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United States Department of Agriculture
Food Safety and Inspection Service

FAX

To: Morley Winograd

Fax #: 456-2830

Subject:

Date:

Pages: 16 including this cover sheet.

COMMENTS:

Some background materials and a tentative agenda for the March 23 presentation to NAS.

3/17

Jean Logan's FYSA,

Morley

cc: J. Rosenfeld

Tom Mondschein

From the desk of.....

Thomas J. Billy
Administrator
331-E Jamie L. Whitten Building
Washington, DC 20250

202-720-7025
or 720-8217
Fax 205-0158

Tel - 720-4150

United States Department of Agriculture | Agricultural Research Service | Office of the Administrator | Washington, D.C. 20250

March 12, 1998

Ms. Charlotte Kirk Baer
Senior Staff Officer, Board on Agriculture
Suite HA397
2001 Wisconsin Avenue, NW.
Washington, D.C. 20007

Dear Charlotte:

As discussed with you yesterday, a USDA group met on March 10 to coordinate our plans for the March 23 afternoon presentation to the NAS Committee to Ensure Safe Food from Production to Consumption. The following are our suggestions:

1. As study contract officer, I will provide opening remarks on expectations, but a 15-minute period should be sufficient. This picks up a little time on your original draft agenda.

2. The 30-minute time allotment for the overview of the President's Food Safety Initiative might be a little tight, given that there will be two spokespersons. We suggest this be increased to at least 40 minutes. This will allow 20 minutes each. Dr. Catherine Woteki, Under Secretary, Food Safety, plans to make this presentation on behalf of USDA.

3. For the USDA program reports on food safety, we propose a four-part presentation, starting with a USDA overview statement by Deputy Secretary Richard Rominger. This will require about 10 minutes. We are in the process of checking the availability of Mr. Rominger's calendar for this purpose. In the event he is not available, another USDA spokesperson TBD would make this presentation.

   This overview would be followed by three 20-minute presentations at the USDA Mission Area level: (1) Food Safety; (2) Research, Education, and Economics; and (3) Marketing and Regulatory Programs. The suggested spokespersons are:

   (1) Food Safety

   Mr. Tom Billy, Administrator, Food Safety and Inspection Service
   Room 331-E, Jamie Whitten Federal Building
   1400 Independence Avenue, SW.
   Washington, D.C. 20250 (202) 720-7025

   (2) Research, Education, and Economics (REE)

   Dr. Eileen Kennedy, Deputy Under Secretary, REE
   Room 217-W, Jamie Whitten Federal Building
   1400 Independence Avenue, SW.
   Washington, D.C. 20250 (202) 720-8885

Dr. Kennedy's presentation will cover USDA food safety research and education programs in the Agricultural Research Service (ARS); Cooperative State Research, Education, and Extension Service (CSREES); and the Economic Research Service (ERS).

(3) Marketing and Regulatory Programs (MRP)

Dr. Isi Siddiqui, Deputy Assistant Secretary, MRP
Room 228-W, Jamie Whitten Federal Building
1400 Independence Avenue, SW.
Washington, D.C. 20250 (202) 720-7813

Dr. Siddiqui's presentation will cover USDA food safety related programs in the Animal and Plant Health Inspection Service (APHIS), Agricultural Marketing Service (AMS), and the Grain Inspection and Packers Stockyard Administration (GIPSA).

Key staff persons from the individual USDA agencies will be in attendance to help address questions that arise and to be introduced to the panel for future reference and contact.

4. Regarding the membership of the study panel, USDA feels that a consumer organization should be represented. We are providing the following names for your consideration:

(1) Carol Tucker Foreman
Safe Food Coalition

(2) Caroline Smith Dewaal
Center for Science in the Public Interest

5. I will arrange to deliver to you by tomorrow copies of several relevant food safety documents for advance distribution to panel members.

I will be in continuing contact with you on these and other matters. In the meantime, let me know if additional input is needed.

Sincerely,

Ed Kinpling

EDWARD B. KNIPLING
Associate Administrator

FAX TRANSMISSION COVER SHEET

NATIONAL ACADEMY OF SCIENCES
COMMITTEE TO ENSURE SAFE FOOD FROM PRODUCTION TO CONSUMPTION
2101 Constitution Avenue, N.W. Washington, D.C. 20418

FOOD AND NUTRITION BOARD
INSTITUTE OF MEDICINE
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Allison A. Yates, PhD, RD
Study Director
ayates@nas.edu
202-334-1732 (phone)
202-334-2316 (fax)

NUMBER OF PAGES (including this page): 3

DATE: March 4, 1998

TO: Ed Knipling,
Assoc. Administrator,
USDA/ARS
FAX # 720-5427

COMMENTS:

Attached is a list of the agencies whose current programs in food safety we would like presented to the Committee at it's first meeting March 23-25. We'd like to schedule the open sessions during which such presentations can be made for the afternoon of the 23rd (between 1 and 5 pm) and the morning of the 24th. Please look over the list of agencies; we'd appreciate input regarding whether the individuals named or their designees are the most appropriate to provide this perspective, or whether others might be more appropriate for this initial background discussion. If there are other agencies or offices that we should include, please let me know.

Where question marks appear, we really don't have a good suggestion for who would be the most appropriate, so your help there would really be appreciated. Also, please don't feel that the time slots are fixed; once we start contacting the appropriate individuals about participating, I'm sure we'll have to make many modifications of who goes when.

Feel free to give me a call if you want additional information or would rather discuss the list in person.

Allison

Draft of Public Discussion, Meeting #1,
Committee to Ensure Safe Food from Production to Consumption

March 23,
Open Session:

1:00 pm Focus and Expectations of the Project
Edward Knipling, Associate Administrator, Agricultural Research Service
Contract Officer for the Committee to Ensure Safe Food from Production to Consumption

1:30 pm Congressional Expectations
Rep. Joe Skeen, R-2-NM
Rep. Vic Fazio, D-3-CA

2:30 pm President Clinton's Food Safety Initiative
Jim O'Hara, Dep. Asst. Secretary, DHHS
Cathie Woteki, Undersec. for Food Safety, USDA

3:00 pm Break

U.S. Department of Agriculture's Role in Ensuring Safe Food

3:20 pm Food Safety Inspection Service
Tom Billy, Administrator, FSIS
Questions

4:00 pm Agricultural Research Service
Ed Knipling, Assoc. Administrator, ARS
Questions

4:20 pm Cooperative State Research, Education, and Extension Service
??
Questions

4:40 pm Animal Plant and Health Inspection Service
??
Questions

March 24

Department of Health and Human Service's Role in Ensuring Safe Food

8:30 am	Food and Drug Administration *Michael A. Friedman, Lead Deputy Commissioner* Questions
9:15 am	Centers for Disease Control *Morris Potter* Questions

Other Agencies

9:40 am	Environmental Protection Agency's Role in Food Safety *Lynn Goldman, Asst. Admin., Office of Prevention, Pesticides, and Toxic Substances* Questions
10:00 am	Break
10:20 am	Office of Science and Technology Policy *Gerold Mande*
10:40 am	Executive Office of the President *Tom Freedman, Spec. Asst to the President for Policy Planning*
11:00 am	Review Statement of Task, Study Plan Input on Planning of Workshop on *Ensuring Safe Food* *John Bailar* Workshop Goals Suggestions for Speakers

NATIONAL ACADEMY OF SCIENCES
COMMITTEE TO ENSURE SAFE FOOD FROM PRODUCTION TO CONSUMPTION
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February 25, 1998

Edward B. Knipling
Associate Administrator
Agricultural Research Service
U.S. Department of Agriculture
Whitten Building, Room 302A
1400 Independence Avenue, SW
Washington, DC 20250

Dear Dr. Knipling,

I am pleased to provide you with the roster and biographical sketches for the members of the National Academy of Sciences' Committee to Ensure Safe Food from Production to Consumption (enclosed).

We have just set the first meeting of the Committee for March 23–25, and are now working on the agenda. As the program officer for this study, I'd like to invite you to meet with the Committee during an open session in order to discuss your understanding of the focus of the study and any comments you may wish to provide to the Committee.

We are in the process of asking some of the other federal agencies involved in food safety issues to name individuals who could provide information to the Committee on their agency's programs.

The new Federal Advisory Committee Act Amendment of 1997 that pertains to the committees of the National Academy of Sciences became effective December 17, 1997. Thus, we have modified some of our procedures accordingly. I have enclosed a description of the operating system, and the required posting of the committee for 20 days prior to finalizing the committee. Thus, the appointment process is not completed until after the first meeting.

I would like to invite you to suggest background materials regarding food safety that you think would be useful for the Committee to have. We have already provided the Committee with a copy of the President's Food Safety Initiative.

We will contact your office by the end of the week to determine a mutually convenient time for the committee to meet with you.

Thank you for your assistance in this endeavor.

Sincerely,

Allison A. Yates, Ph.D., R.D.
Study Director

c: M. Phillips
S. Schlicker
C. Kirk

NATIONAL ACADEMY OF SCIENCES

COMMITTEE TO ENSURE SAFE FOOD FROM PRODUCTION TO CONSUMPTION

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Committee Roster

John Christian Bailar III, M.D., Ph.D.
Chair
Department of Health Studies
The University of Chicago

Carole Ayres Bisogni, Ph.D.
Associate Director for Academic Affairs
and Associate Professor
Division of Nutritional Sciences
Cornell University
Ithaca, NY

David L. Call, Ph.D.
Professor Emeritus
Cornell University
Ithaca, NY

Marsha N. Cohen, J.D.
Professor of Law
Hastings College of the Law
University of California, San Francisco

Michael P. Doyle, Ph.D.
Professor and Director
Center for Food Safety and Quality
Enhancement
University of Georgia, Griffin

Lonnie J. King, D.V.M.
Professor and Dean
College of Veterinary Medicine
Michigan State University, East Lansing

Gilbert A. Leveille, Ph.D.
President
Leveille Associates
Denville, NJ

Richard A. Merrill, LL.B.
Daniel Caplin Professor of Law
University of Virginia School of Law
Charlottesville

Sanford A. Miller, Ph.D.
Professor and Dean
Graduate School of Biomedical Sciences
The University of Texas Health Science
Center at San Antonio

Harley William Moon, D.V.M., Ph.D.
F.K. Ramsey Chair in Veterinary Medicine
Veterinary Medical Research Institute
Iowa State University, Ames

Michael T. Osterholm, Ph.D.
State Epidemiologist and Chief
Acute Disease Epidemiology Section
Minnesota Department of Health
Minneapolis

Thomas D. Trautman, Ph.D.
Principal Scientist
Toxicology and Regulatory Affairs
General Mills
Minneapolis, MN

Staff
Allison A. Yates, Ph.D.
Study Director and Director, Food and
Nutrition Board

Sandra Schlicker, Ph.D.
Senior Staff Officer, Food and Nutrition Board

Charlotte L Kirk Baer, M.S.
Senior Staff Officer, Board on Agriculture

Biographical Sketches

Dr. John C. Bailar (IOM) is Chair of the Department of Health Studies at the University of Chicago. He received his M.D. from Yale University and his Ph.D. from American University. His research involves quantitative health risk assessment with emphasis on the erosion of standards for scientific inference, pressures causing this erosion, and the ways the pressures might be reduced and quality preserved. He retired from the Commissioned Corps of the Public Health Service in 1980, served as a Senior Scientist at the Environmental Protection Agency from 1980 to 1982 and the Department of Health and Human Service's Office of Disease Prevention and Health Promotion from 1983 to 1992. In 1989, Dr. Bailar became a Professor in the Department of Epidemiology and Biostatistics at McGill University and assumed his present position at the University of Chicago in 1996. He has served on numerous committees including those of the National Academy of Sciences, American Medical Association, American Statistical Association and the Society for Risk Analysis. In 1993, Dr. Bailar was elected to membership in the Institute of Medicine. A well-known lecturer on science and public policy, Dr. Bailer is the author of over 200 scientific publications.

Dr. Carole A. Bisogni is Associate Professor and Associate Director for Academic Affairs in the Division of Nutritional Sciences at Cornell University, where she also holds joint appointments in the Institute for Food Science and the Institute for Comparative and Environmental Toxicology. She received her Ph.D. in Foods, Nutrition, and Microbiology from Cornell University. Her research interests include consumer food choices, risk communication and public perceptions about food safety. She has published in scientific journals, written about food safety for the public, and worked with community nutritionists and other professionals in developing educational programs for adults and youth in different settings.

Dr. David L. Call is former dean of the College of Agriculture and Life Sciences at Cornell University. Throughout his career, Dr. Call's research has focused on analyses of government food and nutrition programs, identification and analysis of factors causing changes in nutrition and food consumption, and international economic and development issues. He has served on numerous national advisory panels including the National Advisory Committee to the Commissioner of the Food and Drug Administration, the Office of Technology Assessment Food Advisory Panel and the White House Conference on Food, Nutrition, and Health. Dr. Call is a former member of the Institute of Medicine's Food and Nutrition Board, the 1978 National Academy of Sciences Committee for a Study on Food Safety and Food Safety Policy, and former chair of the National Academy of Sciences Committee on Technological Options to Improve the Nutritional Attributes of Animal Products. Having served as a member of the national level Board of Trustees for the Food Safety Council from 1979 through 1982, he has addressed food safety issues for many years. He has served at the state and local level on numerous commissions dealing with social and economic aspects of food and nutrition priorities. Dr. Call received his B.S., M.S., and Ph.D. degrees in agricultural economics from Cornell University and has published widely on food systems and consumer issues. He is currently a Director of The Seneca Foods Corporation and a Trustee of The Mutual of New York Insurance Company.

Marsha N. Cohen is Professor of Law at Hastings College of The Law University of California, where she has been since 1976. She received her undergraduate degree from Smith College and a J.D. from Harvard Law School. Professor Cohen teaches courses in Administrative Laws and Torts. She represents the interest of consumers on the Institute of Medicine's Food Forum and was a member of its Committee on State Food Labeling. Presently, she is a consultant to the Food Advisory Committee of the Food and Drug Administration and has consulted extensively on food safety issues for Consumers Union. Professor Cohen was a member of the Keystone National Policy Dialogue on Food, Nutrition, and Health.

Dr. Michael P. Doyle is Professor of Food Microbiology, Director of the Center for Food Safety and Quality Enhancement, and Head of the Department of Food Science and Technology at the University of Georgia. He is an active researcher in the area of foodborne bacterial pathogens and works closely with the food industry on issues related to the microbiological safety of foods. Dr. Doyle's research focuses on the study of the mechanisms of pathogenicity, the development of methods for pathogen detection, and the identification of means to control or eliminate pathogens from foods. He received his Ph.D. in food microbiology from the University of Wisconsin. He was with Ralston Purina Company from 1977 to 1980 and on the faculty at the University of Wisconsin from 1980 until 1991. He is a currently a member of the Institute of Medicine's Food Forum and is a past member of the Food and Nutrition Board and Board on Agriculture's Panel on Animal Health and Veterinary Medicine. He has published more than 200 scientific articles including editor of two authoritative books, *Foodborne Bacterial Pathogens* and *Food Microbiology: Fundamentals and Frontiers*.

Dr. Lonnie King is currently Dean of the College of Veterinary Medicine at Michigan State University. He was administrator of the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture from 1992 to 1996. Before beginning his government career in 1977, Dr. King was in private veterinary practice for seven years in Dayton, OH and Atlanta, GA. Until joining APHIS, his experiences have included field veterinary medical officer in Georgia and station epidemiologist in Texas. He spent five years in Hyattsville, Maryland in staff assignments in Emergency Programs as well as Animal Health Information. While in Hyattsville, Dr. King directed the development of the Agency's National Animal Health Monitoring System. He left APHIS briefly to serve as the Director of the Governmental Relations Division of the American Veterinary Medical Association. From 1988 to 1991, Dr. King was the deputy administrator for APHIS Veterinary Services. He received his B.S. and his D.V.M. from Ohio State University. He also holds an M.S. in epidemiology from the University of Minnesota and an M.S. in public administration from American University.

Dr. Gilbert A. Leveille recently retired from his position as Vice President, Research & Technical Services with Nabisco, Inc. where he was responsible for fundamental science, analytical services, and extrusion research. He received his Ph.D. from Rutgers University. Previously, Dr. Leveille was Professor and Chairman of the Department of Food Science and Human Nutrition at Michigan State University and was Director of Nutrition and Health Sciences at General Foods Corporation. He is a past president of the Institute of Food Technologists and of the American Institute of Nutrition and is a member of numerous other professional organizations. Dr. Leveille lectures widely and has published over 300 scientific papers and several books.

Richard A. Merrill (IOM) is Daniel Caplin Professor of Law at the University of Virginia School of Law, where he has been since 1969 and is Special Counsel to the Washington, D.C. law firm of Covington & Burling. Professor Merrill earned his A.B. at Columbia College and his LL.B. at Columbia University School of Law. He also received a B.A. and M.A. from Oxford University where he was a Rhodes Scholar. From 1975 to 1977, he was Chief Counsel of the Food and Drug Administration. Professor Merrill teaches courses in Food and Drug Law, Administrative Law, and Environmental Law. He has served as a member of several committees of the National Academy of Sciences and was elected to membership in its Institute of Medicine in 1978. He has been a consultant to the former Office of Technology Assessment of the Congress and the White House Office of Science and Technology Policy. Professor Merrill is a fellow of the American Law Institute and the Virginia Law Foundation and serves on the board of numerous law foundations. He is the author of law school texts, as well as numerous articles on Food and Drug Law and Administrative Law.

Dr. Sanford A. Miller is Dean of the Graduate School of the Biomedical Sciences and Professor in the Departments of Biochemistry and Medicine at the University of Texas Health Science Center at San Antonio. He is the former Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration. Previously, he was a Professor of Nutritional Biochemistry at the Massachusetts Institute of Technology. Dr. Miller has served on many national and international government and professional society advisory committees, including the Federation of American Societies for Experimental Biology Expert Committee on GRAS Substances, the National Advisory Environmental Health Sciences Council of NIH, the Institute of Medicine's Food and Nutrition Board and Food Forum, the Joint FAO/WHO Expert Advisory Panel on Food Safety (Chair), and the Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standard Issues (Chair). He has received many honors including the Esther Peterson Consumer Service Award from the Food Marketing Institute and the Atwater Memorial Lectureship Award from the U.S. Department of Agriculture and the Institute of Food Technologists. He has authored over 200 scientific publications. Dr. Miller received his M.S. and Ph.D. from Rutgers University in Physiology and Biochemistry.

Dr. Harley Moon (NAS) is F.K. Ramsey Chair of Veterinary Medicine at Iowa State University. He has been a member of the National Academy of Science since 1991. Dr. Moon is most widely recognized for his contributions to the basic understanding of intestinal diseases of human and animals. His expertise includes the development of vaccines for preventing *E. coli* infection in farm animals, livestock disease eradication, infectious diseases affecting humans and animals, and prevention of edema disease in swine with genetically-modified vaccines. Dr. Moon has served on numerous advisory committees including the World Health Organization's Expert Panel on enteropathogenic *E. coli* and Working Group on Immunology and Vaccine Development for Bacterial Enteric Infections, the Department of Agriculture's Task Force on Scrapie and Bovine Spongioform Encephalopathy, Pioneer Hi-Bred International's Institutional Biosafety Committee, and the Council for Agricultural Science and Technology Task Force on Antibiotics in Animal Feeds. His scientific publications number in excess of 200, with numerous book chapters on aspects of infectious disease. Prior to his current position, Moon was director of the Plum Island and National Animal Disease Centers, ARS/USDA, and professor in the Department of Veterinary Pathology at Ohio State University. He received his B.S., D.V.M., and Ph.D at the University of Minnesota.

Dr. Michael T. Osterholm is State Epidemiologist and Chief, Acute Disease Epidemiology Section, Minnesota Department of Health. He is also an adjunct professor in the Division of Epidemiology, School of Public Health, University of Minnesota. Dr. Osterholm is considered a leader in the area of infectious disease epidemiology. He has led numerous investigations of infectious disease outbreaks, including foodborne diseases and is the author of more than 150 papers and 12 book chapters regarding infectious disease epidemiology. Dr. Osterholm is past president of the Council of State and Territorial Epidemiologists. He participates in the NAS IOM Forum on Emerging Infectious Diseases and recently served on the CDC Board of Scientific Counselor. He chairs the Committee on Public Health and serves on the Public and Scientific Affairs Board, the Task Force on Biological Weapons, and the Task Force on Antibiotic Resistance of ASM. Dr. Osterholm is a frequent consultant to NIH, FDA, CDC and currently serves as a principal investigator of CDC's Emerging Infections Program.

Dr. Thomas D. Trautman is Principal Scientist, Toxicology and Regulatory Affairs for General Mills, where he has been for nearly 20 years. He received his Ph.D. in Comparative Pharmacology and Toxicology from the University of California at Davis. Dr. Trautman has been actively involved in food industry efforts to address numerous food safety and regulatory issues including: the safety of food and color additives, pesticide residues, food allergy, packaging and other indirect additives, and various aspects of current and emerging risk assessment methodologies. He is a Diplomate of the American Board of Toxicology and is Vice-Chair of the Food Safety Section of the Society of Toxicology. Dr. Trautman is a former member of the National Academy of Sciences Board on Agriculture, is a member and former Chair of the Toxicology and Safety Evaluation Division of the Institute of Food Technologists, and was the founding Chair of the Residence Committee of the International Life Sciences Institute.

HR 2977 RDS

105th CONGRESS
1st Session
IN THE SENATE OF THE UNITED STATES
November 10, 1997

AN ACT

To amend the Federal Advisory Committee Act to clarify public disclosure requirements that are applicable to the National Academy of Sciences and the National Academy of Public Administration.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE

This Act may be cited as the "Federal Advisory Committee Act Amendments of 1997."

SECTION 2. AMENDMENTS TO THE FEDERAL ADVISORY COMMITTEE ACT

(a) EXCLUSIONS FROM DEFINITION
Section 3(2) of the Federal Advisory Committee Act (5 U.S.C. App.) is amended in the matter following subparagraph (C), by striking "such term excludes" and all that follows through the period and inserting the following: "such term excludes
(i) any committee that is composed wholly of full-time, or permanent part-time, officers or employees of the Federal Government, and
(ii) any committee that is created by the National Academy of Sciences or the National Academy of Public Administration."

(b) REQUIREMENTS RELATING TO THE NATIONAL ACADEMY OF SCIENCES AND THE NATIONAL ACADEMY OF PUBLIC ADMINISTRATION
Such Act is further amended by redesignating section 15 as section 16 and inserting after section 14 the following new section:

REQUIREMENTS RELATING TO THE NATIONAL ACADEMY OF SCIENCES AND THE NATIONAL ACADEMY OF PUBLIC ADMINISTRATION"
SEC. 15.
(a) IN GENERAL
An agency may not use any advice or recommendation provided by the National Academy of Sciences or National Academy of Public Administration that was developed by use of a committee created by that academy under an agreement with an agency, unless
(1) the committee was not subject to any actual management or control by an agency or an officer of the Federal Government;

(2) in the case of a committee created after the date of the enactment of the Federal Advisory Committee Act Amendments of 1997, the membership of the committee was appointed in accordance with the requirements described in subsection (b)(1); and

(3) in developing the advice or recommendation, the academy complied with

(A) subsection (b)(2) through (6), in the case of any advice or recommendation provided by the National Academy of Sciences; or

(B) subsection (b)(2) and (5), in the case of any advice or recommendation provided by the National Academy of Public Administration.

(b) REQUIREMENTS

The requirements referred to in subsection (a) are as follows:

(1) The Academy shall determine and provide public notice of the names and brief biographies of individuals that the Academy appoints or intends to appoint to serve on the committee. The Academy shall determine and provide a reasonable opportunity for the public to comment on such appointments before they are made or, if the Academy determines such prior comment is not practicable, in the period immediately following the appointments. The Academy shall make its best efforts to ensure that

(A) no individual appointed to serve on the committee has a conflict of interest that is relevant to the functions to be performed, unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable,

(B) the committee membership is fairly balanced as determined by the Academy to be appropriate for the functions to be performed, and

(C) the final report of the Academy will be the result of the Academy's independent judgment. The Academy shall require that individuals that the Academy appoints or intends to appoint to serve on the committee inform the Academy of the individual's conflicts of interest that are relevant to the functions to be performed.

(2) The Academy shall determine and provide public notice of committee meetings that will be open to the public.

(3) The Academy shall ensure that meetings of the committee to gather data from individuals who are not officials, agents, or employees of the Academy are open to the public, unless the Academy determines that a meeting would disclose matters described in section 552(b) of title 5, United States Code. The Academy shall make available to the public, at reasonable charge if appropriate, written materials presented to the committee by individuals who are not officials, agents, or employees of the Academy, unless the Academy determines that making material available would disclose matters described in that section.

(4) The Academy shall make available to the public as soon as practicable, at reasonable charge if appropriate, a brief summary of any committee meeting that is not a data gathering meeting, unless the Academy determines that the summary would disclose matters described in section 552(b) of title 5, United States Code. The summary shall identify the committee members present, the topics discussed, materials made available to the committee, and such other matters that the Academy determines should be included.

(5) The Academy shall make available to the public its final report, at reasonable charge if appropriate, unless the Academy determines that the report would disclose matters described in section 552(b) of title 5, United States Code. If the Academy determines that the report would disclose matters described in that section, the Academy shall make public an abbreviated version of the report that does not disclose those matters.

(6) After publication of the final report, the Academy shall make publicly available the names of the principal reviewers who reviewed the report in draft form and who are not officials, agents, or employees of the Academy.

(c) REGULATIONS
The Administrator of General Services may issue regulations implementing this section."

(c) EFFECTIVE DATE AND APPLICATION

(1) IN GENERAL
Except as provided in paragraph (2), this section and the amendments made by this section shall take effect on the date of the enactment of this Act.

(2) RETROACTIVE EFFECT
Subsection (a) and the amendments made by subsection (a) shall be effective as of October 6, 1972, except that they shall not apply with respect to or otherwise affect any particular advice or recommendations that are subject to any judicial action filed before the date of the enactment of this Act.

SECTION 3. REPORT.

Not later than 1 year after the date of the enactment of this Act, the Administrator of General Services shall submit a report to the Congress on the implementation of and compliance with the amendments made by this Act.

Passed the House of Representatives November 10 (legislative day, November 9), 1997.
Attest: Robin H. Carle, Clerk.

United States Department of Agriculture
Food Safety and Inspection Service

FAX

To: Morley Winograd

Fax #:

Subject:

Date:

Pages: 12 **including this cover sheet.**

COMMENTS:

Current thinking on presentations from USDA.

Tony

From the desk of.....

Thomas J. Billy
Administrator
331-E Jamie L. Whitten Building
Washington, DC 20250

202-720-7025
or 720-8217
Fax 205-0158

1 Food Safety and Inspection Service
U.S. Department of Agriculture
Thomas J. Billy, Administrator

2 FSIS Responsibilities
- Ensure the safety of meat, poultry and egg products
- Legal authority
  - Federal Meat Inspection Act
  - Poultry Products Inspection Act
  - Egg Products Inspection Act

3 Foodborne Illness--the Problem
- Meat, poultry and egg products are high-risk foods
- 5 million illnesses and 4,000 deaths attributed to meat and poultry products each year
- Traditional FSIS food safety program did not adequately address microbiological hazards

4 Most Common Pathogens
- *Campylobacter jejuni/coli*
- *Salmonella*
- *E. coli* O157:H7
- *Listeria monocytogenes*

5 FSIS Activities
- Set food safety standards
- Domestic and import inspection
- Emergency response and epidemiological investigations
- Enforcement
- Food safety education

6 Set food safety standards
- Microbiological
- Facilities and equipment
- Labeling

7 Inspection
- Domestic
  - 6,500 Federal plants and 2,550 State plants
  - Inspect 137 million livestock and 8 billion birds each year
  - Inspect allied industries
- International
  - Review foreign inspection programs for equivalence

- Point-of entry inspection

8 Emergency response and epidemiological investigations
- Retention, detention, or voluntary recall
- Investigate reports of foodborne hazards and disease outbreaks

9 Enforcement
- Withhold inspection from adulterated product
- Suspend inspection if process not under control
- Withdraw inspection if plant does not adequately address problem

10 Food Safety Education
- Ensure safe handling of meat, poultry, and egg products by food handlers
- Farm-to-table food safety education

11 Strategy for Change
- Began in 1994
- Expert studies guided strategy
  - NAS report on meat and poultry inspection--1985
  - NAS report on poultry inspection--1987

12 Strategy for Change--Elements
- Reorganization
- Inspection modernization
- Improved public health focus
- Regulatory reform
- Farm-to-table food safety

13 Reorganization
- Streamlined management structure
- Consolidated field force
- Increased public health focus
- Increased focus on policy, rulemaking, and program development

14 Inspection Modernization
- Pathogen Reduction and HACCP final rule
  - HACCP
  - Performance standards for *Salmonella*
  - Standard operating procedures for sanitation
  - Testing for generic *E. coli*

15 Improved public health focus
- Reorganization created Office of Public Health and Science
- Heightened focus on pathogens, including emerging
- FoodNet active surveillance network

- Improved emergency response system
- Greater reliance on epidemiology and risk assessment

16 ☐ Regulatory Reform

- Review of existing regulations-1996
- Goal is to revise regulations
  - Consistent with HACCP
  - Performance standards
  - Remove unnecessary regulatory obstacles to innovation
- Accomplishments
  - Eliminate prior approval for facility blueprints, equipment, and PQC plans
  - Proposal to merge sanitation regulations for meat and poultry
  - Proposal to amend standards of identity

17 ☐ Farm-to-table food safety

- Animal production
- Transportation
- Retail
- Consumer

18 ☐ Partnerships

- Federal, State, local government
- Industry
- Consumer

19 ☐ Research

- Guide and support research addressing public health needs
- Food Safety Research Agenda--1997

20 ☐ Future Directions

- Complete HACCP implementation
- Redeploying resources
- Farm-to-table food safety
- Risk assessment

Agricultural Research Service

FAX

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To:	Joan Mondschein, FSIS Bill Franks, AMS Craig Reed	**Date:**	March 17, 1998
Fax #:	690-0550 720-6496 720-3054	**Pages:**	7, including this cover sheet.
From:	Edward B. Knipling		
Subject:	NAS Food Safety Meeting		

COMMENTS:

These are draft overheads for the REE part of the food safety briefing to the NAS Committee. They may be useful as a model for preparing something similar for the Food Safety and MRP mission areas presentations.

Enclosures

cc:
Jeff Becker, MRP (720-5775)

David Knipling

U. S. DEPARTMENT OF AGRICULTURE

Research, Education, and Economics (REE) Mission Area

- **Agricultural Research Service (ARS)**
- **Cooperative State Research, Education, and Extension Service (CSREES)**
- **Economic Research Service (ERS)**
- **National Agricultural Statistics Service (NASS)**

REE FOOD SAFETY PROGRAMS AND BUDGETS

	FY 1998	Proposed FY 1999
• Research (ARS and CSREES)	$ 56.6 M	$ +17.8 M
• Risk Assessment (ARS, CSREES, and ERS)	4.7 M	+2.8 M
• Education (CSREES and ERS)	2.8 M	+5.0 M
Total	$ 64.1 M	$ +25.6 M

REE FOOD SAFETY RESEARCH (FY 1998)

- **ARS ($50.4 M)**
  - **Microbial Pathogen Reduction**
  - **Mycotoxins**
  - **Chemical Residues**
  - **Poisonous Plants**
- **CSREES ($6.2 M)**
  - **Formula Funds to Land Grant Universities**
  - **Competitive Funds (National Research Initiative)**
  - **Special Grants**

REE PATHOGEN REDUCTION RESEARCH APPROACHES (ARS and CSREES)

- **Multiple Microbial Pathogens**
- **Multiple Commodities (Meat, Poultry, Fruits, Vegetables)**
- **Pre- and Post-Harvest**
- **Diagnostic Methods**
- **Microbial Biology/Ecology/Etiology/Epidemiology**
- **Interventions**
- **Pathogen Resistance to Treatments**

REE FOOD SAFETY RISK ASSESSMENT (FY 1998)

- **ARS ($4.5 M)**
  - **Evaluate Pathogen Reduction Strategies**
  - **Develop Pathogen Growth and Survival Models**
  - **Improve Modeling Techniques**
  - **Collect Baseline Data (e.g., Food Consumption Surveys)**
- **CSREES ($150 K)**
  -
  -
- **ERS ($33 K)**
  - **Evaluate Costs/Benefits of Alternative Pathogen Control Strategies**
  -

REE FOOD SAFETY EDUCATION (FY 1998)

- **CSREES ($2.4 M)**
  - **Consumer Education**
  - **Retail Sector Outreach via Land Grant Universities**
- **ERS ($420 K)**
  -
  -

NATIONAL COMMISSION ON THE FUTURE OF FEDERAL FOOD SAFETY REGULATION

BACKGROUND

Federal regulatory oversight that is effective and credible in ensuring the safety, wholesomeness and proper labeling of food is important to public health, to public confidence in the food supply, and to the strong competitive position of the U.S. food industry in world markets. Progress has been made recently toward needed modernization of the current system with the establishment of HACCP (Hazard Analysis and Critical Control Points) as the conceptual framework for the Federal government's food safety program: HACCP requirements are being implemented for meat, poultry, and seafood and under consideration for other segments of the food supply.

The major remaining obstacle to the long term success of the Federal program is maintaining the capabilities and credibility of the food safety agencies themselves in the face of enormous pressure to reduce Federal spending. The capabilities and successful functioning of the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) are especially important in three areas: (a) providing sufficient and effective inspection oversight of HACCP and other regulatory requirements; (2) identifying and understanding food safety hazards and setting scientifically and technically sound food safety performance standards to address the significant hazards; and (3) encouraging and effectively overseeing the introduction of new food technologies that can improve the safety, nutritional quality, convenience, and economy of the food supply.

PROPOSAL

Establish a Congressionally-chartered National Commission to define the current and future needs of the Federal food regulatory system in the three key areas of inspection, scientific and technical infrastructure, and technology transfer and to make recommendations regarding legislative, administrative, organizational and funding changes required to meet those needs.

COMMISSION MEMBERSHIP

The membership of the National Commission would include leaders from business, government, the scientific and public health communities, and consumer and public interest organizations. Members would be appointed by the President on the basis of nominations made by the leadership of both houses of Congress and the Secretaries of Agriculture and Health and Human Services. The National Commission would be chaired by a person of independent national stature and credibility and with experience germane to the topics of food safety and public administration.

QUESTIONS TO BE ADDRESSED

Among the questions the Commission would be expected to address are:

(1) Inspection: What is the appropriate objective, manner and frequency of Federal food safety inspection? What is the appropriate relationship among the FDA, FSIS, state and local inspection programs? What are the acceptable alternatives, if any, to the inspectional oversight provided by government inspectors?

(2) Scientific and Technical Infrastructure: What scientific and technical capabilities should the Federal food safety agencies have to do their jobs? What are the current shortfalls, if any, in the current scientific and technical capabilities of the agencies? How should those shortfalls be addressed?

(3) Technology Transfer: What is the appropriate role of the Federal agencies in encouraging and overseeing the introduction of new food technologies? What are the current obstacles to technology transfer? What changes are required to address these obstacles?

The Commission would be expected to recommend specific changes in current legislative authorities, administrative practices, and organizational structure required to meet current and future needs regarding inspection, scientific infrastructure and technology transfer. The Commission would also identify the financial and human resources required by the Federal agencies to carry out their roles and present options for financing the agencies through appropriated funds, user fees, or some combination of financing measures.

RESOURCES AND TIMETABLE

The National Commission would be funded jointly by the U.S. Department of Agriculture and the Department of Health and Human Services. The two departments would support the Commission's work by providing staff support and such data, information and analyses as the Commission may request. The Commission would also solicit input from interest groups and the general public through public hearings and other means. The Commission would submit its report and recommendations to the President and Congress by December 1998

Partial Listing of Outbreaks Traced to FDA-Regulated Foods, 1990-1997

	Date	Vehicle	Etiology	Reported Cases	States/ Provinces
1	1990	Cantaloupe	Salmonella chester	245	30
2	1990	Tomatoes	Salmonella javiana	174	4
3	1990	Strawberries	Hepatitis A	18	2
4	Nov. 1991	Apple cider	E. coli O157:H7	23	1: MA
5	1991	Cantaloupe	Salmonella poona	>400	23
6	1992	Oysters	Norwalk virus	250	Not available
7	1993	Oysters	Norwalk-like virus	27	1: NC
8	1993	Apple cider	Cryptosporidia	213	1: ME
9	1993	Tomatoes	Salmonella montevideo	84	3
10	1994	Scallions	Shigella flexneri	72	2
11	Feb.-May 1994	Milk	E. coli O104:H21	19	1: MT
12	April 1994	Potatoes	Clostridium botulinum	29	1: TX
13	June 1994	Clam chowder	Clostridium botulinum	2	1: CA
14	July-Dec. 1994	Ice cream	Salmonella enteritidis	593	41
15	Fall 1994	Potato salad (unconfirmed)	Listeria monocytogenes	Not available	12
16	Sept. 1994	Bean dip	Clostridium botulinum	1	1: CA
17	Jan. 1995	Oysters	Norwalk-like virus	44	3: FL, TX, GA
18	Mar.-July 1995	Alfalfa sprouts	Salmonella stanley	242	17/ Finland
19	May-June 1995	Orange juice	Salmonella hartford	63	21
20	July 1995	Lettuce (leafy green, red, romaine)	E. coli O157:H7	70	1: MT
21	Sept. 1995	Lettuce (romaine)	E. coli O157:H7	20	1: ID
22	Sept. 1995	Lettuce (iceberg)	E. coli O157:H7	30	1: ME
23	Oct. 1995	Lettuce (iceberg)	E. coli O157:H7	11	1: OH
24	Jan.-Feb. 1996	Oysters	Not available	71	Not available
25	May-June 1996	Lettuce (mesclun)	E. coli O157:H7	18	1: CT
26	May-June 1996	Lettuce (red leaf)	E. coli O157:H7	27	1: IL
27	May-June 1996	Raspberries	Cyclospora cayetanensis	1465	21/2: ON, QUE
28	Fall 1996	Apple cider	E. coli O157:H7	6	1: WA

Compiled by CSPI
Updated August 22, 1997

Partial Listing of Outbreaks Traced to FDA-Regulated Foods, 1990-1997
Page 2

	Date	Vehicle	Etiology	Reported Cases	States/ Provinces
29	Sept. 1996	Eggs	Salmonella enteritidis	250	1: SC
30	Sept.-Oct. 1996	Apple cider	Cryptosporidia	31	1: NY
31	Oct. 1996	Apple cider	E. coli O157:H7	14	1: CT
32	Oct. 1996	Apple juice	E. coli O157:H7	66	3: WA, CA, CO/ 1: BC
33	Jan. 1997	Oysters	Norwalk virus	432	5
34	Mar.-April 1997	Strawberries	Hepatitis A	236	1: MI
35	Mar.-June 1997	Raspberries; Lettuce (mesclun)	Cyclospora	1450	8/ 1: ON
36	June -July 1997	Basil	Cyclospora	260	3: MD, DC, VA
37	June-July 1997	Alfalfa sprouts	E. coli O157:H7	70	2: VA, MI

Compiled by CSPI
Updated August 22, 1997

CSPI Center for Science in the Public Interest

Publisher of *Nutrition Action Healthletter*

Date: 5/7

Time: 5pm

FAX COVER SHEET

TO: Jerry Mand

Company: Domestic Policy Council

Fax Number: 456-6027 Phone Number:

Total Number of pages INCLUDING this cover sheet: 9

SENDER: Sherry Farr for Caroline Smith DeWaal

SENDER'S Phone Number: X361

SUBJECT: NAS letter, Bailar letter,

COMMENTS: Suggested question for NAS

-Faxed again in order - Sorry.

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Congress of the United States

House of Representatives

Washington, DC 20515–0503

April 17, 1998

Dr. Allison Yates
National Academy of Sciences
Committee to Ensure Safe Food From Production to Consumption
2101 Constitution Avenue, N.W.
Washington, D.C. 20418

Dear Dr. Yates:

Thank you for the invitation to attend the initial meeting of the Committee to Ensure Safe Food from Production to Consumption. Although I was unable to attend, I have some comments to pass on to the committee to help understand congressional intent. As the chief proponent of the study and the inclusion of funds in the Agriculture Appropriations Act for FY '98, I have a personal interest in seeing that your committee make recommendations that will be useful to Congress in deciding food safety related policy questions.

I have to express concern from the outset at the composition of the panel. My preference would have been a panel comprised of members, in addition to representing academic and scientific backgrounds, with significant experience with the operation of the regulatory food safety system. I believe there were outstanding candidates recommended to you representing both affected industries as well as consumer-oriented groups who possessed real world experience with the regulatory system. In my view, representatives from those groups combined with panel members with strong academic backgrounds would have strengthened the panel.

Because of the composition of the panel as determined by NAS, I believe it will be a real challenge to understand the complexity of the existing system well enough to make useful recommendations. I especially urge you not to get bogged down by overly focusing on scientific questions. Two of your task statements are: "determine the scientific basis of an effective food safety system," and "identify scientific needs and gaps within the current system." Those questions are important, but Congress is particularly interested in recommendations that can translate any scientific-based findings into changes that will make the regulatory structure more effective. Our conference report language specifically poses the question of "which current functions" ... "should be assigned or reassigned to existing food safety agencies or an independent food safety agency." With the exception of a vague reference to "organizational changes," I find this important question missing from your Statement of Task, and I challenge you not to overlook it.

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FAX TRANSMITTAL FROM

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I am also concerned that your upcoming public meeting contain balanced viewpoints. Certainly feedback from groups affected by food safety issues is important. But the congressional need is that you translate such feedback and analysis into recommendations about the current regulatory and agency framework. Having balanced input from federal and state regulators would seem to be one of the highest needs in your composition of any public forums.

A great deal of interest has been generated by the initiation of this study, and Congress is eagerly awaiting your recommendations. The Committee's consideration of a possible two-phase study was based on feedback from NAS personnel and assurances given that the first phase of the study could be completed by August 15. As one of your champions, I urge you move forward accordingly.

Sincerely,

Vic Fazio

VIC FAZIO
Member of Congress

VF/ml

See last page. I typed this part of his letter over.

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Sincerely,

VIC FAZIO
Member of Congress

RICHARD J. DURBIN
ILLINOIS

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March 27, 1998

John Christian Bailar, M.D., Ph.D.
Chairman, Department of Health Studies
The University of Chicago
5841 South Maryland Ave.
MC 2007
Chicago, Illinois 60637-1470

Dear Dr. Bailar:

I understand that the National Academy of Sciences Committee to Ensure Safe Food From Production to Consumption held its first meeting this week to address the scientific and organizational needs for an effective food safety system. As the Committee undertakes this important study of the current mechanisms in place for assuring a safe food supply, I want to convey my support for this important undertaking.

Also, I would like to congratulate you on your recent appointment as Chairman of this Academy Committee. Professionally, it is a great honor that you have been selected to chair this prestigious Committee, and is a testimony to the excellence of the system of higher education in Illinois.

As you may be aware, I have introduced legislation -- The Safe Food Act (S. 1465) -- to replace the current fragmented federal food safety system with a consolidated, independent agency with responsibility for all federal food safety activities. This legislation would empower a single, independent agency to enforce food safety regulations from farm to table as well as better coordinate research and facilitate the implementation of new technologies.

Make no mistake, our country has been blessed with the safest and most abundant food supply in the world. However, we can do better. I commend the Committee in its efforts to serve the American people through the assessment of the current system for food safety from production to consumption.

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MAY 07 '98 12:04PM US SEN DICK DURBIN P.3/3

Enclosed is a list of questions which focuses on the scientific, budgetary, organizational and jurisdictional issues which the Academy Committee will be addressing. I would like the Committee to take these questions into consideration as it proceeds with its study. I would be happy to meet with you in Washington or Chicago to discuss the Committee's work in more detail.

Sincerely,

Richard J. Durbin
U.S. Senator

Enclosure

RJD:km

Suggested Questions for the NAS Committee on Ensuring Safe Food From Production to Consumption

General

What is the role of the federal government in reducing the risk of foodborne illness?

Are we spending our current federal resources in a manner to maximize achievement of our public health goals?

Is the current organizational structure a barrier to making the best possible use of resources?

What is the experience of states or foreign governments who have unified food safety functions in a single agency?

Organizational

Does the current organizational structure help or hinder the government's ability to devise effective strategies to reduce the risk of foodborne illness associated with *E. coli* O157:H7 throughout the food supply, *Salmonella enteritidis* in eggs, dioxin in animal feed, and other unaddressed or emerging food safety issues?

Does the current organizational structure help or hinder the government's ability to allocate inspection and other resources on the basis of risk and in a manner that will maximize their contribution to reducing the risk of foodborne illness?

Does the current organizational structure help or hinder the approval of new food safety technologies?

Budget and Strategic Planning

Does the current organizational structure help or hinder the federal government's ability to contain costs while improving the delivery of safe food products to the US consumer?

How are resources allocated among the food safety agencies and among key functions, including research; policy development and standard setting; inspection, compliance and enforcement; retail food safety; food safety education; international affairs; and overhead (administrative and management support)?

How do the food safety agencies, including CDC and the research agencies, coordinate budget development to ensure optimal use of the federal government's food safety resources?

Do any mechanisms exist to formulate strategic objectives for the federal food safety programs and ensure that the objectives are systematically pursued by the agencies?

Risk Reduction and Standard Setting

What is the government's risk reduction goal? What should it be?

What role does risk assessment play in priority setting, resource allocation, and management of the food safety programs? What role should it play?

Who is in charge of food safety risk assessment in the federal government, including research, methods development, and consistency among the agencies?

What is the government's strategy for reducing the risk of foodborne illness associated with *E. coli* O157:H7 in beef, produce, and fruit juice? What agencies are involved? Who is in charge? Who is responsible for attacking the problem at its source in the gut of cattle?

What is the government's strategy for reducing the risk of foodborne illness associated with *Salmonella enteriditis* in eggs? What agencies are involved? Who is in charge? Who is responsible for attacking the problem at is source in the henhouse?

Statutory

What are the differences in food safety-related statutory authority among FDA, FSIS, and EPA? Are they justified from a public health perspective?

Do the current statutory requirements impede risk-based decision making and resource allocation?

Inspection

Are the differences between FDA and FSIS inspection programs justified from a public health perspective? How is this determined?

Does the current organizational structure present obstacles to allocating inspection resources based on risk?

Outbreak Management

What mechanisms exist to coordinate outbreak management among the federal and state agencies? Are they adequate?

Who is in charge of an outbreak investigation when the food source is unknown? What role do FDA and USDA play in an outbreak investigation when the food source is unknown?

Who is in charge of outbreak communications?

International

What mechanisms exist to coordinate oversight of imported food? Are import inspection resources adequate? Are they allocated optimally on the basis of risk?

Are the differences between the FDA and FSIS import inspection programs justified in terms of public health?

Who is responsible for determining U.S. policy on international issues affecting food safety, such as the meaning of equivalence under the SPS Agreement with respect to inspection and HACCP implementation?

What political level official is responsible for U.S. strategy and policy concerning Codex standards setting?

Research

What resources are currently devoted to food safety research in the federal government? By what agencies?

What are the current priorities of the federal food safety research program? Who sets them?

Does the allocation of research dollars reflect current public health priorities? How is this determined?

What mechanisms exist to coordinate research among the agencies?

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10/08/97- Updated 06:45 AM ET

Food safety program falls short of goals

During his re-election campaign last July, President Clinton announced sweeping changes in meat and poultry inspection that would "give families the security to know that the food they eat is as safe as it can be."

More than a year later, critics both inside and outside the government say the program has been oversold.

New scientific methods to spot microscopic killers and new monitoring systems at the nation's 6,200 slaughterhouses and processing plants were aimed at eliminating outbreaks of food-borne disease. But a close examination of the new regulations and interviews with U.S. agriculture department officials, food experts and government inspectors reveal the program falls far short of Clinton's promise.

Much-hyped bacterial testing will be used on only a small percentage of meat, and high levels of contamination will continue to be permitted in some products, officials say. Government and industry inspectors are unclear about what their jobs will be just three months before the program goes into effect in late January.

And the job of monitoring the safety of meat will soon be given to the companies that process it, angering department inspectors who say they will become little more than paper shufflers.

Despite the new regulations, which were drafted by the Agriculture Department and approved by Clinton, government officials remain powerless to recall tainted meat or fine violators. Recognizing the weakness in the plan, Agriculture Secretary Dan Glickman goes before Congress Wednesday to repeat his requests for more authority to enforce safety.

"We are changing the way we regulate based on the company setting up its own systems," he says. "We need the authority to hold them accountable."

Critics warn that Clinton's claims of quick improvements create a

dangerous complacency about **food safety** at a time when the number and severity of food-borne illnesses is rising.

"It gives the impression that you can guarantee an infectious agent is not there, and you can't," says Michael Osterholm, Minnesota state epidemiologist, who serves on an advisory board for the Agriculture Department.

Traditional 'poke and smell' giving way

As the nation's first line of defense against tainted meat, inspectors for the Department of Agriculture monitor operations at the 2,700 facilities where animals are slaughtered and at another 3,500 processing plants where meat is turned into products like hamburger or chicken parts. Large plants have resident inspectors; smaller ones are visited on a daily basis.

USDA inspectors traditionally check for disease by eyeballing carcasses for tumors, tuberculosis and other diseases. This "poke and smell" style will be replaced with a system that uses microscopes and petri dishes to spot dangerous organisms.

Tougher measures began last January, when all slaughterhouses began testing for a generic form of E. coli, bacteria that indicate fecal contamination. Beginning this January, USDA inspectors also will test for salmonella, the bacteria responsible for a major percentage of food poisoning cases.

The new year will mark a more radical change. Company employees will take over some responsibility to monitor health and safety in 314 of the largest slaughterhouses and processing plants. Those plants are responsible for 75% of all slaughter and 50% of all meat processing in the USA.

The remaining 5,900 facilities will adopt the new system over the next two years at a cost the industry estimates at $80 million.

The new testing program "moves us beyond what is seen," says Tom Billy, head of the USDA's **Food Safety** Inspection Service. "It gives us the ability to look with greater depth at a plant's sanitary operation. . . . It will bring a discipline to the food production business that hasn't existed before."

But among the concerns:

- Only a scant percentage of meat is now checked for E. coli. Thousands of smaller slaughterhouses are required to test only 13 samples a year.
- The new testing program doesn't look for E. coli 0157:H7, a rare but dangerous strain that was behind the summer's massive hamburger recall. In contrast, fast-food companies demand meat suppliers regularly test for the lethal bug.
- The new regulations permit high levels of contamination in some cases. For instance, a plant is considered safe if as many as one out of five chickens tests positive for salmonella.

Agriculture officials have never been able to mandate the recall of

tainted meats or to fine plants that fail to meet standards. And the new regulations don't expand their powers.

"The Highway Safety Administration can recall dangerous products and we can't," says Glickman.

Glickman's inspectors are angry and anxious about the new system. They say it transfers some of their oversight responsibilities to companies, a move they say opens the door to abuse. And while new rules take effect in January, training to teach inspectors their new duties is just beginning.

"The packers claim they can police themselves but in my mind, it's like putting the fox out there to guard the hen house," says Charles Limoges, an Iowa USDA inspector.

Despite the gaps, the system still could work. Critics say meat quality and safety will improve if the USDA follows through on fine-tuning after all rules take effect in 2000.

As long as 12 years ago, organizations like the National Academy of Science were calling for changes in the way the nation monitors its food. After years of negotiations between the government, consumer groups and the meat and poultry industries, the new rules were agreed on, written by Agriculture Department staff and then approved by Clinton. Glickman says the rules "should raise consumer confidence knowing we are modernizing our standards."

But in the short term, consumer advocates warn it is too early to claim success. Says Caroline Smith DeWaal of the Center for Science in the Public Interest: "Everyone's optimistic that they are going to make a big difference, but we really won't know for several years."

100% guarantee an impossibility

Any debate over **food safety** forces an uncomfortable truth on producers, regulators and consumers alike: Short of testing every bite of your dinner, there is no way to ensure dangerous bacteria are not in your food. Bacteria, from the benign to the dangerous, live in the guts of all warm-blooded animals. When they are slaughtered, there is always risk of contamination.

The good news is that dangerous microbes are easily eliminated if meat is properly handled and cooked. But consumer advocates say the government has a responsibility to keep risk to a minimum. "A cooking error shouldn't be a death sentence," DeWaal says.

The call for greater government oversight is bolstered by a rise of food-borne diseases over the past 20 years. Incidents of salmonella infections, including a new drug-resistant strain, have doubled in two decades. E. coli 0157:H7, first discovered in 1982, now is blamed for as many as 20,000 illnesses and 500 deaths annually, including a 1993 outbreak that killed four youngsters and sickened thousands who ate tainted burgers.

It is estimated that food-borne disease strikes between 6.5 million and 81 million people each year and kills as many as 9,000.

Scientists say the dangers will increase with changes in the food business.

The hamburger you bite into today may come from parts of 80 different cows. That means a small batch of bad meat can create widespread chaos, as it did this summer when 25 million pounds of Hudson Foods ground beef were recalled.

"The very nature of food processing is vulnerable to new pathogens," says Mitchell Cohen of the Centers for Disease Control and Prevention.

Fast-food standards tighter

The nation's 600 largest slaughterhouses are required to sample only one out of 300 beef carcasses and one out of 22,000 chickens. The remaining 2,000 smaller facilities need only check one carcass a week for three months to meet the annual standard.

Testing is not required at processing plants that do not slaughter animals, a loophole consumer advocates fear will leave the nation vulnerable to repeats of this summer's hamburger recall.

In fact, the fast-food industry has tighter standards for its burgers.

Nearly ruined by the 1993 outbreak in the Northwest, Jack-in-the-Box now requires meat suppliers to test the production line for E. coli 0157:H7 every 15 minutes. David Theno, vice president for quality assurance and product safety, says Jack-in-the-Box pays less than a extra penny per pound of ground beef.

But officials say the testing is not being done to pass or fail meat moving through production lines. It is intended to keep contamination levels within standards set by an nationwide survey of sanitary conditions at slaughterhouses and processing plants.

Key to the change is a quality control technique called Hazard Analysis and Critical Control Point. Developed to monitor astronauts' meals, HACCP shifts attention from the health of the individual meat product to the health of the production line.

A HACCP plan for a processing plant may establish criteria for the way meat grinders are kept clean. Key microbial "kill points," where meat is cooked, frozen, cut or washed are identified; standards are set for variables like time, temperatures and testing.

The company keeps records on operations of the key points, which will be reviewed by federal inspectors to make sure the companies keep to their own standards.

While the new HACCP system has been praised for its scientific approach, some fear the emphasis on record review diminishes the oversight of federal inspectors.

"HACCP represents a shift from monitoring the meat to monitoring the paperwork," says Ray Leonard, a former head of meat and poultry safety at USDA who now runs the Community

Nutrition Institute.

Dave Evans, a USDA inspector in Colorado, is troubled by the changes he's seen. "We've already seen some plants that fail one beef for every 13 the USDA inspectors would fail," he says. "It is impossible for them to do an impartial job."

Bill Smith, head of field operations for the inspection service, says many of the inspectors' complaints are due to anxiety.

"It's a significant culture and mindset shift," he says.

Those who fight food-borne disease on a daily basis remain pessimistic that any changes in the inspection system can stem the rise of food-borne disease.

Osterholm, the Minnesota epidemiologist, sees food-related illness reports each day. He talks of other methods to combat contamination, including irradiation of some foods.

"Microbes are . . . a reality you have to deal with," he says. "Even with the best of inspection and processing, you can reduce the risk but you can't remove it."

By Fred Bayles, USA TODAY

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CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

Statement of Caroline Smith DeWaal
Director of Food Safety
at the National Food Policy Conference

National Press Club
March 23, 1998

The Clinton administration has taken a number of important steps to improve food safety in the United States, such as HACCP for seafood, meat and poultry; the Food Quality Protection Act; and the President's Food Safety Initiative. While these improvements are important, there is still a long journey ahead of us to truly improve the safety of food for the American consumer.

New hazards are showing up almost monthly: parasites and viruses on imported berries; hazardous strains of *E. coli* on lettuce, sprouts and in unpasteurized apple juice; *Salmonella* in orange juice and on alfalfa sprouts. Old hazards remain unaddressed: *Salmonella* in eggs and poultry; harmful bacteria and viruses in shellfish. Public health officials estimate that up to 33 million illnesses and 9,000 deaths occur each year from contaminated food.

At the same time, food safety regulation is undergoing a fundamental restructuring. Past reliance on government inspectors to ensure safety is slowly giving way to new systems of preventative controls, known as HACCP, which are implemented and monitored by industry. In the long run, this means that the focus of food safety inspections must change. While in some areas, inspection may be reduced, in others it will have to be increased in order to prevent the

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new HACCP systems from becoming a regulatory failure. This is especially true for FDA-regulated food plants where the average inspection frequency is once every 10 years.

With all these challenges facing the federal food police, food safety regulation is in dire need of streamlining. Responsibility for food safety is spread among a number of federal agencies, including EPA, APHIS, and NOAA, and hundreds of state and local agencies. The two top federal agencies, FDA and USDA, utilize entirely different regulatory approaches to food safety, with USDA inspecting plants on an ongoing basis while the FDA rarely even visits food plants unless there is an illness outbreak associated with the particular food they produce. Such discrepancies will make HACCP implementation uneven and raise questions regarding the federal government's ability to address food safety problems proactively.

Today, meat, poultry and some egg products are regulated by USDA's Food Safety and Inspection Service (aka FSIS) and subject to continuous oversight by government inspectors. All other foods are regulated by FDA, which has an inspection frequency of once every ten years for food processors. FDA has jurisdiction over a number of very high risk foods, such as seafood, shell eggs, and fruits and vegetables.

This system has given rise to a number of bizarre situations:

- ***The same plant gets two entirely different "food safety" inspections.*** The classic example is a processing plant that produces both pepperoni and cheese frozen pizza. The pepperoni line will get daily visits from a USDA inspector to check on conditions in the plant as they slice the pepperoni and apply it to the pizza. The cheese line will be subject to FDA inspection once every 10 years.

- ***Our trading partners require tougher standards.*** Seafood processors are inspected by FDA about once every two to three years. This is not enough however for processors that want to export their products. As a result, the National Marine Fisheries Service developed a voluntary program for seafood processors that mimics the USDA program for meat — including on-sight government inspectors and an inspection mark, to help the seafood industry promote their products for export. Apparently, the inspection system that FDA delivers for US consumers isn't good enough for our foreign trading partners.
- ***Public health problems are unaddressed for over a decade.*** Eggs are regulated both by FDA and USDA, and neither agency has developed an effective containment strategy to prevent the spread of *Salmonella enteritidis* in shell eggs, an issue that CSPI fully documented in a report we released last year called *Scrambled Eggs*: ..... Instead, the agencies have acted like keystone cops, tripping over each other and bungling each attempt. Today, twelve years since SE inside eggs was first identified as a public health concern by the CDC, consumers still await an effective strategy to eradicate SE in shell eggs.
- ***Quality inspections occur more frequent than safety inspections.*** One item we learned during the development of the *Scrambled Eggs* report was that there are many shell egg plants that receive regular inspection from US government inspectors, but they are part of AMS's quality inspections. Many plants receive quality checks from the Agricultural Marketing Service each quarter and may be under a voluntary grading program where they receive continuous inspection by AMS. Under this inspection, our government ensures that each has a yolk of the proper diameter, but nothing in the program checks for

the presence of SE. FDA, the agency charged with food safety oversight of shell eggs, inspects on average once every 10 years, and also does not check for SE.

- ***HACCP is two different systems at FDA and at USDA.*** The new HACCP systems for seafood, meat and poultry share almost as many differences as similarities. For example, both frequent inspection and laboratory verification are essential to give the government appropriate oversight over plants utilizing HACCP. Otherwise, the program becomes little more than an industry honor system. While USDA requires both on-sight inspection by government inspectors and two levels of laboratory verification of meat and poultry products, FDA requires neither for seafood plants. FDA inspects plants once every two or three years and made laboratory verification optional for the processors.
- ***Imported products treated differently at FDA and USDA.*** Imported meat and poultry are subject to a two-stage approval process. First, the country's system must be approved by USDA, then, the individual plant must be inspected by a US government inspector before it can ship meat to the US. Even then, it is subject to random verification checks at the border. FDA meanwhile only inspects food at the border but has the staff to check less than two percent of import shipments. FDA can't send inspectors to foreign countries except by invitation, even when they are checking the source of food involved in an outbreak in the US.
- ***Harmonizing an irrational system.*** There is increasing international pressure to "harmonize" our systems with the systems used in foreign countries. We need to harmonize domestically before we try to harmonize internationally and this alone should provide some urgency to developing a more rational basis for our food safety system today.

- ***Multiple agencies prolongs time to bring the benefits of new technologies to the consumer.*** Finally, let's look at research and technology. Under the existing system we have at least 20 government agencies involved in food safety research. Just last week, we netted the benefit of one of their projects when Secretary Glickman announced the commercial availability of a biological inoculation for young chicks against *Salmonella.* This product was developed by the Agricultural Research Service and then spent years being considered for approval at the Food and Drug Administration. For several other heralded technologies, like TSP for poultry and irradiation for red meat, FDA approval is followed often by approval for use on meat and poultry products, which is a separate rulemaking at FSIS.

Last April, CSPI joined with Safe Tables Our Priority, a food poisoning victim-support and advocacy group, to call on President Clinton to consider combining food oversight functions into a single independent food agency. Washington insiders say creating an independent food safety administration can't be done. Apparently, combining the current hodge-podge of federal agencies in order to make food protections more effective would offend too many high ranking government officials and committee chairmen. On behalf of CSPI's members and other outside-the-beltway consumers, we can no longer afford to have government programs that protect "turf" better than they protect consumers. The structure of federal food safety programs today is an obstacle to an improved food safety system.