters, handlers, and transporters of fresh fruits and vegetables as requested in a Presidential Directive on Oct. 2, 1997. This report outlines the progress made -- and the steps still to be taken -- to develop the voluntary guidance by October 1998. The guidance -- the first-ever specific safety standards for fruits and vegetables -- will address potential food safety problems

throughout the production and distribution system and help ensure the sanitation and safety practices of all those seeking to sell produce in the U.S. market. The report also provides both short- and long-term plans for technical assistance, education, and outreach activities to support the implementation of the guidance.

III. PARTICIPANTS

Briefing Participants:

The Vice President
Secretary Shalala
Secretary Glickman
Bruce Reed or Elena Kagan

Event Participants:

The Vice President
Senator Barbara Mikulski
Gloria Doyle, Chevy Chase, MD, who became ill after eating imported raspberries.

Standing on stage, but not speaking:

Secretary Shalala
Secretary Glickman
Lead Deputy Commissioner, FDA Michael Friedman
Congresswoman Eshoo and other Members of Congress

IV. PRESS PLAN

Open Press.

V. SEQUENCE OF EVENTS

- The Vice President will make welcoming remarks and introduce Senator Mikulski.
- Senator Mikulski will make remarks and introduce Gloria Doyle.
- Gloria Doyle will make remarks and introduce YOU.
- YOU will make remarks and then depart.

VI. REMARKS

Remarks Provided by Speechwriting.

**Q&A for Presidential Announcement on Food Safety Legislation
and Report to Ensure Safety of Imported Fruits and Vegetables
March 4, 1998**

Q: What did the President announce today?

A: The President announced the introduction of food safety legislation in the Senate that will ensure that the FDA denies the entry of imports of fruits, vegetables, or other food from any foreign country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required. The legislation also permits FDA to consider refusal of inspection as a factor in halting imports from a facility or country. This legislation was introduced in the House in November of last year. The President also announced the release of a report on how the Secretary of Health and Human Services, in cooperation with the Secretary of Agriculture and the agricultural community, will develop guidance on good agricultural and good manufacturing practices for any fruits and vegetables that are sold in the U.S. market.

Q: Why is your Administration proposing these actions?

A: There have been dramatic changes in the produce department of the grocery store. Thirty years ago, most produce sections only had around a dozen items year round, increasing to as many as 50 in the summer. Today, the chances are that there are 400 or more items in the produce section and they are there all year round. Last year, 38 percent of the fruit and 12 percent of the vegetables Americans ate were imported.

We have changed as well. Americans are eating more fresh fruits and vegetables than ever before, and our nation's health experts tell us we will live longer, better quality lives as a result. Our environment is also changing. We are finding "new" exotic bugs such as cyclospora and *E. coli* O157:H7 on our food that once were not there.

We must ensure that these changes do not increase the risk to American consumers of foodborne illnesses. Although raw produce -- including that imported from foreign countries -- is now safe, experts have suggested ways to make further improvements, and my actions accord with their recommendations.

Q: Are you saying that imported produce is unsafe?

A: There is no data indicating that imported fruits and vegetables are more unsafe than domestic products. But some recent outbreaks of foodborne illness have been traced back to imports, and it is important to ensure that foreign fruits and vegetables meet U.S. food safety requirements or otherwise achieve the level of protection required. The steps we are taking today are adding additional layers of protection. We are making sure that there

are no gaps in our food safety system -- that high safety standards apply to imported as well as domestic food, and to fruits and vegetables as well as to meat, poultry, and seafood.

Q: What steps is the Administration taking to improve food safety?

A: Last year we launched a new Presidential food safety initiative, and added more than \$40 million to the FY '98 budget. With that money we started putting in place new science-based preventive systems to improve the safety of seafood, meat and poultry and began work on a new early warning system to help detect and respond to outbreaks of foodborne illness. This year, our budget seeks an even more substantial increase in resources, \$101 million, to improve food safety. The resources will go to a variety of initiatives, including: giving FDA authority to prevent the import of produce from countries without safety precautions equivalent to our own; hiring FDA inspectors to improve the safety of our nation's fruits and vegetables, both domestic and imported; developing new ways for federal inspectors to detect food-borne illnesses in meat and poultry and determine the source of contamination; improving educational outreach on proper food handling; and further expanding our early warning system and strengthening state surveillance activities for foodborne illnesses.

Questions on Food Safety Legislation

Q: What does the legislation do?

A: This legislation helps ensure that the FDA will refuse imports of any food regulated by the FDA, including fruits and vegetables, from any country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required. The legislation also permits FDA to consider refusal of inspection as a factor in halting imports from a facility or country.

Q: How is this different from current authority?

A: This legislation increases the FDA's authority to refuse imports for foods from countries or facilities that do not meet U.S. food safety requirements or otherwise achieve the level of protection required. Currently, the FDA can only refuse imports after inspection or testing at the border when the FDA determines that the food appears to be unsafe or otherwise violates U.S. law. This new legislation will enable the FDA to ensure that food products entering this country were grown and processed in conditions that meet U.S. food safety requirements or otherwise achieve the level of protection required. This authority is necessary because experience has shown that inspection and testing of products at the border may not be sufficient in all cases to ensure the safety of food products. It may be necessary to identify and address the source of potential

contamination to ensure that products offered for sale in the United States meet domestic food safety requirements or otherwise achieve the level of protection required. FDA currently has such authority with respect to domestic production.

Q: Does this legislation give FDA additional authority to inspect in other countries?

A: No. Foreign inspections will continue to be done by consent. In making the determination that a food offered for import into the U.S. is adulterated, the legislation does permit the Secretary to consider whether FDA has been refused access to conduct inspection of the places where such food has been prepared, packed or held. The Secretary may deny importation to foods from such location or establishment on the basis of such refusal and other relevant factors. Because denying reasonable access is one factor in making that determination, the exporting country and the food establishment both have a strong incentive to allow such access.

Q: There is concern that this legislation is the first step in providing FDA with the authority to inspect farms in the U.S. Is that next?

A: Under current law, FDA already has authority to inspect establishments where food is prepared, packed, or held, which would include places where food is grown, such as domestic farms. While such inspections are infrequent, FDA has taken action against a U.S. farmer when a violation occurs. When FDA is involved in a food safety problem that is found to originate on a farm, the agency's focus generally is on identifying the source of the problem and removing the unsafe food from commerce.

Q: Doesn't this legislation impose trade barriers to food imports at a time when you are saying you want to lower them? Is this legislation consistent with free trade?

A: This legislation is consistent with free trade and all our treaty obligations. We have no obligation to open our borders to imports that pose a greater risk than domestic products to American consumers. As long as we are not imposing any greater requirements on foreign countries -- as long as we are only holding them to our standards -- we are acting consistently with our trade policy and international obligations.

Q: What makes you think this new legislation can be effective? Do you seriously think you are going to be able to put FDA inspectors in every country abroad?

A: The new legislation would give the FDA the same kind of responsibility that the USDA already has for meat and poultry. The USDA system has worked well to ensure that unsafe meat and poultry, produced in foreign facilities which do not provide the same level of protection that is required in domestic facilities, will not be imported. The FDA should be able to run a similarly effective system that ensures food safety and prevents

imports from any foreign country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required.

Questions Related to Report on Guidance

Q: Why has this report been prepared?

A: On October 2, 1997, President Clinton announced an initiative to ensure the safety of imported and domestic fruits and vegetables which included the development of good agricultural practices and good manufacturing practices for fresh fruits and vegetables that would include ways to prevent potential contamination. This voluntary guidance will address potential food safety problems throughout the production and distribution system and help ensure the sanitation and safety practices of all those seeking to sell produce in the U.S. market. The guidance effort will include outreach and education, reflecting the Administration's commitment to direct resources toward improving food safety and the availability of food safety technologies.

The President requested this status report about progress made toward providing industry with good agricultural and good manufacturing practices guidance for fresh fruits and vegetables. It also presents a plan for outreach to the domestic and foreign industry.

Q: When you say good agricultural practices (GAPs) and good manufacturing practices (GMPs), are you talking about mandatory GAPs and GMPs?

A: No, the GAP/GMP guidance is voluntary. We are developing this science-based guidance with input from USDA, states, the agricultural community, industry, academia, consumers, and organizations representing the foreign produce industry. The guidance is intended for appropriate use by growers, packers, manufacturers of minimally processed products and produce distributors. Because the guidance is broad-based, it may be used, where applicable, by both the domestic and foreign produce industry to reduce the risk of microbial contamination.

Q: Does the report give a timeline for publishing the guidance?

A: Yes, we anticipate publishing the draft guidance in late March with a 75-day comment period. We anticipate that the guidance will be available in final form in October 1998.

This may come up because the deadline for the importation of Guatemalan raspberries is March 15.

Q: What is the status of the Guatemalan raspberries?

A: On November 20, 1997, FDA notified the Guatemalans that fresh raspberries will not be allowed entry into the U.S. during the period of March 15 through August 15, 1998. However, if the source of *Cyclaspora* contamination is found and corrected or if intervention technologies are developed that will prevent cyclosporiasis in humans, we will revisit this decision. FDA has assisted Guatemala in seeking a resolution to this problem since 1996. In fact, we currently have people in Guatemala reviewing the interventions they have reportedly put in place.

**PRESIDENT CLINTON:
SAFE FOOD, HEALTHY FAMILIES**

March 4, 1998

"Food safety is part of the basic contract between American consumers and their government. Any food that doesn't meet our clear and strict standards shouldn't make it into the United States. It's that simple."

President Bill Clinton
March 4, 1998

Today, President Clinton calls for legislation ensuring the safety of all imported foods, including fruits and vegetables. This legislation will enhance the Food and Drug Administration's authority to prevent the import of fruits, vegetables, and other food products that do not meet U.S. food safety requirements. The President also announces the release of a report that provides a blueprint on how the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) will work cooperatively with the agricultural community to develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

ENHANCING FDA OVERSIGHT FOR IMPORTED FOODS. President Clinton is calling on Congress to pass food safety legislation that gives the FDA greater authority over imported foods. This legislation will ensure that the FDA bans imports of fruits, vegetables, and other food products from any foreign country with food safety systems that do not provide the same level of protection required for U.S. products. The legislation also permits the FDA to consider refusal of inspection as a factor in halting imports from a country or facility. The President already has committed approximately \$25 million in his Fiscal Year 1999 budget to enable the FDA to dramatically expand its international food inspection force in order to implement this legislation.

IMPROVING AGRICULTURAL AND MANUFACTURING PRACTICES. The President is announcing the release of a report outlining the progress already made -- and the measures that must still be taken -- to develop guidance for the growing, processing, shipping, and marketing of fruits and vegetables by October 1998. The guidance -- the first-ever specific safety standards for fruits and vegetables -- will address potential food safety problems throughout the production and distribution system and help ensure the sanitation and safety practices of all those seeking to sell produce in the U.S. market.

BUILDING ON A STRONG RECORD OF ACCOMPLISHMENT. 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. Major accomplishments include:

- Announcement of the FY'99 proposed food safety budget, including an approximate \$101 million increase for food safety initiatives.
- A 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.
- Safe Drinking Water Act of 1996, requiring drinking water systems to protect against dangerous contaminants like cryptosporidium, and giving people the right to know about contaminants in their water.
- Announcement of 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.



THE SECRETARY OF AGRICULTURE
WASHINGTON, D.C.
20250-0100

*Food
Labeling
Food Safety*

MEMORANDUM TO THE CHIEF OF STAFF

OCT 23 1997

FROM: SECRETARY DAN GLICKMAN

Subject: Country of Origin Labeling

Senator Bob Graham recently wrote you a letter regarding S. 1042, which would require country of origin labeling of imported perishable agricultural commodities. You may be aware that Congressman Sonny Bono has introduced identical legislation in the House (H.R. 1232).

The bill would apply only to fresh fruits and vegetables that are imported and sold as fresh. Fresh produce that is imported and then processed into canned goods, for example, would not be covered. While flexible in how its labeling requirements are met, the bill does require that domestic retailers inform consumers at the final point of sale of the country of origin of perishable agriculture products and subjects them to fines for failing to do so.

I want to make several points. First, country of origin labeling is not a food safety issue. Food safety experts throughout the Administration believe that country of origin labeling would not improve our ability to detect and control outbreaks of foodborne illness. It is possible that a sophisticated system of bar coding would help from a food safety perspective, but mere country of origin labeling would not.

If the Administration were to support country of origin labeling, it should not do so on the basis of food safety. One potential justification could be that consumers have the right to know a product's country of origin. However, some groups have expressed skepticism that consumers do in fact believe that country of origin is important information. Other groups have raised concerns that such labeling will be used to stigmatize imported food products through negative advertising campaigns. Finally, a consumer right to know argument could have implications for other labeling disputes, such as our current disagreement with the European Union over the labeling of products of biotechnology.

Second, at the request of Senator Daschle, the Administration has recently agreed to develop guidelines to assist the domestic meat and poultry industry in voluntarily labeling their products as being of U.S. origin. We would prefer that a similar voluntary approach be developed for perishable agricultural commodities. If the Administration were to support Senator Graham's legislation, it would be difficult not to support similar mandatory labeling requirements for imported meat and poultry products.

Third, industry and the retail sector are strongly opposed to country of origin legislation because of the costs it would impose. While many agricultural producers support such legislation, others do not, in part because of concern that country of origin labeling would be used unfairly against U.S. exports. As you know, the U.S. exports nearly 60 percent more agricultural products than it imports.

Fourth, the Administration has generally objected to country of origin labeling when it has been considered by our trading partners. If the Administration were to support country of origin labeling, it could be seen as protectionist by our trading partners and would obviously limit our ability to object to such requirements in the future.

Fifth, it is possible to require country of origin labeling of imported products under our GATT and WTO obligations, provided that all imports are treated similarly, the difficulties are reduced to a minimum, and the labeling does not seriously damage the product or unduly increase its costs or decrease its value.

In general, Senator Graham's legislation appears to be consistent with U.S. rights under Article 9 of the WTO agreement. However, it is possible that an exporting country could challenge these labeling requirements as unduly increasing the costs of their product, for example, because the labeling requirements imposed on domestic retailers will (1) either be passed on to the exporting countries, making their product less competitive, or (2) make domestic retailers less likely to market imported products.

Sixth, the Department of Agriculture would be required to enforce Senator Graham's legislation, as well as any similar legislation on meat and poultry, without any additional personnel or funding. At a time of limited budgets, we question whether this would be the most effective use of our resources, particularly given the need to more effectively address food safety.

I appreciate the concerns that have given rise to this legislation, but I am concerned about its potential adverse effects in terms of costs on domestic industry, possible export problems, and resource implications with respect to food safety. I have directed USDA officials to develop alternative legislation that would minimize these potential problems should the Administration decide to support country of origin labeling. I expect this draft legislation to be ready for interagency clearance by the end of next week.

Please let me know your thoughts. I would like to discuss this issue with you further.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
and
U.S. DEPARTMENT OF AGRICULTURE
Washington, D.C.



FEB 24 1998

The Honorable William Jefferson Clinton
The White House
Washington, DC 20500

Dear Mr. President:

Attached is our report, as requested in your October 2, 1997 Directive, on progress made on the Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables. The report is a synopsis of the progress we have made in providing Good Agricultural Practices and Good Manufacturing Practices guidance to domestic and international growers, harvesters, handlers, and transporters of fresh fruits and vegetables.

The report also discusses our plans for extending existing programs in order to improve the monitoring of agricultural and manufacturing practices domestically and abroad, to assist domestic and foreign producers to improve those practices, where necessary, to prevent the distribution and importation of unsafe produce, and to accelerate research to support these activities.

Sincerely,

Donna E. Shalala
Secretary of Health and Human Services

Dan Glickman
Secretary of Agriculture

Enclosure

Initiative to Ensure the Safety of Imported and Domestic Fresh Fruits and Vegetables: Status Report

Background

American consumers enjoy one of the safest food supplies in the world. However, over the last several years there has been an increase in reported outbreaks of foodborne illness associated with both domestic and imported fresh fruits and vegetables. In May 1997, as part of the President's Food Safety Initiative, the Department of Health and Human Services (DHHS), the Department of Agriculture (USDA), and the Environmental Protection Agency (EPA) sent to the President a report that identified produce as an area of concern. On October 2, 1997, President Clinton announced a new initiative to ensure that our fruits and vegetables, including those imported from other countries, meet the highest health and safety standards.

The President called on Congress to give the Food and Drug Administration (FDA) the authority to better assure that food imports meet existing United States food safety laws and regulations. Legislation has been introduced in the House of Representatives that would enhance FDA's ability to ensure the safety of all foods imported into the U.S. The legislation would enhance FDA's ability to protect U.S. consumers while being consistent with U.S. trade rights and obligations.

In addition, the President directed the Secretary of Health and Human Services and the Secretary of Agriculture to work together in close cooperation with the agricultural community to develop the first-ever safety guidance for the growing, processing, shipping, and selling of fruits and vegetables. This voluntary guidance will address potential food safety problems throughout the production and distribution system and help ensure the sanitation and safety practices of all those seeking to sell produce in the U.S. market. This second component of the President's Directive — voluntary guidance — is an important outreach and education effort, reflecting the Administration's commitment to direct resources toward improving food safety and the availability of food safety technologies.

The President's FY 1999 budget includes funds necessary to expand FDA's international capabilities; full implementation in FY 1999 will be contingent on receiving adequate appropriations.

This Report

The President asked the two Secretaries to report back to him with a plan and schedule for developing this guidance. This report presents the progress made to develop voluntary guidance for the growing, processing, shipping, and selling of fruits and vegetables and the schedule and plans to accomplish these and the other elements of the President's produce initiative. To meet the President's goal that our produce meet the highest health and safety standards, the Departments will develop voluntary Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) guidance for produce (henceforth referred to as guidance). GAPs cover production practices including growing, harvesting, handling, and transportation. GMPs primarily address harvesting and transportation, but also include aspects of manufacturing such as processing and packaging. GAPs and GMPs by necessity, overlap and are interrelated.

This report also describes interdependent activities that will help industry successfully apply the voluntary guidance. For example, the domestic and foreign industry may require technical assistance from U.S. agencies to effectively apply the voluntary guidance. Education and outreach efforts will be provided to the domestic and foreign industry and these activities will be based on a strong underlying, accelerated research program. In the long-term, research and risk assessment on fresh produce will be incorporated in the multi-year Food Safety Initiative research planning process. Development of this interagency research planning process is being facilitated by the White House Office of Science and Technology Policy.

The U.S. produce industry, states, and many countries exporting fresh fruits and vegetables to the U.S. have already taken significant steps to develop and implement improved agricultural practices and guidelines. Activities in this initiative, particularly in developing the voluntary GAP/GMP guidance, recognize this effort and build on it.

I. Good Agricultural Practices/Good Manufacturing Practices Guidance

Status: FDA, working with the USDA, is preparing a general GAP/GMP guidance document. FDA plans to publish the document as proposed voluntary guidance with opportunity for public comments. This guidance, titled "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables", describes science-based good agricultural practices that farmers and producers may use for water quality, manure management, sanitation (both field and facility sanitation, as well as worker hygiene), and handling and transportation. The guidance also describes use of producer identification and information on the flow of the product through distribution channels. This information can facilitate source identification, should a commodity be associated with a foodborne illness outbreak. This guidance can be used by both domestic and foreign fresh fruit and vegetable producers to help ensure the safety of their produce. The guidance, which is a science-based evaluation of risks, will be consistent with World Trade Organization obligations and will not impose unnecessary or unequal restrictions or barriers on either domestic or foreign producers. The agencies recognize that appropriate use of pesticides and related antimicrobial agents play an important role in controlling microbial contamination, but caution that excessive or inappropriate use of these substances does not take the place of GAPs/GMPs.

FDA and USDA sponsored, with states, a series of public meetings from mid-November to mid-December, 1997, in which the agricultural community, the international trade community, consumers, and the scientific community participated. The purpose of these meetings was to give participants the opportunity to offer their perspective on the working draft guidance and provide comments, technical information, and suggested modifications to the draft guidance. The National Advisory Committee on Microbiological Criteria for Foods' Fresh Produce Subcommittee (a USDA/FDA advisory committee) was present at the first public meeting. Based on information exchanged at that first public meeting and Subcommittee members' expertise, the Subcommittee provided recommendations that were incorporated into the working draft guidance document. This revised working draft document was subsequently used as the basis of discussion at a series of meetings for the agricultural community. These "grassroots" meetings were held at six regional locations around the country during December. The agencies also presented the draft guidance to representatives of embassies and individuals associated with importing produce into the U.S. at an international meeting in December. Feedback from the agricultural community through the "grassroots" meetings and other fora is essential to be sure that the guidance being developed is practical and applicable. Development of the final guidance will draw on scientific data and

other information that describes the fresh fruit and vegetable industry domestically and in countries exporting products to the U.S.

FDA, with USDA, will oversee a task force (with representation from other federal agencies and states) to assist in developing additional guidance if sound science, risk, or experience with general guidance indicate a need. The additional guidance may be tailored to reduce the potential for microbial contamination with specific pathogens (e.g., *E. coli* O157:H7, *Cyclospora*) and to reduce contamination associated with particular hazards (e.g., microbially-derived toxins) and commodities. This type of guidance can also be designed to minimize microbial contamination through particular pathways, such as control of water quality, worker sanitation and health, field and facility sanitation, and transportation and handling of produce. Options are being explored to determine the most efficient ways to provide industry with effective guidance that yields the most benefit for the resources expended. Any additional guidance will be developed through an open process involving industry, consumers, academia, states, and public health professionals, including the FDA public review and comment process.

The general guidance may be augmented as information about scientific advances and risks associated with fresh produce received from a variety of sources, (e.g., foodborne illness outbreaks and research) indicates the need for targeted guidance or refinement of the general guidance.

Timeline:

Short-term — October - December 1997

- a. FDA drafted proposed voluntary GAP/GMP guidance
- b. FDA and USDA held a public meeting and a meeting of the National Advisory Committee on Microbiological Criteria for Foods to solicit comments and recommendations on the guidance
- c. FDA and USDA conducted grassroots and international meetings to receive comments and information from the public

Mid-term — January - May 1998

- a. FDA, working with representatives from USDA, EPA, Occupational Safety and Health Administration (OSHA), and the State Departments of Agriculture and of Health from California, Florida, and Michigan, will analyze comments and information from the public, grassroots, and international meetings and revise guidance incorporating that information
- b. Publish revised guidance as a proposal in the Federal Register
- c. Comment period of 75 days for public to submit comments and information pertaining to the guidance

Long-term — June 1998 and beyond

- a. Evaluate comments and revise guidance into final guidance
- b. Publish final guidance in the Federal Register by October 2, 1998
- c. Create an interagency committee to evaluate the need for additional guidance and, if additional guidance is needed, oversee and direct the development of that guidance
- d. Develop a strategy to refine existing guidance, incorporating advances in science and knowledge about produce safety and information about new risks
- e. Develop risk assessment techniques to use in evaluating the effectiveness of and refining (based on that evaluation) implemented food safety control strategies

Supporting Information: To complement data and information being developed domestically, comparable data and country information, such as epidemiologic data on human health and food safety legislation and regulations affecting production, handling, and storage of produce for selected countries that export produce to the U.S. will be compiled by mid-July, 1998.

Timeline:

Short-term — November 1997 - June, 1998

- a. Identify and compile current data concerning primary sources of fresh fruits and vegetables
- b. Identify and compile available data about domestic agricultural practices and foreign food safety legislation and regulation for selected countries that export produce to the U.S. This information will support the scientific (including evaluation of risks) approach.
- c. Identify gaps in current data

Mid-term — June - August 1998

Federal and state government agencies will develop a proposal to fill data gaps in consultation with industry

Long-term — September 1998 and beyond

Using available funding, implement a plan to fill gaps.

II. Technical Assistance and Education and Outreach

Technical Assistance:

Technical expertise and resources must complement the voluntary guidance to achieve improvement in the safety of fresh fruits and vegetables. The guidance will be most effective when safety is bolstered at every step in the process, from in-field operations through distribution to the consumer. U.S. government agencies, FDA and USDA in particular, will work with appropriate U.S. and foreign government public health and agricultural agencies, as well as with industry groups, to provide technical assistance needed to support appropriate application of the guidance by the produce industry. If a foreign government is interested in learning more about the U.S. guidelines and systems for assuring the safety of domestically produced and imported fresh fruits and vegetables, overseas personnel from USDA and State Department will collaborate as necessary to facilitate these visits. Likewise, in order to provide technical assistance or followup to foodborne illness outbreaks, these overseas personnel will facilitate visits of FDA and/or Centers for Disease Control and Prevention (CDC) investigators or scientists to foreign operations to ascertain the source of problems that may pose a safety hazard in produce exported to the U.S.

USDA and FDA plan to work with a broad spectrum of representatives from the public and private sector in foreign countries and in the U.S. to promote appropriate application of the guidance and improve production and processing practices. These include officials from the health and agriculture agencies in foreign countries, the Food and Agriculture Organization, the World Health Organization, and subsidiary organizations (e.g., Pan American Health Organization), as well as exporter associations and multinational banks. In the U.S., the agencies will work with appropriate land grant colleges and universities, state agencies, and industry associations. In working with domestic and foreign groups, it is critical that in addition to technical assistance, we provide clear guidance on the legal requirements for offering fresh food for sale in the U.S. With this understanding, the foreign and domestic government, industry, and academic groups can

guide producers' decisions about what, if any, modifications of current practices are appropriate for industry to satisfy U.S. legal requirements for foods. As part of this effort, USDA and FDA will share new technologies as they are developed to enhance the safety of fresh fruits and vegetables, such as improved manure treatment methods, more sensitive analytical methods, and post-harvest treatments to reduce levels of or eliminate pathogens on produce.

Timeline:

Short-term — November 1997 - September 1998

- a. Form an interagency cadre to establish procedures to develop technical assistance and education outreach programs, to identify gaps in data to understand agricultural practices, and to assess effectiveness of the programs
- b. Identify ongoing programs providing technical assistance to domestic producers and selected foreign countries that export to the U.S. related to produce safety
- c. Integrate the goals of the President's Directive into ongoing programs where appropriate
- d. Identify gaps where technical assistance may not be available

Long-term — September 1998 and beyond

- a. Develop and implement a strategy to provide technical assistance necessary to achieve the goals of the President's Directive
- b. Evaluate effectiveness of GAP/GMP guidance and update the guidance accordingly

Education and Outreach: Education and outreach programs are essential to foster appropriate application of the guidance by the domestic and international fresh fruit and vegetable industry. These programs are pivotal to industry's understanding of the essential principles of the guidance, as well as the scientific and practical reasons for application of the guidance as everyday production and processing practice. Others in the distribution chain from the fruit and vegetable producers to the final user—the consumer—must be reached by these programs in order to assure that the care taken to prevent microbial contamination in growing, harvesting, processing, and transporting is not thwarted by later mishandling.

USDA, through its partnership with State Cooperative Extension Services in the United States, will provide leadership for the Directive's producer outreach and educational strategy. USDA, FDA and CDC will plan a national food safety scientific and education conference in 1998 to share current scientific and educational information on food safety risks that can further enhance the microbiological safety of fresh fruits and vegetables, to apprise scientific experts and extension professionals of the voluntary general guidance document, and to discuss methods for promoting appropriate application of the guidance. The guidance will be incorporated into extension programs focused on the best management practices in fruit and vegetable production. It will also serve as a basis for directing program resources to help assure appropriate application of production practices which minimize contamination of fruits and vegetables. State and local extension agents can play a vital role in the successful application of the guidance, since they are knowledgeable about on-farm production practices and can provide expert advice on how producers can incorporate interventions recommended in the guidance to reduce the risk of microbial contamination at the farm level.

To reach the domestic produce industry workforce, the guidance and associated educational materials must be available in native languages and must use terms understood by this diverse community. Multi-lingual materials are also needed for use in foreign countries. To meet these needs, FDA and USDA will work with industry and foreign governments to provide translations of the guidance documents, as well as associated training and information materials, as the documents are finalized.

We anticipate that education and outreach activities will reach beyond the immediate needs of the growers, harvesters, processors, and distributors of fresh produce to the wholesale and retail segments of the industry and to the consumer. Expanded education efforts will be directed to increasing awareness of how to enhance the safety of fresh fruits and vegetables, as well as about use of safe practices for handling and storing fresh produce.

The information provided at the grassroots and international meetings will help the agencies prioritize outreach activities and preparation of materials. FDA and USDA anticipate drawing on the resources and expertise of other agencies and industry groups to provide outreach and education, particularly targeted to specific regional needs in the U.S. The agencies have met with representatives of state agriculture departments and the industry to begin discussions of how best to make available needed training and information. We anticipate that industry itself will be a primary vehicle for outreach and education activities.

In the international arena, USDA will be instrumental in facilitating the development of education and training programs. The USDA's International Cooperation and Development staff can facilitate development of cooperative training programs on the guidance, in collaboration with other agencies capable of providing funding for these activities. The State Department will facilitate FDA and USDA contacts with foreign governments and industry groups to inform them of the guidance and provide technical assistance. USDA will also explore mechanisms to obtain the resources and expertise from other international organizations, such as the Food and Agriculture Organization and the Inter-American Institute for Cooperation on Agriculture, in order to facilitate discussions on produce safety issues. FDA and USDA will evaluate the scope of GAP/GMP education programs and materials needed to educate foreign governments and organizations, factoring in information provided at the international meeting:

Timeline:

Short-term — March - May 1998

- a. Working with industry, develop a program to provide growers, harvesters, distributors, and other aspects of the industry with background and information about the hazards, particularly microbial, associated with fresh produce
- b. FDA and USDA will convene a National food safety and education conference on fruits and vegetables to discuss the draft guidance
- c. Pending finalization of the guidance, take preliminary steps to determine mechanisms for providing information and assistance to the domestic industry in applying guidance. Likewise, preliminary steps will be taken to develop a program targeted to foreign producers.

Mid-term — July - September 1998

- a. FDA and USDA will develop a strategy to educate producers and promote the appropriate application of the final voluntary general guidance which involves federal agencies, states, and the industry.

- b. Work with other groups (foreign governments, foreign industry groups) to develop a strategy for promoting the appropriate application of voluntary guidance

Long-term — October 1998 and beyond

- a. Develop a strategy for refining outreach efforts to meet needs identified by specific producer and industry sectors.

III. Focused Inspections and Verifying Application of Guidance

Inspection and Testing: Inspections of fresh fruit and vegetable operations in combination with sampling and testing provides FDA and USDA with scientific information about the microbial quality of both domestic and imported products. Identification of microbiological problems allows implementation of prevention or intervention measures before illness occurs. It also aids in targeting educational outreach and technical assistance.

FDA will expand its fresh fruit and vegetable inspection and testing program for domestic and imported produce. Additional resources will be focused particularly on sampling products from areas, in the U.S. and abroad, where there is evidence that a potential hazard exists and preventive measures are lacking.

Verification: Verifying the application of the guidance, particularly in segments of the industry where microbial foodborne illnesses have occurred, is integral to determining its effectiveness in reducing the risk associated with fresh fruits and vegetables. The USDA and FDA will use evaluation of risks and survey techniques, such as USDA's Fruit Survey and Vegetable Survey and FDA field surveys of processors, to determine the extent of application of the guidance by both the domestic and foreign industry and the effectiveness of the GAP/GMP program in reducing the occurrence of pathogenic microorganisms and the incidence of produce-associated illnesses. The first survey will be conducted to determine current practices, specifically those practices that have the most impact on public health and those that are covered in the general guidance. This baseline information will be augmented with information from other sources, such as foreign governments and state agencies, on current practices. A second, more extensive, survey on practices will be conducted at a later date. This information — from the surveys and other sources — will be used to evaluate application of the guidance and to make necessary adjustments in the GAP/GMP program, including refinements of the guidance.

Timeline: FDA's inspection and sample collection and analysis activities will be expanded. Increased inspection and testing efforts are budget dependent and would be desirable to help evaluate the effectiveness of the general and additional guidance. The verifying activity will begin in FY 1999.

IV. Accelerated Food Safety Research

Successful implementation of this initiative relies on scientific research and characterization of the risks to public health posed by microbial contamination. The overall research goal identified in this initiative is development of cost-effective intervention and prevention strategies to reduce the incidence of foodborne illness. Research will also support development of improved detection methods useful in a variety of environments and targeted to sources of contamination. These methods will be used to support long-term surveillance and monitoring of both domestic and

imported produce at the point of production and harvest (e.g., methods for detection of *Cyclospora* and Hepatitis A on produce) and to support development of control and prevention strategies that augment use of general and additional GAP/GMP guidance.

FDA and USDA both have vigorous research programs in areas related to development of pathogen detection and quantification methodology, as well as development of control and prevention interventions. EPA and USDA research would be conducted to assess the significance of pathogen concentrations in natural (free-flowing) and agricultural water supplies and potential subsequent contamination of fruits and vegetables through irrigation practices.

FDA and USDA are individually and collectively reviewing their respective FY 1998 research projects related to fresh fruits and vegetables to identify specific research that can be accelerated. USDA and FDA have held research planning meetings with other agencies conducting food safety related research, including the CDC, EPA, Department of Defense, Department of Energy, National Science Foundation, and National Institutes of Health (NIH). In addition, the agencies have met with industry and consumer representatives to determine what food safety research is currently ongoing or in the developmental stages outside the government and to identify research needs from this outside perspective.

The agencies are developing a coordinated research plan for reducing microbial risk in produce. The research plan is scheduled to be available in early 1998. Four specific areas for research focus have been identified as: improved detection methods, resistance to traditional preservation techniques, antibiotic resistance, and development of intervention strategies. Research is currently underway in all these areas. Among the areas to be further investigated are: packaging, storage, and preservation technologies; production practices; and use of post-harvest treatments to reduce levels of unavoidable microbial contamination. NIH research on pathogenicity and clinical human disease will support both development of detection methods and the risk assessments necessary to evaluate control strategies for the target pathogens.

Research and characterization of risks is a high priority. Research on preventive technologies and intervention strategies to reduce or eliminate microbial contamination is a specific priority. Work will be conducted on manure treatment or composting techniques to assure that the manure is acceptable for application to a specific commodity. Post-harvest chemical (such as use of antimicrobial agents in wash water) and physical treatments will be investigated for fruits and vegetables, as will methods of preventing the persistence and growth of pathogens on both whole and minimally processed produce during storage and transportation. Another area of research that will be accelerated is methods development, specifically methods to detect *Cyclospora* and Hepatitis A on produce. Studies of chemical pattern recognition (trace-element fingerprints) to identify where specific foods were grown or processed will also aid in tracebacks to determine both the source of foods and the pathogens implicated in foodborne illness outbreaks.

Timeline:

Short-term — September 1997 - March 1998

- a. Initiated interagency review of research related to safety of fresh fruits and vegetables
- b. Research plan will be available in early 1998 that will identify fresh fruit and vegetable-related research

Long-term — April 1998 and beyond

- a. Develop an ongoing process for interagency review of research progress and identification of new research needed
- b. Develop schedule for making the updated research plan available periodically

V. Participants in this Initiative

The following agencies are contributing to this initiative: the Food and Drug Administration, the National Institutes of Health, and the Centers for Disease Control and Prevention in the Department of Health and Human Services; the Agricultural Marketing Service, the Agricultural Research Service, the Animal and Plant Health Inspection Service, the Cooperative State Research, Education, and Extension Service, the Economic Research Service, the Foreign Agricultural Service, the Food Safety and Inspection Service, the National Agricultural Statistics Service, the Natural Resources Conservation Service, and the Office of Risk Assessment and Cost Benefit Analysis in the U.S. Department of Agriculture; the Environmental Protection Agency; the Department of Labor's Occupational Safety and Health Administration; and the Department of Defense's U.S. Army-Natick Research Development and Engineering Center are also working on segments of the initiative.

Food Safety

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES
SECRETARY OF AGRICULTURE

SUBJECT: Initiative to Safeguard Imported Fruits and Vegetables

During my Administration, we have taken significant steps to strengthen our entire food safety system, including expanded research, education, and surveillance activities. We also have put into place enhanced safety standards relating particularly to meat, poultry, and seafood products. These measures have greatly improved the safety of the nation's food supply and reduced the incidence of foodborne illness.

We need to build on these efforts, and today I ask you to do so by focusing on the safety of fruits and vegetables, and particularly those imported from foreign countries. Last year, 38 percent of the fruit and 22 percent of the vegetables consumed by Americans came from overseas. We must ensure that these fruits and vegetables are produced under safety systems equivalent to those existing in the United States, at the same time as we upgrade our own domestic standards.

As you know, I am introducing legislation in Congress that will help accomplish this task. This legislation will authorize the Food and Drug Administration (FDA) to halt imports of fruits, vegetables, or other food from any foreign country whose food safety systems and standards are not on par with those of the United States. This authority, which is equivalent to power the USDA now has to halt the importation of meat and poultry, will enable the FDA to prevent the importation of potentially unsafe foreign produce. In addition, I will ask Congress for an increase in FDA funding in Fiscal Year 1999 to allow the agency to expand dramatically its international inspection force. With this greatly increased ability to inspect food safety conditions abroad, the FDA will be able to determine when to halt the importation of fruits and vegetables from foreign countries.

At the same time, I direct you to take administrative actions that will better ensure the safety of fruits and vegetables coming from abroad, while continuing to improve the safety of domestic produce. You should accelerate whatever food safety research is necessary to support these actions.

First, I direct the Secretary of Health and Human Services, in consultation with the Secretary of Agriculture, to report back to me within 90 days with a plan on how to improve the use of existing and projected resources to monitor agricultural and manufacturing practices abroad, assist foreign countries to improve those practices, and prevent the importation of unsafe produce, including by detecting unsafe food at the dock or border. I especially urge you to consider the best ways to target inspection and testing resources toward those foreign areas where problems are especially likely to occur.

Second, I direct the Secretary of Health and Human Services, in consultation with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue

within one year guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. This guidance should deal with such matters as sanitation, worker health, and water use, and should take into account differences in both crops and regions. By providing the first-ever specific safety standards for fruits and vegetables, the guidance will improve the agricultural and manufacturing practices of all those, foreign and domestic, seeking to sell produce in the U.S. market. To ensure that this guidance has the widest possible effect, I also direct the development of coordinated outreach and educational activities regarding these new safety standards.

These steps, taken together and in coordination with the legislation I will send to Congress, will ensure to the fullest extent possible the safety of fruits and vegetables for all Americans. I will also direct the Administrator of the Environmental Protection Agency and the Secretary of Labor to provide you with assistance in achieving this goal.

"We have built a solid foundation for the health of America's families. But clearly we must do more. No parent should have to think twice about the juice they pour their children at breakfast, or a hamburger ordered during dinner out."

- President Bill Clinton, Radio Address, January 25, 1997

Today, Vice President Al Gore accepted a major report -- "Food Safety From Farm to Table" -- on how to reduce the incidence of foodborne illnesses from Health and Human Services Secretary Donna E. Shalala, Department of Agriculture Secretary Dan Glickman, and Environmental Protection Agency Administrator Carol M. Browner. The report, requested by President Clinton in January, sets forth new steps the Administration will take this year to strengthen food safety and details how we will use \$43.2 in new funds the President has requested in his 1998 budget.

Working with consumers, producers, industry, states, universities, and the public, the Administration has developed measures to reduce foodborne illness from microbial contaminants; the Administration will:

- o **Improve inspections and expand preventive safety measures:** FDA will use \$8.5 million of the new funds, in part, to hire additional Food and Drug Administration (FDA) inspectors for seafood plants and to expand the Hazard Analysis and Critical Control Point (HACCP) approach to the fruit and vegetable juice industries. U.S. Department of Agriculture (USDA) will propose preventive measures, including HACCP, this year for egg products.
- o **Increase research to develop new tests to detect foodborne pathogens and to assess risks in the food supply:** The agencies will target \$16.5 million to critical research needs, such as giving federal, state and local food safety officials new tools to detect these pathogens, some of which -- like the Hepatitis A virus and cyclospora -- cannot now be detected in many foods.
- o **Build a national Early Warning System to detect and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks:** With \$13.7 million of the new funds, USDA, FDA, and Centers for Disease Control and Prevention will increase the number of active "sentinel sites" across the country from 5 to 8 (current sites are in Northern California, Oregon, Minnesota, Georgia and Connecticut; new sites added this year are in New York and Maryland, and the eighth will open next year) and will equip these sites with new technology to identify the diseases and their sources and to communicate these findings nationwide rapidly.
- o **Establish a national education campaign that will improve food handling in homes and retail outlets.** FDA, USDA, CDC, and the Department of Education will launch a new public-private partnership with industry,

producer and consumer groups, and states to raise public awareness of safe food practices. Using public and private funds, the partnership will develop, disseminate, and evaluate a single food-safety slogan and several standard messages. USDA and FDA will use \$4 million of the new 1998 funds to support this and other education activities.

- o **Strengthen coordination and improve efficiency:** USDA, CDC, FDA and EPA will form a new intergovernmental group to improve federal, state and local responses to outbreaks of foodborne illnesses. Working with all stakeholders, the agencies will develop a strategic plan to further improve coordination, use resources more efficiently, and measure progress toward our common goal of reducing foodborne.

Building on Our Accomplishments

Food safety is a major public health challenge: millions of foodborne illnesses and thousands of food-related deaths occur annually. From the beginning, the Clinton Administration has made improving the safety of the nation's food supply a top public health priority.

- o **Building on the recommendations of the Vice President's National Performance Review, the President put in place new science-based, hazard prevention systems for seafood, meat, and poultry.** In late 1995 the Administration issued new rules to ensure seafood safety. In July, 1996 President Clinton announced new regulations to modernize the nation's meat and poultry inspection system for the first time in 90 years. The new Early Warning System will gather critical scientific data to further improve these prevention systems
- o **In August, 1996 President Clinton signed the Food Quality Protection Act -- a comprehensive overhaul of our laws that regulate pesticides in food** putting in place reforms that the Clinton Administration had urged since 1993. These reforms will ensure health and safety for American families through a more protective, more stringent health-based standard plus special new provisions to protect the health of infants and children from pesticide risks.
- o **Last August, President Clinton also signed a new safe drinking water law** that strengthens protections to ensure that American families have clean safe tap water -- improvements that the Clinton Administration has called for since September 1993.

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 Mostly accurate
 Trade press story
 This is same reporter broke the survey announcement mid-1995
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EK — We're not putting manure regulation in the press release, are we?
 BR

Food safety initiative final version carries provisions for enhanced seafood surveillance, food safety council, education partnership, manure regulation and more

The seafood industry will see increased government attention on *Vibrio vulnificus* and the Norwalk virus if Congress approves funding for the multi-agency food safety initiative, sources told *Food Chemical News*. The final version of that initiative calls for increased surveillance for *Vibrio vulnificus* by CDC, FDA and states through boosts in personnel and epidemiological and lab resources.

BR — First paragraph as currently written.
 EK

That effort, detailed in a final version of the initiative submitted to President Clinton, would comprise an enhancement of the Gulf Coast *Vibrio vulnificus* surveillance program. The report, which is about 50 pages long, calls for research to develop new decontamination methods for such contaminants as *Vibrio* and Norwalk on seafood, as well as for hepatitis A on strawberries. The entire report emphasizes the need for research to find and improve pathogen detection methods. The federal agencies involved in the initiative are CDC, FDA, USDA and EPA.

One source close to the initiative noted that even if the government had known ahead of time about the hepatitis A recently linked to Mexican strawberries, the hepatitis A could not have been detected because the government lacks reliable methodology for such detection. Pathogen detection in the food supply is complicated by the fact that detection is different for almost every type of food. That is, detection of pathogens in milk is different from detection in berries, which is different from detection in meat, etc.

The White House was scheduled to announce the final version of the initiative April 29, but that was postponed due to conflicts with other White House press events. At press time, sources said that an announcement of the initiative by Vice President Al Gore was scheduled for May 12, but that date — and Gore's availability for the event — could change again.

(See FSI, Page 37)

May 5, 1997

FOOD CHEMICAL NEWS 37

"If ... improved objective performance standards can be crafted through additional, scientifically based rulemaking," Boyle added, "AMI will support and participate in those efforts."

Consumer groups not satisfied with spinal cord safety

On Monday, April 28, Billy and his colleagues in FSIS held another meeting focusing on AMR, this one with representatives from the consumer advocacy groups Public Voice, National Consumers League, Center for Science in the Public Interest, and the Safe Food Coalition.

The meeting was prefaced by an April 22 letter from NCL's Linda Golodner to Billy and Agriculture Secretary Dan Glickman. NCL appears to be backing off its earlier demands that back and neck bones be kept out of AMR systems altogether, an action taken by Britain more than a year ago. Instead, Golodner suggested that USDA impose bone scoring requirements, "an iron limitation of not more than 2 mg per 100 g," a calcium test performed "after separator and before the desinewer" for a maximum level of 20 mg per 100 g, and a prohibition on presizing.

"Resolving the spinal cord and marrow issues through lengthy rulemaking procedures is unnecessary legally and represents an unacceptable abdication of responsibility," Golodner wrote. "The British waited much too long to act decisively and have paid a very dear price." NCL and other consumer groups are concerned that spinal cord in AMR meat may expose many American citizens to a higher risk of transmissible spongiform encephalopathies, Britain's deadly "mad cow disease."

At their meeting, the consumer groups reiterated these issues, focusing on the BSE risk from spinal cord. They cited risk factors, including the imports of British cattle into the U.S. in the 1980s, the imports of Mexican cattle into the U.S. that continue every year, and the limited resources FDA will have to enforce its proposed mammalian-to-ruminant feed ban.

According to one of the consumer group participants, the spinal cord directive will be "closing the barn door after the horse is out." Since spinal cord is only an economic

adulterant, not a health hazard, suspect product would go into distribution even if some of it is sent off for tests.

"We're not convinced that the directive itself will provide a complete assurance that spinal cord won't get into end products," one consumer advocate explained. The advocate noted, however, that the directive may be useful in putting pressure on industry to keep spinal cord out of AMR systems. "The next step is for us to meet with industry," the advocate said.

Under the terms of USDA's 1994 reorganization, FSIS cannot propose a "major regulation" dealing with human health or safety (changing the definition of meat to exclude spinal cord would qualify) without performing a risk assessment and cost-benefit analysis, which would take a minimum of six months to complete. The entire rulemaking process would last for one to two years. "They're doing the best that they can," the consumer advocate admitted.

On the bone marrow issue, the consumer groups requested that FSIS propose a rule aimed against "unacceptably high" marrow levels in AMR product. Bone scoring requirements might be used, as in NCL's proposal. But the performance standards proposed in Billy's letter to AMI may fulfill this request, one source said. "We'll wait to see what they come up with." (7FCN 1102, 3 pages, \$5, and 7FCN 1103, 2 pages, \$5)

— Wendy Love Anderson

(FSI, continued from Page 3)

The initiative is structurally the same as its draft predecessor, i.e., presented in seven sections, and most of the concepts from the draft survived in the final report (See *Food Chemical News*, April 7, Page 38).

Regulation of manure likely

Regulation of manure is likely in the near future, as the report cites the need to control the various ways that manure can contaminate the food supply. The report does not detail any manure regulations, but emphasizes that controls are needed.

The report also calls for the establishment of a National Council on Food Safety, which would include an independent scientific board to review food safety messages. The board would include representation from the scientific and academic communities and would use a risk-based methodology for prioritizing its work.

A public/private partnership for food safety education also would be established by the initiative, but details on that effort were sketchy. The report places new emphasis on education of health care professionals, a goal that was accentuated repeatedly by participants in a March 31-April 2 public meeting on the draft initiative. Health care professionals need to recognize foodborne illness, test for it and report it, the source said. The agencies will try to be "appropriately multilingual" in all public and educational efforts, the source said.

Egg and produce HACCP appear imminent

Egg HACCP and produce HACCP appear imminent, as the report indicates that regulatory options will be proposed for controlling pathogens in eggs and in fresh fruits and vegetables.

Federal outreach to states and cooperation with states are linchpins of the plan, and that strategy is in line with the federal government's need to share the resource burden for implementing the initiative.

Federal agencies must maintain a dialogue with all parties who have a stake in the initiative, in order to establish and follow a strategic plan for developing, implementing and reviewing the initiative's components, the report said.

It remains uncertain whether Congress will give the agencies the \$43 million requested for the initiative. While it is tough for any congressional members to argue against the concept of a safer food supply, Congress will be very wary in the current budgetary climate to approve new funding for projects.

— John Briley

Performance standards featured in FSIS regulatory agenda

The switch from requirements to performance standards, part of the "Reinventing Government" effort, dominates the semiannual regulatory agenda of USDA's Food Safety and Inspection Service, published in the April 25 *Federal Register*.

No fewer than six proposed rules explicitly establish performance standards. In June, FSIS plans to give notice that it is establishing performance standards "for the production of certain meat and poultry products with established standards of identity. ... Performance standards spell out the objective level of performance establishments must meet during their operations to produce safe products, but allow the use of customized, plant-specific processing procedures."

In this case, FSIS plans to establish food safety performance standards specific to the standards-of-identity products instead of relying on "statutory authorities, general regulations, regulations for similar products, or FSIS directives." Similarly, FSIS is developing new performance standards "to limit the amount of water absorbed and retained by single-ingredient raw meat and poultry products to the amount that is unavoidable in carrying out washing or chilling procedures." Water-added raw products may have to bear a label attesting to their absorbed water content, according to the proposal, which was scheduled for publication in April 1997.

In other cases, however, the agency is replacing its own specific regulations. For instance, proposed performance standards will replace "command-and-control" procedures for thermal processing of meat and poultry products; irradiation of poultry to control foodborne pathogens; handling, chilling and freezing of poultry; cutting carcasses into primal parts within an establishment; and preventing physical or chemical contamination of meat and poultry products and product ingredients.

Food Safety

11/1/96

NOTE TO BRUCE REED -

Wanted to be sure you'd gotten the message that the Department cannot agree to anything more than the expansion of five to 10 sites, and a directive asking us to report back with other measures in 60 days. As I mentioned, this is a substantive argument, and it will take us at least that long to forge a consensus between CDC and FDA.

Mary Beth Donahue, who works with Kevin Thurm, is collecting edits on the radio address now and getting them to Elizabeth Drye, but I wanted to be sure you got our first cut.

We're still preparing a fact sheet, and working on the directive too.

Melissa

DRAFT 11/1/96

PRESIDENT WILLIAM J. CLINTON
RADIO ADDRESS TO THE NATION
NOVEMBER 2, 1996

Good morning.

Today, I am pleased to announce a major new step toward protecting the health and safety of all Americans -- especially our children.

I believe this is a positive and hopeful time...an age of enormous possibility...a chance for us to build a country and a world that is stronger and safer and full of more possibility than any that existed before.

The way we will master this moment of change is the way we always have: By holding fast to our enduring values. Central among these is the belief that Americans are owed the basic security of knowing that the food we eat, the air we breathe, the water we drink will not make us sick. Hard-working American parents deserve the peace of mind that comes from knowing the wholesome meal they set before their children is safe.

That's why I was so concerned by what happened in Washington State earlier this week. Several children, some as young as 2, got very sick from drinking apple juice contaminated with a deadly strain of E Coli bacteria.

I imagine just about every parent in America remembers what E Coli can do. In 1993, tragedy struck hundreds of families in the Western United States when they took their kids to fast food restaurants that served them hamburgers tainted by the E Coli bacteria. 500 people became ill -- some of them, severely ill; and 4 children died.

Fortunately, we have made progress since 1993. Because of the careful work of state and local health authorities, and the swift and efficient action of the Centers for Disease Control and Prevention and the Food and Drug Administration, we stopped this week's outbreak of E Coli in its tracks. As soon as we got the news, we went on an around-the-clock alert. We notified health officials in all 7 states where the juice was available. We worked with the manufacturer to get it off supermarket shelves. And we put doctors and hospitals across the country on watch for symptoms of E Coli infection. Now, of the 5 children who were hospitalized, all are expected to make a full recovery.

This quick response is part of our larger effort to protect the health and safety of all our people. Under my administration, we strengthened the Community Right to Know law, which requires industries to tell our citizens what substances are being released into the world around us. We put in place strong new protections to ensure that seafood is safe. We announced steps to modernize our meat and poultry inspection system for the first time in 90 years. I signed into law legislation that protects our fruits and vegetables from harmful

pesticides -- and legislation that keeps our drinking water safe and pure.

And, just a year ago, I stood with America's families to fight off efforts to weaken our most basic safeguards for clean air, clean water, and clean food.

Today, we add to the solid foundation of food safety we've built for our families. I am announcing new steps to keep our food safe and to protect our children from deadly bacteria. No parent should have to think twice about the juice they pour their children at breakfast, or a hamburger ordered during a dinner out.

First, we will put in place a nationwide early-warning system for food-borne illness. Right now, the CDC sponsors 5 centers across the country whose mission is to post a lookout for food-borne illnesses -- like E Coli and Salmonella. Working with state and local governments, these "sentinel sites" stand watch over our public health. Today, I am announcing that we will double the number of these sites from 5 to 10. This national system will enable us to catch outbreaks sooner, and give us the data we need to prevent outbreaks from happening in the first place.

Second, I am directing the Secretary of Health and Human Services, the Secretary of Agriculture, and the Administrator of the Environmental Protection Agency to report back to me within 60 days with additional measures to further improve the safety of our food.

These recommendations should tell us how we can further improve inspections, research, education, and coordination among local, state, and federal health authorities. I want the agencies to look at ways to increase the number of expert disease detectives to investigate and control food-borne disease outbreaks...to give health officials state-of-the-art technology to trace infectious agents to their source...to use advanced communications networks to speed outbreak information to health authorities across the country.

With this new early-warning system to track food-borne illness, we are saying, loud and clear, that we will do everything in our power to make sure that the world's most bountiful food supply is also the safest.

By protecting the public health, by bringing our people together around our basic values of opportunity, responsibility, and community, we will surely make this an age of possibility for all Americans.

Thanks for listening.

DRAFT 11/1/96

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NOVEMBER 2, 1996

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This quick response is part of our larger effort to protect the health and safety of all our people. Under my administration, we strengthened the Community Right to Know law, which requires industries to tell our citizens what substances are being released into the world around us. We put in place strong new protections to ensure that seafood is safe. We announced steps to modernize our meat and poultry inspection system for the first time in 90

years. I signed into law legislation that protects our fruits and vegetables from harmful pesticides -- and legislation that keeps our drinking water safe and pure.

And, just a year ago, I stood with America's families to fight off efforts to weaken our most basic safeguards for clean air, clean water, and clean food.

Today, we add to the solid foundation of health security we've built for our families. I am announcing new steps to keep our food safe and to protect our children from deadly bacteria.

First, we will put in place a nationwide early-warning system for food-borne illness. Right now, the Centers for Disease Control sponsors 5 centers across the country whose mission is to post a look-out for food-borne illnesses -- like E Coli. Working with state and local governments, these "sentinel sites" stand watch over our public health. Today, I am announcing that we will double the number of these sites from 5 to 10. This national system will enable us to catch outbreaks sooner, and give us the data we need to prevent outbreaks from happening in the first place.

Second, we will use state-of-the-art technology to keep our food safe. We will increase the number of expert disease detectives to investigate and control food borne disease outbreaks. We will give these experts the technology to use revolutionary new DNA fingerprinting methods to trace infectious agents to their source, and create a permanent fingerprint library, so we can immediately recognize an illness if it reappears. And we will use cutting-edge communications networks to speed outbreak information from these centers to hospitals and public health agencies all across the country.

Third, I am directing the Secretary of Health and Human Services, the Secretary of Agriculture, and the Administrator of the Environmental Protection Agency to report back to me within 60 days with additional measures to ensure the safety of our food.

With these initiatives we say, loud and clear, that we will use the world's best science to make the world's most bountiful food supply safer than ever before for our families and our children.

Clinton Targets Tainted Food Imports

Recent Outbreaks Cited; Measure Aims to Prevent 'Port Shopping'

Associated Press

President Clinton announced a new measure aimed at warding off contaminated food imports while Republicans advocated a \$1 trillion tax-cut proposal yesterday in their weekly radio addresses.

Clinton is instructing inspectors at American ports to brand food products rejected for health or safety reasons with a "Refused U.S." to assure that such products are conspicuously marked and not easily slipped past inspectors at another U.S. port—a practice known as "port shopping."

Clinton also is ordering the Customs Service and the Food and Drug Administration to "rigorously enforce and expand our policy of destroying imported food that poses a serious health threat rather than risk letting it reach our grocery stores or

the global market."

But he said he does not want to be unduly alarmist. "There's no evidence that these fruits and vegetables are less safe than those grown here," Clinton said. "But some recent outbreaks of food-borne illness have been traced in imported foods."

The president said he is acting because imported food is now on more American menus than ever before. In a memo to the secretaries of the Treasury and Health and Human Services departments, Clinton noted that food imports have doubled over the past seven years and that a further 30 percent increase is expected by 2002.

The president called on Congress to grant the Agriculture Department authority to impose civil penalties and order mandatory recalls of unsafe meat and poultry.

A food industry representative ob-

jected to that proposal. "Government mandates may score political points, but they won't make the system safer," said Gene Grabowski, spokesman for the Grocery Manufacturers of America. "Companies have every incentive to act swiftly and responsibly to protect the food supply."

Clinton also asked Congress to approve the \$72 million he requested to increase the number of inspections of high-risk food products in the United States and of food producers around the world.

In the Republican weekly address, Rep. J.D. Hayworth (Ariz.) pushed a \$1 trillion tax cut, marking the Fourth of July with a call for "financial independence" for U.S. families.

"For too long, you've been asked to sacrifice so that Washington could supposedly do more," he said.

House Republicans say the federal budget surplus is so big that Congress can cut taxes by nearly \$1 trillion and still brace Social Security and Medicare for retiring baby boomers. Democrats and some moderate Republicans, however, say the surplus should first be used to increase spending on education and other programs once Medicare and Social Security are safeguarded and the national debt is erased.

A tax package to be drafted within

the next two weeks by the House Ways and Means Committee will include reduction of the so-called marriage penalty, an end to the death tax and safeguards so that Americans aren't penalized for investing and seniors don't suffer for working past age 65, Hayworth said.

Hayworth, who is a Ways and Means member, criticized Clinton's plan to provide a prescription drug benefit to all Medicare recipients.

Republicans have questioned whether such a benefit is needed by all 39 million Medicare beneficiaries

when two-thirds already have drug coverage—mainly from private insurance or retirement benefits from employers.

"One of my constituents got it right when she said that under the president's plan she'd be subsidizing the likes of Donald Trump and Ross Perot," Hayworth said.

Medicare can best be strengthened by attacking waste, allowing recipients more control over their health care and providing prescription drug benefits to low-income seniors, Hayworth said.

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point. Some will call back and she said she was trained to say we have lawyers to fight this. She said then everybody gives up."

"It's all over the country, these phony medical review services," said Daniel J. Gatti, a personal injury lawyer who represented Foltz. "They have a computer program that says all soft tissue injuries heal in six months. To put everybody in the same group and use a computer program to say this is what they get is [expletive]. We think it's fraud."

Another person who will talk about this system is James Mathis, a former State Farm supervisor who sued the company in 1997 for wrongful discharge from his job in Washington state three years earlier. Last year, a federal judge issued a summary judgment against Mathis in the case. He is appealing.

Mathis said that when he was in charge of processing medical claims by State Farm policyholders in Washington state the insurer's position was "you don't use an [outside utilization] company that did not provide you with at least a 20 percent reduction in the billing. Otherwise it would not be cost effective."

Mathis said one company that he considered "too aggressive" in cutting medical claims was Comprehensive Medical Review (CMR), which is headquartered in San Diego and is headed by William J. Marvin, a former chairman of the San Diego County Republican Party. CMR provided the medical reports in the Foltz case.

"CMR had a mind-set. They were going to prove to State Farm that they were a profit machine," said Mathis, who gave testimony in the Robinson and Foltz cases. "They were going to cut every bill."

Attempts to reach Marvin by phone were unsuccessful.

David Snyder, assistant general counsel of the American Insurance Association, a trade association of property and casualty insurers, said that during the 1990s there has been "tremendous pressure on insurers to reduce expenses and premiums. One

way a number of insurers have responded is to more closely review medical bills to make sure they are 'reasonable and necessary,' which is the standard."

Snyder said this was particularly important because in some states the amount of medical charges set the parameters for the amount of awards for "pain and suffering" in lawsuits stemming from automobile accidents. "The higher you can drive the medical bills the greater the litigation value of the case," he said. "That's why insurers need to control medical costs, because otherwise this can greatly increase the cost of insurance for everybody."

Snyder added that the utilization review system is one factor behind a trend toward stable or lower auto insurance premiums and is considered so important in Pennsylvania and New Jersey—two historically high-cost insurance states—that such reviews are mandated by law.

Friedman, Robinson's lawyer, said, "Most people would agree that there is a place for paper review in handling insurance claims, but like any tool it can be misused." Speaking of the two companies that reviewed the Foltz and Robinson claims, he added, "I don't think that you would find that these are two bad apples out of a healthy barrel, but that half the barrel is rotten. What's going on, in my opinion, is the insurance industry is waging an undeclared war against American consumers. They know exactly what they are doing."

"The insurance industry is making more and more use of utilization firms," said Matthew Whitman, an Oregon lawyer who is working with the consumer groups. "It's an out for the insurance company."

Whitman and other lawyers for the consumer groups argue that the sealing of records in the cases that have been settled makes it difficult to determine if there is widespread abuse in the industry and unnecessarily shields companies from public accountability. They also charge that the extent of secrecy in the Foltz case is virtually unprecedented, involving

not only the court record but also the very existence of the case itself.

According to Whitman, when he visited the federal courthouse in Eugene last April, the court clerk told him that *Foltz v. State Farm* did not exist because it did not show up in the court's internal computer system. A physical search later located the thin case file that is public. But Whitman said the file contained references to about 450 motions and other items that have been sealed.

Sarah Posner, a staff attorney for Trial Lawyers for Public Justice, said that as recently as last week an attempt to locate the case through a nationwide computer system that lawyers routinely use came up blank.

"Inevitably, this favors big corporations such as insurance companies and other defendants," Whitman said of the system that enables companies to demand silence in exchange for large monetary settlements. "Debbie Foltz cannot defend the rights of everyone to access to the courts. At some point the money gets too big."

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