

Monday
Food Safety
E-Coli

Safer Diets for Cows

Microbiologists at Cornell University have found that what cattle eat can affect the safety of hamburgers, opening a whole new path to controlling food-borne illnesses. Strains of E. coli bacteria have caused illness and death in humans who have eaten undercooked ground beef, lettuce and unpasteurized fruit juice. Thus far most efforts to control the spread of E. coli have focused on improving safety in slaughtering and food-handling practices. But the new research shows that the E. coli problem can also be managed by changing the diet of cattle. It turns out that cattle fed mostly grain are more likely to harbor harmful E. coli bacteria than cattle fed hay or grass. Grain-fed cattle develop more acid in their colons, which promotes acid-resistant bacteria in their digestive tracts. Such bacteria are more likely to survive in the human

Tom - Can we/should we require the industry to do this? Elena cc: Bruce

stomach, causing illness. Switching the cattle to hay or grass for even five days can reduce acid and virtually eliminate acid-resistant E. coli.

The data should prompt the cattle industry to adjust its feed practices. There is little chance that American cattle will be fed hay alone because grain feeding is efficient and economical. But widely publicized incidents in recent years of E. coli contamination in beef have been highly costly for the industry. Making the change to hay for the few days prior to slaughter would likely involve only minimal expense. It is unclear whether the Department of Agriculture can require such a change. But meat-packing plants, armed with the new research, may find it in their financial interest to insist that producers certify that their animals meet these dietary standards.

\$5 mil - 5th level
→ lab
→ 3 Cows
→ USDA not in
control



Food
Safety -
ECOL

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

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FAX COVER SHEET

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MESSAGE: _____

FYI - per my phone call.

**STATEMENT OF AGRICULTURE SECRETARY DAN GLICKMAN ON NEW E COLI
RESEARCH**

September 10, 1998

Research by a team of USDA and Cornell University scientists indicates that cattle fed hay for about five days before slaughter contain significantly fewer acid-resistant *E. coli* bacteria that might later sicken people who eat the meat.

including
0157:H7

This deceptively simple finding, if confirmed by further research, has the potential to greatly assist our efforts to fight food-borne illness. While there is no one silver bullet when it comes to food safety, this finding underscores, yet again, the value of agricultural research as a tool in our arsenal to prevent the adverse health and economic impacts of foodborne illness.

-Inserting Budget list

TALKING POINTS ON ACID-RESISTANT *E. COLI* STUDY

* A USDA-Cornell University research team did studies that showed that when cattle were fed hay rather than grain for about five days before slaughter, their bodies contained significantly fewer numbers of acid-resistant *E. coli* bacteria that might sicken people who eat the meat. Cattle are typically fed starch-containing grains to increase growth rate and produce tender meat. A brief switch to hay just before slaughter is not expected to affect either market size or carcass quality.

* The USDA-Cornell research team included microbiologist James B. Russell of USDA's Agricultural Research Service and Cornell students Francisco Diez-Gonzalez, Todd Callaway and Menas Kizoulis. Russell is based at Ithaca, N.Y., but is affiliated with the USDA-ARS U.S. Dairy Forage Research Center at Madison, Wis. Diez-Gonzalez completed his Ph.D. in animal science at Cornell in 1996 and is currently a post-doctoral fellow. Callaway is a Ph.D. candidate in microbiology. Kizoulis is a Cornell senior in biological sciences.

* *E. coli* is a normal bacterium in the gastrointestinal track of animals and humans, and most types of *E. coli* are not harmful. But disease-causing strains such as *E. coli* O157:H7 produce toxins that cause bloody diarrhea and even kidney failure in humans. *E. coli* contamination is responsible for more than 20,000 infections and 200 deaths each year in the United States. *E. coli* O157:H7 can be killed by cooking or irradiation.

* Only a very small number of cattle--estimated at 1 to 2 percent at any given time--shed *E. coli* O157:H7 in their feces. If beef cattle are accidentally contaminated by feces at slaughter, these bacteria can enter the human food supply.

* The USDA-Cornell study indicated that a continuous grain-based cattle diet can increase the likelihood that some *E. coli* bacteria naturally present in the animal's gastrointestinal tract would develop resistance to acids. That's because as the grain ferments in the cow's digestive system, it creates an acidic environment. If disease-causing *E. coli* bacteria can survive in that environment in the animal's body and subsequently find their way into the food supply, they might also be able to survive in the human stomach and cause illness.

* Acid-resistant strains of bacteria have evolved over time to overcome the protective barrier of the animal's gastric stomach. The ongoing process of natural selection allows organisms with the appropriate genes to survive multiply where others cannot. Further studies are needed to identify the acid-resistance genes of *E. coli*, but it appears that common laboratory strains of *E. coli* lack the necessary DNA to survive acidic gastrointestinal environments.

* Switching cattle from a grain-based diet to a hay-based diet for as little as five days before slaughter reduces the likelihood of the development of acid-resistant *E. coli* that could contaminate beef carcasses. Carbohydrates in hay are not as easily fermented as those in grain. In the USDA-Cornell tests, when the researchers switched cattle from a grain-based diet to hay for only five days, they could no longer detect any acid-resistant *E. coli* in the animals.

* In the USDA-Cornell tests, beef cattle that ate grain-based rations typical of commercial feedlots had 1 million acid-resistant *E. coli* per gram of feces, and dairy cattle fed only 60 percent grain also had high numbers of acid-resistant bacteria. By comparison, cattle fed hay or grass had only *E. coli* that were susceptible to acid, and those bacteria were killed by exposure to an acidic environment similar to that of the human stomach. Sixty-one cattle were used in the study.

- Food Safety Council*
- 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

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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	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 90 (7-97)

FAX TRANSMITTAL

of pages **2**

To <u>Juan</u>	From <u>Torre</u>
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GENERAL SERVICES ADMINISTRATION

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

àD?sðæ½@@,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.

10-11-98 THE WHITE HOUSE 10/27/2000
CSREES ADMINISTRATOR OFC 0002
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 E. 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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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 Joliet 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.

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

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

08/22/88 TEL 15.07 FAX 202/206887 CSKES ADMINISTRATOR OFC 010

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.

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

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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.

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

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.

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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

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

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.

**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 Matyas, 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 zaps 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 Bala 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 1996, 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 12 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."

THE WHITE HOUSE

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

For Immediate Release

August 25, 1998

EXECUTIVE ORDER

- - - - -

PRESIDENT'S COUNCIL ON FOOD SAFETY

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

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

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

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

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

more

(OVER)

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

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

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

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

WILLIAM J. CLINTON

THE WHITE HOUSE,
August 25, 1998.

#

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.



Food Safety
E. Coli

UNITED STATES DEPARTMENT OF AGRICULTURE**OFFICE OF THE SECRETARY**

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FAX (202) 720-5437

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TALKING POINTS

CLARIFYING ADULTERATION POLICY FOR E COLI 0157:H7 IN BEEF

1. In 1994 the Food Safety and Inspection Service (FSIS) announced its policy that raw ground beef contaminated with E coli 0157:H7 is adulterated unless processed in a manner to make the product safe (e.g., fully cooked).
2. This policy is based on virulence and severe health consequences of E coli 0157:H7, and the fact that E coli 0157:H7 is not destroyed by common cooking procedures for ground beef.
3. The National Advisory Committee for Microbiological Criteria in Foods (NACMCF) advised FSIS in 1998 that concerns regarding E coli 0157:H7 in raw ground beef also apply to raw beef that has been sectioned and formed, injected, etc. (i.e., non-intact beef).
4. Grinders of ground beef, both inspected plants and retailers, have expressed concern that they have little or no control over the product they receive to grind. Some grinders, including some large retail chains, now require their suppliers to test product, including trimmings for E coli 0157:H7, prior to shipment. Grinders who do not have such a requirement (generally smaller firms) fear that product that tests positive may be diverted to them without their knowledge.
5. This notice, scheduled to publish next week, will clarify FSIS's policy on the status of raw beef contaminated with E coli 0157:H7. This notice states that any non-intact raw beef (including trimmings) contaminated with E coli 0157:H7 is adulterated unless processed so as to be safe.
6. The notice also explains that FSIS is not, at this time, expanding its raw ground beef E coli 0157:H7 sampling and testing program to include all types of non-intact beef.
7. The Notice seeks input from the public about regulatory requirements that may be appropriate to prevent the distribution of products adulterated with E coli 0157:H7.
8. FSIS will publish in the Federal Register on the same day the Notice is published its guidance to beef grinders for minimizing the impact associated with a food safety hazard in raw ground beef.

January 13, 1999

**UNITED STATES DEPARTMENT OF AGRICULTURE****OFFICE OF THE SECRETARY**

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FAX (202) 720-5437

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MESSAGE: _____

FROM: CDC

FAX NO.: 4846397111

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

AUG 7 1998

Mr. Thomas J. Billy
Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture
1400 Independence Avenue, S.W.
Washington, D.C. 20250

Dear Mr. Billy:

Recent reports in *Food Chemical News* and other print media suggest that the Centers for Disease Control and Prevention (CDC) has revised estimates of the burden of foodborne illness and death and that recent FoodNet data demonstrate a substantial decline in the incidence of foodborne infections. These reports are inaccurate and may have caused confusion. The following information should clarify the status of efforts underway at CDC to improve our understanding of occurrences of foodborne illnesses and indicates the interagency collaboration involved in these efforts.

In 1987, CDC used surveillance and outbreak data, published reports, and expert opinion to estimate the overall incidence of illness and the number of deaths caused by foodborne microorganisms in the United States. The incidence of symptomatic illness was estimated at 6.5 million cases annually, with about 9,000 related deaths. These estimates were published in a Carter Center document, *Closing the Gap: the Burden of Unnecessary Illness*, and were part of the basis for estimates published in 1994 by the Council for Agricultural Science and Technology.

CDC has recently begun a multidisciplinary effort to revise these national estimates for foodborne illness. This is a complex process that will draw upon new sources of data, including results of active surveillance at FoodNet sites, as well as sources used previously, and the revised estimates will be accompanied by documentation of all data sources and assumptions. Efforts currently underway involve CDC scientists from the National Center for Infectious Diseases and the National Center for Health Statistics. CDC will seek input from its National Food Safety Initiative partners at the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Agriculture (USDA) as the process of revision proceeds. The revised estimates will not be available

Page 2 - Mr. Thomas J. Billy

for several months. While the data used for these estimates will be greatly improved from those in the 1987 report, substantial future efforts will be required to further improve estimates of the burden of illness caused by certain bacterial, parasitic, and viral foodborne pathogens.

CDC, in collaboration with USDA, FDA, and the active surveillance sites, is also preparing a report on FoodNet surveillance data for publication in the *Morbidity and Mortality Weekly Report* (MMWR). FoodNet began collecting detailed data on the frequency, burden, and causes of foodborne illness in 1996. We anticipate publishing a summary of the 1996-1997 surveillance data in the next several weeks, after the draft has been reviewed and approved by all collaborators. The current draft report indicates that the incidence of culture-confirmed infections with some of the pathogens under surveillance decreased between 1996 and 1997, while the incidence of others increased. As you know, many factors can influence disease incidence on a year-to-year basis. Therefore, it will be necessary to collect several years of data to be confident of the stability of trends. We will carefully review the 1996-1997 data and our interpretations of them with our collaborators before the report is submitted to the MMWR for publication.

Ongoing FoodNet activities in 1998 will be analyzed after data collection for this year has been completed. While it would be gratifying to document "a remarkable decline in disease rates" when we report the 1998 FoodNet results, attempting to infer this from the preliminary data currently available would be premature and possibly misleading.

Sincerely,



Claire V. Broome, M.D.
Acting Director

CDC to release dramatically lower foodborne disease illness estimates

Armed with the latest FoodNet data, the Centers for Disease Control and Prevention is poised to release new foodborne illness estimates that will be dramatically lower than what have been publicly cited for years. The new numbers may place government officials in the difficult position of defending spending increases for food safety programs in light of a significantly lower illness rate.

In the next several months, CDC plans to release new estimates on foodborne deaths and illnesses that afflict Americans each year, sources say. CDC has been reevaluating its data and plans to report significant reductions, said a source, who added that health officials are preparing for a backlash once the new numbers are released.

The food industry has repeatedly questioned the government's widely quoted 9,000 deaths per year estimate from tainted food, as the number was used to rally support for the president's Food Safety Initiative. With CDC's expanded surveillance and monitoring network, that estimate is expected to drop significantly to about 2,000-3,000 deaths from foodborne illness.

CDC's data will present new estimates for all foodborne diseases. For example, public health officials have maintained that as many as 250 deaths were attributed each year to *E. coli* O157:H7 poisonings. The new estimate is closer to 100 deaths, said a CDC official. In the same vein, up to 1,000 deaths each year were linked to *Salmonella* infections. Now, CDC is finding closer to 500 people die each year from *Salmonella* infections. Some 2 million to 4 million people each year were estimated to suffer from salmonellosis, but the new estimate may be closer to 1.6 million, said the source.

FoodNet data are showing a "remarkable decline" in disease rates so far this year. Some of the decline may be linked to USDA's HACCP program, which went into effect in January. USDA is anxious for CDC to release this information, said the source. After six consecutive months, public health officials are seeing a dramatic reduction in certain foodborne illnesses.

— Joan Murphy



4-6/10

D R A F T

Media contact: Don Comis, (301) 504-1625,
dcomis@asrr.arsusda.gov
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jdequatt@asrr.arsusda.gov

RESEARCH TO PASTEURIZE MANURE FEATURED AT CHESAPEAKE BAY DAY

BELTSVILLE, Md., Sept. 22, 1999--Agricultural Research Service administrator Floyd P. Horn announced today the start of an experiment to see if pasteurization is an effective means of killing *E. Coli*, *Cryptosporidium parvum* and other pathogens possibly lurking in cow manure, to make sure it can be used safely to improve soils.

"N-Viro, International, of Toledo, Ohio, has loaned the U.S. Department of Agriculture patented equipment used to pasteurize biosolids--the solids remaining after wastewater treatment," Horn said. "The equipment turns the sludge into "N-Viro Soil," a product that meets the strictest federal standards for safe biosolids."

Horn said N-Viro moved the equipment—a vertical and horizontal silo with a manure hopper and mixing bins in between—to a composting facility at USDA's Beltsville (Maryland) Agricultural Research Center. He said the equipment mixes recycled materials like cement or lime kiln dust, coal ash from electric power plants, and gypsum with manure. A natural chemical reaction occurs when the lime or other high-calcium material hits the manure, creating heat, ammonia, and high pH that kill pathogens.

The equipment can be seen on a tour of the composting facility as part of the first Beltsville Chesapeake Bay Day activities on Sept. 28 at the research center, operated by ARS, USDA's chief scientific agency.

Horn said Patricia D. Millner, research leader of the Soil Microbial Systems Laboratory in Beltsville, has begun experiments to compare pasteurization with composting. Millner said she will assess each system for its ability to kill pathogens and control odor. She will also test a hybrid system that combines quicker composting with the pasteurization technique.

Millner said she wants to see if the pasteurization process will also convert phosphorus in manure to a form less likely to leach into streams and rivers. "We will also test the addition of materials such as alum residue from wastewater treatment plants for their ability to stabilize phosphorus in manure," she said.

Horn said if the experiment works it could help areas such as the Chesapeake Bay both by preventing the escape of pathogens and phosphorus and by providing a safe outlet for two materials found in excess in Chesapeake Bay coastal areas: high-phosphorus chicken litter and harbor dredging spoils.

"We will try pasteurizing chicken manure in a mixture of dredging spoils to convert the spoils into a substitute soil for reclamation of road cuts, stripmines, and other degraded soil sites



ANDY SOLOMON <ANDY.SOLOMON@usda.gov>

09/12/99 03:57:00 PM

Food Safety
E-coli

Record Type: Record

To: smith_ml@a1.eop.gov (Receipt Notification Requested) , Thomas L. Freedman/OPD/EOP,
Eric.Olsen@usda.gov (Receipt Notification Requested)

cc:

Subject: FYI...e coli testing

We released this at the end of the day Friday after it became clear that it had been leaked to a number of trade publications.....

GLICKMAN ANNOUNCES IMPROVEMENT IN TESTING FOR E. COLI O157:H7

WASHINGTON, Sept. 10, 1999 -- Agriculture Secretary Dan Glickman today announced that USDA's Food Safety and Inspection Service (FSIS) has begun using a more sensitive method for detecting E. coli O157:H7 in raw meat products. The new method is approximately four times more sensitive than previous methods, greatly increasing the probability of detecting very low levels of the potentially dangerous pathogen.

"This is another significant step forward in our continuing efforts to protect consumers from foodborne illness," said Glickman.

FSIS conducts E. coli O157:H7 tests on samples collected at federally-inspected plants that produce ground beef and at the approximately 100,000 retail outlets that grind beef on a regular basis. FSIS's testing program has also stimulated industry action to reduce the presence of the pathogen in ground beef. The new testing method, called "immunomagnetic separation" (IMS), will be incorporated into the standard procedures in use in all three FSIS field service laboratories.

E. coli O157:H7 can cause serious illness or death when consumed in contaminated foods. Water and a variety of foods can harbor the pathogen. Because consumers may not cook meat thoroughly enough to kill pathogens that have been introduced below the surface, FSIS has declared that raw ground beef and other non-intact raw beef contaminated with E. coli O157:H7 is adulterated. FSIS advises consumers to use a thermometer and cook ground beef to an internal temperature of 160 degrees F.

The IMS method begins after a screening test identifies a potentially positive sample. Antibody-coated magnetic beads recognize and capture E. coli O157:H7 cells in meat product enrichment broths. A magnetic device captures the beads after they bind to the pathogen. As a result, live E. coli O157:H7 cells are concentrated to facilitate growth and detection on special agar culture media. E. coli O157:H7 is then confirmed by standard FSIS procedures.

The test will be used effective immediately in FSIS' Athens, Ga., laboratory and will be incorporated at the other FSIS laboratories in Alameda, Calif., and St. Louis, Mo., as soon as the necessary equipment is in place. Until all laboratories are properly equipped, all E. coli O157:H7 tests will be conducted at the Athens laboratory.

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9-20-99 Marshall
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Balderson

UNITED!

RICULTURE

- Tom, EL + return
Tom, can we
do anything? For
- ✓
- **D** USDA's Economic Research Service released a detailed analysis of the financial impact of the Mid-Atlantic drought showing, relative to 1998, damage to commodity receipts of \$1.29 billion, \$315 million worse than previously expected. Additionally, the report shows a damage to net farm income of \$1.35 billion, \$230 worse than preliminary estimates. The estimated impacts on net income for the *extreme* and *severe* drought areas totaled over \$840 million alone, while many farm businesses in these areas were already experiencing cash flow problems resulting from unusually low commodity prices. In *severe* drought areas, the share of farms that generate insufficient income to repay debt is expected to more than double, from 8 percent in 1998, to 17 percent in 1999.
 - **Debt Collection:** For the first eight months of 1999, USDA collected \$100.8 million in delinquent debt through the Tax Refund Offset Program (TROP) and the Treasury Offset Program (TOP); a 30 percent increase over the \$77.7 million collected during the same period in 1998.
 - **Commodity Markets:** Wheat cash prices were supported by worries about late harvest in the Northern Plains, but futures were unchanged as traders focused on weakening export prospects. Corn cash prices rose along with soybeans, but the impending larger-than-expected harvest sent futures down. Soybean prices surged across the board on good exports, especially to Mexico and Asia. Rice cash prices were steady, but futures moved higher on prospects for smaller supply and a positive export sales report. Cotton prices rose sharply as USDA's latest production forecast was much lower than the trade expected. Cattle prices advanced in the face of strong retail demand. Declining wholesale carcass values helped send hog prices lower. Broiler prices slipped in the face of large supplies and tepid food service demand.

✓

E. coli: On September 13, Safe Tables Our Priority (S.T.O.P.) called on USDA and the cattle industry to adopt new measures to control E. coli. The food safety interest group recommended that research be made on prevention and eradication of the pathogen in animals; efforts be made to prevent slaughter of infected animals; USDA make mandatory the HACCP food inspection program from farm to the slaughter plant; that strict regulations be imposed on the use of manure as a fertilizer; and that USDA implement mandatory animal waste disposal programs.

cc: Reed
what
about
this
Re

DEPARTMENT OF COMMERCE

- **Small Manufacturers Summit:** On September 22, Secretary Daley will deliver remarks at a National Manufacturing Summit to be hosted by DOC's National Institute of Standards and Technology. The conference is being held as part of the Secretary's