



U.S. DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY

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FAX COVER SHEET

DATE: _____

NUMBER OF PAGES _____, INCLUDING COVER SHEET

PLEASE DELIVER TO: Tom Friedman / Mary Smith

Fruits & Veggies

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

- FROM:
- ☐ DAN GLICKMAN, SECRETARY
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 - ☒ 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 growers will fear
retaliation...

Food Safety
Guatemala
EW

FEB-27-1998 01:48

ITP

INCOMING

FOREIGN AGRICULTURAL SERVICE

TELEGRAM

UNCLASSIFIED

GUATEMALA 729

PAGE: 1 OF 2

FAS ACTION:

FAS INFO:

APHIS10

ERS_CABLES

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24-FEB-1998 20:28Z

FM AMEMBASSY GUATEMALA

TO RUEHC/SECSTATE WASHDC IMMEDIATE 0765

RUEHRC/FAS WASHDC

RUEMPH/CDC ATLANTA GA

RUEAUSA/DEPT OF HHS WASHDC

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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FEB-27-1998 01:48

ITP

202 720 0069

P.03/03

INCOMING

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TELEGRAM

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PAGE: 2 OF 2

GUATEMALA 729

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

UNCLASSIFIED



United States Department of Agriculture
Food Safety and Inspection Service

Food Safety Briefing
FAX

To: MARY Smith

Fax #: 456-7431

Subject: (Talking Points for Tom Freedman)

Date: Jan Monahan

Pages: 3 including this cover sheet.

COMMENTS:

Let me know if you need
anything else.

From the desk of

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TALKING POINTS FOR FOOD SAFETY INITIATIVE

- **I want to thank you for coming today to the White House to hear the President's goals for his FY 1999 Food Safety Initiative. My name is Tom Freedman from the Domestic Policy Council and I want to welcome you to the White House**

ENSURING THE SAFETY OF THE FOOD SUPPLY

- **Ensuring the safety of the nation's food supply is a top public health priority for the Administration. We here today—share the same goal of building a food safety system with new protections in place that will reduce the number of foodborne outbreaks and illnesses.**
- **Every parent in America remembers what *E coli 0157:H7* can do and every parent in America wants the peace of mind that the juice their children drink and the hamburger that they order for dinner will be safe.**
- **That is why the president has announced new steps and requested additional funds for his FY 1999 Food Safety Initiative.**
- **Since 1993, the Administration has been committed to meeting the goal of a safe food supply, clean air, and safe drinking water. We signed into law the Safe Drinking Water Act and the Food Quality Protection Act, and modernized the nation's meat, poultry and seafood inspection system by putting in place science based controls and microbiological testing.**
- **In may 1997, the Administration announced a new comprehensive food safety Initiative—that takes a farm to table approach and focuses on the hazards that present the greatest risks. It includes preventative measures that will reduce foodborne illness.**

THE FY 1999 FOOD SAFETY INITIATIVE—HOW WE ARE GETTING THERE

- **First, we put in place a nation-wide early warning system for food-borne illness. Right now the Center for Disease Control, The Food and Drug Administration, and the United States Department of Agriculture are working with data generated by this system to monitor outbreaks and prevent illnesses by tracing dangerous bacteria to its source.**

- **Second, this proposal strengthens the foodborne outbreak response coordination between FDA, USDA and CDC and will develop standard operating procedures to ensure an effective, rapid and coordinated response by our Federal Food Safety Agencies.**
- **It continues to pay special attention to research-- detecting emerging pathogens and using rapid cost effective tests to identify a broader range of hazards in products including fruits and vegetables**
- **And it will continue to build our Private-Public Partnerships to promote Food Safety Education with the emphasis on changing unsafe behaviors used by home food handlers and food handlers in our school cafeterias.**
- **Finally, there is a strong focus on preventing problems--instead of catching problems after they occur --by using the science-based Hazard Analysis and Critical Control Points (HACCP) food inspection approach for food products and by seeking additional authorities for FDA to improve the safety of imported foods.**
- **With these added public health investments, we are saying loud and clear that we will use the world's best science to make the world's most bountiful food supply safer than before for our families and children and that you and the Federal Food Safety Agencies will help to prepare our nation for the 21st century.**
- **I am going to ask Dr. Mori Potter, Dr. Catherine Woteki and Dr. Freidman to go into more details on the FY 1999 Food Safety Initiative and we would like to hear any thoughts, suggestions, that you may have.**
- **I want to conclude by thanking you on behalf of the Administration, for the support that you have given to these initiatives and for the accomplishments that we have achieved together in identifying, targeting and preventing foodborne illnesses.**

FOOD SAFETY FROM FARM TO TABLE: A NATIONAL FOOD SAFETY INITIATIVE

EXECUTIVE SUMMARY

A Consolidated, Multi-Agency Plan for Improving Food Safety

The fiscal year (FY) 1999 integrated food safety initiative budget presents a coordinated proposal of actions to enhance the safety of the Nation's food supply by building on the accomplishments that have begun to be realized in FY 1997 and will be furthered in FY 1998. The FY 1998 budget initiative brought new resources to enhance surveillance of foodborne disease outbreaks and better coordinate our response to outbreaks, improve inspections and compliance, target important new research and risk assessment to critical scientific gaps, and expand education and training especially to promote the use of safe food handling practices. The FY 1999 initiative will build on gains made in these areas, and place increased emphasis on ensuring the safety of domestic and imported fresh produce. Our experience of working together for the past year has also helped us identify new opportunities to avoid duplication of effort and to leverage agency resources.

The Administration, through a Presidential Directive issued on October 2, 1997, is taking additional actions to improve the safety of domestic and imported fresh fruits and vegetables. The President has proposed additional funds to enable the Food and Drug Administration (FDA) to expand dramatically its coverage of imported foods and will continue to seek legislation that would enable FDA to prevent the import of fruits, vegetables, or other foods from any foreign country whose food safety systems for exported products are not on par with those of the United States. Additional funds are included in the budget for the U.S. Department of Agriculture (USDA) and FDA for research that will enhance our understanding of pathogenic contamination on fruits and vegetables and lead to improved controls for ensuring the safety of these commodities. In addition, the President has directed the Secretaries of the Department of Health and Human Services (HHS) and USDA to work together with the agricultural community to develop guidance on good manufacturing practices and good agricultural practices for fruits and vegetables as well as to accelerate food safety research, and provide education and outreach to domestic and foreign producers. FDA, working with USDA, undertook development of these guidelines and public outreach to the broad agricultural community with no new resources in FY 1998.

The impetus to focus increased Federal attention on food safety came from a number of sources. The most important of these sources is the rapidly increasing number and complexity of food safety problems (such as newly recognized pathogens and their appearance on foods, such as fresh produce, where they had not been detected before). These trends, along with the increasing number of foodborne disease outbreaks, and increasing public concern, highlighted the need for significant new

resources to help the food safety agencies will not be able to meet the challenges of the 21st century. Estimates cited in the report released by the Vice President in May 1997 are that every year from 6.5 million to 33 million Americans become ill and as many as 9,000 die as a result of foodborne pathogens. These illnesses and deaths are far too many. Our challenge is to continue to build the best food safety system possible and to reduce the burden of avoidable human suffering and economic loss to the greatest extent possible.

The FY 1998 Food Safety Initiative

The increase of \$42.8 million approved by Congress for FY 1998 to support the President's National Food Safety Initiative is the first installment of a major governmentwide effort to enhance the safety of the Nation's food supply. The initiative has won wide support among industry and consumer groups and the general public.

The FY 1998 Food Safety Initiative cited seven critical elements of a comprehensive and more effectively coordinated nationwide program required to improve the safety of the food supply and, thereby reduce the possibility that consumers will suffer the adverse health and economic consequences of foodborne infections. Key components of this interagency initiative included the following activities:

- Build enhanced "early warning" and surveillance systems to help detect and respond to foodborne illness outbreaks, and to provide the data needed to prevent future outbreaks.
- Achieve better coordination of interagency responses to foodborne disease outbreaks including electronic communication and data exchange among Federal, State, and local health authorities.
- Develop and implement inspection strategies that provide greater assurance of the safety of foods, including implementation of Hazard Analysis Critical Control Point (HACCP) and other food safety control systems, and enhanced inspection coverage of food processors and imported foods.
- Improve risk assessment methods for foodborne pathogens and develop data bases needed to help food safety agencies to better characterize the nature and size of risk to humans and make decisions on how to best allocate resources to control the hazards.
- Expand food safety education and training particularly for consumers and retail food service workers to acquaint them with safe food processing, storage, and handling techniques.
- Conduct research to develop more effective methods for detecting, controlling, and preventing foodborne hazards.
- Continue long-range strategic planning for improving the food safety system.

The FY 1999 Food Safety Initiative

The FY 1999 Food Safety Initiative further reflects the coordination between the Federal food safety agencies and builds on the key components identified in the FY 1998 initiative. A new focus is being placed on enhancing the safety of domestic and imported fruits and vegetables, facilitating the adoption of HACCP systems, improving the food handling practices of school food service providers, and develop information and tools necessary to cover a broader range of food safety hazards.

Surveillance

CDC, USDA, and FDA will continue to build the capabilities of the national early-warning surveillance system to help detect and respond to outbreaks of foodborne illness earlier, and will add new emphasis on training, technical assistance, and investigations.

Enhance surveillance and investigative systems: CDC and FDA will direct additional resources to FoodNet sites and other State and local health departments to improve outbreak investigations, to expand the range of pathogens under surveillance, to begin implementing and evaluating control strategies, and to facilitate intrastate, interstate, and State-Federal information sharing. In addition, CDC will enhance foodborne disease surveillance and control activities, including standardized molecular subtyping methods for bacterial foodborne pathogens.

Epidemiologic and technical studies of emerging and drug-resistant pathogens and other contaminants: FDA will work with CDC and USDA to monitor the incidence of foodborne disease associated with emerging and drug-resistant pathogens. CDC will initiate training and technical assistance to State and local health agencies to improve diagnostic capacity for foodborne diseases and to support development of better diagnostic assays for clinical specimens.

Improve and enhance workforce competency: CDC will provide four new Epidemic Intelligence Service (EIS) officers to improve investigation of foodborne diseases, and will establish a training program in pathogen identification with an emphasis on new technologies aimed at a wide range of State Health Department professionals.

Coordination

Federal agencies and State representatives have formed an intergovernmental group, the Foodborne Outbreak Response Coordinating Group (FORCG), to evaluate and make recommendations for improving responses to interstate outbreaks of foodborne illness. This cooperative effort will be continued and expanded to provide rapid, efficient response to foodborne outbreaks and minimize their spread.

Expand assistance to State and local Governments: FDA, USDA and CDC will work with other Federal agencies to expand assistance to State and local Governments to develop the infrastructure necessary to ensure quick and accurate detection and coordination of response to outbreaks, and evaluation of those responses.

Inspections and Compliance

Monitoring the food supply to ensure its safety must occur at several levels to be effective: for example, Federal assessment of agricultural and production practices in foreign countries; Federal oversight of imported and domestic products in the United States; local oversight of food processing and manufacturing facilities, retail food, food service, and institutional establishments such as school lunch programs. FDA, USDA, CDC and the Environmental Protection Agency (EPA) will build on and expand efforts already underway through the President's National Food Safety Initiative. These will include additional steps to ensure the safety of imported foods; development of good agricultural and good manufacturing guidance for produce; continued progress to implement HACCP for seafood, meat and poultry products; continued development of HACCP for appropriate sectors of the food industry; and additional progress toward development of partnerships among agencies at the Federal, State, and local levels.

Seek statutory authority to assure imported food safety: FDA is seeking statutory amendments to the Food, Drug and Cosmetic Act to enable the agency to assure that imported products are produced under systems that provide the same level of protection as the U.S. system.

Develop Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) Guidance: FDA and USDA, will work with the agriculture community to develop and issue GAPs and GMPs to minimize microbial hazards in fresh produce.

Expand HACCP and HACCP training: FDA, working with industry partnerships, will expand HACCP in appropriate sectors of the food industry, such as implementing HACCP in the juice industry. USDA will provide HACCP training to State meat and poultry inspectors and provide special assistance to facilitate the transition of State programs to HACCP by 2000.

Develop assistance and outreach to State and local programs: FDA and USDA will work to expand efforts to achieve adoption of the Food Code.

Risk Assessment

Risk assessment methods help characterize the nature and magnitude of risks to human health associated with foodborne hazards and assist regulators in making decisions about where in the food chain to allocate resources to control those hazards. Risk assessment also focuses data collection and scientific research in the most critical areas. Working together, the Federal agencies with food safety and risk assessment responsibilities will build on and expand efforts already underway through the National Food Safety Initiative announced in May 1997. Intensive work is needed to develop better risk assessment methods and models to make it possible to carry out quantitative risk assessments for microbial agents.

Develop and evaluate risk-based pathogen reduction strategies for food animal producers: USDA will evaluate science-based pathogen reduction systems that are compatible with HACCP-based inspection systems. Evaluate costs and benefits of alternative pathogen control strategies using risk assessment results.

Expand activities of the Risk Assessment Consortium: In FY 1997, FDA, USDA, and EPA established an interagency risk assessment consortium at the Joint Institute of Food Safety and Applied Nutrition at the University of Maryland. The goal of the consortium is to cooperatively advance the science of microbial risk assessment. The agencies will work to further focus critical research needs and reach consensus on the priorities of those needs based on their potential to reduce the uncertainty of risk management decisions.

Develop better data on human exposures to foodborne agents: FDA, CDC, USDA, and EPA will work together to conduct several risk assessment activities including food-consumption surveys targeted to specific subpopulations, development of more effective exposure modeling techniques, and development of better animal models for infectious microorganisms.

Develop better modeling techniques: FDA, USDA, and EPA will develop more effective modeling techniques for the growth, death and adaptation of foodborne and waterborne pathogens at all points from farm to table.

Education

Food safety education is an integral part of a successful, coordinated food safety program. In FY 1997, FDA, Food Safety and Inspection Service (FSIS), Cooperative, State, Research, Education, and Extension Service (CSREES), and CDC laid the foundation for a nationwide food safety education campaign, in a new public-private partnership with industry, consumer groups, and State representatives through the Association of Food and Drug Officials. The basis of the campaign is four key food safety messages based on research to be used by educators nationwide. In FY 1998, the agencies are focussing on consumers. The goal for FY 1999 is to develop

product-specific and audience-specific messages to address risks relevant to groups throughout the food chain.

Improve producer and distributor education: FDA and USDA will initiate communication about GAP and GMP guidance to appropriate audiences. USDA will continue coordination with States to educate producers, processors, and distributors on risk management, risk communication, and safety assurance.

Improve retailer and food service worker education: USDA will provide education to local school food service professionals based on the Food Code (a 1999 revision is planned). FDA and USDA will continue training for State sanitarians on new retail and restaurant food processing techniques. Development of multilingual training programs (begun in FY 1998) will be expanded.

Develop education programs for school children: CDC, FDA, and USDA will train school teachers to teach food safety concepts to school children (in collaboration with State, territorial, local, and other relevant organizations).

Improve consumer and health professional education: FDA and USDA will continue to develop and implement research-based education materials to convey food safety information. CDC will educate and train epidemiologists and public health laboratory workers in proper detection, surveillance, and outbreak investigation of foodborne disease and, internationally, will work with the World Health Organization and other organizations to train health professionals in those settings.

Research

Food safety practices and programs must be science-based to effectively detect and identify pathogens, minimize their presence, assess risk, and respond to outbreaks. Basic research is needed to understand the ecology and etiology of foodborne pathogens, their genetic content, how they multiply, how they are transmitted, and under what conditions they grow. Applied research is then needed to develop the practices and technologies that will enable pathogen detection and control. To better coordinate food safety research, the FY 1999 food safety initiative includes development of an interagency process coordinated by the National Science and Technology Council for reviewing ongoing research and identifying basic research needs and that which is helpful to regulatory agencies. Agencies include USDA's FSIS, Agricultural Research Service (ARS), and CSREES, and HHS' FDA and CDC, and EPA.

Develop rapid, cost-effective tests for pathogens in foods: FDA, USDA, CDC, and EPA will collaborate to develop effective methods to detect, identify, and quantify pathogens, with particular emphasis on imported and domestic fresh fruits and vegetables and on pathogens in animal wastes.

Enhance understanding of how pathogens become resistant to food preservation techniques and to antibiotics: FDA and USDA will conduct research into physiological, genetic, and other factors that cause hazardous foodborne microorganisms to develop resistance to preservation techniques, and into the factors that contribute to development of drug resistance by pathogens.

Develop prevention techniques for pathogen avoidance, reduction, and elimination: USDA and FDA will work with other agencies at the Federal and State level, as well as industry and academia to identify points of contamination and to develop new production, processing, and distribution practices that avoid the introduction of contaminants into food producing animals and food, or if contamination is present, reduce levels of or eliminate the contamination. Technologies will include antimicrobial agents, and thermal and non-thermal pasteurization, including irradiation. Collaborative work will also focus on developing systems for improved sanitation of animal production facilities and for handling liquid and solid animal wastes.

Develop better food handling, distribution, and storage procedures: FDA and USDA will evaluate conditions that influence the possibility of food contamination during handling, transportation, and storage, and will develop methods to minimize those conditions.

Develop microbiological baselines for pathogens on fruits and vegetables: Utilizing existing program infrastructure, USDA will conduct a scientifically-sound microbiological survey program for foodborne pathogens on domestic and imported fruits and vegetables. Program costs will be minimized by using the existing infrastructure of the Pesticide Data Program for statistically reliable sampling, participating laboratories, and data reporting capabilities.

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- **Since 1993, the Administration has been committed to meeting the goal of a safe food supply, clean air, and safe drinking water. We signed into law the Safe Drinking Water Act, the Food Quality Protection Act, implemented Seafood HACCP and modernized the nation's meat and poultry inspection system by putting in place science based controls and microbiological testing.**
- **In may 1997, the Administration announced a new comprehensive food safety Initiative—that takes a farm to table approach and focuses on the hazards that present the greatest risks. It includes preventative measures that will reduce foodborne illness.**

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- It continues to pay special attention to research— detecting emerging pathogens and using rapid cost effective tests to identify a broader range of hazards in products including fruits and vegetables
- And it will continue to build our Private-Public Partnerships to promote Food Safety Education with the emphasis on changing unsafe behaviors used by home food handlers and food handlers in our school cafeterias.
- Finally, there is a strong focus on preventing problems—instead of catching problems after they occur —by using the science-based Hazard Analysis and Critical Control Points (HACCP) food safety control system approach for food products and by seeking additional authorities for FDA to improve the safety of imported foods.
- With these added public health investments, we are saying loud and clear that we will use the world's best science to make the world's most bountiful food supply safer than before for our families and children and that you and the Federal Food Safety Agencies will help to prepare our nation for the 21st century.
- I am going to ask Dr. Morri Potter, Dr. Michael Feidman and Dr. Catherine Woteki to go into more details on the FY 1999 Food Safety Initiative and we would like to hear any thoughts, suggestions, that you may have.
- I want to conclude by thanking you on behalf of the Administration, for the support that you have given to these initiatives and for the accomplishments that we have achieved together in identifying, targeting and preventing foodborne illnesses.

in budget - ~~not~~ \$101 million
 \$25 million to new inspectors

Background

U.S. Department of Agriculture

Department of Health and Human Services

Revised February 1998

1999 National Food Safety Initiative

On January 25, 1997, the President announced the National Food Safety Initiative. The initiative includes components for reducing the incidence of foodborne illness from farm-to-table. Key components include expansion of the Federal food safety surveillance system, improved coordination between Federal, State, and local health authorities, improved risk assessment capabilities, increased inspection, expanded research, consumer education, and strategic planning. Utilizing the funds provided by Congress in 1998, an increase of \$43 million, the U.S. Department of Agriculture (USDA) and Department of Health and Human Services (HHS) have initiated changes to ensure the safety of a wider variety range of food products from a broader range of hazards. In addition, USDA and HHS have identified measures that need to be taken to ensure the safety of fresh fruits and vegetables consistent with the President's directive on this issue. USDA, HHS, and other interested parties will seek input on measures that can be taken to improve food safety during production, transportation, storage, distribution, and in the home.

1999 Budget Request

For 1999, the Administration is proposing an increase of \$101 million for the National Food Safety Initiative. Of this amount, \$46 million is allocated to USDA and \$55 million to HHS. The 1999 National Food Safety Initiative builds on the successes of the 1998 initiative as well as fills the gaps that have been identified in the past year. In 1999, the focus of the initiative is on enhancing the safety of imported and domestic fruits and vegetables, targeting food safety education, implementing of Hazard Analysis and Critical Control Point (HACCP) systems in appropriate sectors of the food supply, and developing of scientific information and tools to control a greater range of food safety hazards. Funding is requested for the following activities:

Enhance surveillance and investigation to improve outbreak response (+\$7 million):

HHS (+\$6.7 million): The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) will work with States to identify potential food safety threats early. CDC and FDA will further build the capabilities and coverage of the FoodNet early-

warning surveillance system and will improve monitoring of threats to food by expanding the range of pathogens under surveillance. The agencies also will improve information sharing among agencies and with the public, and provide training and technical assistance to State/local agencies for outbreak investigation.

USDA (+\$0.3 million): The Economic Research Service (ERS) will evaluate the effectiveness of food safety measures by analyzing foodborne illness surveillance data. New estimates will be developed for the national incidence of foodborne disease, distribution of illness among subpopulations, and rates of illness.

Strengthen coordination and improve efficiency (+\$0.2 million):

HHS will work with other Federal agencies and States to expand assistance to states and local governments in developing the infrastructure necessary to ensure proper detection, evaluation, and coordination in response to foodborne outbreaks. Standard operating procedures for sharing information and data among agencies and with the public on foodborne outbreaks will be developed.

Improve capability to estimate risks associated with foodborne hazards (+\$11 million):

HHS (+\$7 million): FDA will initiate a program of research in quantitative risk assessment (particularly for microbial hazards) that is targeted to address the limitations in risk assessment methodologies and available data related to 1) dose-response relations for the general population and high risk groups (e.g. neonates, elderly, immune-compromised), 2) the impact of production, processing, distribution, marketing, and preparation practices, and 3) the quantification of factors contributing to incidence and prevalence of pathogenic microorganisms in raw ingredients and finished products. FDA will continue to build the activities of the interagency Risk Assessment Consortium at the Joint Institute for Food Safety and Nutrition (JIFSAN) that provides a forum for coordination of federal microbial risk assessment research and serves as a clearinghouse for risk assessment information and expertise.

USDA (+\$4 million): The Agriculture Research Service (ARS), Cooperative State Research, Education and Extension Service (CSREES), ERS, FSIS, and the Office of the Chief Economist (OCE) will conduct quantitative risk assessments to identify food safety hazards and controls, make faster and more accurate regulatory decisions, target program resources more effectively, and facilitate the development and evaluation of surveillance plans and risk reduction strategies.

Expand inspection and compliance efforts, implement new preventive measures with a new emphasis on domestic and imported produce, and facilitate the implementation of HACCP (+\$36 million):

HHS (+\$28 million): FDA will enhance protection of American consumers by seeking legislation that would decrease the risk of importing unsafe food products from countries with food safety systems for exported products that are not on a par with the U.S. system or that refuse to allow entry of U.S. investigators into facilities producing products offered for import. FDA will verify implementation of seafood HACCP and implement HACCP for juices. FDA will provide technical assistance and educational outreach to promote the appropriate application of voluntary good agricultural practices/good manufacturing practices (GAP/GMP) guidance in the domestic fresh produce industry.

USDA (+\$8 million): The Food Safety and Inspection Service (FSIS) will provide special onetime assistance to State meat and poultry inspection programs to facilitate implementation of HACCP.

Continue to build the national food safety education campaign (+\$14 million):

USDA (+\$10 million) and HHS (+\$4 million) for the following activities:

Consumer and Food Handler Education--USDA (+\$5 million) and

HHS (+4 million): Building on the national campaign launched by the public-private Partnership for Food Safety Education in 1997, FSIS, CSREES and FDA will target specific programs to change unsafe behaviors used by home food handlers, cooks and food handlers in retail settings and in congregate feeding sites. CDC, FSIS and FDA will begin development of materials to assist in educating school children about how to prevent foodborne illness. FDA will target vulnerable groups (e.g., those affected by *Vibrio* in raw oysters and pregnant women and *Listeria*) with specific food safety messages. FDA will develop multilingual training programs for food service and retail workers and provide technical assistance to domestic and foreign fresh produce industries to promote appropriate application of good agricultural and manufacturing guidance. FSIS will target vulnerable groups (e.g., senior citizens and people with compromised immune systems) and will launch a campaign to promote thorough cooking of meat and poultry products.

School Food Service Provider Education--USDA (+\$2 million): The Food and Nutrition Service (FNS) will develop and operate training workshops to educate local school food service professionals about the latest safe food handling practices specific to their needs and the updated Food Code.

Producer Education--USDA (+\$3 million): FSIS and CSREES will work with industry and academia to educate food animal producers and fruit and vegetable producers on food safety assurance practices, risk management, and risk communication.

Accelerate food safety research efforts (+\$33 million):

(USDA +\$24 million and HHS +\$9 million)

Research will be conducted to enhance understanding of pathogen growth and control and will focus in the four areas identified in interagency research planning as critical to reducing microbial risk in produce. Improved detection methods, particularly rapid tests, will be developed that identify a broader range of pathogens on food products, particularly fresh fruits and vegetables, throughout the food production, manufacturing, and distribution system. Development of prevention/intervention strategies is another area of focus, with research on development of alternative food production, processing, and handling systems that eliminate or reduce pathogen contamination. Research on identification of conditions under which food products become contaminated during food handling, distribution, and storage will play an integral role in this research. FDA and USDA will conduct research on resistance to traditional preservation techniques and antibiotic resistance. USDA will develop a microbiological baseline for pathogens on fresh fruits and vegetables utilizing existing program infrastructure.

Food Safety
Fruits & Veggies
- w

February 13, 1998

Wendy, Jim, Adrienne, Lisa, Margaret, Tom, and Jerry:

Here is an FYI copy of the interagency Fruits and Vegetables research plan. They are not seeking WH clearance on this document, but thought we might be interested. If you have comments, please get them to me, and I'll pass them on the Karen Hulebak and Maureen Kelly.

Cliff



**MULTI-YEAR RESEARCH NEEDS UNDER
THE PRODUCE AND IMPORTED FOOD SAFETY INITIATIVE
- DRAFT -**

Background

Research provides the information and technologies essential to successful implementation of the guidance, inspection and compliance, education, surveillance, and risk assessment components of the Food Safety Initiative (FSI) and the Produce and Imported Foods Safety Initiative (PIFSI). Under these initiatives the Food and Drug Administration (FDA), within the Department of Health and Human Services (DHHS), and the Department of Agriculture (USDA) share jointly the responsibility for developing a research program aimed at reducing disease caused by food borne microbes and their natural products. FDA's Center for Food Safety and Applied Nutrition (CFSAN) and USDA's Agriculture Research Service (ARS) are the designated leads for developing this research plan. CFSAN requested input, within FDA, from the Center for Veterinary Medicine (CVM), the National Center for Toxicological Research (NCTR), and the Office of Regulatory Affairs (ORA), in developing this research strategy. ARS requested input, within USDA, from the Economic Research Service (ERS), the Food Safety and Inspection Service (FSIS), the Animal and Plant Health Inspection Service (APHIS), the Cooperative State Research, Education and Extension Service (CSREES), the Agricultural Marketing Service (AMS), the Foreign Agricultural Service (FAS), the National Agricultural Statistics Service (NASS), the Natural Resources Conservation Service (NRCS), and the Office of Risk Assessment and Cost Benefit Analysis (ORACBA). Contributions also have been received from additional agencies including the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Environmental Protection Agency (EPA), the Department of Energy (DOE), the Department of Defense (DOD), and the National Science Foundation (NSF). Together, these groups have coordinated their resources and expertise to work collaboratively to enhance food safety, and are accelerating their efforts to reduce microbial risk associated with fresh produce.

Under PIFSI, the President directed the FDA and USDA to use existing authorities to issue guidance on good agricultural practices (GAPs) and good manufacturing practices (GMPs) and to provide "a plan on how to ... (a) improve the monitoring of agricultural and manufacturing processes abroad, (b) assist foreign countries to improve those practices where necessary, to prevent the importation of unsafe produce, (c) consider the best ways to target inspection and testing toward those areas where problems are most likely to occur, and (d) accelerate whatever food safety research is necessary to support" all of the above tasks. Implicit in this directive is the need to address the microbial food safety concerns of produce that are specifically applicable to the needs of small businesses (farmers and manufacturers) and developing nations, through education, outreach, and technology transfer.

Currently, regulators, scientists, and the food industry are evaluating new methods of safeguarding the food supply from microbial hazards. One approach is a proactive system of preventive controls called Hazard Analysis Critical Control Point (HACCP), which emphasizes process control of food production and/or processing at critical points to assure the safety of the food product. HACCP relies less on end-product testing and more on valid, safe processing plans and procedures, with appropriate verification methods. For fresh produce (fresh and/or minimally processed fruits and vegetables), that are produced in a myriad of ways to preserve important nutrients and sensory qualities, a formal HACCP approach may not be currently applicable. Instead, a general guidance mechanism, based on the best available science, is presently being developed.

To fill knowledge gaps and to establish credible guidelines for fresh produce GAPs and GMPs, new and accelerated research must consider how recent insights into the rapid evolution and promiscuous nature of microorganisms affect our understanding of the pathogenic phenotype, the mechanisms by which a microbe

acquires resistance to antibiotics and/or to traditional barriers of food processing (e.g., preservatives, low pH, or lowered water activity), and the acquisition of virulence traits that allow survival and growth in the host. As human demographics change--i.e., the human population continues to grow, people live longer, and modern health care allows continued life for those with chronic disease--the immunity of an increasing portion of the population is compromised. Thus, any guidelines developed for control of pathogenic microbes must be based on a sound knowledge of the inherent variability in the pathogenicity and virulence of the microbes and the susceptibility of the human population.

The increased importance of the evolution of microorganisms is driven by several factors, most notably continual modernization of production/processing technologies, large scale production, and globalization of trade. Food, previously grown only in specific regions for consumption by the local population, is now transported, by various means, to a world population. Moreover, advances in agronomy and plant sciences have allowed crops to be grown in non-traditional regions. The microbial ecology of these foods, including pathogenic microbes and/or microbially-derived toxic contaminants (e.g., mycotoxins, biogenic amines, botulinal toxin, *Staphylococcal* enterotoxins), is thus relocated to new environments, and exposure to different populations and cultures occurs. The requirements for global commerce underscores the PIFSI directive to establish equivalence of food safety procedures for both (1) domestically grown produce for distribution in the United States and foreign markets and (2) foreign grown produce imported into the United States market place.

The primary regulatory responsibility for ensuring the safety of fruits and vegetables lies with the FDA, including setting standards for safeguarding human health and enforcing these standards in a scientifically and legally defensible manner. While the primary regulatory responsibility of USDA is for meat, poultry and egg products,

the USDA has the research mission to provide the means to ensure that the food supply is safe for consumers and that it meets foreign and domestic regulatory requirements. Therefore, USDA agencies carry out research to ensure the safety of fruits and vegetables to support action and regulatory agencies (including FDA) and to develop the means for producers and processors to provide safe food products. The EPA sets standards (tolerances) for pesticides and disinfectants in food, but relies on FDA to enforce those standards. EPA also sets municipal water quality standards and establishes microbiological and chemical criteria, methods, and indicators for surface waters potentially used for irrigation of produce and for the application of chemicals to produce. Furthermore, EPA promulgates sewage biosolids regulations that are used for final use or disposal, which affects cropland fertilization uses. EPA also provides sewage discharge guidance, under the National Pollutant Discharge Elimination System (NPDES), for protection of shellfish growing areas. FDA has authority over bottled drinking water and sets quality standards in close consultation with EPA.

Both USDA and FDA support research to (1) develop the science upon which regulatory decision making and enforcement relies, and (2) assist industry in developing solutions to food safety problems. Within USDA, ARS conducts research in-house, and CSREES supports extramural food safety research to university partners and other cooperators through competitive grants and mandated programs. These research programs often involve collaboration with industry. To complement in-house research, FDA partners with industry and/or academia through the establishment of consortia, such as the National Center for Food Safety and Technology (NCFST) in Summit-Argo, IL and the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) in College Park, MD. These FDA consortia support educational and outreach programs mandated by the Public Health Service Act.

The research of FDA and USDA address many food safety problems, including a plethora of technological practices, an array of animal and plant species and varieties, a range of climatic and regional differences, and a vast array of food products and consumer practices. To prevent duplication of effort both agencies have committed to a formal program of communication and collaboration that ensures effective utilization of available resources and transfers expertise and technology to appropriate venues. Both agencies and their research partners are committed to developing, in concert with industry and the public, an integrated Food Safety Research Plan consistent with the FSI and PIFSI objectives. The results of several meetings on research among the aforementioned agencies, between these agencies and industry representatives, and between these agencies and the public have identified the following priority areas: (1) improved detection methods; (2) resistance to traditional preservation techniques; (3) antibiotic resistance; and (4) intervention strategies (microbial ecology, production and processing factors, traditional and non-traditional treatments).

Improved Detection Methods

For fresh produce, there are concerns that the present methods used to monitor microbial contamination consume excessive time and resources and, thus, may negatively affect free trade. There is also concern that the present methods do not adequately ensure food safety. For example, improved methods are needed to detect and quantify microbes in irrigation, washing, and sanitation waters and in conjunction with crop fertilization where biosolids or manures have been used. Moreover, tests that are precise and rapid enough to detect contaminated foods prior to their entry into commerce will help ensure a safe food supply. The short shelf-life of fresh produce necessitates the development of rapid methods.

Research Activities to be Accelerated.

FDA, USDA and EPA will:

- Refine, improve, determine applicability and validate laboratory methods for recovery, identification, and enumeration of microbial pathogens, their toxic metabolites, and/or indicators thereof.
- Develop on-site detection methods for the farm, processing plant, and other needed areas.
- Develop appropriate sampling strategies for the detection of low-level microbial/chemical contamination.

NIH will:

- Develop detection methods for use in clinical situations.

NSF will:

- Solicit bioengineering research for development of biosensors to detect pathogens in real time in the food processing environment.

The development of improved detection methods encompasses several general analytical concerns, which may vary, depending upon the specific needs of industry, regulatory agencies, and action agencies. Rapidity of a method is relative to its need because the time required for detection may impact either public health or the free trade of a commodity with limited shelf life. The sensitivity of a method is essential in determining the level of a pathogen or its metabolite in a commodity with statistical confidence. The statistical validity of the sampling plan is also imperative. These factors affect the degree of food safety. Enumerative methods aid risk assessment by providing information pertinent to the elucidation of dose-response relations for susceptible populations. Methods that delineate the distribution of a contaminant in/on a commodity are also important for risk assessment. Recovery procedures must account for the possibilities that (1) the target pathogen may be stressed and thus inhibited by selective medium components or by the overall physiological design of the medium, (2) some of the

myriad of foods to be analyzed have constituents that inhibit pathogen detection, and (3) differences in background flora among commodities and geographical regions can affect detection of the target pathogen. All of the above recovery concerns are exacerbated if the target pathogen is typically an infrequent and low-level contaminant of fresh produce.

Molecular methods, specific for certain virulence attributes of a pathogen or for uniquely evolved pathogens, may enhance the ability to detect known pathogens or predict emerging or "quick-change" pathogens. Methodology of this type, however, depends on knowledge of the pathogen (microbial pathogenesis, evolution, physiology) to exactly determine the molecular target for detection. For molecular methods to achieve their potential, effective procedures to remove, isolate and concentrate pathogens from produce (e.g., *Cyclospora*) may be required. It may also be necessary to amplify pathogen signals by enrichment/growth (e.g., *Cyclospora*, Hepatitis A virus) and/or to overcome matrix inhibition of molecular biology reagents. To resolve matrix inhibition problems, additional research on the chemical/nutritive components of food is necessary to support methods development.

Appropriate detection methods are an integral part of any program to assure food safety along the farm to table continuum. If the tests are to be effective, they must be applied at appropriate sites. Thus, development of methods to support GAPs and GMPs should be pursued, as well as validation studies to enhance technology transfer. Because methods development is a major focus of most agencies identified within FSI and PIFSI, research to support this need should be carefully coordinated to ensure effective collaboration rather than unnecessary duplication. An **Interagency Methods Development Working Committee**, composed of

appropriate expertise from the various agencies, will be organized to enhance communication and information exchange, review on-going projects and prioritize research needs.

Resistance to Traditional Preservation Techniques

Recent food borne outbreaks have emphasized that microbes are evolving to overcome traditional processing and preservation techniques. The emergence of acid tolerant *Escherichia coli* O157:H7 is a recent example that microbes adapt to and establish new niches. Thus, research is needed to determine how pathogens associated with fresh fruits and vegetables become tolerant to traditional food safety barriers.

Research Activities to be Accelerated.

FDA and USDA will:

- Determine factors and conditions in production and processing environments that influence the development, amplification and maintenance of resistance. (For example, processes that do not kill 100% of the pathogen population may select for survivors which are more resistant to the process).
- Define physiological and/or genetic mechanisms that microbes utilize to become resistant to traditional food safety barriers such as heat or cold, low pH, low water activity, and disinfectants.

Understanding these mechanisms will allow modeling of microbial pathogen emergence in the food supply, provide the science to support guidance (GAPs and GMPs), enable detection and classification of potential pathogens, and aid the development of new intervention strategies.

Antibiotic Resistance

The development of antibiotic resistance during live animal production and the detection of resistant pathogens of domestic animal origin in produce point to a logical link between animals and produce as a possible source for transfer of resistant pathogens to humans. Research is needed to develop an understanding of the ecology of antibiotic resistant pathogens from animals, through produce and finally in humans where disease results. Current data provide evidence of the development of antibiotic resistant pathogens in both humans and animals following use of the antibiotic. However, the data do not provide a clear understanding of the mechanism of resistance development from both a physiological and molecular perspective. In addition to research describing development of resistant microorganisms from antibiotic administration in animals, research is also needed to characterize resistance that could occur from direct application of antibiotics in the field (e.g., controlling blight in fruit trees).

Research Activities to be Accelerated.

FDA, USDA, and EPA will:

- Define potential mechanisms of antibiotic resistance in different environments and characterize the development and evolution of antibiotic resistant pathogens in animal feed, in the animal (including fish), in water and the environment from fecal excretion, and in/on animal-derived food and fresh produce.
- Develop molecular characterization methods to facilitate identification of the resistant pathogen detected in food back to the source (e.g., environment, manure, water, feces, animal, animal feed).
- Define - using the basic, molecular understanding of antibiotic resistance - transfer mechanisms of resistant microbes from feces/manure to waters used for irrigation, processing, animal husbandry or human consumption, and to other animals, animal-derived food, and produce.

- Develop prevention/intervention strategies to eliminate or minimize the presence of resistant pathogens in/on food.

The characterization of resistance development is important to our understanding of antibiotic resistance transfer from the carrier animal to other animals and from manure to animal-derived food and produce. This research will examine resistance development at the genetic level such that resistant organisms can be effectively traced from detection in a particular commodity to their ultimate source. Enhanced understanding of the molecular basis of antibiotic resistance will aid the development of prevention/intervention strategies to eliminate or minimize the presence of resistant pathogens in/on food. The following section of this document details the intervention strategies for development.

Intervention Strategies

Improved microbial detection methods and systematic environmental surveys have made it clear that microbial pathogens can be found throughout the food production and processing environment. Practical and economical intervention methods are needed to prevent microbial contamination of fruits and vegetables both pre- and post-harvest. Intervention methods are also needed to prevent contamination that may occur in retail or wholesale distribution, in food service establishments, and in the consumer's home. Traditional and alternative intervention strategies which inactivate microbes by different physiological mechanisms will be refined or developed to (1) prevent the emergence and occurrence in food of pathogenic microorganisms resistant to antibiotics and traditional preservation technologies, (2) provide flexibility to industry in meeting guidance and HACCP critical limits, and (3) facilitate science-based safety decisions by FDA towards expediting the food additive petition approval process. The development of pathogen reduction practices will focus on practical methods that may be economically adopted by small

and large producers, both domestically and in developing countries, through technology transfer.

Research required for development of effective intervention strategies to prevent pathogen contamination of fresh fruits and vegetables will include:

- Investigating the microbial ecology of food borne pathogens, including their environmental sources.
- Determining the influence of production and processing factors.
- Developing traditional and non-traditional physical, chemical, and biological treatments.

Microbial Ecology

Numerous environmental factors can contribute to pathogen contamination of fresh produce. Potential vectors for many microorganisms, such as *Cyclospora*, are not well understood. Manure has been suspected as a source of pathogens on contaminated fruits and vegetables. By minimizing the colonization of the gastrointestinal tract of animals by human pathogens, the shedding of viable pathogenic microorganisms in manure can be reduced. Practical and economical pathogen reduction processes (e.g., composting), which are suitable to farm size and manure production levels and that have well-defined process parameters, are needed. Wherever water comes in contact with produce its source and quality dictate the potential for pathogen contamination. Irrigation and surface run-off waters can be sources of pathogenic microorganisms that contaminate fruits and vegetables in the field. Likewise, contaminated water used during processing can be a source of pathogens on produce.

Research Activities to be Accelerated.

USDA, FDA, and EPA will:

- Investigate manure, wild animals and other vectors, and the role of wastewater discharges from publicly owned treatment works and animal feedlot systems, as potential sources of contamination.
- Determine pathogen survival and dissemination in manure sources.
- Investigate methods of reducing pathogen carriage and shedding by farm animals.
- Determine active and passive manure treatment or composting techniques that will reliably, predictably, and consistently reduce or eliminate pathogens in manure.
- Develop mechanisms to prevent recontamination of properly composted manure.

FDA will:

- Evaluate mycotoxin contamination of produce with mold profile studies, and isolate, identify, and quantitate mycotoxins in produce.

Development of effective intervention strategies for reducing or eliminating microbial pathogens on fresh fruits and vegetables cannot be based solely on identification of sources of contamination; ecological interactions between the pathogenic and natural bacterial flora associated with fresh produce must also be considered. Control of pathogens on fresh fruits and vegetables by manipulation of the ecology of food production and processing environments requires a firm understanding of the genetic, biochemical, and physiological factors affecting microbial presence, persistence and proliferation on these foods. Information gained from such studies will be used to guide application of specific intervention techniques and may lead to the development of alternative, novel treatments to reduce contamination.

Research Activities to be Accelerated.

FDA and USDA will:

- Investigate the macro- and micro-environments that microbes inhabit in production and processing facilities, including assessing the role of biofilm formation on pathogen attachment.
- Investigate competitive, antagonistic, and symbiotic interactions between pathogens and natural microflora of produce.

FDA, USDA, and NIH will:

- Characterize pathogen virulence mechanisms.

Production and Processing Factors

Adverse production or processing conditions may result in contamination of fruits and vegetables with molds and human pathogens or may affect the state of microorganisms such that they survive decontamination interventions. Reducing the consumers' exposure to pathogenic microorganisms on fresh fruits and vegetables can be achieved only by addressing production and processing factors throughout the entire system. Production of structurally sound, unblemished fruits and vegetables that are less likely to support mold and pathogen growth is important for helping to prevent microbial contamination. Because natural barriers to microbial contamination are broken when produce is harvested or minimally processed (e.g. fresh cut), post-harvest practices involving transport, handling, packaging, storage, and preparation provide opportunity for contamination by pathogens that may survive or multiply on the product. Intervention methods are needed to prevent the persistence, propagation, and recontamination by pathogens post-harvest. Proper handling procedures and the efficacy of rinse and wash procedures must be investigated to help distribution, retail and food service operations, as well as consumers in the home, achieve safer food.

Research Activities to be Accelerated.

USDA will:

- Investigate pre-harvest production practices and techniques, including breeding of resistant plant cultivars, that could reduce the likelihood of contamination by molds and human pathogens.

FDA and USDA will:

- Conduct studies to determine the effect of post-harvest practices, relative to mold and pathogen survival and product quality, to devise effective intervention methods.
- Investigate proper handling procedures and the efficacy of rinse and wash procedures in reducing pathogen populations on fresh produce.
- Determine how bacterial stress responses to stimuli such as heat or cold, low pH, low water activity and disinfectants can be utilized to enhance practical methods of reducing pathogens associated with fresh produce.

Traditional and Non-traditional Treatments

Traditional food safety treatments involving heat or cold, low pH, low water activity and disinfectants, although somewhat effective for certain produce commodities, are also sometimes ineffective or inappropriate for decontaminating others, at least when administered at levels required to maintain sensory quality. For example, traditional heat pasteurization, while effective for many food matrices, is impractical for use on perishable commodities. Research is required to establish and optimize the effectiveness of traditional physical and chemical treatments currently employed during minimal processing of produce. Moreover, new interventions are needed for fresh produce that preserve quality appearance, preserve sensory properties, and maintain nutrient content, while providing pathogen control. Such interventions must overcome constraining factors, such as the presence of microorganisms within biofilms, cracks or other inaccessible sites. Investigation of these alternative control strategies, including physical treatments such as pressure, high intensity light,

irradiation and modified atmospheres, may result in effective methods of reducing pathogens. New intervention strategies involving chemical treatments (e.g., novel sanitizing solutions, surfactants, and natural antimicrobial agents) or biological treatments (e.g., bacteriocins, competitive microbial inhibition, microbial growth stimulants) will also aid pathogen reduction.

Research Activities to be Accelerated.

FDA, USDA and DOD will:

- Evaluate and refine traditional methods for improving the microbiological quality and safety of fresh-cut products.
- Investigate novel physical, chemical and biological treatments for reducing pathogen contamination of fresh produce.
- Develop improved packaging and transportation systems that facilitate safe handling and storage of fresh produce.

Risk Assessment and Food Safety Research

As described in the May 1997 FSI Report to the President, carefully formulated risk assessments are based on high quality data and scientific analyses generated from research. In turn, risk assessment guides research directions by describing the data gaps that create the most uncertainty in the risk assessment. In recognition of this close relationship between research and risk assessment, an interagency **Risk Assessment Consortium (RAC)**, composed of microbial risk assessors and scientists from applicable federal agencies (FDA, USDA, EPA, DOC, CDC, NIH) and their partners, has been established at the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), College Park, MD. RAC is formally tasked with coordinating scientific endeavors to support risk management responsibilities for food safety. Research coordination activities by RAC to develop effective risk assessment for PIFSI are presently ongoing.

Research Activities be Accelerated.

The consortium will facilitate research by its member agencies in the following areas:

- Determine research needs for quantifying the effects of changes in production practices, estimating the relative risks of domestic and imported fruits and vegetables, and tracking the consumption of fruits and vegetables.
- Develop and validate predictive microbiology models and related mathematical means for describing the effects of various unit operations along the food production, processing, and preparation continuum on the extent and frequency of contamination.
- Develop and validate predictive models using physical, chemical, and microbial analyses, ecological data, and epidemiologic findings to assess prevention technologies.
- Determine research needs for conducting effective epidemiology to identify hazards, characterize risk, and contribute to understanding dose-response relationships.
- Determine research needs for developing and standardizing pathogen subtyping methods to improve the sensitivity and specificity of molecular epidemiologic results.
- Determine research needs for:
 - animal studies to correlate dose and severity measures to human susceptibility.
 - *in vitro* studies to examine virulence factors for dose and severity correlations.
 - enhancing vaccine trials and other clinical studies to address data gaps in dose-response models.
 - developing biomarkers of exposure and susceptibility in human hosts.

To - Greg, Patrick, Charles
Paul, + Dave

Food
Safety -
w

We are meeting next week to discuss
this.

Erz

news

Campylobacter

February 10, 1998

MEMO TO: File

Times - found 70 to
- budget ->
-> new tests

On February 23, 1998, Consumers Union will release its March 1993 *Consumer Reports* article on the safety of chicken purchased at retail. On February 17, Consumers Union will provide **embargoed** copies of this article and related information to the press, and to USDA (so that it may respond to press inquiries), **for release no sooner than the evening of March 23, 1998**. This memo highlights some of the key points of the materials to be provided on February 17 and the information in this memo is subject to the same restrictions on public release.

CU Testing

- CU tested for salmonella and campylobacter plate count about 1K fresh whole chickens purchased at retail in 36 cities over a 5-week period in the autumn of 1997
- Campylobacter was found in 63% of the chickens; salmonella in 16 percent; both pathogens were in 8 percent; 29 percent were free of both
- The levels CU found were slightly lower than the 1994-95 USDA baseline levels [but the samples were obtained at retail, not at the plants, and sampling spanned a briefer period of time than the government samples, and CU shipped its samples on ice, all of which could contribute to these slight variations]
- Although CU purchased its samples at retail, it can identify the plants that processed each bird, and a 4 percent salmonella rate from one plant indicates that it is possible to keep levels for this pathogen very low
- The generic E. coli count was almost always low, despite the high levels of other pathogens
- One in 20 birds was nearly spoiled
- The USDA seal is no guarantee of cleanliness



Washington Office
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This release may be used for legitimate purposes only. Use of material from Consumers Union for advertising or other purposes is prohibited.

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Food Safety -
E. coli:

request for assistance from the Kenya Ministry of Health and in collaboration with WHO and the DoD. CDC dispatched a six-member team.

Tim - Can we
get into this
in summary?
How is it being
funded? What's
the timetable
of further
experiments, etc?

E. coli Vaccine: On February 9, scientists at the National Institute of Child Health and Human Development announced that they have developed an experimental vaccine against E. coli O157, the pathogenic bacterium that causes severe food poisoning. The results of this clinical trial are reported in the February issue of the *Journal of Infectious Diseases*. Although further clinical trials are required before the vaccine is declared protective in humans, scientists are considering another strategy to eradicate E. coli O157 -- mass vaccination of cattle -- which would eliminate the pathogen at its source.

Cult

Hospital Fraud and Abuse: On February 11, the Office of Inspector General (OIG) released its voluntary compliance program for hospitals. The guidance is intended to combat fraud and abuse in the hospital industry.

- **Tobacco and Children:** On February 13, the FDA expects to sign a contract with NC to enforce FDA regulations prohibiting retailers from selling cigarettes and smokeless tobacco products to children under 18. This is the first such contract of 1998. In 1997, FDA contracted with ten states to enforce the tobacco regulation: FL, WA, IL, TX, MA, CA, MN, AR, PA, and CO. Under the contract, a state conducts unannounced retail compliance checks. Information about the compliance checks is sent to FDA, which issues a warning for the first violation to retailers found selling to adolescents and seeks a fine of \$250 for the second violation and greater fines for subsequent violations.
- **Guatemalan Berries:** On February 9, FDA issued a letter to the Guatemalan Embassy stating that since fresh blackberries and frozen blackberries and raspberries from Guatemala had not been implicated in the 1996 and 1997 outbreaks of cyclosporiasis in the U.S., FDA will not object to the importation of these products, subject to normal FDA import and sampling procedures. Last summer, the Guatemalan authorities were informed that importation of Guatemala's 1998 Spring crop of fresh raspberries would not be allowed unless information on the cause and prevention of cyclosporiasis from Guatemalan raspberries was available or if alternative processing methods become available which would ensure the destruction of *Cyclospora*.
- **Depression and Smoking:** In the February issue of the AMA's *Archives of General Psychiatry*, researchers supported by the National Institute of Mental Health report on a study which found that a history of major depression was associated with progression of smoking and that a history of daily smoking was associated with increased risk for major depression. According to the researchers, their study is the first report on the influence of major depression on the progression of smoking among people who have ever smoked.



U.S. DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

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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:

*You need to be aware
of this.*

Where will Admin be??

We have not taken a position.

02/20/99 14:10 FAX MON 000 2110 0000 0000

I know you are both swamped but you need to be aware of the following:

I don't know how involved either of you are on developing the Administration's position on S. 981, the Thompson-Levin regulatory reform bill.

But I thought you should see the testimony of Safe Tables Our Priority, a group of families who suffered from foodborne illness, on the legislation. As you will see, STOP strongly opposes the legislation for a number of reasons, including delays, judicial review etc.

Should this legislation start to move (I believe there is a markup next week), I expect that the public interest community, including consumer groups, will try to launch a media strategy that attacks the bill as a way for business to slow down or stop public health, safety, and environmental regulations.

I am also sending you USDA's comments on the legislation. As you'll see, we are strongly concerned about how the legislation would delay our ability to issue major rules to improve food safety. I believe that other public health, safety, and environmental agencies have similar concerns.

There are some Democratic Senators who support the bill, while others have argued that additional hearings are necessary.

Let me know if you want to discuss.

Eric

Nancy Donley
President
S.T.O.P. - Safe Tables Our Priority
Testimony on the Substitute Amendment for S. 981
"Regulatory Improvement Act of 1998"
Senate Committee on Governmental Affairs
February 24, 1998

Thank you Senator Thompson and Senator Levin for inviting me to testify at this very important hearing. I am the president of Safe Tables Our Priority, a national, non-profit foodborne illness victims' organization. My only child died from eating *E. coli* O157:H7 contaminated hamburger in July 1993. Alex was only 6 years old when he died. His illness and death were brutal. My husband and I wanted to donate Alex's organs to live on in other children, but were told it was impossible because they were all destroyed. Portions of his brain were liquefied.

Senators, Alex was not the only "statistic" in this tragedy. My mother would tell you that she lost not only her grandchild, but her daughter as well. Our family and our entire community were sickened and destroyed by Alex's death, and these numbers aren't accounted for in a risk assessment or cost-benefit analysis. Just this past December, a neighbor whose son played with Alex, stopped by my house, asking if I would please tell her where Alex was buried. She hoped that by taking her child to Alex's grave, 4-1/2 years later, her son could finally find peace. He's been in counseling all these years and so has his entire family. This is another example of statistics that aren't captured in a cost-benefit analysis. And I defy anyone to put a value on my son's life, Alex wanted to be a paramedic when he grew up so that he could help others. His life would have benefited the American public. Would that have been included in a cost-benefit analysis? I highly doubt it. How do you put a value on health and safety itself? What's the price of grief?

I venture to say that if I asked you to give me an acceptable number of deaths from contaminated food, you would probably respond with "zero". Even the meat industry has stated that one death from contaminated meat is one death too many. S. 981 directly contradicts these statements by seeking to establish acceptable levels of illness and death through cost-benefit analysis as part of decision-making criteria in the regulatory process. Section 2 (8) of this bill states "The Federal Government should develop a better understanding of the strengths, weaknesses, and uncertainties of cost-benefit analysis and risk assessment and conduct the research needed to improve these analytical tools." This bill conducts a policy experiment on the public's health and safety. A more appropriate experiment would be on regulations affecting financial institutions or the introduction and marketing of new products, areas exempted in this bill.

My son's death caused me to question the safety of America's food supply. For obvious reasons my immediate attention focused on the safety of meat and poultry. I was actively involved during the entire regulatory process to get a HACCP-based inspection system rule passed. I personally attended dozens of meetings and briefings during the 2-1/2 year process from proposed rule to final rule, at great personal expense. All interested parties, including small businesses, were invited to participate. The economic impact of public health and safety regulations on small businesses should not be a factor. If small businesses can't or won't adopt public health and safety regulations, they shouldn't be in the business. Nor should they have any more rights in challenging existing or pending regulations. My son's death wouldn't be any more acceptable or palatable had his hamburger meat come from a small, family producer than from a huge conglomerate.

The HACCP rulemaking process took entirely too long as it was and S. 981 would prolong the process. This bill allows for continuous inflow of new information during risk assessment and requires agencies to revise its conclusions as each new bit of information dribbles in. There must be a deadline at some point or parties can stall the process indefinitely.

Both risk assessments and cost-benefit analyses are required to undergo peer review, which will add further delay. Of great concern is the "balance" of these panels and the fact that they are exempt from the Federal Advisory Committee Act (FACA). I am one of three consumer representatives on the 16-member Federal Advisory Committee for Meat and Poultry Inspection. There are three subcommittees. When you do the math you get a 4:1 ratio on each subcommittee. At one meeting I had to use the restroom and during my absence, it was suggested that microbial testing for O157:H7 be dropped. Peer review panels must always be balanced and be subject to the sunshine provision of FACA. Regulated entities, meeting behind closed doors, should not compromise the peer review panels for the obvious reason of conflict of interest.

Our food safety agencies are already woefully underfunded. The additional requirements heaped on these agencies by S.981 are an unfunded mandate and will drain resources away from inspection and enforcement activities that protect public health. Funds will have to be diverted to statisticians, economists, bureaucrats and lawyers. This is not what the American public expects or wants. We want and need additional and stronger food safety regulations and we want and need them now.

Senators, I really appreciate the opportunity to testify here today. Thank you.

Tom — —

Rm 213

Following on the VP's
Conrad bill event, Sen.
Mikulski wants the VP
to attend her food safety
bill announcement.

What do you think?

-Toby

x 6.62.65

FEB. 23 1998 (MON) 18:16

TEL: 202 228 0547

P. 002

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

NOV 13 1997

The Honorable Albert Gore, Jr.
President of the Senate
Washington, D.C. 20510

Dear Mr. President:

Enclosed for the consideration of the Congress is the Administration's draft bill, the "Safety of Imported Food Act of 1997".

The purpose of the bill is to add to existing safeguards in the Federal Food, Drug, and Cosmetic Act, and thus enhance the Secretary's ability to prevent the importation of unsafe food, in a manner consistent with U.S. trade agreements. The bill would amend the Act to provide that food imported into the United States will be considered adulterated if it has not been prepared, packed, and held under a system or conditions, or subject to measures, that meet the requirements of the Act or otherwise achieve the level of protection required for foods produced domestically. The bill authorizes the Secretary to consider, in determining whether such requirements or level have been achieved, whether the Food and Drug Administration (FDA) has requested, but been denied, access in order to conduct an inspection of the location or establishment where a food was prepared, packed, or held.

Under current law, FDA has authority to deny importation of foods that appear to be adulterated (section 801 of the Act). Under the bill, foods that do not adhere to the criteria of the new legislation could be denied entry under FDA's current authority to prevent the importation of foods that appear to be adulterated. Current seizure authority under the Act (section 304) could also be used to deal with such foods.

FEB. -23 98 (MON) 18:16

TEL:202 228 0547

P.003

The Honorable Albert Gore, Jr. - Page 2

This proposal will improve FDA's ability to ensure that food imported into the United States affords a level of safety comparable to that for domestically produced foods, and is part of a broader Administration initiative to enhance the safety of the food supply.

We recommend that the Congress give the draft bill its prompt and favorable consideration.

The Office of Management and Budget has advised that there is no objection to the transmittal of this draft legislation from the standpoint of the Administration's program.

Sincerely,



Donna E. Shalala

Enclosure

FEB -23-98 (MON) 18:17

TEL: 202 228 0547

P. 004

**Congress of the United States
House of Representatives**

Washington, DC 20515

January 28, 1998

Dear Colleague,

We're writing to ask for your support of legislation we introduced on the last day of the First Session of the 105th Congress. The Imported Food Safety Act (H.R. 3052) is a key component of the Administration's Food Safety program and is a common sense approach to enhancing the Food and Drug Administration's (FDA) ability to ensure that the food which comes across our borders is safe.

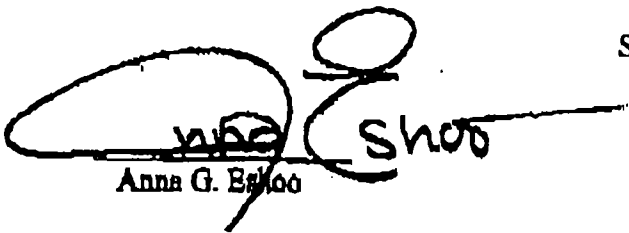
Under current law, FDA conducts border inspections of imported foods and may prevent any adulterated (unsafe) food from entering the country. However, the agency only has the resources to inspect 1-2% of the food that crosses our borders. Clearly this situation is cause for concern to the American public.

H.R. 3052 addresses this concern in two ways. First, the bill sets a standard for imported food that it must be prepared, packed and held under conditions that achieve the same level of protection required for food in the United States. Second, it provides FDA with the authority to prevent the importation of food if the Agency has requested and been refused the right to inspect the food producer's facilities. These two provisions will encourage greater interaction between FDA and their foreign counterparts so that food which eventually will be imported into the United States is produced under conditions that will ensure its safety.

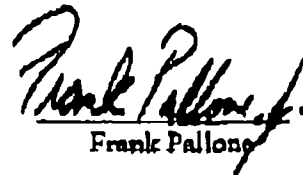
It is our hope that this legislation will have broad bipartisan support in the House. It is a critical component of the Administration's overall food safety effort and will give all our constituents greater peace of mind that food crossing our borders is as safe as that which is grown in their backyards.

If you'd like to cosponsor the bill or get additional information, please call Bill Bates (Eshoo) at 5-8104 or Rob Garagiola (Pallone) at 5-4671. Thank you in advance for your consideration of this important legislation.

Sincerely,



Anna G. Eshoo



Frank Pallone

Page 224-4527

1000

PHOTOCOPY
PRESERVATION

VP issue

Internet & books

1. ~~Paper~~

2. ~~Schedule~~

3. ~~Read OSHA testimony~~

4. Fazio - include stuff on Minorities

5. * ~~Full~~ Minorities stuff to Klein

6. Learn about budget resolution

7. * Get package together of minority issue

8. * ~~Mangus/Ross action~~

express advisory ASDC(3)CIS
- snow accident

9. Equal Pay - follow-up - Caroline Friedrichson 224-2321
Linda Luch - wait - aggressive - Amy Nafin
not much more

10. Free TV time

11. Vaccine info to EK

12. * ~~Consumer prices bill of the~~

13. * ~~in a tobacco - Myers, Waxman, Jacoby~~

14. ~~Chairman letter to 4 Sen.~~

15. ~~2/14~~

16. ~~Mtis~~ 296-5469

12/17/84 Fla. bill board

145025
- Equal pay
- Internet opportunity
- Gene & tech.

18. Scali - ?

19. FDA report on
clay injection
- 1000

20. ~~Toshko~~ - policy to
BR

21. ~~Ads to BR~~

22. ~~Child nutrition~~

301
537
442

Alcohol ad

Smc

Single Food agency

Farmers (not tobacco)

WRFA

Sex Social Worker

Africa democracy

Nancy Gist

United Airlines - defibrillators Shelly Longman

Chen

The Administration recognizes the importance of addressing foodborne illness caused by Campylobacter and has taken a number of steps in this regard:

- Under the President's Food Safety Initiative, the Administration added Campylobacter to the FoodNet, which collects data on foodborne illness, in 1997 to gain knowledge on its incidence.
- According to the first year survey results from FoodNet, Campylobacter is the most common foodborne illness, causing approximately 4 million illness per year.
 - It is a relatively mild illness, seldom, almost never fatal. It has been possibly linked to Guillame-Barre syndrome, a temporary neurological disorder.
- Under the Food Safety Initiative, research on the Campylobacter organism is a high priority. USDA is working on a new rapid testing method for Campylobacter to improve our ability to detect the pathogen.

Also under the Administration's food safety initiative, FDA, CDC, and USDA have initiated surveillance to gain greater understanding of strain of campylobacter that has been shown to be resistant to fluorquinolone (a class of antibiotics).

The Administration spent \$1.3 million in FY 97 on Campylobacter research, \$435,000 of which was for a rapid test. In FY 98, the Administration will spend \$2.2 million on research, a little of over 1 million of which will be for rapid tests.

There are two flourquinolones approved for food animals in the U.S., both for broilers and turkeys. FDA is reevaluating these products based on the new information about flouroquinolone.

FDA and USDA officials recently participated in a World Health Organization meeting at which this issue was addressed. A follow up meeting is scheduled.

- As HACCP is implemented in January of 1998, USDA expects that Campylobacter will be an identified hazard that will be appropriately addressed in HACCP plans.
- Proper handling is very effective against Campylobacter because it is one of the more easily destroyed bacteria. Safe handling includes

Cooking to 160 degrees,

Avoiding cross-contamination by washing hands and preparation surfaces, and

Keeping raw product separate from cooked product.

AGL
6/10/24

Spring - Economist

CEA - Black

3/3 - Proclamation

Child Care

Economic report - CEA
NSC

105
Industry, consumer groups praise food safety move

WASHINGTON, Oct 2 (Reuter) - President Clinton's plan to block imports of fruits and vegetables that fall short of U.S. standards was praised by several groups as a way to protect the food supply but some criticized it for linking food safety issues to regional trade agreements.

Public Citizen's Global Trade Watch said the Clinton proposal for additional legislation would actually weaken U.S. contamination standards for imported food.

"The obvious strategy of the Clinton Administration is to try to deflect criticism from imported food safety problems in an effort to pass fast track," said Lori Wallach, director of the group. "The proposal would implement the NAFTA requirement that the U.S. begin importing food which does not meet our standards but has been deemed 'equivalent' by trade officials."

The NAFTA accord allow food safety standards from other countries to be declared equivalent to U.S. standards, which Wallach called an "inexact concept" that lets countries with weaker food safety systems to export to the United States.

She also criticized the plan's creation of voluntary guidelines for foreign producers to follow as not going far enough to protect U.S. consumers.

Grocery Manufacturers of America also expressed concern about food safety issues being linked to fast-track legislation.

"Contrary to some critics, fast track will not weaken U.S. food safety," the trade group representing brand-name food companies said. "The safety of the food supply will continue to remain a top priority for the food industry as well as the government."

Grocery Manufacturers of America also said plans to expand FDA authority and increase the budget for inspectors should be "carefully reviewed" to prevent additional bureaucracy for food packaging and marketing firms.

Center for Science in the Public Interest, a consumer advocacy group, endorsed the Clinton proposal to give the Food and Drug Administration more power and inspectors to enforce food safety standards at the border and in the exporting country.

"Better inspections are urgently needed to restore consumers' faith in the safety of imported foods," said Michael Jacobson, executive director of CSPI. Only an estimated one to two percent of food imports are currently inspected by federal officials.

In recent months, there have been outbreaks of food poisoning caused by harmful bacteria or parasites on imported lettuce, alfalfa sprouts, tomatoes, carrots and berries. Consumers have also been rocked by E.coli contamination of U.S.-produced hamburger.

((Washington commodities/energy desk, 202 898 8467

email: washington.commodsenenergy.newsroom@reuters.com))

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PRESIDENT WANTS F.D.A. TO REGULATE FOREIGN PRODUCE

ILLNESSES LEAD TO ACTION

N.Y. Times 10/3/97

Fruit and Vegetables Could Be Banned if Farming Methods Did Not Meet Standard

10/3/97 41
By JAMES BENNET

WASHINGTON, Oct. 2 — Acting after several outbreaks of disease linked to the burgeoning global trade in produce, President Clinton announced today that he would ask Congress to require Federal regulators to ban imports of fruit and vegetables from countries that did not meet expanded American food safety standards.

The move, urged by regulators since shortly after Mr. Clinton first took office and welcomed today by industry and consumer groups, would empower the Food and Drug Administration to insure the safety of foreign fruit and vegetables in much the same way that other Federal regulators check meat and poultry from overseas.

Mr. Clinton said he would ask for more money from Congress next year for the F.D.A. to hire investigators to inspect not just produce but also foreign farming methods and government safety systems. In a change that might irk some United States trading partners, countries that blocked the new inspections would be forbidden to sell fruit and vegetables in the United States, the Administration said.

"At the time when Americans are eating more and more food from around the globe, we must spare no effort to insure the safety of our food supply from whatever source," Mr. Clinton said at a Rose Garden ceremony to announce his proposals today. "Our food safety system is the strongest in the world, and that's how it's going to stay."

Imports of produce have increased sharply in recent years, to 38 percent of the fruit consumed by Americans and 12 percent of the vegetables. With those imports, however, have come recent outbreaks of diseases brought across borders by Guatemalan raspberries, Mexican cantaloupes and Thai coconut milk, causing public alarm that might make Congress sympathetic to Mr. Clinton's proposals. But American trading partners may eventually choose to protest any ban on their products to the World Trade Organization,

much as the United States on Wednesday said it would file a complaint with that organization protesting Japan's stringent test for pesticides on American nectarines, cherries and other fruit. The United States sells twice as much food abroad as it imports.

Donna E. Shalala, the Secretary of Health and Human Services, said that Mr. Clinton would ask for \$24 million annually to support the Food and Drug Administration's new international inspections. Another official said that if Congress acted on Mr. Clinton's proposal, the F.D.A. would phase in its system for such inspections over the next several years.

Today, Mr. Clinton also directed Dr. Shalala and Agriculture Secretary Dan Glickman to develop new voluntary standards within a year for growing, processing, shipping and selling fruit and vegetables. The President said he also expected a

Proposing the same scrutiny of foreign fruit and vegetables as of meat.

report from them within 90 days on how to improve the monitoring of fruit and vegetables grown abroad.

Though they backed the President's proposal, consumer and industry groups said they were anxious about the details in the legislation, which the Administration plans to offer next year.

"What the President proposed today addresses many of the gaps," said Caroline Smith DeWaal, director of food safety for the Center for Science in the Public Interest. But, she added, "I would like to have mandatory standards rather than voluntary guidelines" for food manufacturers and handlers. For their part, White House aides predicted that meeting the voluntary guidelines would become an eye-catching industry selling point.

A senior White House official, who spoke on the condition of anonymity, said it was hard to predict whether the President's initiative could raise produce prices. But producers or sellers may have to pass on the costs of any modifications to consumers, he said.

The main initiative announced today, requiring the F.D.A. to bar foods imported from countries with substandard safety systems, was recommended more than four years ago by David A. Kessler, then the Commissioner of Food and Drugs. Dr. Kessler warned then that the nation's food-safety laws, essentially unchanged since 1938, were in "urgent need" of an overhaul.

Contaminated food, he noted, kills an estimated 9,000 Americans a year and sickens millions, perhaps tens of millions. It still does. The food-safety system was marked by "enormous inefficiencies," he warned. It still is, according to a Federal report published in May.

The White House has already moved to institute one of Dr. Kessler's central proposals, a scientific system for controlling the risk of disease borne by seafood, meat and poultry. But no such system yet exists for fruit and vegetables, domestic or imported.

The White House said today that Mr. Clinton has been adopting Dr. Kessler's proposals piecemeal, addressing the most urgent needs first. Michael D. McCurry, the White House press secretary, said that Mr. Clinton was prompted to tighten monitoring of fruit and vegetables partly by several outbreaks of illness and reporting on the potential hazards by news organizations, including The New York Times.

Mr. Clinton's move on food safety comes as he is seeking enhanced authority from Congress to negotiate trade deals. His opponents have charged that the new rules, under which trade deals once negotiated would have to be voted on quickly and without amendment by Congress, would lower barriers to food-borne diseases.

Some opponents of granting the President such fast-track authority hailed Mr. Clinton's announcement today. "I'm glad the fast-track debate has energized the President to do this," said Representative Sherrod Brown, Democrat of Ohio. Mr. Brown and 85 other members recently sent President Clinton a letter linking food safety and trade pacts.

The White House said Mr. Clinton did not connect food safety to promoting his trade goals. The senior Administration official said that he expected some members of Congress to use the initiative as political cover for voting to give the President greater trade authority.

Senator Richard Lugar, the Indiana Republican who heads the Agriculture Committee, will hold hearings on the initiative next week.

The Administration consulted with some foreign governments before today's announcement, one Administration official said, but still expected criticism from abroad. "There will be some negative reaction in some places, but it won't be the end of the world," he said.

Some foreign representatives here worried that Mr. Clinton's proposals might be used to create trade barriers. The safety of imported food is "a serious issue coming very fast toward all of us in this new global world," said Ambassador John Biehl of Chile. He called the President's

Clinton seeks ban of foreign foods

By Lorraine Woollett
THE WASHINGTON TIMES

10/3/97 B8

President Clinton yesterday asked Congress for the authority to ban imported food that doesn't meet U.S. safety standards, an action immediately criticized as a way to boost public relations rather than dramatically affect public policy.

"Our food-safety system is the strongest in the world, and that's how it's going to stay," Mr. Clinton said yesterday in a formal Rose Garden ceremony.

In principle, the hastily drafted proposal won't necessarily make the nation's food supply safer. The Food and Drug Administration and other federal agencies already have the authority to stop tainted food at the border and inspect overseas farms and manufacturing plants under global trade rules.

"This proposal is designed to try to deflect criticism from imported food-safety problems in an effort to pass [the] fast-track [bill]," said Lori Wal-

lach, director of Public Citizen's Global Trade Watch, a consumer group that last week issued a study critical of the nation's food-safety efforts.

The so-called fast-track bill would give the president freedom to make trade agreements that Congress could not amend. The measure has alarmed some lawmakers, who fear in part that lower trade barriers could allow tainted foreign food to slip into the United States.

Trade rules under the North American Free Trade Agreement and the World Trade Organization already have led the FDA to draw up guidelines for ensuring that foreign food producers meet standards "equivalent" to those in the United States. However, trade critics question whether "equivalent" standards will be enough to protect the nation's food supply.

"This is a battle over fast track, it's not a question of food-safety authority or legislation," said Rod Leonard, ex-

see FOODS, page B12



Photo by Roger Richards/The Washington Times

President Clinton, watched by administration and food industry officials, signs his proposal to have foreign food inspected before it crosses the border.

FOODS

From page B8

ecutive director of the Community Nutrition Institute.

Food manufacturers yesterday expressed concern that the Clinton plan, though still vague, could lead to more regulation and complicate existing trade agreements. About 20 percent of the fruit and vegetables Americans eat annually is imported.

"The whole question is, is this new authority needed? That has yet to be determined," said Brian Sansoni, spokesman for the Grocery Manufacturers of America. "We are concerned about the timing of this to a certain extent. This issue should not be mixed up with fast-track trading authority."

Mr. Clinton said his proposal should not complicate the trade environment.

"We're not trying to unfairly target foreign producers of food into our market," he said.

Mr. Clinton said he would boost next year's FDA budget for foreign-food inspections by about \$24 million from the current level of \$43 million.

He also ordered the secretaries of health and human services and agriculture to draw up voluntary guidelines on growing, processing, shipping and selling produce.

FDA officials said the Clinton plan will give them more authority to guarantee food safety at the source, not at the border.

"Currently, the inspection of produce from foreign countries is done only when those materials reach the United States," said Richard Rominger, deputy secretary of agriculture.

"By looking more carefully at the land-management practices, the farming practices, the fertilization, the water supplies at each of these areas, it's possible to look at the public-health issues in a particular country and then to realize how best one can minimize the risks and maximize the benefits."

(107) 1072
Clinton Seeks Stricter Food Safety Rules

By Kathy Lewis, The Dallas Morning News
Knight-Ridder/Tribune Business News

WASHINGTON--Oct. 3--As more Americans eat from a global garden, President Clinton said Thursday he will seek authority to ban fruits and vegetables from nations that don't meet U.S. food safety standards.

Administration officials said he will ask Congress for about \$24 million next year to expand a team of international food inspectors.

"At a time when Americans are eating more and more food from around the globe, we must spare no effort to ensure the safety of our food supply from whatever source," Mr. Clinton said.

His actions come after a series of incidents in recent years where scientists have blamed health problems on either U.S. or imported food.

Raspberries from Guatemala, strawberries from Mexico and coconut milk from Thailand have been suspected culprits. But in some cases, officials said, it was not possible to tell whether contamination took place before or after a product entered the United States.

Mr. Clinton and his advisers said Thursday that the U.S. food supply is the world's safest, but more must be done.

"With these efforts, we can make sure that no fruits and vegetables cross our borders, enter our ports or reach our dinner tables without meeting the same strict standards as those grown here in America," he said.

Mr. Clinton seeks authority for the Food and Drug Administration that would be similar to what the Agriculture Department already has to ban meat and poultry from nations with inferior standards and from countries that won't allow inspections.

Officials said the Agriculture Department now checks for pesticide residue and the FDA for general quality, but they lack jurisdiction to test for disease-causing organisms.

The federal Centers for Disease Control and Prevention estimates as many as 33 million Americans every year suffer food-caused illnesses, resulting in as many as 9,000 deaths.

Mr. Clinton also asked Health and Human Services Secretary Donna Shalala and Agriculture Secretary Dan Glickman to work with industry to develop safety standards for growing, processing, shipping and selling specific fruits and vegetables.

During a Rose Garden ceremony, Mr. Clinton said such measures would improve sanitation and safety practices of all who want to sell produce in the United States.

Mr. Clinton said 38 percent of fruit and 12 percent of vegetables consumed last year came from other countries.

Some critics have said Mr. Clinton is merely trying to dispel concerns that his efforts to reach free-trade pacts with Chile and other nations could pose health problems. Others have said the problem has been overstated and that these steps would complicate trade negotiations.

Mr. Clinton said federal officials have no higher responsibility than to protect health and safety.

"I don't want it to complicate the trade environment, but I'm not interested in trade in things that will make the American people sick," he said.

Mr. Clinton also said steps taken early in his administration were aimed at ensuring the safety for food products that the United States exports.

Thomas Stenzel, president of the United Fresh Fruit and Vegetable Association, said the industry wants to do everything it can. But he said there is no report that shows a major problem. Less than 3 percent of all U.S. disease outbreaks attributed to food have involved fruits and vegetables, he said.

"We have to be very careful not to scare consumers about the safety of the food supply," he said.

U.S. officials said they have not found a higher incidence of problems with imported food. Overall, fruit and vegetable consumption has skyrocketed.

Although most food products are safe, officials said they are concerned because of new disease-causing organisms and ones particularly resistant to treatment.

(107) 2-12

Ms. Shalala said the United States has shifted from old-fashioned "eyeball" visual food safety inspections to scientific ones. The president's announcement is part of that modernization, she said.

FDA officials said they want to consider factors such as water supply, fertilization procedures and health of workers rather than simply focusing on the food once it is ready to go to the supermarket.

A government official from Mexico, who requested anonymity, said Mexican exports already are inspected and meet the highest standards for both nations. He said he was confident that additional measures would reassure consumers.

Guatemalan ambassador Pedro Miguel Lamport issued a written statement, saying his government supports initiatives to enhance food safety.

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7/17
initiative "a good thing as long as it is equal for everyone" and not "used as an artificial barrier to free trade."

Administration officials repeatedly said today that there was no evidence that imported fruit and vegetables were less safe than American ones. But there is little data about the relative safety of domestic versus imported food, according to the Centers for Disease Control and Prevention, in Atlanta. One percent or fewer of the actual number of food-borne illnesses are reported, analyzed, identified and successfully traced.

While the Department of Agriculture monitors meat and poultry, produced here or abroad, the F.D.A. is charged with safeguarding all other food, including fruit, vegetables, grains and seafood. But, unlike the Agriculture Department, the F.D.A. can now send its investigators abroad only if they are invited, and agency inspections of the imports have dropped to less than half what they were five years ago. If Congress approves the President's proposal, the F.D.A. is expected to hire 100 more investigators, who will examine foreign farming methods and food safety systems.

WSJ 10/3/97 A4

Clinton Seeks Ban on Fruit Imported From Some Places

WASHINGTON (AP) — President Clinton proposed barring imports of fruits and vegetables from countries that don't meet U.S. safety standards.

A Mexican farm official denounced the plan. "It is very clear to us that behind all this are economic interests which want to prevent Mexican vegetables from entering the U.S.," said Luis Cardenas, part of an agriculture group in the Mexican state of Sinaloa, a big tomato producer.

Other critics charge that the new program is an attempt to disarm those who say Mr. Clinton's push for free-trade legislation would increase the risks of tainted foods entering the country.

But the Food and Drug Administration has been pushing for the changes since 1993. Similar rules concerning meat imports have caused friction with some U.S. trading partners, particularly the European Union. A crackdown on foreign produce could cause tensions as well.

There is no evidence that imports are more dangerous than U.S.-grown produce, said Morris Potter, assistant director of foodborne diseases at the government's Centers for Disease Control and Prevention. "The concern is arising now," he said, "because imports are on the rise." Last year, 38% of fruits and 12% of vegetables consumed in the U.S. came from abroad, double the 1986 levels.

New safety rules urged for imported produce

By Bill Nichols
and Daniela Deane
USA TODAY 10/3/97

WASHINGTON — President Clinton urged Congress Thursday to pass new measures to ensure that imported fruits and vegetables are as safe to eat as those grown in the U.S.

The proposal, to be submitted next year, would allow the Food and Drug Administration to ban imported fruits and vegetables that don't meet U.S. safety standards. The FDA al-

ready can ban meat imports. Clinton also wants new FDA inspectors to monitor produce production and safety abroad.

At present, only a sampling of imported produce is inspected by the Agriculture Department for general quality and pesticide residues.

"At the time when Americans are eating more and more food from around the globe, we must spare no effort to ensure the safety of our food supply," Clinton said.

Imports make up 10% of all

vegetables eaten in the United States and 30% of the fruits.

The action was prompted partly by incidents this year, including one in which 179 schoolkids got hepatitis from Mexican strawberries.

And it could cause tensions with trading partners.

"Behind all this are economic interests which want to prevent Mexican vegetables from entering the U.S.," said Luis Cardenas in the Mexican state of Sinaloa, a tomato producer.

Others said Clinton was try-

ing to bolster support for his request for Congress to grant him "fast-track" authority to negotiate trade agreements that Congress could vote up or down but could not modify. One argument against fast-track is that it might increase the chance for tainted food to enter the U.S.

Food safety "should be based on sound food science not political science," said Brian Sansoni of the Grocery Manufacturers of America.

▶ Tainted produce, 5A

[B] Full: Clinton seeks safeguards for fruit, vegetable imports

By United Press International/The Associated Press

Washington--Oct 2--President Bill Clinton today moved to toughen safety standards for fruits and vegetables as well as other imported foods. Clinton promised to set aside money in the next fiscal year to greatly expand the Food and Drug Administration's international food inspection force in a bid to ensure imports are as safe as US products.

Taking the first step in a broad plan to get safer produce into American kitchens, Clinton proposed barring fruits and vegetables from countries that don't meet US safety standards.

Clinton said that countries that block FDA inspections should not sell their produce here.

The president also said he will direct federal health and agriculture officials to work with US farmers to develop new sanitation guidelines for domestic produce. He ordered guidelines developed within a year.

"With these efforts, we can make sure that no fruits or vegetables cross our borders, enter our ports or reach our dinner tables without meeting the same strict standards as those grown here in America," Clinton said in a Rose Garden ceremony.

"Our food safety system is the strongest in the world, and that's how it's going to stay," he said.

Clinton didn't offer specifics of the proposed legislation, but an administration official said the bill would seek up to \$24 million for new FDA international inspections.

The new agricultural guidelines, which would be crop-specific to help build safety into production here and abroad, could be wide-ranging. They might call for certifying that fields are irrigated with clean water, hiring farm workers free of such diseases as hepatitis and ensuring manure used as fertilizer is free of E. coli bacteria, said an official who spoke on condition of anonymity.

A Mexican farm official denounced the plan.

"It is very clear to us that behind all this are economic interests which want to prevent Mexican vegetables from entering the US," said Luis Cardenas, of an agriculture group in the Mexican state of Sinaloa, a big tomato producer.

Other critics charge that Clinton is adopting the new program in an attempt to disarm those who say his push for free-trade legislation would increase the risks of tainted foods entering the country. They argue that the US food supply already is the world's safest.

"Clearly, being the world food police complicates the trade environment we operate in," said John Aguirre of the United Fresh Fruit and Vegetable Association. Risks from overseas produce are low enough that "this is unwarranted," he added.

But the FDA, which has been pushing for the changes since 1993, said its inspection program hasn't kept pace.

"The whole infrastructure of food safety needs to be strengthened," Associate Commissioner William Hubbard said.

FDA figures show that because of budget constraints, its inspections of domestic food supplies plummeted from 21,000 in 1981 to just 5,000 last year. Foreign food imports have doubled to 2.2 million shipments a year since 1992, while FDA border inspections were cut in half. A mere 2% of imported food is sampled for contamination at the docks.

Under the Clinton plan, FDA inspectors would check foreign food-safety systems and ban imported fruits and vegetables from countries that don't regulate strictly enough, said an administration official.

Such authority is identical to USDA's practice of regulating meat imports.

These practices have caused friction with some US trading partners, particularly the EU, and a crackdown on foreign produce conceivably could cause tensions as well.

Key to the produce plan would be "good agricultural practices" that can

build safety into a crop. In the case of the Guatemalan raspberries, it is

not known how they were tainted with the parasite cyclospora. End

Clinton Calls For Changes On Produce

Plan Aims to Boost Safety for Imports

W Post 10/3/97

By Peter Baker 121
Washington Post Staff Writer

In response to public skittishness over food safety, President Clinton yesterday proposed a new program of standards and inspections aimed at blocking contaminated fruits and vegetables grown overseas from reaching the United States.

During a Rose Garden ceremony, Clinton detailed his plans to ask Congress to authorize the Food and Drug Administration to halt imports of produce from foreign countries that have lower safety requirements or do not permit FDA inspections. The administration also will develop new guidelines and monitoring procedures, he said.

"With these efforts, we can make sure that no fruits and vegetables cross our borders, enter our ports or reach our dinner tables without meeting the same strict standards as those grown here in America," the president said. "Our food safety system is the strongest in the world, and that's how it's going to stay."

The plan, the broad outlines of which were released last week, was fashioned to reassure consumers worried by recent outbreaks of food-borne illnesses that fruits and vegetables will be examined as closely as meat and poultry. The FDA recommended more scrutiny of produce in 1993, but the administration did not act until recent widely publicized incidents raised political pressure.

Even as it was being unveiled, though, the proposal immediately became entangled in the politics of Clinton's "fast-track" free trade proposal. On one side, critics charged that the food initiative was a ploy to allay congressional fears that lower trade barriers would make it easier for tainted food from other countries to get into the United States. On the other, industry officials warned the plan could hurt domestic growers if foreign governments retaliate by adopting their own stricter standards against American products.

This whole plan of his is pure



BY WILFREDO LEE—ASSOCIATED PRESS

Flanked by officials outside the White House, President Clinton outlines a food safety plan for new guidelines, monitoring and FDA powers to halt the importation of fruits and vegetables that fail to pass inspection.

cosmetics to get fast track passed," Rep. Sherrod Brown (D-Ohio) said by telephone from the Mexican border, where he was studying the impact of the North American Free Trade Agreement (NAFTA). "I don't think anybody in Congress is going to change their vote because of this rather inadequate food safety proposal of the president's."

The Clinton legislation would give the FDA the same kind of power over produce imports that the Agriculture Department already has over meat and poultry, officials said. While fruits and vegetables are not the main source of food illnesses, there is some evidence that their involvement is growing. Vegetables now are involved in about 15 percent of E. coli 0157:H7 outbreaks in the United States, three times as much as several years ago.

The administration plans to ask for \$24 million for more international inspectors to travel abroad to examine produce suppliers. Clinton asked aides to report back in 90 days with plans to toughen border inspections and aid foreign countries and in a year with specific safety standards for growing, processing, shipping and selling produce.

About 38 percent of the fruit and 12 percent of the vegetables consumed by Americans last year came from foreign growers, according to the administration. Officials said they were not responding to any great threat from overseas produce. "We don't see a huge problem out

there," Deputy Agriculture Secretary Richard E. Rominger said.

However, some food industry officials said they fear a backlash from foreign governments because of the Clinton plan.

"I've seen countries do a lot of things to protect their markets, and it wouldn't surprise me at all to see other countries use this to protect their markets if our government isn't careful how they structure this program," said Chris Schlect, president of the Northwest Horticultural Council, which represents growers of apples, pears and cherries in the Pacific Northwest.

But Ralph Nader's Public Citizen group sharply dissected Clinton's plan, calling it weak in some elements and counterproductive in others.

Lori Wallach, director of the group's trade section, said the FDA already has the power to seize contaminated fruit and vegetables at the border. Moreover, she said, Clinton's proposal would apply a looser standard than current law—requiring that foreign safety standards be equivalent rather than equal to U.S. rules.

The most beneficial aspect of the plan, she said, is the provision allowing the FDA to block produce imports if its inspectors are barred from another nation.

"It's a crass political move," she said. "It's about fast track, not food safety."

Staff writer Paul Blustein contributed to this report.

107

Clinton seeks to ensure safety of imported produce

(Adds details, background, comment from industry groups)

By Arshad Mohammed

WASHINGTON, Oct 2 (Reuter) - President Bill Clinton asked Congress on Thursday for authority to ban fruit and vegetable imports from countries that do not meet U.S. safety standards or permit U.S. inspections.

Clinton's request was part of a broader effort to ensure the safety of foreign produce after an outbreak of hepatitis caused by tainted, imported strawberries this spring focused national attention on the issue.

Some in the food industry also viewed it as an effort to give Clinton's request for "fast-track" trade negotiating authority a boost by neutralizing criticism from those worried about the safety of imported foods.

U.S. imports of foreign produce have increased sharply over the past decade, giving consumers a wide choice of fruits and vegetables throughout the year, but U.S. regulation of foreign food has not kept pace.

Clinton asked Congress to pass legislation requiring the Food and Drug Administration to stop imports from countries whose standards do not equal those of the United States or who refuse to permit U.S. inspections, giving the FDA a power over produce that it already enjoys over meat and poultry imports.

"With these efforts we can make sure that no fruits and vegetables cross our borders, enter our ports or reach our dinner tables without meeting the same strict standards as those grown here in America," Clinton told reporters in the White House Rose Garden.

As part of the effort, Clinton said he would boost next year's FDA budget for foreign food inspections. U.S. officials said the increase would be in the range of \$24 million, about a 50 percent rise from the current level of \$43 million.

In a bid to improve the safety of domestic and imported produce, Clinton also ordered the secretaries of health and human services and of agriculture to draw up voluntary guidelines on growing, processing, shipping and selling produce. The White House said this would be the first time the United States had drawn up specific safety standards for fruits and vegetables.

Several food industry and consumer groups praised Clinton's plan as a way to protect the food supply but criticized it for linking food safety issues to regional trade agreements.

Public Citizen's Global Trade Watch said that the Clinton proposal for additional legislation could actually weaken U.S. contamination standards for imported food.

"The obvious strategy of the ... administration is to try to deflect criticism from imported food safety problems in an effort to pass fast track," said Lori Wallach, director of the group. "The proposal would implement the NAFTA requirement that the U.S. begin importing food which does not meet our standards but has been deemed 'equivalent' by trade officials."

The NAFTA accord allows food safety standards from other countries to be declared equivalent to U.S. standards, which Wallach called an "inexact concept" that lets countries with weaker food safety systems to export to the United States.

NAFTA opponents recently criticized Clinton's request for fast track authority, which allows a president to negotiate trade deals that cannot be changed by Congress.

Clinton told reporters he did not want the food initiative to roil the waters in the trade debate, saying: "I don't want it to complicate the trade environment, but I'm not interested in trade in things that will make the American people sick." Clinton said he would direct the secretaries of HHS and agriculture to report within 90 days on ways to improve the monitoring of agriculture and manufacturing practices abroad. In part, the White House has concentrated on the foreign food safety issue because of a highly publicized incident earlier this year when 179 school children developed hepatitis after eating tainted strawberries imported from Mexico.

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Food Safety, 0641

U.S. would inspect foreign farms to ensure safe food

WASHINGTON (AP) Expanding the sweep of U.S. food safeguards, President Clinton proposed sending inspectors to farms around the world to ensure that foreign-grown fruits and vegetables are safe for American consumers.

Clinton, in a Rose Garden ceremony Thursday, also said he would ask Congress to empower the Food and Drug Administration for the first time to ban produce from countries whose safety precautions do not meet American standards.

The moves are intended to help convert the U.S. food safety system to a scientific basis from "the old-fashioned eyeball system of trying to guess whether the food was safe," said Donna Shalala, the Health and Human Services secretary.

"We don't have any evidence that foreign foods coming into this country are any less safe than American foods that are manufactured in this country," Shalala said. "What we're trying to do is to translate this new scientific way of improving standards into the international arena."

Currently, a sampling of imported fruits and vegetables is inspected by the Agriculture Department for general quality and pesticide residues.

Clinton's proposal would expand that by sending FDA inspectors abroad to check on everything from illness rates to farm practices such as irrigation, water safety, land management and fertilization.

"These are scientific issues that very much affect the quality of the food that comes to the people in the United States," said Agriculture Deputy Undersecretary Richard Rominger.

The proposal would give the FDA the same authority over fruits and vegetables that Agriculture has to ban meat imports from countries that don't meet U.S.-equivalent meat regulations.

These practices have caused friction with some U.S. trading partners, particularly the European Union, and a crackdown on foreign produce conceivably could cause tensions as well.

"I hope it doesn't complicate the trade environment," Clinton said. "But, you know, it seems to me that we have no higher responsibility than to protect the health and safety of our citizens."

Other critics charged Clinton was trying to disarm those who say his push for free-trade legislation would increase the risks of tainted foods entering the country. They argue that the U.S. food supply already is the world's safest.

On the other side, the Center for Science in the Public Interest praised Clinton's initiative. "The absence of federal standards regarding the use of manure or contaminated water increases the risk of tainted fruits and vegetables," said Michael F. Jacobson, executive director of the advocacy group. "New mandatory standards for fruits and vegetable production are urgently needed if we are to stem the tide of food-safety problems."

The proposals also drew support from the National Food Processors Association and the Florida Fruit & Vegetable Association.

American farmers also would face new sanitation guidelines. Clinton ordered the establishment of safety standards to be completed within a year for the growing, processing, shipping and selling of fruits and vegetables.

"These standards will address potential food safety problems throughout the production and distribution system," the president said. "And they'll improve the sanitation and safety practices of all those seeking to sell produce in the United States' market."

Shalala indicated she would ask for \$24 million for inspectors who would roam the world to sample conditions at farms.

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Produce industry questions motive behind food plan

By Daniela Deane
and Anita Manning
USA TODAY

10/3/97 AS

The president's latest food safety proposal follows a series of outbreaks of food poisoning traced to contaminated berries, lettuce, sprouts and other fruits and vegetables, many of them imported.

Among recent outbreaks:

► About 1,400 Americans became ill this year and last after ingesting cyclospora, a parasite that causes diarrhea and other symptoms, including weight loss and fatigue that can last for weeks.

Most cases were linked to raspberries imported from Guatemala, but this year, outbreaks were also traced to basil and lettuce. Scientists believe the basil and lettuce were imported but have not yet determined their country of origin.

► In March, an outbreak of hepatitis A linked to frozen strawberries from Mexico affected 230 people in Michigan, including 179 school children. Hepatitis A infection causes fever, jaundice, nausea and appetite loss for several weeks.

► Alfalfa sprouts grown from seeds contaminated with *E. coli*, a dangerous bacterium that can cause severe diarrhea and hemorrhagic colitis, made more than 100 people sick (60 in Michigan and 48 in Virginia). The source of the sprouts hasn't been traced.

Industry officials insist these incidents are isolated and do not represent a widespread food safety problem. They argue that with Americans eating a half billion servings of fruits and vegetables every day, outbreaks such as these are minuscule when compared with the vast amount of fresh produce consumed in this country. Americans are increasingly seeking healthier diets, with lots of fruits and vegetables, prompting retailers to troll world markets in an effort to stock a year-round supply of fresh produce.

"We reject 100% that we have a food safety problem," says John Aguirre of the United Fresh Fruit and Vegetable Association. He called the measures "unwarranted."

President Clinton asked Congress Thursday to pass legislation allowing the Food and Drug Administration

(FDA) to ban imports of fruits and vegetables that do not meet U.S. food safety standards. He also sought to boost the FDA's budget for foreign food inspections.

Critics charge that the food plan is an effort by the president to bolster support to grant him "fast-track" trade authority.

That enables him to negotiate trade agreements that Congress would have to approve or reject but could not amend. Opponents say that legislation, currently pending in Congress, could open the door to more tainted food from overseas.

"We are concerned about fast-track legislation getting linked to food safety," says Brian Sansoni of the Grocery Manufacturers of America. "We hope the motivation behind this isn't to appease opponents of fast-track legislation."

But the FDA, which has been pushing for the changes since 1993, says it hasn't kept pace with Americans' food supply. "The whole infrastructure of food safety needs to be strengthened," Associate Commissioner William Hubbard says.

Foreign food imports have doubled to 2.2 million shipments a year since 1992, while FDA border inspections were cut in half. Only 2% of imported foods are checked for contamination at entry docks.

If Congress approves the legislation, the FDA will have the same authority to halt imported produce that the U.S. Department of Agriculture has over imported meat and poultry.

But industry officials worry what effect the proposal would have on trade and trading partners.

"We do not want to see anything that would increase trade barriers, or unnecessarily increase tensions between trading partners," Sansoni says.

"Clearly, being the world food police complicates the trade environment we operate in," Aguirre says.

They also argue that since a recent report found that 40% of cancers were avoidable with a proper diet, which includes plenty of fresh fruit and vegetables, the consumption of fresh produce should be strongly encouraged, rather than discouraged, among Americans.

► Food crackdown urged, 1A

Congress of the United States

Washington, DC 20515

September 24, 1997

The Honorable William Jefferson Clinton
1600 Pennsylvania Ave., N.W.
Washington, DC 20500

Dear Mr. President:

We urge you to give serious consideration to remedying the inadequate food safety provisions in the North American Free Trade Agreement (NAFTA). Because of your commitment to ensuring the safety of our nation's food supply, we expect that you will not agree to fast track authority that does not contain adequate food safety protections. Current fast track proposals do not address these concerns.

In an effort to increase trade with Mexico, NAFTA limited border inspections of food and allowed Mexican trucks to enter the U.S. with limited inspection.

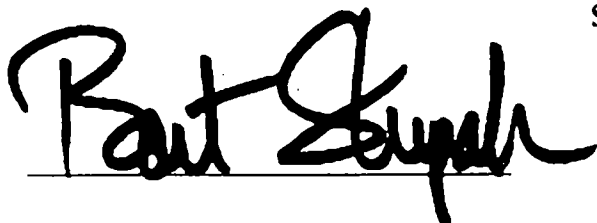
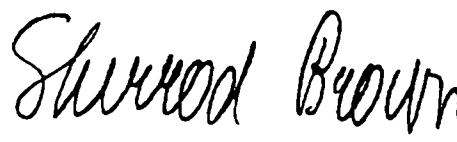
These lax inspection practices contributed to a sharp increase in food imports from Mexico: imports of Mexican fruit have increased 45%, and vegetable imports have risen 31%. More than 70% of these imports are carried into the U.S. on trucks. The General Accounting Office (GAO) recently found that 99% of Mexican trucks enter the U.S. without any inspection.

These provisions in NAFTA have resulted in imports of fruits and vegetables contaminated with diseases and unhealthy pesticides. We were alarmed earlier this year when 179 Michigan school children contracted hepatitis after eating tainted Mexican strawberries. In order to prevent similar incidents in the future, we urge you to take the following action:

- Renegotiate the provisions in NAFTA that relate to border inspections and food safety, and ensure that any fast track authority include strong food safety protections.
- Increase the funding for border inspections or, alternatively, limit the increasing rate of food imports to ensure the safety of our food supply.
- Begin an aggressive program to label all food stuffs -- including fresh and frozen fruits, vegetables and meats -- with their country of origin.

We look forward to working with you on these vital public health issues.

Sincerely,

Congress of the United States
House of Representatives
Washington, DC 20515

September 23, 1997

SEP 25 PM5:36

The Honorable Bill Clinton
The White House
Washington, D.C. 20500

Dear Mr. President:

We, the members of the Florida congressional delegation, are writing to express our problem in supporting the renewal of fast track authority.

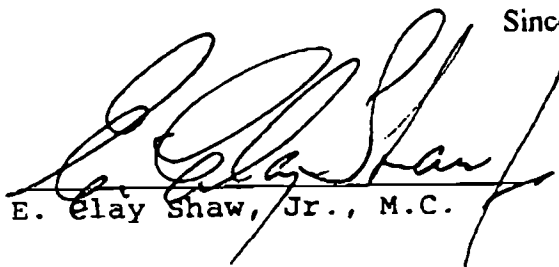
While we support free trade, we are hesitant to support fast track legislation in light of the fact that existing agreements regarding Florida fresh fruit and vegetable commodities have not been fully enforced. For example, in the recent past, tomatoes from Mexico were dumped in this country below cost in elevated surging quantities. And because current safeguards were not effective, Florida's tomato industry was severely damaged.

Furthermore, it is our understanding that not one Florida orange has been exported to Mexico since the passage of NAFTA. This situation demonstrates the inherent unfairness against Florida produce by the Mexican government.

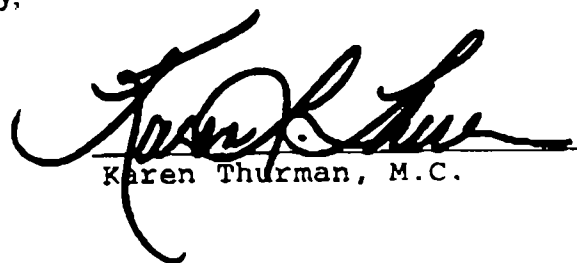
We understand that expanding free trade is crucial to continue growing America's economy. However, we are reluctant to support renewing fast track authority for agreements with other nations when promises made in the past to fairly treat Florida produce have gone largely unfulfilled. Therefore, we believe the existing foreign trade inequities concerning Florida agriculture should be addressed and resolved before fast track authority is renewed.

Thank you for your consideration of our views.

Sincerely,

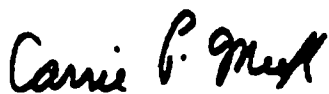


E. Clay Shaw, Jr., M.C.



Karen Thurman, M.C.

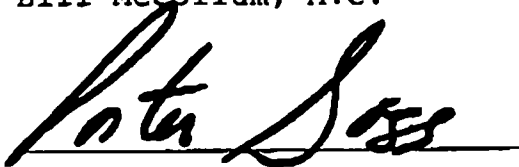
The Honorable Bill Clinton -- Page 2



Carrie Meek, M.C.



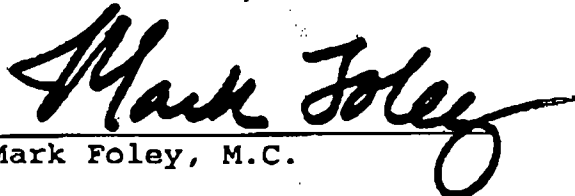
Bill McCollum, M.C.



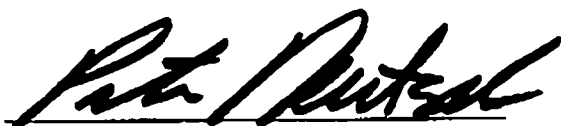
Porter Goss, M.C.



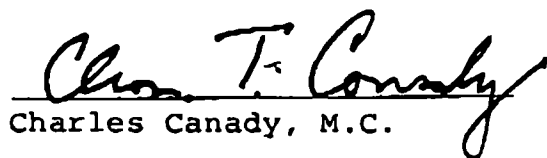
Tillie Fowler, M.C.



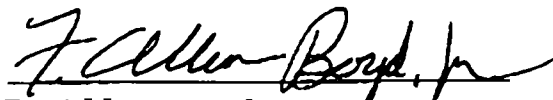
Mark Foley, M.C.



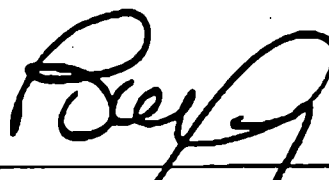
Peter Deutsch, M.C.



Charles Canady, M.C.



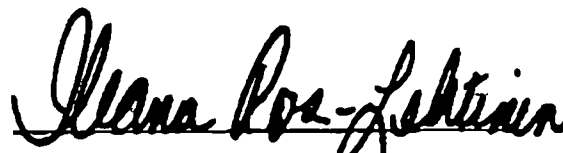
F. Allen Boyd, Jr., M.C.



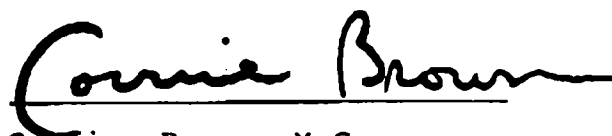
C.W. "Bill" Young, M.C.



Michael Bilirakis, M.C.



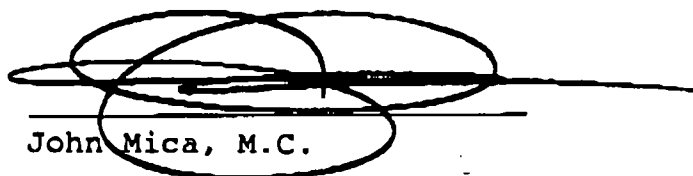
Ileana Ros-Lehtinen, M.C.



Corrine Brown, M.C.



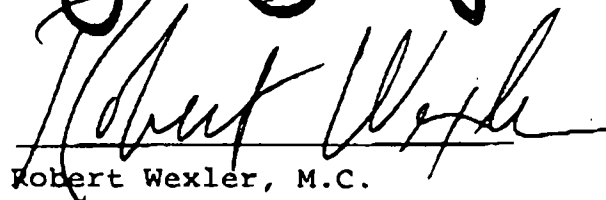
Alcee Hastings, M.C.



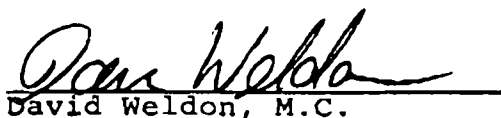
John Mica, M.C.



Joe Scarborough, M.C.



Robert Wexler, M.C.



David Weldon, M.C.

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Rod Blagovich

Patty T. Munk

Blert Weyler

Paul Kanyinski

John Sanders

Maureen Kunkin

Bob W. Zeng

J. L. Fink

Mike Deke

Burt Ascroft

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Ted Strickland

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Martin O. Ochoa

Eliot L. Engel

St. John

Marlene Waters

Lisa V. Gutierrez

Wayne D. Dineen

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William L. Lutz

James L. Lutz

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William L. Lutz

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Jim Barcia

John A. Coburn

Sam W. Johnson

Danny L. Davis

Tom Lantos

Ron Kind

Tom

C.D.C. The Centers for Disease Control still know little about the parasite. But they established this spring that cyclospora is a common cause of diarrhea in Guatemalan children, and is still present in the water that runs through the highlands. The C.D.C. has shown that a polluted stream in a third world field can spawn a mysterious bug that can sicken a diner in midtown Manhattan.

"We eat out of everybody else's garden now," said Dr. Dan Colley, director of the Centers for Disease Control's division of parasitic diseases. And on an increasingly crowded planet, not everyone's garden is well kept.

When cyclospora struck in the United States again this spring, Guatemalan berry growers acted swiftly. First, they voluntarily suspended their shipments. Then they kicked the C.D.C.'s field investigator off their farms. Then they denounced the American scientists as snipers fighting a trade war on behalf of the growers' California competitors.

Roberto Castenada, vice president of the Guatemalan Berries Commission, said in an interview: "Last year the guerrillas were in the fields asking my workers about their conditions, asking, 'Do you have bathrooms?' And this year, it was the C.D.C. The C.D.C. is killing us. They kill us every time they open their mouths."

Gabriel Biguria, a former president of Gexpront, the Guatemalan agricultural export group, said his country was the victim of an unfair trade practice.

"Cyclospora?" he said. "They can't find it. We find a tremendous possibility that people in California are using this as a very dangerous tool for protectionism. Protectionist forces find bugs or whatever to protect their market. It's a commercial war."

This dispute illustrates how science and politics collide in the arena of trade.

Some of the biggest food-trade fights have centered on the safety of American products. European nations did not want hormone-injected beef or chlorine-rinsed chicken. So far, the United States has won those cases. But now the United States sometimes finds itself on the other side of the fence, fighting with trading partners about the safety standards for their imports.

"Where we see a safety issue, they see a trade issue," said Dr. I. Kaye Wachsmuth, a leading Federal food-safety official.

The Inspectors

Import-Ban Power For the F.D.A.

Things were simpler when most of the food Americans ate was grown near their homes. Traditionally, food illness came from undercooked or mishandled domestic meat and poultry. Today, people depend more on global trade to satisfy their hunger.

"Go to a restaurant and take a look at your supper," said Dr. Robert Tauxe, chief of the food-borne and diarrheal disease branch at the Centers for Disease Control. "How many different continents are on your plate?"

The food chain that fills those plates has become unimaginably intricate.

For example, alfalfa sprouts gave salmonella to hundreds of people in 24 states this year and last. The seeds for those sprouts

were bought from Uganda and Pakistan, among other nations, shipped through the Netherlands, flown into New York and trucked around the United States, Dr. Tauxe said.

Previously unknown pathogens are being discovered years after they arrive in the United States. Take the case of the Peruvian carrots, which took years to break.

In a coming issue of the Journal of Infectious Diseases, Dr. Osterholm and his colleagues will report their discovery of a new strain of E. coli bacteria, linked to a shipment of carrots from Peru. It took them six years to connect the new strain to a 1991 outbreak at a Minneapolis convention.

Most of the data on food-borne disease come from a relatively small number of outbreaks at big gatherings — conventions, restaurants and receptions. Most cases are never reported at all, said Dr. Osterholm, Minnesota's chief epidemiologist.

"If you get an outbreak of 500 people in a state, but no more than a few in any one household, you'll never pick it up," he said.

Because one percent or less of the actual number of outbreaks are reported, analyzed, identified and successfully traced back to the source, the C.D.C. says, its scientists cannot identify the causes of a great majority of food-borne diseases.

International food-borne outbreaks, said Dr. Colley of the Centers for Disease Control, are increasing and "can be expected to worsen as the world moves toward a global food economy."

Detecting microbes at the border is about as effective as detecting illegal drugs.

The Food and Drug Administration's inspectors test an ever-dwindling fraction of the 30 billion tons of food now imported into the United States. The responsibilities of individual inspectors have increased, but their resources have dwindled. They sampled 17,000 food items in 1996, less than one percent of 2.2 million food shipments, down from 30,000 samples, or about 3 percent of 1.1 million shipments, in 1992.

A more fundamental defense — insuring the safety of food at its source — does not exist. The F.D.A.'s inspectors can seize suspect imports, but they lack the power to automatically bar imported food just because it comes from a country with an inferior food-safety system.

Congress has never granted them that power. The White House has never publicly asked for it — until now, as it seeks fast track authority for trade pacts that is being seriously challenged in Congress over food-safety issues. The Administration plans to announce a proposal seeking to give the Food and Drug Administration the new powers this week.

The need has been apparent for years, Federal food-safety officials said. They cited the case of the tainted coconut milk from Thailand. In 1991, frozen coconut milk processed at a Bangkok plant, and exported by a Thai trading company to the United States, set off an outbreak of cholera. The life-threatening disease was thought to have been eradicated in this country.

"The Thai authorities were unaware of the existence of the plant," Dr. Tauxe said. "It was unlicensed, uninspected, unregulated."

Nor is it clear that the new powers the White House is planning to seek would have prevented the outbreak.

"I can't imagine an F.D.A. inspector in

every country overseas," said Peggy Foege, a principal author of a landmark 1994 study on food-borne pathogens.

The United States is second to none at stopping food-borne disease after it breaks out. The Clinton Administration says it will lift up public-health and food-safety standards around the world until they meet those of the United States, in order to insure the safety of imported food.

But the United States' public-health systems today "cannot properly identify, track and control food-related illness, or prevent, to the extent possible, future cases from occurring," said a Federal report published in May as part of a food-safety initiative now nearing passage in Congress.

The Safety Net

Eroding Resources For Surveillance

Some Federal agencies are helping their foreign counterparts improve their public health systems. But "the United States cannot really build public health structures for the world," said Kerri-Ann Jones, a top White House science official.

The Clinton Administration says it wants more surveillance, more research, more F.D.A. inspectors. But "Federal budget constraints will likely prohibit significant funding increases in the future" for the F.D.A., said the food-safety initiative report published in May.

Many state health departments are overburdened and underfinanced, in part because of the AIDS crisis. Twelve states have no system for reporting food-borne disease, largely because of budget restrictions, public health officials say.

And many countries are reducing their own disease-surveillance abilities. "Economic globalization has also increased the need for governmental budget austerity," and countries around the world are cutting spending on public health to streamline their economies, according to a coming study by World Health Organization officials.

Scientists have fought new diseases spread by trade, travel and technology before. One night in 1849, a British doctor, John Snow, had a brainstorm. Having realized that cholera was spread by contaminated water, he ripped the handle off a water pump in a London slum and stopped an epidemic.

Global trade, the gigantic pump bringing the essentials and luxuries of life, and the small but rising threat of disease pose more intricate challenges for scientists.

Dr. Kessler and other prominent scientists, while acknowledging the problems with domestic food, said those challenges could be summarized by two questions:

As the world's nations become more intertwined, interdependent and intensely competitive, will the rest of the world's standards become more like those of the United States, with its relatively safe water, sound hygiene and state-of-the-art science? Or will the United States, despite its high standards, become more vulnerable to the rest of the world's microbes?

"The challenge for the United States," Dr. Kessler said, "is to raise everyone else's standards."

U.S. Reshaping Cancer Strategy As Incidence in Children Rises

Increase May Be Tied to New Chemicals in Environment

A1

By JOHN H. CUSHMAN Jr.

WASHINGTON, Sept. 26 — The rate of cancer among American children has been rising for decades. Although the reasons remain unclear, many experts suspect the increase may be partly the result of growing exposure to new chemicals in the environment.

That suspicion, while still unproved, is beginning to shape Federal research priorities and environmental strategies.

Depending on which types of cancer are counted, and in what age groups among the nation's youth, the rate of increase has amounted to nearly 1 percent a year, according to the National Cancer Institute.

Over a few decades, that has meant striking double-digit increases.

Childhood cancer is still far less common than cancer in adults, and its very rarity makes it especially hard to discern what might be causing the increase. Its creeping spread has also been masked by better news, as recent medical gains have made it much more likely that a child with cancer will survive.

But childhood cancer, even when its young victims are cured, can inflict wrenching costs on children and their families, whether its toll is measured in financial, emotional or physical terms. Patients can suffer permanently from brain damage, stunted growth or secondary cancers later in life, partly as a result of radiation and chemical therapies.

And today, according to experts in the field, a newborn child faces a risk of about 1 in 600 of contracting cancer by age 10.

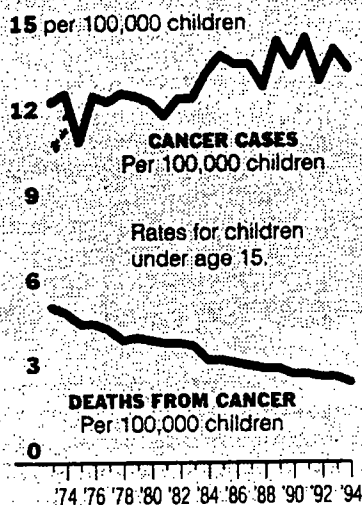
In the United States, cancer is diagnosed each year in an estimated 8,000 children below the age of 15. Cancer, although it kills fewer children than accidents do, is the most common form of fatal childhood disease, accounting for about 10 percent of all deaths in childhood.

The increases surprise even people who are predisposed to think the worst about the ill effects of chemical pollution.

"I had not realized that the numbers were going up that way," said Karen Florini, a lawyer specializing in health issues at the Environmental Defense Fund. "I think it indicates a very disturbing trend that we had better get to the bottom of."

Acute lymphoblastic leukemia in boys and girls increased 27 percent between 1973 and 1990; since then, the rate in boys has declined, but it is still rising in girls. Brain cancer, or glioma, increased nearly 40 percent from 1973 to 1994. These two forms of cancer account for most of the dis-

The rate of childhood cancer has been rising since the early 1970's, though the death rate has been dropping.



Source: National Cancer Institute

The New York Times

Continued From Page A1

ease in children.

Other forms of cancer, such as the form of bone cancer called osteogenic sarcoma and the kidney cancer known as Wilms's tumor, have also been rising, although the numbers of cases remain so small that the trends may not be statistically significant. The increases are big enough that better diagnosis and reporting of the diseases are unlikely to be the principal explanation, experts say; childhood cancer is such a serious ailment that it is usually detected.

Although the causes are not known and are probably many, some experts say, toxins in the air, food, dust, soil and drinking water are prime suspects.

So with the Clinton Administration putting a high priority on issues of children's health and the environment, and with Congress last year overwhelmingly approving new laws taking children's exposures into account when setting standards for pesticide residues in food and contaminants in drinking water, Federal authorities are moving to review the epidemiological data much more closely and to review environmental regulations that may help fight the trend.

At a meeting in Washington last week, a team assembled by the Environmental Protection Agency drafted a research plan that could steer millions of dollars toward better understanding the problem, beginning next year.

"The increases are too rapid to reflect genetic changes, and better diagnostic detection is not a likely explanation," said Dr. Philip J. Landrigan, a pediatrician who directs the division of environmental medicine at the Mount Sinai School of

Medicine and who is the senior adviser to a new office of children's health at the E.P.A. "The strong probability exists that environmental factors are playing a role."

Not all environmental factors involve pollution. Dr. Landrigan said that changes in life style, especially diet, must also be considered and may play some role. Viruses may be implicated in some cancers, but there is scant evidence.

Instead, he and many other experts are inclined to examine the estimated 75,000 new synthetic chemicals introduced in the last half century, the emissions from cars, the pesticides in foods and in neighborhoods, the runoffs in drinking water — the whole collection of chemicals out there, mostly untested for toxicity to humans, let alone for possible cancerous effects in children.

If their suspicions prove to be well founded — and that could take many years to determine — it could usher in a new generation of tighter controls on pesticides, toxic wastes, and other chemicals based on the theory that it may take less of a carcinogen to afflict a child or a fetus, that their health may be affected by combinations of chemicals and that their needs ought to come first in dictating pollution controls.

But first, an expansion of federally supported research is likely.

"I'm talking about new research on air pollutants, water pollutants and pesticides and their effects on children," said Carol M. Browner, the administrator of the E.P.A., "and new testing guidelines that routinely incorporate children's issues into E.P.A.'s risk assessments. I'm talking about moving beyond the chemical-by-chemical approaches of the past, and instead looking at a child's total cumulative risk from all exposures to toxic chemicals."

She promised to pursue better interdisciplinary and collaborative studies of suspected environmental causes and mechanisms of childhood cancer, an initiative that was endorsed at the agency's conference.

Industry representatives who attended the meeting, though, cautioned against the Government's moving too fast to react to such sketchy scientific information.

"It doesn't appear that anyone really knows yet what the causes are," said Nancy Doerr, vice president for scientific and policy programs at the American Industrial Health Council, which represents a diverse group of manufacturing companies. "Yes, there may be some role for environmental causation for childhood cancer. But there is also a role for life style, and the prenatal vitamin supplementation during pregnancy also seems to be very important in preventing some cancers."

Ms. Doerr said that the E.P.A. was acting properly by announcing that it would select a few major regulations for scientific review to determine whether they adequately protected children.

The group also recommended developing a National Childhood Cancer Registry, which would contain information such as exposure histories and family health data, and for

Continued on Page A14

The New York Times

MONDAY, SEPTEMBER 29, 1997

1
2

struction of a large housing project in East Jerusalem.

The latest American mediation effort came against a distinctively menacing drumbeat.

According to the Israeli radio, the Israeli Army held exercises in the northern West Bank last week focused on ways to counter a major Palestinian uprising, from the defense of threatened Jewish settlements to full-scale operations in Palestinian-controlled areas. The exercises were held on the first anniversary of the bloody clashes following the opening of a Western Wall tunnel, and were seen as a signal to the Palestinians that Israel stood ready for any level of conflict.

Israeli security officials continued to issue warnings that the same Hamas cell responsible for suicide bombings in July and this month might strike again. Popular gathering places like the Ben Yehuda pedestrian promenade, site of the attack on Sept. 4, and Jerusalem's large Malcha Mall, which is usually packed in advance of the holidays, drew unusually sparse crowds.

The warnings followed the announcement by Mr. Netanyahu last week that four of the five suicide bombers in the last two attacks had been identified by Israeli intelligence as residents of a West Bank village. He triumphantly brandished the disclosure in a number of interviews as proof of his assertion that Mr. Arafat was not combating terror.

Mr. Arafat, who had claimed that the attackers might have come from abroad, now charges that the village in question was under Israeli security control.

Mr. Netanyahu's announcement drew unusually open criticism from Israeli intelligence agencies, which put out a series of leaks in the Israeli press saying that they had counseled the Prime Minister against the early disclosure, and that it may have harmed their investigation by tipping off members of the cell. An official of the Shin Bet secret service was quoted in Haaretz as saying the Prime Minister had created a "terrible problem," and similar charges were published in other newspapers.

Mr. Netanyahu was also reported to have clashed with senior intelligence officials over their assessment of how Mr. Arafat could be made to fight Islamic terrorism. According to Zeev Schiff, a longtime security reporter for Haaretz, senior officers of Shin Bet and army intelligence told the Israeli Cabinet last week that Mr. Arafat had little incentive for cracking down on the Islamic organizations as long as the diplomatic process was stalled and Israel was not

Hope for committee talks, but not much for renewal of full peace negotiations.

keeping its part of the agreements.

The assessment was assailed by Tourism Minister Moshe Katzav, a close ally of Mr. Netanyahu, who declared that the only choice it left the Government was "to change our basic concepts, or resign." Mr. Netanyahu agreed, Mr. Schiff wrote, saying, "I don't accept the military intelligence assessment either."

In the meantime, Hamas issued new threats of violence after a mysterious attack on a senior Hamas official in Amman, Khaled Mashal. Hamas insisted that the attack, which led to the hospitalization of Mr. Mashal, was an assassination attempt, while the Jordanian authorities said it was a fight between his driver and two Canadian citizens.

The dismal state of Israeli-Palestinian relations was the theme of a series of parting interviews by Mr. Indyk, who left Tel Aviv on Saturday after two and a half years as the American Ambassador. Mr. Indyk, who is now Assistant Secretary of State for Near Eastern Affairs, had been intimately involved in the Oslo process, and though he made little secret of his dismay as the process unraveled, he was unusually blunt in farewell speeches and interviews.

"I leave Israel with a heavy heart," he said in a speech to the Israeli Council for Peace and Security. "Increasingly people have the sense that we are headed back toward conflict, that peace — real peace — with the Palestinians is somehow no longer a realistic expectation."

"Somehow, the partnership has to be restored," he said. "Somehow we have to get back to the notion that both sides benefit from the process, that it is not a zero-sum game, that your interests are advantaged by helping the other side achieve their interests."

Mr. Indyk's replacement in Tel Aviv will be Edward S. Walker, currently Ambassador to Egypt.

Company News:
Tuesday through Saturday,
Business Day

The New York Times

MONDAY, SEPTEMBER 29, 1997

2
2

Imports Swamp U.S. Food-Safety Efforts

By JEFF GERTH
TIM WEINER

WASHINGTON, Sept. 28 — Since the 1980's, food imports to the United States have doubled. But Federal inspections of those imports by the Food and Drug Administration have dropped to less than half what they were five years ago.

Now, public-health scientists say they are seeing more and more outbreaks of disease linked to imported food, particularly fresh fruit and vegetables.

These are known to have sickened thousands of Americans, and those reported cases are a small fraction of the actual number of people made ill, according to scientists at the Centers for Disease Control and Prevention in Atlanta.

The scientists' list of outbreaks in the 1990's implicates imported foods — including raspberries from Guatemala and carrots from

TAINTED IMPORTS

A special report.

Peru; strawberries, scallions and cantaloupes from Mexico; coconut milk from Thailand; canned mushrooms from China; an Israeli snack food, and a multinational batch of alfalfa sprouts — in a variety of infectious diseases.

The increase in imports has strained the nation's food-safety system, said Dr. David A. Kessler, the Food and Drug Administration commissioner, from 1990 through February 1997. "We built a system back 100 years ago that served us very well for a world within our borders," he said in an interview. "We didn't build a system for the global marketplace."

Most of the food imported to the United States is wholesome. Consumers, knowing that fresh produce is good for their health, can now buy reasonably priced fruits and vegetables imported from around the world, regardless of the season, and without ill effect.

But the illnesses that have been

Continued on Page A10

Continued From Page A1

imported along with some of the produce are an unintended byproduct of the boom in international trade — a boom long advocated by the Reagan, Bush and Clinton Administrations as crucial to economic growth.

There is "a tension between the two goals of safety and trade," said Mickey Kantor, President Clinton's first trade representative, who helped push global trade to the top of Mr. Clinton's agenda. "You want to open markets but not lower standards. And that's easy to say, but very, very difficult to carry out."

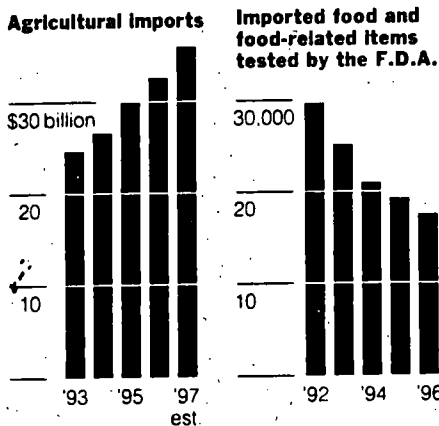
Scientists are recognizing that "free trade may present problems that are associated with food poisoning," said Dr. Marguerite A. Neill, an infectious disease specialist and a member of a Federal advisory panel drafting new food-safety standards. These problems cut both ways: radish sprouts from Oregon seeds sickened people in Japan in March, and South Korea said it detected *E. coli* bacteria in a shipment of frozen United States beef last week.

The problems imports may pose for American consumers include polluted water used to grow food in third-world nations, faulty safety systems in countries where the foods are produced, and a lack of natural immunity to exotic microbes rarely seen in this country. "Certain viruses, bacteria and parasites may be posing a unique problem

NUMBERS

More Imports, Fewer Tests

Food imports into the United States have risen while the F.D.A. has reduced the number of imports it examines.



All years are fiscal years ended in September.

Source: Agriculture Department

in the U.S. because we haven't tended to be exposed to them," Dr. Neill said.

Dr. Yasmine Motarjemi, a World Health Organization food-safety scientist, said the organization also believed that global trade "brings new pathogens into countries which are not immune."

Those problems were foreseeable — and foreseen.

In 1994, a Centers for Disease Control report said, "As trade and economic developments like Nafta take place, the globalization of food supplies is likely to have an increasing impact on food-borne illnesses."

In 1993, the Food and Drug Administration, in a memorandum citing "enormous inefficiencies in the current food-protection system" and the "ever-increasing challenges" posed by rapidly growing imports, asked the Clinton Administration for legislation giving it power to bar all food — including fruits, grains, vegetables and fish — imported from any country with an inferior food-safety system.

The Department of Agriculture has such authority over imported meat and poultry. But the F.D.A. never acquired that power through legislation or executive order.

Dr. Kessler said in an interview that he had told the Bush and Clinton Administrations that the safety system for imported food was inadequate and outdated.

"How is it physically possible to insure the safety of imported food?" he said. "You don't have police power throughout the world. Inspecting at the border has a limited value. You're left with real risks."

Now these risks figure in the political debate about free trade.

The Clinton Administration wants the power to sign new free-trade pacts without Congress's changing the language of those agreements. Opponents of this "fast track" authority raise the food-safety flag. Some food growers say that the risks from imports are insignificant, and that the C.D.C. exaggerates them.

The C.D.C. says diseases borne by domestic and foreign foods kill thousands of Americans and sicken millions, perhaps tens of millions, every year — mostly the very young, the very old and the very ill. Its scientists say almost none of those cases are ever traced back to their cause. As a result, they say, they lack the data to show how many people get sick from imported food, and whether that food is safer or less safe than domestic food.

Both sides in the fast track debate use the Centers for Disease Control's data to make their cases — and both sides mischaracterize what the data show, according to the scientists.

Now the Administration is preparing a proposal to address the problems posed by imported food — nine months after announcing a sweeping food-safety initiative that largely ignored them, and days after a bill to revamp the Food and Drug Administration was passed by the Senate.

The Food Chain

Modern-Day Travels Of Tainted Products

The United States has its own food-safety problems at home. Urgent questions about the integrity of America's food supply were raised when three American children died and 144 people were hospitalized after eating fast-food hamburgers in 1993. A reminder of the problem came this summer, when tainted hamburger meat from a Nebraska plant made 16 people sick.

But this spring and last, in an outbreak that attracted less attention, tainted raspberries from Guatemala made thousands of Americans sick. They were victims of a nearly invisible, dimly understood parasite called *cyclospora*, a species almost never seen in the United States before 1996.

To know the story of raspberries and *cyclospora*, Dr. Michael T. Osterholm, one of the nation's leading epidemiologists, wrote recently, "is to know food-borne disease in the modern world."

Not a single raspberry grew in Guatemala a decade ago. They grow today because the United States helped introduce them.

In the 1980's, during the height of the Guatemalan Army's campaign against leftist guerrillas, the United States Agency for International Development tried to win over the peasants by introducing them to the riches of global trade. Spurred by the Reagan Administration's Caribbean Basin Initiative, a 1983 free-trade measure that cut or eliminated tariffs on imports, the agency spent tens of millions of dollars promoting "nontraditional" agriculture in Guatemala.

It persuaded rural Guatemalans to switch from planting corn and beans for themselves to growing exotic crops for North Americans. It financed Guatemalan exporters and American importers who bring raspberries and other produce to the United States.

The raspberry trade exploded two years ago. Guatemala shipped less than 4,000 pounds of raspberries to the United States in 1992 — and about 700,000 pounds in 1996. The growers timed their first harvest of 1996 for late April and early May, when they would have the United States market almost completely to themselves.

But every April and May, when the spring rains come to the highlands, thousands of Guatemalans fall ill. They think something in the water flowing from the mountains makes them sick. And when the raspberries came to the United States in spring 1996, thousands of Americans fell ill as well. Many experienced weeks of misery — debilitating diarrhea, severe cramps, chills, fever, nausea, weight loss, depression.

The Centers for Disease Control's scientists never found *cyclospora* on the raspberries, but they found it in the stools of the Americans who ate them. And they are fairly certain that the parasite lay hiding in the water in Guatemala — the water with which the berries were sprayed and irrigated just before they were picked, shipped and eaten fresh and raw days later in the United States.

The case underscores the C.D.C.'s recent warning that "improving the microbiological safety of drinking water and food production" overseas is crucial "to insure the safety of the increasing amounts of food imported to the United States."

After that experience, American scientists and Guatemalan growers, working together, did everything they could to prevent another outbreak. But when this spring came, it happened again: Hundreds, perhaps thousands, of Americans who ate Guatemalan raspberries fell sick.

The *cyclospora* case is now the biggest outbreak of food-borne disease in the United States in years. The Centers for Disease Control count at least 2,300 people sickened this year and last. They are "the tip of the iceberg, and we don't know how big the iceberg is," said Dr. Barbara Herwaldt of the

Dear Representative Stupak:

Thank you for your letter dated September 24, 1997, expressing concern about the effects of increased trade on food safety. I share your concern about the safety of food for all Americans, and I will not permit any trade policy to impair the health and safety of the American people.

I have committed this Administration to ensuring that the food that Americans eat is the safest in the world. We have put in place improved safety standards for meat, poultry, and seafood products, and have begun the process of developing enhanced safety standards for fruit and vegetable juices. Together, we have enacted legislation in this area, including the Safe Drinking Water Act of 1996 and the Food Quality Protection Act of 1996.

This month, I announced an initiative to upgrade domestic food safety standards and to ensure that fruits and vegetables coming from overseas are as safe as those produced in the United States. I asked Congress to enact legislation that will require the Food and Drug Administration to halt imports of fruits, vegetables, and other food products from any foreign country with food safety systems and standards that are not on par with those of the United States. I also directed the Department of Health and Human Services and the Department of Agriculture to work cooperatively with the agricultural community to develop guidance on agricultural and manufacturing practices for fruits and vegetables within one year. Finally, I committed to providing the necessary funds in my Fiscal Year 1999 budget to enable the FDA to dramatically expand its international food inspection force so it can inspect food safety conditions abroad and at points of entry. The added resources will allow the FDA to make effective use of its new legislative authority. I am attaching a fact sheet on my new proposal, as well as the directive I sent to Secretaries Glickman and Shalala.

This new initiative will help guarantee the safety of food in the United States. It provides the improved inspection capacities and increased regulatory powers we need to prevent contaminated imports from reaching American tables. I am committed to continuing to improve the safety of food that Americans eat, and I look forward to working with you on this vital project. Thank you again for your letter.

Sincerely,

Phil Caplan--

This disk has the draft letter to Members. Its called "Radd.let". Vicki Radd should know if there are any last minute changes in the morning.

Also, I've attached a fact sheet and a dirty copy of the directive (I hope you have access to a more official looking one).

Finally, I've put in a copy of the letter we received from Congress. I take it that we respond only to the first signature?

Regards,

Tom Freedman x65587

Food
Safety -
Guidance

THE WHITE HOUSE
WASHINGTON

From the Office of:

The Domestic Policy Council

Elena Kagan
Deputy Assistant to the President
for Domestic Policy

TO: Tom

FAX: 67431

PHONE: _____

PAGES: 4

MESSAGE: _____

Please call (202) 456-5584 if there are any problems with the transmission.

Jackie -

Karen Cameron
205-7
205-51410

international food inspection force.

PRESIDENT CLINTON ANNOUNCES INTRODUCTION OF SENATE FOOD SAFETY LEGISLATION AND REPORT TO ENSURE THE SAFETY OF IMPORTED AND DOMESTIC FRUITS AND VEGETABLES

March 4, 1998

← Today President Clinton will announce the introduction of legislation by Senators Milkulski and Kennedy to ensure the safety of all imported foods, including fruits and vegetables. This legislation will enhance Food and Drug Administration's authority to prevent the imports of fruits, vegetables, and other food products which do not meet U.S. food safety requirements. This legislation was introduced in the U.S. House of Representatives by Reps. Eshoo and Pallone. This legislation is part of the President's food safety initiative that was announced last October. The President also will announce the release of a report that provides a blueprint on how the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) will work cooperatively with the agricultural community to develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

Enhanced FDA Oversight for Imported Foods. The food safety legislation to be introduced today in the Senate will provide greater assurance that imported foods meet U.S. food safety requirements or achieve the same level of protection required for comparable domestic products. The legislation also will permit the FDA to consider halting imports from countries or facilities that do not allow FDA inspections to occur. This legislation gives FDA authority that is comparable to USDA's existing authority to prevent the importation of unsafe meat and poultry. The President has already committed to providing approximately \$25 million in his Fiscal Year 1999 budget to enable the FDA to dramatically expand its international food safety capabilities. This legislation is part of a broader Administration initiative to enhance the safety of our Nation's food supply. Reps. Eshoo and Pallone previously have introduced this legislation in the House of Representatives.

Development of Guidance on Good Agricultural and Manufacturing Practices. The President will announce the release of a report that provides a roadmap for the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in cooperation with the agricultural community, to develop guidance on good agricultural and manufacturing practices. This report outlines the progress made to develop the voluntary guidance for the growing, processing, shipping, and marketing of fruits and vegetables and the time lines leading to the final publication of the guidance in October 1998. The guidance -- the first-ever specific safety standards for fruits and vegetables -- will address potential food safety problems throughout the production and distribution system and help ensure the sanitation and safety practices of all those seeking to sell produce in the U.S. market. The report also provides both short- and long-term plans for technical assistance, education, and outreach activities to support the appropriate application of the guidance.

already made -- and the measures still to be taken -- to

Clinton Administration Accomplishments In Improving Food Safety

The President's announcement builds on a strong record of food safety initiatives, ensuring that Americans eat the safest possible food. The Administration has put into place improved safety standards for meat, poultry, and seafood products, and has begun the process of developing enhanced standards for fruit and vegetable juices. The Administration also has expanded research, education, and surveillance activities throughout the food safety system.

~~*March, 1998. The President announces the introduction of Senate legislation for imported food safety.~~

*February, 1998. Administration announces its proposed food safety budget, which requests an approximate \$101 million increase for food safety initiatives.

~~*October, 1997. President announces new initiative to enhance FDA oversight over imported foods and develop guidance on good agricultural and manufacturing practices for fruits and vegetables.~~

*May, 1997. Administration announces comprehensive new initiative to improve the safety of nation's food supply ("Food Safety from Farm to Table" -- detailing a \$43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.

*January, 1997. President announces new Early-Warning System to gather critical scientific data to help stop food borne disease outbreaks quickly and to improve prevention systems further. *one word?*

*August, 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like cryptosporidium, and gives people the right to know about contaminants in their tap water.

*August, 1996. President signs Food Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.

*July, 1996. President Clinton announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent E.coli bacteria contamination in meat.

*December, 1995. Administration issues new rules to ensure seafood safety, ^{utilizing} ~~utilizes~~ HACCP regulatory programs to require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety assurance actions.

*1994. CDC embarks on strategic program to detect, prevent, and control emerging infectious disease threats, some of which are food borne, making significant progress toward this goal in each successive year.

*1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.

**Q&A for Presidential Announcement on Food Safety Legislation
and Report to Ensure Safety of Imported Fruits and Vegetables
March 3, 1998**

Q: What did the President announce today?

A: The President announced ^{ensure that} the introduction of food safety legislation in the Senate that will ^{list} permit the FDA ~~to deny~~ the entry of imports of fruits, vegetables, or other food from any foreign country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required. The legislation also will permit the FDA to ~~consider halting~~ imports from countries or facilities that do not allow FDA inspections to occur ~~in addition to other factors~~. This legislation was introduced in the House in November of last year. The President also announced the release of a report ~~that provides~~ ^{ok him} a roadmap for the Secretary of Health and Human Services, in cooperation with the Secretary of Agriculture and the agricultural community, ^{will} to develop guidance on good agricultural and good manufacturing practices for any fruits and vegetables that are sold in the U.S. market.

Q: Why is your Administration proposing these actions?

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

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

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

Q: Are you saying that imported produce is unsafe?

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

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are taking today are adding additional layers of protection. We are making sure that there are no gaps in our food safety system -- that high safety standards apply to imported as well as domestic food, and to fruits and vegetables as well as to meat, poultry, and seafood.

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

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

Questions on Food Safety Legislation

Q: What does the legislation do?

A: This legislation ^{helps ensure that} provides the FDA ^(will) with the authority to refuse imports of any food regulated by the FDA, including fruits and vegetables, from any country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required. The legislation also will permit the FDA to ~~consider halting~~ imports from countries or facilities that do not allow FDA inspections to occur in addition to other factors.

Q: How is this different from current authority?

A: This legislation increases the FDA ^{1/3} authority to refuse imports for foods from countries or facilities that do not meet U.S. food safety requirements or otherwise achieve the level of protection required. ~~do not have food safety systems that are comparable to those in this country~~. Currently, the FDA can only refuse imports after inspection or testing at the border when the FDA determines that the food appears to be unsafe or otherwise violates U.S. law. This new legislation ~~would give FDA the authority~~ to ensure that food products entering this country were grown and processed in conditions that meet U.S. food safety requirements or otherwise achieve the level of protection required. This

authority is necessary because experience has shown that inspection and testing of products at the border may not be sufficient in all cases to ensure the safety of food products. It may be necessary to identify and address the source of potential contamination to ensure that products offered for sale in the United States meet domestic food safety requirements or otherwise achieve the level of protection required. FDA currently has such authority with respect to domestic production.

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

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

a strategy

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

A: ~~No~~ *already* 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 occurs. When FDA is involved in a food safety problem that is found to originate on a farm, the agency's focus generally is on identifying the source of the problem and removing the unsafe food from commerce.

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

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

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

A: The new legislation would give the FDA the same kind of responsibility that the USDA already has for meat and poultry. The USDA system has worked well to ensure that

unsafe meat and poultry, produced in foreign facilities which do not provide the same level of protection that is required in domestic facilities, will not be imported. The FDA should be able to run a similarly effective system that ensures food safety and prevents imports from any foreign country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required.

Questions Related to Report on Guidance

Q: Why has this report been prepared?

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

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

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

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

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

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

Q: Is the development of commodity-specific guidance part of the future plans discussed in the report?

A: FDA, along with USDA, will oversee a task force to assist in developing additional guidance if sound science, risk, or experience with general guidance indicate a need. Any additional guidance will be developed through an open process involving industry, consumers, academia, states, and public health professionals, including the FDA public review and comment process.

Q: What kind of technical assistance and educational outreach is envisioned and who will provide it?

A: The plan involves a broad input from both the public and private sectors, including public health agencies, domestic and foreign industry groups, international organizations, and academia. In the U.S., the Cooperative State Research, Education, and Extension Service within the USDA has lead responsibility for developing the outreach and education strategy for domestic growers.

USDA and FDA intend to work with appropriate U.S. and foreign government public health and agriculture agencies, as well as with industry groups, to provide technical assistance needed to support application of the guidance by the produce industry overseas. The State Department will help facilitate visits to foreign countries for this purpose. We also anticipate that international organizations, such as FAO/WHO and subsidiary organizations (e.g., Pan American Health Organization), and exporter organizations will play a role in international activities.

Q: The Directive calls for "an acceleration" of food safety research. What is being "accelerated"?

A: Research is an essential element of the President's initiative. Food safety research focuses on development of rapid detection methods for pathogens and of prevention and intervention strategies that may be used to reduce the risk of microbial foodborne illness. A coordinated, interagency fresh produce research plan will be available in early 1998.

Additional Information: In September, 1997, FDA initiated an interagency meeting to review ongoing research on fresh fruits and vegetables. Since that time, several interagency meetings involving USDA, CDC, EPA, the Department of Defense, NIH, and others have been held, as well as a public meeting to discuss what research is being conducted by industry and academia and to identify research priorities. In coordinating the fresh produce research programs of all the agencies, four primary research areas have been identified. They are: improved detection methods, resistance to traditional preservation techniques, antibiotic resistance, and development of intervention strategies. Research is currently underway in all of these areas.

Research and characterization of risks is a high priority. Research on preventive technologies and intervention strategies to reduce or eliminate microbial contamination is a specific major area of focus. An interagency research plan has been developed and will be available in early 1998.

Q: 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?

A: When the President announced an initiative to ensure the safety of imported and domestic fruits and vegetables on October 2, 1997, he directed the Secretary of Health and Human Services and the Secretary of Agriculture, to work together in close cooperation with the agricultural community, 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.

Q: We expected the report at the beginning of January? Why the delay?

A: The fresh fruits and vegetables initiative is highly complex because it may not only impact the domestic industry, but also the foreign produce industry. Our main concern was that the report accurately portray the good agricultural and good manufacturing practices guidance and the planned support activities (technical assistance, education, outreach, evaluation, and research) and public participation in the process. The timing of the report in no way affects that the guidance will be available in October of this year, as the President announced.

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

Q: What is the status of Guatemalan raspberries?

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

interventions they have reportedly put in place.

03/04/98 08:45 FAX NATE ECONOMIC COUNCIL

PRESIDENT CLINTON ANNOUNCES INTRODUCTION OF SENATE FOOD SAFETY LEGISLATION AND REPORT TO ENSURE THE SAFETY OF IMPORTED AND DOMESTIC FRUITS AND VEGETABLES

March 4, 1998

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

President will call on Congress to pass the
Enhanced FDA Oversight for Imported Foods. The food safety legislation to be introduced today in the Senate will provide greater assurance that imported foods meet U.S. food safety requirements or achieve the same level of protection required for comparable domestic products. ~~The President will call on Congress to promptly enact this crucial next step in improving the safety of all the food that reaches Americans' tables.~~ The legislation also will permit the FDA to halt imports from countries or facilities that do not allow FDA inspections to occur. This legislation gives FDA authority that is comparable to USDA's existing authority to prevent the importation of unsafe meat and poultry. The President already has committed to providing approximately \$25 million in his Fiscal Year 1999 budget to enable the FDA to dramatically expand its international food inspection force. Reps. Eshoo and Pallone previously have introduced this legislation in the House of Representatives.

In order to implement this legislation
Development of Guidance on Good Agricultural and Manufacturing Practices. The President will announce the release of a report that provides a roadmap for the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in cooperation with the agricultural community, to develop guidance on good agricultural and manufacturing practices. This report outlines the progress already made -- and the measures still to be taken -- to develop guidance for the growing, processing, shipping, and marketing of fruits and vegetables by October 1998. The guidance -- the first-ever specific safety standards for fruits and vegetables -- will address potential food safety problems throughout the production and distribution system and help ensure the sanitation and safety practices of all those seeking to sell produce in the U.S. market. The report also provides both short- and long-term plans for technical assistance, education, and outreach activities to support the appropriate application of the guidance.

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to give the FDA ~~complete~~ greater ~~and~~ authority over
~~ensure the safety of~~ the imported foods.

This legislation will ~~enhance~~ ~~authorize~~ the FDA

to inspect ~~the~~ ~~imported~~ ~~and~~ ~~other~~ food products

from any
foreign country
with food safety
system and
standards that
are not equal
to the U.S.

FDA

Chicken

Issues on Antibiotic-Resistant *Campylobacter* in Poultry

- Campylobacteriosis is the most prevalent food borne diarrheal disease in the United States; most recent estimates from FoodNet indicate approximately 4 million cases of Campylobacteriosis each year. Although there are usually few deaths associated with campylobacteriosis, serious sequelae may occur, including Guillain-Barré Syndrome.
- Fluoroquinolone resistance has recently emerged in isolates of *Campylobacter jejuni* and *Campylobacter coli* from humans and poultry in the United States. This resistance is based on National Committee for Clinical Laboratory Standards (NCCLS). State health departments in Washington and Minnesota have been monitoring isolates of *Campylobacter* and have linked the appearance of the fluoroquinolone resistance in humans to the approval of a fluoroquinolone for use in poultry.
- In response to this emerging problem, FDA has initiated surveillance of antimicrobial resistance in isolates of *Campylobacter* in humans as part of the National Antimicrobial Resistance Monitoring Program administered by FDA, CDC (NCID) and USDA (ARS). The National Antimicrobial Resistance Monitoring Program is part of the National Food Safety Initiative. Surveillance of *Campylobacter* isolates from animal sources will begin in January, 1998.
- FDA and USDA officials recently participated in a World Health Organization meeting on the Medical Impact of the Use of Antimicrobial Drugs in Food Animals at which this issue of fluoroquinolone-resistant *Campylobacter* was discussed. A follow-up meeting at PAHO headquarters in Washington, D.C. has been scheduled to discuss specifically the impact of fluoroquinolone use in food animals.
- Currently, there are two fluoroquinolones approved for food animals in the U.S.: sarafloxacin and enrofloxacin, both for broilers and turkeys. FDA is reevaluating the safety of these products based on this new information of emerging fluoroquinolone resistance in poultry and humans.

Congress of the United States

Washington, DC 20515

September 24, 1997

The Honorable William Jefferson Clinton
1600 Pennsylvania Ave., N.W.
Washington, DC 20500

Dear Mr. President:

We urge you to give serious consideration to remedying the inadequate food safety provisions in the North American Free Trade Agreement (NAFTA). Because of your commitment to ensuring the safety of our nation's food supply, we expect that you will not agree to fast track authority that does not contain adequate food safety protections. Current fast track proposals do not address these concerns.

In an effort to increase trade with Mexico, NAFTA limited border inspections of food and allowed Mexican trucks to enter the U.S. with limited inspection.

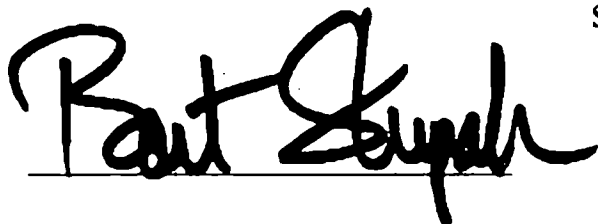
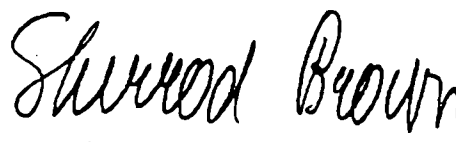
These lax inspection practices contributed to a sharp increase in food imports from Mexico: imports of Mexican fruit have increased 45%, and vegetable imports have risen 31%. More than 70% of these imports are carried into the U.S. on trucks. The General Accounting Office (GAO) recently found that 99% of Mexican trucks enter the U.S. without any inspection.

These provisions in NAFTA have resulted in imports of fruits and vegetables contaminated with diseases and unhealthy pesticides. We were alarmed earlier this year when 179 Michigan school children contracted hepatitis after eating tainted Mexican strawberries. In order to prevent similar incidents in the future, we urge you to take the following action:

- Renegotiate the provisions in NAFTA that relate to border inspections and food safety, and ensure that any fast track authority include strong food safety protections.
- Increase the funding for border inspections or, alternatively, limit the increasing rate of food imports to ensure the safety of our food supply.
- Begin an aggressive program to label all food stuffs -- including fresh and frozen fruits, vegetables and meats -- with their country of origin.

We look forward to working with you on these vital public health issues.

Sincerely,

~~no (mon)~~

Loel Blagojevich

Pat T. Munk

Blent Wexler

Paul Khayrati

John Sedacca

Maureen Dunphy

Bob W. Duggan

J. L. Finkel

Mike Dege

Brett Ascareff

Paul D. By

John D. Smith

William J. Coyne

Bob Boudin

John D. Smith

Errol Haller

Steve Nathan

Lou Evans

Guy J. Costello

Della G. Spindler

Ted Strickland

Robert L. Luce

Frank Palmer, Jr.

Eric McKinn

Betty Z. Clark

Robert H. Johnson

Cole E. Gilder

Marion Furr

George E. Brown, Jr.

Martin O. Pelt

Eliot L. Engle

H. Johnson

Marjorie Waters

Lisa V. Gutierrez

William D. Dineen

Tom Allen

William L. Watt

Jules Carson

John W. Oliver

Allen Smith

Jim McSoreen

Sonny Davis

Robert F. Kennedy

Mark Foley

John F. Trump

Henry R. Zetter

Vic Fazio

Ellen C. Johnson

Gary Miller

James L. Chester

John Longenecker

Matthew L. Martiny

Ernest Duse

Pat Lerner

Ron Kunt

James Mascan

Q. COO

Marcy Kaptur

Paul E. Brown

Law H. M. King

Bruce E. Veale

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William D. Delahert

Paul E. King

Lynn L. Lewis

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Jim Davis

John E. Lerner

Pete Starb

Dennis Kieinich

Henry A. Wexman

Sam Jeph

Jack Metcalf

Neil Abernethy

Ed Hunsley

Carolyn M. Canty

Marty Mah

Ann V. Githens

Jim Barcia

John A. Colman

Sam W. Johnson

Danny K. Davis

Tom Lantos

Ron Kind

Tom

Congress of the United States
House of Representatives
Washington, DC 20515

September 23, 1997

SEP 25 PM5:36

The Honorable Bill Clinton
The White House
Washington, D.C. 20500

Dear Mr. President:

We, the members of the Florida congressional delegation, are writing to express our problem in supporting the renewal of fast track authority.

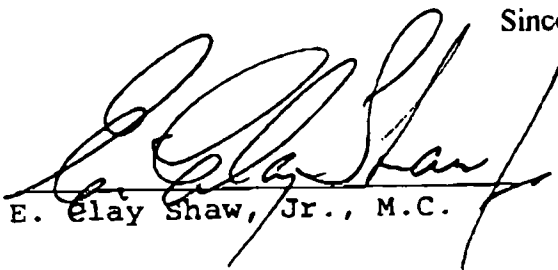
While we support free trade, we are hesitant to support fast track legislation in light of the fact that existing agreements regarding Florida fresh fruit and vegetable commodities have not been fully enforced. For example, in the recent past, tomatoes from Mexico were dumped in this country below cost in elevated surging quantities. And because current safeguards were not effective, Florida's tomato industry was severely damaged.

Furthermore, it is our understanding that not one Florida orange has been exported to Mexico since the passage of NAFTA. This situation demonstrates the inherent unfairness against Florida produce by the Mexican government.

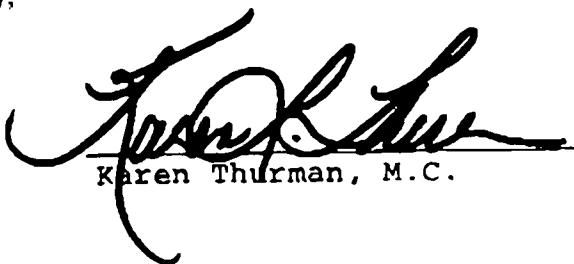
We understand that expanding free trade is crucial to continue growing America's economy. However, we are reluctant to support renewing fast track authority for agreements with other nations when promises made in the past to fairly treat Florida produce have gone largely unfulfilled. Therefore, we believe the existing foreign trade inequities concerning Florida agriculture should be addressed and resolved before fast track authority is renewed.

Thank you for your consideration of our views.

Sincerely,

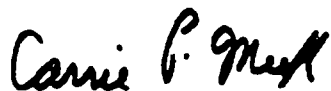


E. Clay Shaw, Jr., M.C.



Karen Thurman, M.C.

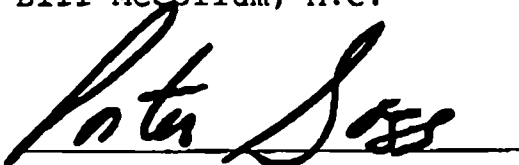
The Honorable Bill Clinton -- Page 2



Carrie Meek, M.C.



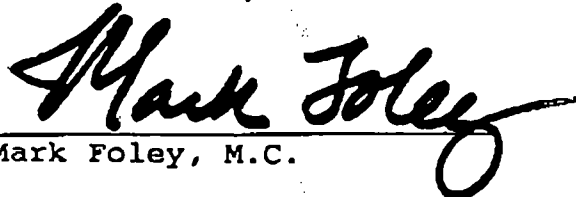
Bill McCollum, M.C.



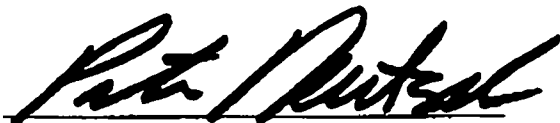
Porter Goss, M.C.



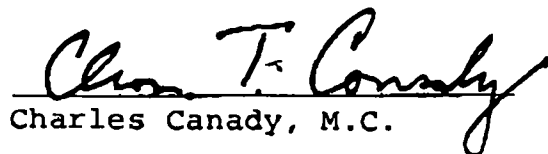
Tillie Fowler, M.C.



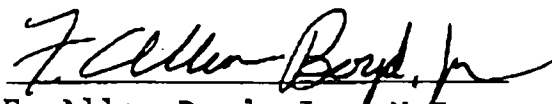
Mark Foley, M.C.



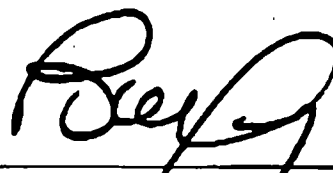
Peter Deutsch, M.C.



Charles Canady, M.C.



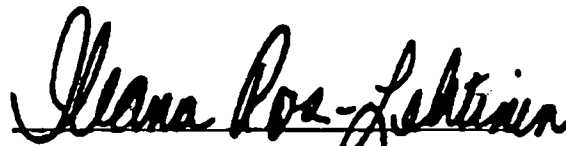
F. Allen Boyd, Jr., M.C.



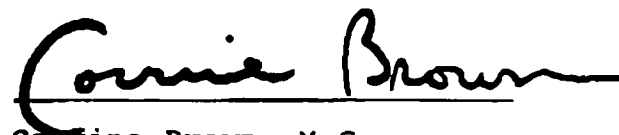
C.W. "Bill" Young, M.C.



Michael Bilirakis, M.C.



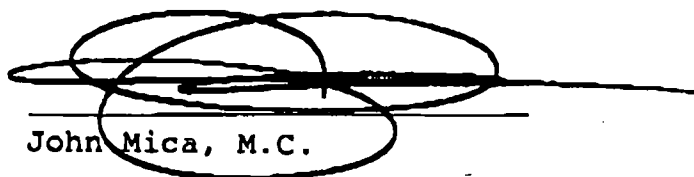
Ileana Ros-Lehtinen, M.C.



Corrine Brown, M.C.



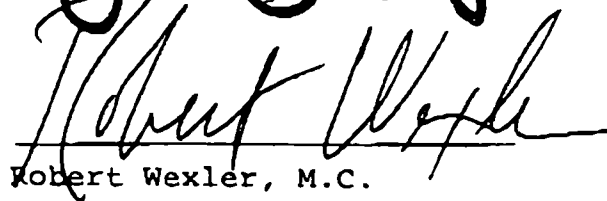
Alcee Hastings, M.C.



John Mica, M.C.



Joe Scarborough, M.C.



Robert Wexler, M.C.



David Weldon, M.C.