United States Senate

COMMITTEE ON
AGRICULTURE, NUTRITION, AND FORESTRY
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Ford Sister Indiana

Fax Cover Sheet

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To: Tom Freedman

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Re: FSI

Date: Mar 23 '99

pages (including this page) 2

Call me when you get a chance.

FOOD SAFETY

Confusion About Food Safety Initiative Apparent at Senate Hearing

Confusion about the Food Safety Initiative was evident last week when FDA Commissioner Jane Henney, USDA Undersecretary for Food Safety Cathy Woteki and CDC director Jeffrey Koplan testified together before the Senate Appropriations subcommittee on agriculture, rural development and related agencies on the subject of food safety.

"There is some confusion in my mind on what is in the [Food Safety Initiative]," Subcommittee Chair Thad Cochran (R-Miss.) said, noting for example that FDA's seafood HACCP is included although the FSIS HACCP program is not. "It's very confusing," he said. But Woteki noted that the scope of the initiative is "all laid out in the May 1997 report to the President" which stated what the FSI would encompass.

Showing further signs of confusion, Sen. Herb Kohl (D-Wis.) asked Woteki, "who is the lead agency for FSI?" She responded that the President's Food Safety Council is working on coordinated budgets (See Page 3). She did not note that FDA has in the past called itself the lead agency for the Food Safety Initiative.

In any event, Sen. Tom Harkin (D-Iowa), who plans to introduce legislation in the near future to boost the safety of fresh fruits and vegetables, said he would give his "strongest support" to the Food Safety Initiative, which, he said, is "a complete menu of innovative programs."

On another issue, the possible consolidation of all food safety activities into a single agency, Kohl said he found the idea "intriguing," but that he was "unsure how to remove the research, economic, regulatory and related functions necessary for food safety activities from USDA, FDA or any other agency without harming other important responsibilities of those agencies."

Cochran asked if FSIS' plans to reassign inspectors to the retail scene would fit with the states' activities. "States are worried" about this, he noted. Woteki assured him that "we will not be duplicating." FSIS Administrator Tom Billy added that the agency has had compliance officers at the retail stage for years. The agency is working with FDA and with the Conference on Food Protection on the issue, he said.

* * *

NEWSBRIEFS

Ellen Haas, former USDA undersecretary for Food, Nutrition and Consumer Services and long-time head of Public Voice, announced at Public Voice's annual food policy conference last week that she will publish a book in the fall about her experiences in the food policy arena. Now president and CEO of a new Internet firm called Foodfit.com, Haas said her company's Web page also will be launched in the fall.

Iceberg lettuce is suspected as the vehicle for an outbreak of *E. coli* O157:H7 illnesses that have affected at least 52 people in Nebraska since February. All the 52 cases occurred among diners at a restaurant in Kearney, Neb. The patients range in age from five to 87 years old, UPI reported. Seven people have been hospitalized, with at least one, an 8-year-old girl, in serious condition.

FDA's proposed health claim linking soy protein and a decreased risk of coronary heart disease is legitimate, Assistant Professor of Nutrition Ross Santrell of the University of Southern Mississippi said in a Feb. 24 comment letter to FDA. But he would only support one version of the claim, that "25 g of soy protein as part of a diet low in saturated fat ..." helps lower CHD risk. He said the second version, "Diets low in saturated fat and cholesterol that include 25 g of soy protein ...," implies that without the soy, these diets may not reduce the risk of CHD.

Restaurants and other food establishments in the U.K. will be required to tell inquiring diners whether their food contains genetically modified ingredients, or face fines of up to $8,000, under new rules announced last week by food safety minister Jeff Rooker. The U.K. is moving to enforce European Union requirements that have been in place since September 1998, requiring the labeling of foods containing GM soy and corn, Reuters reported. The requirement will be phased in over the next six months.

Meanwhile, across the English Channel, U.S. Deputy Secretary of Agriculture Richard Rominger told a Brussels conference on genetically modified organisms that the EU must act quickly to improve its approval system for GM crops because the current slowness of the system is costing U.S. firms millions of dollars annually, Reuters said. "Since several U.S. biotech corn varieties remain unapproved in the EU, it's entirely possible that we won't export any corn to the EU this year," Rominger said.

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

October 20, 1998

cc Tom
EK

Mr. Bruce Reed
Assistant to the President
Office of Policy Development
Executive Office of the President
1600 Pennsylvania Ave, NW
Washington, DC 20500

Dear Mr. Reed:

On behalf of CSPI's one million members, I am writing to thank you for the efforts of you and your staff to restore funding to the National Food Safety Initiative. The final agreement to fund over three-quarters of the President's request represents a significant victory for consumers, and it would not have happened without the active participation of your office.

From the time that it first became clear that the funding was in trouble, your staff worked tirelessly to ensure that we knew the White House's commitment to the funding was unwavering. Tom Freedman, in particular, coordinated between numerous government agencies and constituencies and provided strong leadership and support for those of us working on the front lines to get the funding restored. The Administration's efforts were crucial to the victory when the Senate voted to increase the funding for the Initiative from $2.6 million to $68 million. In addition, when the final agreement was negotiated, the White House again requested full funding, which resulted in an increase in the Agriculture portion of the funding from $52 million (the Conference Committee recommendation) to $75 million. In my 10 years as a lobbyist and consumer advocate in Washington, it is the first time I can recall such active involvement from the White House to restore food safety funding.

I hope that next year, we can use this experience to make sure that future requests for funding of the President's Initiative meet less resistance in Congress. On this point, members of the Safe Food Coalition, coordinated by Carol Tucker Foreman, will be seeking a meeting with you to discuss next year's food safety budgets and our opposition to the inclusion of deficit-reduction user fees.

We hope to continue to work closely with your office to ensure that Congress understands the importance of food safety to the American public. Thanks again for your tremendous food safety leadership.

Very truly yours,

Caroline Smith DeWaal

Caroline Smith DeWaal
Director of Food Safety

1875 Connecticut Avenue, N.W., Suite 300, Washington, D.C. 20009-5728 • (202) 332-9110 • FAX (202) 265-4954
Executive Director: *Michael Jacobson, Ph.D.*

President's Council on Food Safety
Food Safety Strategic Plan

~~October 2, 1998~~
Arlington, Virginia

8:30 **Registration**

9:30 **Welcome**

Dr. Neal Lane
Assistant to the President for Science and Technology, Director of the Office of Science and Technology Policy

Importance of Food Safety, Accomplishments and Successes

Donna Shalala
Secretary of Health and Human Services

Richard Rominger
Deputy Secretary of Agriculture

Introduction of Panel Members—Dr. 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, EPA
Thomas J. Billy, Administrator, Food Safety and Inspection Service, USDA
Joseph Levitt, Director, Center for Food Safety and Applied Nutrition, FDA, HHS
Dr. Morris Potter, Assistant Director for Foodborne Diseases, CDC, HHS

Agency Visions

A Safe & Affordable Food Supply—**Dr. Lynn R. Goldman**
Assuring Food Safety Requires Everyone to Play a Role—**James A. O'Hara**
Protecting the Food Supply Must Be Grounded in Sound Science—**Dr. Catherine E. Woteki**

10:10 **BREAK**

10:25 **Discussion of the Vision/Strategic Plan**

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

10:45 2. What are the barriers to pursuing this vision? What gaps currently exist in the foodsafety 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 **LUNCH**

12:30 **Discussion of Vision**

12:30 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 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 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 **Public Comment**

4:15 **Closing Remarks**

Mistake?

The Food Safety Agency

Research, - USDA
Inspections, - USDA
Surveillance - CDC
Combined.

Timetable

I think you will have care of it.

White House Conference on Food Safety

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Such a conference would be well-received by consumer groups, industry, producers, and academia and would receive strong bi-partisan support in Congress. In fact, one of the leading consumer groups recently requested that USDA host a conference on research and technology. USDA held a similar conference several years ago, which was widely attended.

The Administration's food safety initiative includes substantial increases for food safety research and technology. In addition, the Administration's new regulatory systems also depend on new technologies and research i.e. microbiological testing, interventions to reduce or remove pathogens. As a result, the conference could be viewed as building on Administration initiatives, including in preparation for the FY 2000 budget proposal.

The private sector and academia are also investing substantial resources in new research and technologies. A couple of examples include: a laboratory that has done extensive work for the Department of Energy and for the military is working on converting Gulf War technology that identifies nerve gas to the identification of pathogens; and a number of researchers are working on vaccines against E. Coli O157:H7 in animals.

While a number of options are possible, the conference could include a series of scientific panels that would present the latest research on new technologies. One panel could discuss efforts focused toward on-farm and pre-slaughter research. This could include research on vaccines as well as research to identify where and/or why pathogens appear on farm. There is on-going research in Federal agencies as well as various academic instititions e.g. Washington, Colorado, and Georgia, on this issue for various animal species.

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The mixture can be sprayed in a mist over newly hatched chicks to give them the same level of salmonella resistance that develops in an older bird.

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The work was done under a five-year cooperative research and development agreement between scientists at ARS' Food Animal Protection Research Laboratory in College Station, Texas, and Milk Specialties. ARS scientists Donald E. Corrier, David J. Nisbet and James A.

Byrd and Texas A&M researcher Billy Hargis conducted the field tests.

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Food Safety — Salmonella

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Food Safety Precept

QUESTIONS & ANSWERS: PREEMPT

Q. What is PREEMPT?

A. PREEMPT is a blend of 29 different organisms (bacteria) that are naturally present in the intestines of healthy adult chickens. Tests have shown that these bacteria are the ones that help adult chickens keep salmonella bacteria from establishing themselves in the chickens' intestines. The "good" bacteria basically block all the sites on the intestinal walls where salmonella might take hold, so the salmonella must pass harmlessly out of the chicken's body.

Q. How does PREEMPT work to protect a chicken against salmonella?

A. Think about the interior walls of a chick's intestines as a parking lot with a limited number of parking spaces. When the beneficial bacteria in PREEMPT reach the intestinal walls, they essentially fill up the available parking spaces. When salmonella bacteria subsequently enter the intestines, they have no place to "park" and, therefore, are passed out of the chick's body.

Q. How effective is PREEMPT?

A. PREEMPT greatly reduces salmonella in chickens.

In laboratory tests, the bacterial mixture reduced salmonella in chicks' ceca, small sacks in their intestines, by 99.9 percent. Also, the number of salmonella bacteria per gram of cecal content dropped from 1,000,000 per gram to less than 10 per gram.

In the field tests accepted by FDA, PREEMPT reduced salmonella to zero percent in treated chickens at commerical poultry houses.

In field tests in Puerto Rico, 21 percent of untreated chicks tested positive for the presence of salmonella on their skin and feathers, while only 8 percent of PREEMPT-treated chicks tested positive. When the chicks' intestines were checked at the processing plant, an average of 2.7 percent of treated chicks showed contamination, less than half the 5.7 percent contamination found among untreated chicks.

Q. Are the effects of PREEMPT permanent?

A. Yes. Once the beneficial bacteria have established themselves in the chick's intestines, they continue to live and flourish there, greatly reducing the ability of salmonella to establish themselves in the intestines.

Q. Does PREEMPT protect chickens against other foodborne bacteria such as listeria, campylobacter and E. coli 0157:H7?

A. There is substantial evidence that PREEMPT helps protect chicks against listeria and *E. coli* 0157:H7. Preliminary results also indicate the product help protec chicks against campylobacter. While experimental testing in these areas is promising, field testing has not yet been conducted.

Q. Does PREEMPT have an effect on the eggs produced by chickens that have been treated with it?

A. Hens treated with PREEMPT are less likely to produce eggs that contain salmonella bacteria.

Q. How is PREEMPT used?

A. PREEMPT is mixed with water that contains a special buffer to revive the frozen "good" bacteria. Then the water-bacteria mix is sprayed as a coarse mist over newly hatched chicks after they arrive at the chicken house. As the birds groom their feathers, they swallow the moist droplets, allowing the beneficial bacteria to enter their bodies. These bacteria give the newly hatched chicks the same level of protection against salmonella that mature chickens have naturally.

Q. What is different about PREEMPT?

A. PREEMPT is unusual in several ways. First, scientists have known for years that if the bacteria from an adult chicken's intestines are fed to chicks, those bacteria give the chicks protection against salmonella colonization. But PREEMPT marks the first time that scientists have been able to precisely pinpoint which bacteria--out of the hundreds present in an adult bird's intestines--are the ones that specifically protect against salmonella. PREEMPT is the first product that contains *only* those bacteria known to protect against salmonella.

Also, PREEMPT is the first mixture of bacterial microbes ever approved by the Food and Drug Administration for use as an animal drug.

Q. How is PREEMPT made? Who developed it?

A. To produce PREEMPT, scientists at USDA's Agricultural Research Service (ARS) at College Station, Texas isolated the 29 bacteria and kept them alive and growing in a system known as a chemostat. MS Bioscience of Dundee, Illinois further developed the technology to make it possible to commercially manufacture PREEMPT.

USDA has patented the mixture. MS Bioscience has a license to market the product.

White House Conference on Food Safety

A White House Conference on Food Safety could be held on a number of subjects, ranging from consumer education, partnerships with state and local government, international food safety issues, or research and technology. The recommendation is to hold a conference on new food safety technology and research.

Such a conference would be well-received by consumer groups, industry, producers, and academia and would receive strong bi-partisan support in Congress. In fact, one of the leading consumer groups recently requested that USDA host a conference on research and technology. USDA held a similar conference several years ago, which was widely attended.

The Administration's food safety initiative includes substantial increases for food safety research and technology. In addition, the Administration's new regulatory systems also depend on new technologies and research i.e. microbiological testing, interventions to reduce or remove pathogens. As a result, the conference could be viewed as building on Administration initiatives, including in preparation for the FY 2000 budget proposal.

The private sector and academia are also investing substantial resources in new research and technologies. A couple of examples include: a laboratory that has done extensive work for the Department of Energy and for the military is working on converting Gulf War technology that identifies nerve gas to the identification of pathogens; and a number of researchers are working on vaccines against E. Coli O157:H7 in animals.

While a number of options are possible, the conference could include a series of scientific panels that would present the latest research on new technologies. One panel could discuss efforts focused toward on-farm and pre-slaughter research. This could include research on vaccines as well as research to identify where and/or why pathogens appear on farm. There is on-going research in Federal agencies as well as various academic instititions e.g. Washington, Colorado, and Georgia, on this issue for various animal species.

Another panel could focus on research aimed at improving the ability to rapidly detect pathogens as well as on intervention technologies that are under development in research labs. This could also include work on sensor technology to be used on retail packages. It also might be possible to bring NASA research and technology into the food safety arena. In addition to these panels on research, there could be a panel on new food safety technologies and technological developments that are in use in slaughter and processing operations.

A final panel could be on future trends and challenges of the future, such as continued globabization of the food supply, population demographics, new products, packaging, and production technologies, and the effect those trends may have on our food safety research and technologies. This would complement the long-term strategic planning underway by the Federal food safety agencies.

The conference could be used as a forum for a speech, or the President or Vice President could host a general discussion on these issues, and then panels could be convenee throughout the day. There could also be displays and demonstrations of research and technological developments.

Possible Announcements for Conference

The conference itself would be likely to generate media interest. However, several additional announcements could be considered.

First, the President could issue a directive or an executive order on food safety research and technology. This would include several components:

--**Interagency Food Safety Research Council**--As part of the President's Food Safety Initiative, the Administration has recently formed an interagency food safety research group. There are xx agencies represented on this group, which is charged with developing a comprehensive food safety research agenda. The Executive Order would institutionalize this working group.

--The Executive Order could require the council to hold annual or biannual national public meetings/conference to discuss advances in research and technology.

--The Executive Order could also direct the council to award annual or biannual Presidential Awards for Advances in Food Safety Research and Technology.

Second, the Centers for Disease Control is in the process of completing its analysis of the latest data on the extent of foodborne illness. Depending on the timing of the conference, this could possibly be released at the conference.

Third, depending on the timing of the conference, the Administration could announce implementation of PulseNet, which CDC will implement in the next 6-8 weeks. Pulsenet will electronically link CDC, USDA, and FDA labs with state public health labs in several states (with more states to be added by years end). The labs are all equipped with DNA fingerprinting technology, with the CDC laboratory serving as a hub and database for PulseNet. It works like this--a laboratory isolates E. coli O157:H7 from food--fingerprints it and enters the information into PulseNet. The laboratory then receives information on any similar fingerprints submitted on human pathogens by CDC or the States. In this way, PulseNet can identify a potential outbreak or a potential food source of an outbreak. This approach resembles the FBI national network and database for fingerprinting individuals throughout the United States and centrally generating a "rap" sheet where there is a match.

U.S. DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

Telephone (202) 720-3631 Fax (202) 720-5437

FAX COVER SHEET

DATE:_____

NUMBER OF PAGES_____, **INCLUDING COVER SHEET**

PLEASE DELIVER TO: Tom Freedman / Mary Smith - Fruits & Veggies -

FAX NUMBER: ( ) _____ **PHONE NUMBER:** ( ) _____

FROM:

- ☐ DAN GLICKMAN, SECRETARY
  - ☐ JOHN GIBSON, SPECIAL ASSISTANT
- ☐ GREG FRAZIER, CHIEF OF STAFF
  - ☐ KOFI DEGRAFT-JOHNSON, EXECUTIVE ASSISTANT
- ☐ REBA PITTMAN EVANS, DEPUTY CHIEF OF STAFF, INTERNAL AFFAIRS
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- ☐ PAUL DRAZEK, SPECIAL ASSISTANT FOR POLICY
- ☐ ANNE KENNEDY, SPECIAL ASSISTANT FOR POLICY
- ☒ ERIC OLSEN, SPECIAL ASSISTANT FOR POLICY
- ☐ JANET POTTS, COUNSEL TO THE SECRETARY

MESSAGE: Elena should see this. This is a "perfect" way for this initiative to blow up. President is going to Summit of the Americas in April. Domestic groups will fear retaliation....

INCOMING FOREIGN AGRICULTURAL SERVICE TELEGRAM

UNCLASSIFIED

GUATEMALA 729 PAGE: 1 OF 2

FAS ACTION:
FAS INFO: APHIS10 BFD_CABLES CBL_IMMEDIAT EC_CCC
ERS_CABLES FAA_WEST FSIS HTPD
ISB_CABLES ITP_AAEE_M ITP_MTPAD ITP_OFSTS
ITP_TEID ITP_WEIAD OASHARED PD_CABLES
RO_CABLES TOFAS_CABLES

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RUEHRC/FAS WASHDC
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BT
UNCLAS GUATEMALA 000729

FROM THE AMBASSADOR

WHITE HOUSE FOR COUNSELOR TO THE PRESIDENT MCLARTY; HHS FOR FDA/OIA/MVEEK; CFSAN/CREYNOLDS CDC/DPD FOR SBINDER; FAS/ITP/OFSTS FOR LHARBERT; FAS/ITP/WEIA; FAA/WHAO FOR WESTMAN

E.O. 12958: N/A
TAGS: EAGR, ETRD, GT
SUBJECT: FDA VISIT TO GUATEMALA TO REVIEW BERRY SITUATION

REF A:GUATEMALA 00238; REF B: FDA LETTER OF NOVEMBER 20, 1997 TO GUATEMALAN BERRY COMMISSION; REF C: GUATEMALA 00004; REF D: GUATEMALA 00133; REF E: GUATEMALA 00286

1. REF A OUTLINED STEPS THE GUATEMALANS HAVE TAKEN TO ASSURE THE SAFETY OF RASPBERRIES DESTINED FOR THE U.S. MARKET. THIS SAME MESSAGE URGED THAT FDA SEND A TEAM TO GUATEMALA TO EVALUATE THE GUATEMALAN MEASURES AND TO PROVIDE ASSISTANCE. TO DATE, I HAVE RECEIVED NO RESPONSE TO MY MESSAGE.

2. AS THE MARCH 15 DEADLINE FOR THE EXPORT OF GUATEMALAN RASPBERRIES TO THE U.S. QUICKLY APPROACHES, I AM INCREASINGLY CONCERNED WITH THE REPEATEDLY POSTPONED FDA VISIT. AS WAS EVIDENT DURING THE RECENT VISITS OF CODELS COVERDELL AND LOTT (REFS C AND D), THIS IS A CRITICAL ISSUE FOR PRESIDENT ARZU AND HIS GOVERNMENT.

3. SENATOR COVERDELL'S OFFICE ALSO RECENTLY EXPRESSED

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CONCERN TO ME ABOUT SETTING A DATE FOR THE FDA TEAM'S VISIT. FAILURE TO COME AND, AT A MINIMUM, REVIEW GUATEMALAN EFFORTS WILL BE SEEN AS A DEMONSTRATION OF BAD FAITH ON OUR PART, ESPECIALLY IN VIEW OF REF B LETTER WHICH LED THE GUATEMALANS TO BELIEVE A VISIT WOULD BE FORTHCOMING. ARTICLES HAVE ALREADY APPEARED IN THE MEDIA CHARGING THAT THE U.S. GOVERNMENT HAS FAILED TO FULFILL ITS COMMITMENT TO REVIEW THE BERRY SITUATION. AS THE DEADLINE APPROACHES, I EXPECT THIS BAD PUBLICITY WILL INCREASE.

4. GUATEMALA IS SIMPLY ASKING FOR ASSISTANCE AND COOPERATION IN DEALING WITH THIS HIGHLY-CHARGED ISSUE. THIS IS THE KIND OF POSITIVE, CONSTRUCTIVE APPROACH WE SHOULD ENCOURAGE. WE NEED TO KEEP IN MIND THAT THE U.S. BAN THREATENS A WHOLE INDUSTRY HERE--AN INDUSTRY COMPRISED LARGELY OF SMALL PRODUCERS OF VERY MODEST FINANCIAL MEANS.

5. IN THE FACE OF NO CLEAR GUIDANCE FROM THE U.S. ON REQUIREMENTS FOR RASPBERRY EXPORTS, GUATEMALAN BERRY GROWERS AND THE GUATEMALAN GOVERNMENT HAVE PUT EXTENSIVE EFFORT INTO REVISING THEIR SYSTEMS, GROWING PRACTICES AND OVERSIGHT ACTIVITIES IN ORDER TO MINIMIZE THE RISK OF ANOTHER INCIDENCE OF CYCLOSPORA (REFS A AND E). BERRY EXPORTERS AND OTHER FRUIT AND VEGETABLE GROWERS ARE WELL AWARE OF THE NEGATIVE IMAGE THE CYCLOSPORA OUTBREAKS HAVE GENERATED AMONG U.S. PRODUCE BUYERS AND AMERICAN CONSUMERS, AND THEY ARE DETERMINED TO AVOID A REPETITION OF THIS BAD EXPERIENCE. I BELIEVE THAT SERIOUS AND REAL CHANGES ARE UNDERWAY TO TRY TO CORRECT THE PROBLEM AND MEET OUR STANDARDS.

6. I STRONGLY URGE FDA TO MAKE EVERY EFFORT TO VISIT GUATEMALA AT THE EARLIEST POSSIBLE DATE BEFORE THE BAN ON THE EXPORT OF RASPBERRIES GOES INTO EFFECT. FAILURE TO DO SO WILL SEND A NEGATIVE SIGNAL TO GUATEMALA AND OTHER COUNTRIES TRYING TO COMPLY WITH U.S. FOOD SAFETY REQUIREMENTS. GUATEMALA WANTS TO BE AN EXAMPLE THAT DEVELOPING COUNTRIES CAN, WITH U.S. COOPERATION, MEET THE EXPECTATIONS OF THE U.S. CONSUMER FOR A SAFE FOOD SUPPLY. I BELIEVE WE SHOULD MAKE EVERY EFFORT TO ASSIST OUR GUATEMALAN FRIENDS IN THIS EFFORT.

PLANTY
BT
#0729

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Executive Office of the President of the United States
Office of Management and Budget

Office of Information and Regulatory Affairs
Human Resources and Housing Branch
New Executive Office Building
Room 10235
Washington, DC 20503

FAX TRANSMITTAL

FAX: 202-395-6974

DATE: _____

TO: Tom Friedman/Mary Smith

FROM: Wendy Taylor

Total number of pages (Including Transmittal Sheet): _____

Recipient's Fax Number: 67431

Recipient's Telephone Number: _____

Comments: Imported foods legislation — TPs + Qs + As

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Talking Points on H.R. 3052 "Safety of Imported Food Act"

Why the legislation is needed:

- Many of the authorities under which imported food is regulated are 60 years old and need to be updated. The current system empowers FDA to examine each import and to refuse entry to suspect foods. At the turn of the century, this authority was sufficient because relatively few foods were imported and those that were tended to be bulk staples such as sugar, spices, and molasses.

- Under current legislative authorities, FDA must rely primarily on inspection and testing at the border to ensure that imported food products meet U.S food safety requirements. However, experience has shown that border inspections alone may not be sufficient in all cases to ensure the safety of food products.

- Finished and fully packaged food products (e.g., cooked, ready-to-eat, individually quick frozen shrimp) and fresh produce account for an increasing proportion of all imported food products. As products receive additional processing, the range of potential health hazards increases, and the effectiveness of one-time testing and inspection procedures decreases.

- Imported food entries doubled over the past seven years, and based on recent trends, we expect at least a 30% increase in imported foods by 2002. This increase makes individual inspection of each import very difficult.

- Factors such as these may make it necessary, in some cases, to examine the different sources of existing or potential health risks throughout the production, processing, and distribution system. This legislation provides FDA with the authority to more effectively address those risks and ensure that imported products meet U.S. food safety requirements or otherwise achieve the level of protection required.

- On October 2, 1997, the President issued a two-pronged directive to ensure the safety of all imported foods, which included the import legislation. The President also directed the Secretary of Health and Human Services and the Secretary of Agriculture to work together in close cooperation with the agricultural community to develop the first-ever safety guidance for the growing, processing, shipping, and selling of fruits and vegetables. This voluntary guidance will address potential food safety problems throughout the production and distribution system and help ensure the sanitation and safety practices of all those seeking to sell produce in the U.S. market.

Purpose of the legislation:

- The purpose of the legislation is to provide for improved safety of imported foods consistent with U.S. food safety requirements.

What the legislation does:

- Does expand FDA authority to ensure the safety of imported foods
- Does apply to food safety systems of control
- Does require the Secretary to determine that imported food products do not meet the U.S. food safety requirements or otherwise achieve the level of protection required before an action can be taken against those products
- Does permit the Secretary to consider a refusal to allow necessary inspection, testing, or other relevant factors, in determining whether imported food products meet U.S. food safety requirements or otherwise achieve the level of protection required
- Does require an implementation plan

How the new system compares with the current system:

- Puts emphasis on underlying food systems of control at their source (preventive) rather than on finding contaminated lots at the U.S. border (reactive)
- More effective in that it is better for producers to prevent potential health risks than to only rely on FDA efforts to identify hazards after-the-fact

What the legislation does not do:

- Does not shut borders or immediately deny entry of foreign products upon enactment
- Does not apply to fresh produce only (i.e., applies to all FDA regulated foods)
- Does not require access to foreign firms/plants without consent
- Does not create new authority for FDA to perform on-farm inspections - either domestic or foreign
- Does not require the application of voluntary guidance

What the legislation will accomplish:

- Provides the authority needed to ensure that all imported food products meet the U.S. level of protection and also is consistent with rights and obligations under international trade agreements
- Provides FDA with another effective enforcement tool
- Achieves a better allocation of FDA resources by taking into account the production, processing and handling of food products rather than only focusing on end-product testing
- Provides greater assurance that imported products meet U.S. food safety requirements or otherwise achieve the level of protection required
- May create an incentive for foreign producers where appropriate to upgrade their food safety systems

3/2/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

H.R. 3052 - "Safety of Imported Food Act" Questions and Answers

1. What is the purpose of the legislation?

The purpose of the legislation is to provide for improved safety of imported foods consistent with U.S. food safety requirements.

2. What new authority does the legislation give FDA?

This bill permits the agency under appropriate circumstances to declare foods or specific commodities from a country to be adulterated if FDA determines that a particular facility or country's food system does not provide the same level of protection that is provided for comparable domestic products, and thus, refuse them entry into the United States.

FDA will continue to work with foreign governments and producers to take any steps necessary to help ensure that imported food products meet U.S. food safety requirements or otherwise achieve the level of protection required. If FDA determines that the steps needed to address an existing or potential risk have not been taken and that the affected products therefore will not meet U.S. food safety requirements or otherwise achieve the level of protection required, FDA is authorized to deny such products entry into the United States.

3. How is this different from current authority?

Current law provides FDA with authority to refuse entry if, after inspection or testing of imported products at the border, the agency finds that the food appears to be unsafe or otherwise violates U.S. law. Experience has shown, however, that inspection and testing of products at the border may not be sufficient in all cases to ensure the safety of food products. In addition, it may be necessary to identify and address the source of potential contamination to ensure that products offered for sale in the United States meet domestic food safety requirements or otherwise achieve the level of protection required. FDA currently has such authority with respect to domestic production.

This new provision adds to the Federal Food, Drug, and Cosmetic Act (FD&C Act) a principle that has been reaffirmed in the World Trade Organization (WTO) agreements on food safety. This agreement recognizes the right of signatory countries to set the level of protection each country deems appropriate for the health and safety of its citizens, and to exclude imported foods that do not meet U.S. food safety requirements or otherwise achieve the level of protection required. The FD&C Act currently does not explicitly include this concept.

4. How does FDA screen and review submitted entries offered for import?

Entries of food products that are brought to our attention are reviewed by FDA, either electronically or by review of paper documentation. The implementation of the Operational and Administrative System for Import Support (OASIS) by FDA has had a significant impact on the percentage of food imports for which FDA requires additional paper documentation. Use of this electronic entry system, has minimized the need for FDA to review actual "physical" paper.

OASIS expedites FDA's handling and clearance of imported products, and operates in a largely paperless environment. Data FDA needs to make its admissibility determinations are transmitted electronically to FDA. The entries then are electronically screened against a set of criteria developed and maintained by FDA. The screening determines if the entries match any of the established criteria based on product, manufacturer, shipper, country of origin, or any combination of these four screening elements. The results of the screening are summarized at the entry level and passed as an electronic message back to the filer. The results are either "May Proceed" or "FDA Review". Of FDA regulated entries, approximately 60% receive a "May Proceed", a final agency decision that the entry may proceed to its destination. The remaining 40% receive an "FDA Review". The products flagged as "FDA Review" are made available for review by the initial OASIS user, the FDA entry reviewer. Based on this additional review, the FDA entry reviewer will make a decision to detain the entry, examine the entry, or release the entry.[1]

5. How will pesticides be handled under this legislation? For example, will FDA permit the importation of produce that has been treated with DDT or other pesticides not approved or banned in the U.S.?

This initiative will not change how FDA currently regulates pesticide residues on produce. Pesticides are regulated through the establishment of tolerances established by the Environmental Protection Agency, and FDA enforces these levels. Food containing residue levels in excess of a tolerance is deemed adulterated and refused entry into the U.S.

6. How will FDA assess the ability of foreign producers to achieve the same level of protection required in the U.S. and what criteria will be used to make this assessment?

The agency currently is considering different options for implementing this legislation upon enactment. The statute requires an implemention plan, which the agency would provide after public participation into the development of the plan. The general principles to be followed would logically include: a) implementation on an incremental basis; b) emphasis on working with foreign

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[1]These percentages represent all FDA-regulated products and could be slightly higher or lower for food and food-related products.

governments and producers to ensure exports of foods achieve U.S. levels of protection; and c) focus on where there will be the most benefit to American public health. The U.S. level of protection -- which is the applicable yardstick with respect to both imported and domestic food products, is reflected in the statutory standards set out in the FD&C Act, as well as any regulations promulgated under the Act.

7. Does this legislation give FDA additional authority to inspect in other countries?

No. Currently, there is no statutory provision that requires food exporters to permit FDA to conduct on-site inspections, nor does this legislation create that authority. Foreign inspections will continue to be done by consent.

In making the determination that a food offered for import into the U.S. is adulterated, the legislation does permit the Secretary to consider whether FDA has been refused access to conduct inspection of the places where such food has been prepared, packed or held. The Secretary may deny importation to foods from such location or establishment on the basis of such refusal and other relevant factors. Given that denying reasonable access is one factor in making that determination, the exporting country and the food establishment both have an incentive to allow such access.

8. Will this legislation result in an increase in foreign inspections and how will they be paid for?

No. This legislation does not necessitate an increase in foreign inspections. FDA in the past has and will continue to rely heavily on the knowledge and expertise of our counterparts in the regulatory agencies of foreign governments. We plan to work with countries that supply food to the U.S. to develop a better understanding of their production, processing, and handling practices. What is envisioned is an increase in foreign activity or interactions, in that FDA would be providing technical assistance to and evaluations of foreign food safety systems.

The Administration is proposing in the FY99 budget request to increase FDA resources for increased food safety activities, which would include these foreign activities of providing technical assistance and evaluations of foreign food safety systems. These activities need to be carried out with or without the legislation. The effectiveness of these activities will be enhanced by the legislation.

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

No. Under current law, FDA has authority to inspect establishments where food is prepared, packed, or held, which would include places where food is grown, such as domestic farms. While

such inspections are infrequent, FDA has taken action against a U.S. farmer when a violation of the FD&C Act occurs. For example, intentional use of a banned animal drug, such as DES, might result in an enforcement action. When FDA is involved in a food safety problem that is found to originate on a farm, the agency's focus generally is on identifying the source of the problem and removing the unsafe food from commerce.

10. We have heard about the development of Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) for fresh fruits and vegetables, both of which are intended to help domestic growers meet the U.S. level of protection. What are they and how will they be applied to foreign growers?

When the President announced an initiative to ensure the safety of imported and domestic fruits and vegetables on October 2, 1997, he directed the Secretaries of Health and Human Services and Agriculture to issue guidance on good agricultural and manufacturing practices (GAPs and GMPs).

This voluntary, science-based guidance can be used by both domestic and foreign fresh fruit and vegetable producers to help ensure the safety of their produce. The voluntary guidance will be consistent with U.S. trade rights and obligations and will not impose unnecessary or unequal restrictions or barriers on either domestic or foreign producers.

11. What does "same level of protection required" mean, and how will it be applied?

"The level of protection required", in the context of the proposed legislation, means that foods offered for import have been prepared, packed, and held under a food safety system or subject to conditions or measures that ensure that the imports satisfy the level of protection required by the laws and regulations imposed to ensure food safety in the United States.

12. Are the GAPs and GMPs mandatory or will they become law? Will the GAPs and GMPs be used to determine the Level of Protection?

No. The GAPs and GMPs are not mandatory -- they do not impose binding requirements either on the growers or on the government-- and there is no current plan to make them binding by promulgating them as regulations. The GAPs and GMPs are instructional guidance based on sound science that may be applied by the industry to help minimize the microbial risks associated with fresh produce. The agricultural industry has recognized the need for such guidance in that it has itself drafted similar guidance. The industry, thus, is likely to adopt FDA's guidance if it is science-based and practical.

No. The U.S. level of protection is reflected in the statutory standards set out in the FD&C Act, as well as appropriate regulations promulgated under the Act. The GAPs and GMPs may be used

on a voluntary basis by foreign growers to help them reduce food safety risks. Adherence to this guidance, however, will not be required of domestic or foreign growers.

13. Will HACCP for fresh fruits and vegetables follow?

No. FDA has no current plans for developing HACCP requirements for fresh fruits and vegetables.

14. How can guidance be developed when the exact cause of foodborne illness cannot be traced to the source?

While we cannot trace every case of foodborne illness, in most cases we know the potential source of pathogens and can take steps to protect public health. The guidance will be based on a science-based evaluation of risk. We know that the common pathways for pathogens in fresh produce are through manure, water, worker, field, facility and transportation sanitation. The guidance will not eliminate the possibility of pathogens on produce. If the concepts in the guidance are employed, however, they will help minimize the presence of pathogens in fresh and minimally processed produce.

15. How will a U.S.-owned farm overseas be treated under the new legislation?

Fruits and vegetables grown on a foreign-based U.S.-owned farm are imports under the FD&C Act. Such foods would not be handled any differently by U.S. regulatory agencies than products from other farms in that country.

16. Would country of origin labeling be just as effective in protecting people?

No. Country of origin labeling by itself is not an effective food safety control measure. Imported products are not all unsafe, any more than all domestic products are safe, so the consumer cannot infer safety or lack of safety from product origin. There may be other policy reasons for country of origin labeling. Country of origin labeling, however, is no substitute for the use of good agricultural practices and taking proactive steps to minimize microbial risks.

17. Is it possibile that other countries will impose similar requirements on U.S. products or firms? Could these foreign requirements result in a barrier to trade?

The proposed legislation is consistent with U.S. trade rights and obligations, and thus, we believe, unlikely to result in retaliation. Furthermore, the GAPs and GMPs pose no trade barrier to exporting countries as they are non-binding guidance. The legislation merely gives FDA an

additional tool to use in making the most efficient and effective use of scarce resources directed to ensure the safety of imported foods.

18. How is the $24 million allocated in FY98 for the Food Safety Initative being spent? What portion of it is allocated to implementing the proposed import legislation?

The $24 million allocated in FY98 for FDA is outlined by activity and funding level below. None of the FY98 Food Safety Initiative funds are allocated to the proposed import legislation.

Foods Program	**$20,000,000**
Surveillance Monitoring pathogen levels Support FoodNet foodborne illness surveillance sites	$1,660,000
Coordination of outbreak response	$550,000
Risk Assessment Risk assessment consortium Exposure assessment	$3,950,000
Research Analytical methods Pathogen control and preventive techniques Food handling	$3,900,000
Inspections Implement seafood HACCP State partnerships Lab certification	$7,870,000
Education Consumer/retail education	$2,070,000
Animal Drug and Feeds Program	**$4,000,000**
Surveillance	$1,500,000
Research	$2,500,000
Total FDA	**$24,000,000**

3/2/98

Cuts pro-food safety

Tom- I don't think there's enough here to propose a conference - keep thinking. A couple of questions: (1) Is the CDC analysis mentioned here the same as the report we talked about last week? And on another subject entirely, could you put together a list of the people who would be appropriate to invite to a deputies meeting on country-of-origin labeling? Thanks. Elena

White House Conference on Food Safety

A White House Conference on Food Safety could be held on a number of subjects, ranging from consumer education, partnerships with state and local government, international food safety issues, or research and technology. The recommendation is to hold a conference on new food safety technology and research.

Such a conference would be well-received by consumer groups, industry, producers, and academia and would receive strong bi-partisan support in Congress. In fact, one of the leading consumer groups recently requested that USDA host a conference on research and technology. USDA held a similar conference several years ago, which was widely attended.

The Administration's food safety initiative includes substantial increases for food safety research and technology. In addition, the Administration's new regulatory systems also depend on new technologies and research i.e. microbiological testing, interventions to reduce or remove pathogens. As a result, the conference could be viewed as building on Administration initiatives, including in preparation for the FY 2000 budget proposal.

The private sector and academia are also investing substantial resources in new research and technologies. A couple of examples include: a laboratory that has done extensive work for the Department of Energy and for the military is working on converting Gulf War technology that identifies nerve gas to the identification of pathogens; and a number of researchers are working on vaccines against E. Coli O157:H7 in animals.

While a number of options are possible, the conference could include a series of scientific panels that would present the latest research on new technologies. One panel could discuss efforts focused toward on-farm and pre-slaughter research. This could include research on vaccines as well as research to identify where and/or why pathogens appear on farm. There is on-going research in Federal agencies as well as various academic instititions e.g. Washington, Colorado, and Georgia, on this issue for various animal species.

Need research

Another panel could focus on research aimed at improving the ability to rapidly detect pathogens as well as on intervention technologies that are under development in research labs. This could also include work on sensor technology to be used on retail packages. It also might be possible to bring NASA research and technology into the food safety arena. In addition to these panels on research, there could be a panel on new food safety technologies and technological developments that are in use in slaughter and processing operations.

Global

A final panel could be on future trends and challenges of the future, such as continued globabization of the food supply, population demographics, new products, packaging, and production technologies, and the effect those trends may have on our food safety research and technologies. This would complement the long-term strategic planning underway by the Federal food safety agencies.

The conference could be used as a forum for a speech, or the President or Vice President could host a general discussion on these issues, and then panels could be convenee throughout the day. There could also be displays and demonstrations of research and technological developments.

Possible Announcements for Conference

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First, the President could issue a directive or an executive order on food safety research and technology. This would include several components:

> --**Interagency Food Safety Research Council**--As part of the President's Food Safety Initiative, the Administration has recently formed an interagency food safety research group. There are xx agencies represented on this group, which is charged with developing a comprehensive food safety research agenda. The Executive Order would institutionalize this working group.
>
> --The Executive Order could require the council to hold annual or biannual national public meetings/conference to discuss advances in research and technology.
>
> --The Executive Order could also direct the council to award annual or biannual Presidential Awards for Advances in Food Safety Research and Technology.

Second, the Centers for Disease Control is in the process of completing its analysis of the latest data on the extent of foodborne illness. Depending on the timing of the conference, this could possibly be released at the conference.

Third, depending on the timing of the conference, the Administration could announce implementation of PulseNet, which CDC will implement in the next 6-8 weeks. Pulsenet will electronically link CDC, USDA, and FDA labs with state public health labs in several states (with more states to be added by years end). The labs are all equipped with DNA fingerprinting technology, with the CDC laboratory serving as a hub and database for PulseNet. It works like this--a laboratory isolates E. coli O157:H7 from food--fingerprints it and enters the information into PulseNet. The laboratory then receives information on any similar fingerprints submitted on human pathogens by CDC or the States. In this way, PulseNet can identify a potential outbreak or a potential food source of an outbreak. This approach resembles the FBI national network and database for fingerprinting individuals throughout the United States and centrally generating a "rap" sheet where there is a match.

Food safety

THE WHITE HOUSE
WASHINGTON

EK –

Very preliminary report on the extent of foodborne diseases in U.S. USDA is cautious about its news value but I think it may be useable.

Also, here's the CRS side by side on tobacco.

Tom –

When can the report be released? What can it be combined with?

Elena –

But there needs to be some kind of executive summary with the most notable findings – it's impossible to read this and figure out what's important.

Remarks before the Committee to Ensure Safe Food from Production to Consumption
Jerold R. Mande, Senior Advisor to the Director, Office of Science and Technology Policy
March 24, 1998

- I am here today to tell you about President Clinton's and Vice President Gore's extensive efforts -- past, present, and future -- to ensure that our nation's food supply -- which is already among the world's safest -- is even safer. The administration has been focused on strengthening the nation's food safety systems since its earliest days in office. We have developed an ambitious plan and we are moving forward to implement it just as quickly as we can get the funds from Congress to do so.

- We welcome the efforts of this Committee. As you have already seen over the course of your meeting, the administration is eager to work with you and provide you with the knowledge we have gained over the past five years.

- In January 1993, just days after President Clinton and Vice President Gore took office, they were confronted with one of the first challenges to their new administration. A lethal outbreak of foodborne illness in the Pacific Northwest had sickened hundreds and would ultimately kill four young children. From that day forward President Clinton and Vice-President Gore have been committed to improving the safety of the nation's food supply.

- Government has promised the American people a bountiful and safe food supply since the turn of the century. It is a commitment we have had to renew from time to time, and it is one the administration quickly learned was in need of a lot of work in 1993.

- In response to the 1993 foodborne *E. coli O157:H7* outbreak, President Clinton asked the Vice President to examine our country's food safety system and to put together a plan to strengthen it. In September 1993, Vice President Gore issued a wide-ranging reinventing government report that included food safety recommendations. The report, entitled From Red Tape to Results: Creating a Government that Works Better called on the government regulatory agencies to develop rigorous, scientifically based systems for conducting inspections. This recommendation led to the adoption of the HACCP (hazard analysis and critical control point) system that is revolutionizing food safety.

- The Vice President's review also examined the organization of food safety within the federal government. His reinventing government team studied the important roles played by more than 20 agencies. His team explored the strengths and weaknesses of the current organization. And in the report's recommendations the Vice President began a conversation, which this committee has now joined, on how to best organize the government's resources so that we can have the safest food supply possible. We welcome your participation.

- Vice President Gore's report marked only the beginning of the administration's work on food safety. As you know, FDA and USDA followed the report's recommendation on science-based, preventive controls, and today, after a lot of hard work by the agencies and regulated industry, HACCP is becoming the new standard for insuring the safety of our food. It is now the standard for seafood, and for meat and poultry, and we are continuing to study its broader application. In 1994, CDC embarked upon a new program to detect, prevent, and control emerging infectious diseases, including foodborne diseases. With added resources and help from USDA and FDA, the administration built the FoodNet early warning system the President announced last year. In 1996, President Clinton signed the Food Quality Protection Act, a comprehensive overhaul of our laws that regulate pesticides in food. The administration had laid the groundwork for this historic legislation during the first two years of the President's first term. It was another critically important step for the administration on food safety.

- Also in 1996, work began on the President's Food Safety Initiative, which you were briefed on yesterday. That effort, which the President announced in his first radio address of his second term, serves as the current blue print of much of our ongoing work to continue rebuilding the nation's food safety infrastructure. In 1997, as the President requested, Congress appropriated the $43 million to implement his Food Safety Initiative.

- Today, because of the President's and Vice-President's efforts, the agencies are working more closely together than they ever have before. That has resulted in improvements in our current system that were not possible five years ago. But we know we still have a lot of work to do. We will take another very important step forward if Congress provides the $101 million and the new legislative authority on imports that President Clinton has called for. We welcome this committee's voice to the dialogue on food safety. We recognize the pressure you are under to complete your work by your August deadline. But we urge you to make every effort to finish your report on time, so that we can benefit from your efforts as we plan the next steps in reaching the goals President Clinton and Vice-President Gore set in 1993.

- Thank you.

OFFICE OF THE VICE PRESIDENT
WASHINGTON

March 23, 1998

MEMORANDUM TO: Wendy Taylor, Sally Katzen, Tom Freedman, Rahm Emanuel, Jean Logan, Jack Gibbons, Don Gips

FROM: Morley Winograd

RE: Testimony Tomorrow

Jerry Mande is scheduled to give testimony at 10 am tomorrow morning before the National Academy of Science (NAS) Committee to Ensure Safe Food from Production to Consumption. Your comments would be greatly appreciated. Please return to Jack Gibbons in OEOB 424 as soon as possible.

Not well organized

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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NATIONAL RESEARCH COUNCIL
Telephone: (202) 334-3062
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Open Meeting on Ensuring Safe Food From Production to Consumption

This meeting is being held to gather information to help the committee conduct its study. This committee will examine the information and material obtained during this, and other public meetings, in an effort to inform its work. Although opinions may be stated and lively discussion may ensue, no conclusions are being drawn at this time; no recommendations will be made. In fact, the committee will deliberate thoroughly before writing its draft report. Moreover, once the draft report is written, it must go through a rigorous review by experts who are anonymous to the committee, and the committee then must respond to this review with appropriate revisions that adequately satisfy the Academy's Report Review committee and the chair of the NRC before it is considered an NRC report. Therefore, observers who draw conclusions about the committee's work based on today's discussions will be doing so prematurely.

Furthermore, individual committee members often engage in discussion and questioning for the specific purpose of probing an issue and sharpening an argument. The comments of any given committee member may not necessarily reflect the position he or she may actually hold on the subject under discussion, to say nothing of that person's future position as it may evolve in the course of the project. Any inference about an individuals's position regarding findings or recommendations in the final report are therefore also premature.

NATIONAL ACADEMY OF SCIENCES
INSTITUTE OF MEDICINE
NATIONAL RESEARCH COUNCIL

ENSURING SAFE FOOD FROM PRODUCTION TO CONSUMPTION

Food and Nutrition Board
Board on Agriculture

STATEMENT OF WORK

The National Academy of Sciences, through the Institute of Medicine's Food and Nutrition Board (FNB) and the National Research Council's Board on Agriculture (BA), proposes to undertake initially a 9-month study on Ensuring Safe Food from Production to Consumption. A commission composed of selected members of the FNB, BA, and the Board on Environmental Sciences and Toxicology (BEST), will convene a committee to (1) determine the scientific basis of an effective food safety system, (2) assess the effectiveness of the current food safety system, (3) identify scientific needs and gaps within the current system, and (4) provide recommendations on scientific and organizational changes needed to ensure an effective science-based food safety system for present and future generations. If organizational changes are recommended, a subsequent study on implementing the recommendations could follow if requested. The initial study will examine the current mechanisms in place for ensuring a safe food supply, the extent to which they are effective in addressing food safety issues from production to consumption, and will make recommendations where needed to ensure safe food.

NATIONAL ACADEMY OF SCIENCES
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Table 8: Patient Outcome by Pathogen for All Sites
From January 1, 1997 to December 31, 1997

Pathogen		Alive	Unknown	Dead	Total
Campylobacter	Cases	2972	871	2	3845
	Percent	77.3%	22.7%	0.1%	100.0%
E. coli 0157	Cases	329	4	10	343
	Percent	95.9%	1.2%	2.9%	100.0%
Listeria	Cases	50	5	14	69
	Percent	72.5%	7.2%	20.3%	100.0%
Salmonella	Cases	1843	405	11	2259
	Percent	81.6%	17.9%	0.5%	100.0%
Shigella	Cases	970	262	1	1233
	Percent	78.7%	21.2%	0.1%	100.0%
Vibrio	Cases	25	24	0	49
	Percent	51.0%	17.0%	0.0%	100.0%
Yersinia	Cases	112	23	0	135
	Percent	83.0%	17.0%	0.0%	100.0%
Total	Cases	6301	1594	38	7933
	Percent	79.4%	20.1%	0.5%	100%

This table shows the number of known deaths of patients who tested positive for one of the seven targeted pathogens. Note that these deaths may or may not have been caused by the pathogen, but may be attributable to an underlying illness such as AIDS. Further case control study is warranted.

Food safety 1998

Foodborne Disease Surveillance Network (FoodNet) through CDC's Emerging Infections Program sites in 1996.

The goals of FoodNet are to:

- Describe the epidemiology of new and emerging bacterial, parasitic, and viral food-borne pathogens.
- Estimate the frequency and severity of food-borne diseases that occur in the United States each year.
- Determine how much food-borne illness results from eating specific foods, such as meat, poultry, and eggs.

The public health challenges of food-borne diseases are changing rapidly. Changes in food production have led to new safety concerns. Many foods, previously thought to be safe, such as eggs and fruit juice, have both transmitted *Salmonella* in recent outbreaks. Other food-borne diseases included infections caused by *Shigella, Campylobacter, Escherichia coli O157, Listeria, Yersinia, and Vibrio* bacteria.

Internationally, U.S. government agencies have intensified their efforts to respond to outbreaks of highly contagious, highly lethal, or drug-resistant diseases, especially when they occur in countries that lack the resources and infrastructure to contain them. USAID, CDC, and other agencies are also supporting the efforts of the WHO to improve communications networks and build regional centers for surveillance of and response to infectious diseases. The WHO is sponsoring the development of sub-regional teams, or "hubs," for disease surveillance and outbreak control -- an idea that is in full accord with the goals of the CISET working group.

The DOD has contributed to the international surveillance and response effort by expanding the mandate of its overseas laboratories to include epidemiological training and laboratory capacity related to diagnosis of infectious disease outbreaks. These DOD facilities work closely with experts in the countries where they are located, thereby helping to build local capacity.

Research and Training

A major CISET goal is to promote research on tropical diseases by combining the scientific and clinical experience of doctors and scientists in less-developed countries with the scientific resources of industrialized countries. The NIH is the lead agency in this area.

Over the past year, the National Institute of Allergy and Infectious Diseases (NIAID) at NIH has substantially expanded its research efforts on emerging diseases and the

Fogarty International Center (FIC) at NIH, in close cooperation with NIAID, has launched a $1.9 million program to provide infectious disease training for scientists in developing countries. NIH has also launched a Multilateral Initiative on Malaria that includes participation by other agencies of HHS, French and English research institutes (the Pasteur; INSERM, France's counterpart to NIH; ORSTOM, part of France's overseas development effort; and the British Medical Research Council), the Wellcome Trust, and the European Commission. As part of this initiative, the NIH has committed more than $1 million for a WHO program to strengthen malaria research in Africa.

On Sunday, March 8, the American Society for Microbiology (ASM), CDC, and NIH are convening a workshop, "Training in Emerging and Re-Emerging Infectious Diseases." This and other workshops related to emerging infectious diseases globally will be convened prior to and after the *International Conference on Emerging Infectious Diseases* to be held March 8-11, 1998, in Atlanta. This international conference is being organized by CDC, the Council of State and Territorial Epidemiologists, ASM, and the CDC Foundation, and has more than sixty cosponsors. There will be participation by many of our partner countries as well as WHO, PAHO, the World Bank, and USAID.

I would like to mention two other relatively new areas of infectious disease research that may be of interest to this Committee. One is the use of remote sensing technologies and global positioning systems to examine links between weather changes (such as those due to El Nino) and the incidence of infectious diseases carried by insects and animals. The hope is that this avenue of research will lead to the development of methods for predicting outbreaks of such diseases as malaria and dengue fever. CDC, NIH, NOAA, and NASA are collaborators in these efforts. The other area is research on infectious agents that may cause or exacerbate chronic conditions like ulcers, heart disease, or some types of cancer.

Engaging the Private Sector

FDA has taken the lead in creating partnerships with the private sector. In collaboration with WHO and private sector partners, the CISET agencies are preparing an international procedures manual for obtaining medical products during emergencies. FDA and its partners are also consulting with representatives of the U.S. pharmaceutical industry on how to promote the development of new drugs, vaccines, and diagnostic tests. In addition, FDA has engaged the regulatory bodies and pharmaceutical industries of Japan and the European Union (EU) in an effort to promote international harmonization of standards for medical products.

Private sector partnerships have been crucial in responding to particular outbreaks and emergencies over the past year. For example, CDC and FDA collaborated with drug manufacturers to address the shortage of vaccines for use in controlling a

Food Safety

Tom--

Here's the draft press release on the new salmonella product. It is going to be changed to include an FDA quote as well.

I'm also resending the longer document explaining the food safety research and technology conference. I believe that OSTP is interested in this idea.

One could easily use the announcement of this new product as the hook for announcing the conference. Center for Science in the Public Interest, a major consumer group, has written the Secretary asking that USDA host another conference. A conference would also be supported by industry, academia, and would receive bipartisan support on the Hill.

Our plan is to announce the product at a National Press Club speech on Thursday the 19th.

If you want to pitch this, we need to discuss one potential issue, so give me a call first.

Eric