NLWJC - Kagan

DPC - Box 007 - Folder 017

Consumer Protection - Food Safety
Fruits & Vegetables [1]

Clinton pro-food safety - fruits + veg's

Elena FYI These are the faxed letters that were sent to the Hill on the GAO food safety report Mary

THE WHITE HOUSE

WASHINGTON

May 11, 1998

Dear Mr. Speaker:

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

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

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

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

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

Sincerely,

Bill Clinton

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

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Sincerely,

Bill

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

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Bill Clinton

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

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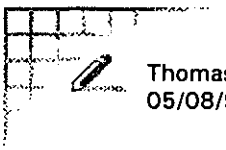
Sincerely,

Ron

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

Cons pro-food safety - fruits + vegs



Thomas L. Freedman
05/08/98 01:53:47 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Bruce N. Reed/OPD/EOP, Mary L. Smith/OPD/EOP

cc: Laura Emmett/WHO/EOP
Subject: Food Safety & GAO

FYI. Jim O'hara called to say they expect Senator Collins to release a GAO report Monday on food imports that recommends more resources and legislative authority for FDA. Those are conclusions that we can say support our position and O'hara planned to have Mike Friedman comment on it to that effect. I'll try and get some q and a together.

Tom - Ask Rahm if he wants to do a statement?

Elena

dem pro - food safety
limits + regs

11:30 a.m.
5/11/98

Statement from Dr. Michael Friedman, Lead Deputy Commissioner of the FDA, on GAO Food Safety Report

The General Accounting Office's study is a wake up call to Congress to pass legislation to help ensure the safety of imported foods. While FDA believes that imported foods are generally safe, recent outbreaks of food-borne illnesses demonstrate that imported foods can introduce new risks and the increased consumption of imported foods heightens those risks. The President has called for increased resources, better coordination, more scientific research and greater authority for the FDA.

GAO recommends legislation that gives FDA new authority that requires food-exporting countries to have in place essentially the same food safety system as the United States. The Department of Agriculture already has such legal authority over imported meats and poultry. In October 1997, President Clinton proposed legislation to give FDA similar authority and the Administration has expressed its support for the "Safety of Imported Food Act" currently langulshing in Congress.

While most of GAO's recommendations mirror solutions FDA already is implementing, the Agency rejects GAO's criticism that the agency falls to use its resources appropriately. The agency has faced a steadily rising workload with the number of food imports more than doubling in the last five years and FDA has warned that it was in danger of being overwhelmed by the volume of products reaching U.S. ports. The Agency is doing what it can with available resources and continues to recommend that additional resources are needed to ensure that the food Americans set on their table – both domestic and imported – is safe, wholesome and nutritious.

FDA Backgrounder on GAO Food Safety Report

The food supply in the United States is among the safest in the world. In recent years, however, there have been a number of serious outbreaks of food-borne illnesses, some of which have been associated with imported foods. Last year, President Clinton launched two separate food safety initiatives designed to lower the risk of food-borne disease from both domestic and imported foods. In his budget submission to Congress for FY '99, the President asked for an additional $100 million for the national food safety program, including $25 million for to enable FDA to expand its international food inspections.

Now, the General Accounting Office has released its evaluation of the safety of imported foods. In its report, "Food Safety: Federal Efforts to Ensure Safety of Imported Foods Are Inconsistent and Unreliable," GAO concludes that some of FDA's import control activities are inadequate. The agency agrees that more needs to be done to safeguard the quality of imported foods and already has undertaken many of the steps outlined in the GAO report. To make adequate progress, however, FDA will require additional legal authority and resources. The GAO itself has recommended legislation to give FDA additional authority.

The major concerns raised by GAO, and FDA's responses, include:

Equivalency Authority. GAO proposes that FDA be given authority to require that food-exporting countries have in place a food safety system that is essentially equivalent to those in the United States. GAO notes that the Department of Agriculture's Food Safety and Inspection Service (FSIS) already has that authority and blocks the importation of meat and poultry from any country whose food safety system does not measure up to the U.S. standard. Under current law, FDA cannot prevent food from being shipped to this country. The agency must attempt to identify all unsafe food at the port of entry, an extremely difficult task given the enormous volume of imports. Thus, FDA and the Administration agree with GAO that it is imperative that Congress enact legislation giving FDA authority to require that, as a condition to exporting to the United States, foreign governments adopt adequate measures in their own countries to ensure that food exported to the U.S. is safe.

Civil Money Penalties. When food importers or brokers bring in shipments, they are required to post a $1,250 bond. If the brokers do not hold the product on the docks while FDA conducts its tests, they may forfeit their bonds. GAO observed that many brokers and importers distribute their products even when ordered to wait and

simply include the bond as the cost of doing business. Once the product enters U.S. distribution, U.S. Customs Service has a difficult time getting it back. There are cases where contaminated foods have been distributed. FDA lacks the legal authority to then penalize brokers who violate the law. GAO recommends – and FDA agrees – that it should have legal authority to seek sufficiently large civil money penalties (fines) to make it too costly for brokers to flout U.S. law. Legislation will be required to give FDA this authority.

Private Laboratories. FDA automatically detains imported foods that, on the basis of prior violations, have a high probability of being contaminated. Importers have the option of hiring private laboratories to test their products and certify that they meet U.S. standards. If the lab report clears the product, it may enter distribution. FDA, however, does not control the choice of samples or laboratories, raising questions about the validity of these reports. FDA lacks the authority to restrict brokers to certain laboratories, but the agency is issuing a new guidance to the district offices, emphasizing that results must come from reliable labs and, in some cases, the results should be verified.

OASIS Computer Update. Last year, in an effort to increase efficiency, OASIS, the Operational and Administrative System for Import Support, became fully operational in every U.S. port of entry where FDA-regulated products come into the country. This computerized system electronically links all FDA inspection offices with the brokers who import foreign products. Based on the information supplied by the broker, OASIS can give automated and immediate clearance for the imports or trigger an inspection by a FDA official. GAO noted that the current computer system requires inspectors to switch between OASIS and other related data bases, such as the FDA Import Alert Retrieval System and the low acid canned food database. Because it takes time to shift from one program to another, the efficiency of the inspector is lessened. FDA has recognized the problem and is already moving to link OASIS to all of the other relevant databases.

Error Rates. FDA agrees with GAO that action should be taken against importers who continue to submit erroneous entry data to FDA. Most of the errors result from the complexity and the recent introduction of the OASIS system. FDA is auditing error-prone brokers and has begun implementing both electronic and paper copies of their import documents until they learn to use the electronic system correctly.

Work Plans. FDA agrees with GAO that the work plans developed each year for the inspectors in regional offices do not always reflect how they actually spend their time, but as with any annual plan, the

workplan sets targets and anticipates that unforseen activities or emergencies will supersede planned/routine tasks. Typically, about 80 percent of the tasks on the annual work plan are completed. FDA disagrees, however, with GAO's conclusion that the work plans have failed. Inspectors do not complete all the items on their annual list because they get reassigned as new problems and emergencies arise. It does not mean they are not working 100 percent of the time. FDA is re-evaluating how it constructs the annual work plans to avoid the appearance of inefficiency.

Overall, there is much in the GAO report with which FDA agrees. The agency shares GAO's concerns about the magnitude of the task it faces in regulating the rapidly rising volume of imported foods. FDA agrees with GAO that it needs additional legislative authority to safeguard the nation's food supply. The American public deserves – and expects – nothing less.

Cons pro - food safety - fruits + vegs

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

FEB 24 1998

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

Dear Mr. President:

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

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

Sincerely,

Donna E. Shalala
Secretary of Health and Human Services

Dan Glickman
Secretary of Agriculture

Enclosure

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

Background

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

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

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

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

This Report

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

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

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

I. Good Agricultural Practices/Good Manufacturing Practices Guidance

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

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

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

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

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

Timeline:

Short-term — October - December 1997

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

Mid-term — January - May 1998

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

Long-term — June 1998 and beyond

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

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

Timeline:

Short-term — November 1997 - June, 1998

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

Mid-term — June - August 1998

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

Long-term — September 1998 and beyond

Using available funding, implement a plan to fill gaps.

II. Technical Assistance and Education and Outreach

Technical Assistance:

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

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

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

Timeline:

Short-term — November 1997 - September 1998

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

Long-term —September 1998 and beyond

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

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

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

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

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

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

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

Timeline:

Short-term — March - May 1998

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

Mid-term — July - September 1998

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

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

Long-term — October 1998 and beyond

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

III. Focused Inspections and Verifying Application of Guidance

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

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

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

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

IV. Accelerated Food Safety Research

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

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

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

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

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

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

Timeline:

Short-term — September 1997 - March 1998

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

Long-term — April 1998 and beyond

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

V. Participants in this Initiative

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

THE WHITE HOUSE
WASHINGTON

Elena,

Here is a copy of the food safety Q&A and talking points that the agencies want to distribute on the Hill for tomorrow's Appropriations briefing.

Wendy Taylor told me that these answers are in response to specific questions from the Hill.

Tom and I have worked out with Wendy Taylor to:

1) Delete entirely question 16 on country of origin labelling;

2) and delete language in question 8 that this legislation will not increase the number of overseas inspections

Mary

Cms pro -
food safety -
fruits + vegs

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

1. What is the purpose of the legislation?

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

2. What new authority does the legislation give FDA?

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

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

3. How is this different from current authority?

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

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

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

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

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

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

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

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

The agency currently is considering different options for implementing this legislation upon enactment. The statute requires an implemention plan, which the agency would provide after public participation into the development of the plan. The general principles to be followed would logically include: a) implementation on an incremental basis; b) emphasis on working with foreign governments and producers to ensure exports of foods achieve U.S. levels of protection; and c) focus on where there will be the most benefit to American public health. The U.S. level of protection -- which is the applicable yardstick with respect to both imported and domestic food products, is reflected in the statutory standards set out in the FD&C Act, as well as any regulations promulgated under the Act.

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

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

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

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

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

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

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

No. Under current law, FDA has authority to inspect establishments where food is prepared, packed, or held, which would include places where food is grown, such as domestic farms. While such inspections are infrequent, FDA has taken action against a U.S. farmer when a violation of the FD&C Act occurs. For example, intentional use of a banned animal drug, such as DES, might result in an enforcement action. When FDA is involved in a food safety problem that is found to originate on a farm, the agency's focus generally is on identifying the source of the problem and removing the unsafe food from commerce.

10. We have heard about the development of Good Agricultural Practices (GAPs) and

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

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

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

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

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

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

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

No. The U.S. level of protection is reflected in the statutory standards set out in the FD&C Act, as well as appropriate regulations promulgated under the Act. The GAPs and GMPs may be used on a voluntary basis by foreign growers to help them reduce food safety risks. Adherencc to this guidance, however, will not be required of domestic or foreign growers.

13. Will HACCP for fresh fruits and vegetables follow?

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

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

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

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

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

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

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

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

The proposed legislation is consistent with U.S. trade rights and obligations, and thus, we believe, unlikely to result in retaliation. Furthermore, the GAPs and GMPs pose no trade barrier to exporting countries as they are non-binding guidance. The legislation merely gives FDA an additional tool to use in making the most efficient and effective use of scarce resources directed to ensure the safety of imported foods.

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

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

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

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rd:CFSAN
edited:CCopp,SLMayl,DThompson,MPlaisier
reformated:MPlaisier 2/19/98
edit:CCopp,MEck,TGardine,BHubbard/SLMayl,CFSAN 2/23/98
revised:MPlaisier 2/23/98
edit:JLevitt,JOliver,LCarson,CCopp,TGardine,SLMayl,MPlaisier 2/24/98
revised:Mplaisier 2/24/98
revised:Mplaisier 2/28/98
comments:JLevitt,JOliver,LCarson,KCarson,CCopp,TGardine,BHubbard,MPlaisier 3/1/98
revised:MPlaisier 3/1/98
conference:USTR,USDA,OMB,HHS,FDA 3/2/98
revised based on conference:MPlaisier 3/2/98
cleared:5:45 pm USTR/SDerragh;USDA/FAS/GYoung
final clearance 7:10pm:OMB/WTaylor
concur:7:50pm:USDA/MKelly

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

Why the legislation is needed:

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

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

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

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

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

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

Purpose of the legislation:

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

What the legislation does:

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

How the new system compares with the current system:

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

What the legislation does not do:

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

What the legislation will accomplish:

- Provides the authority needed to ensure that all imported food products meet the U.S.

level of protection and also is consistent with rights and obligations under international trade agreements

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

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rd:CFSAN,OLA,OP,GC 2/18/98
edit:Ccopp, Bhubbard/SLMayl, Tgardine, CFSAN 2/23/98
revised:Mplaisier 2/23/98

edit:JLevitt,JOliver,LCarson,SLMayl,TGardine,MPlaisier 2/24/98
revised:Mplaisier 2/24/98
revised:Mplaisier 2/28/98
comments:JLevitt,JOliver,LCarson,KCarson,BHubbard,CCopp,TGardine,MPlaisier 3/1/98
revised:MPlaisier 3/1/98
conference:USTR,USDA,OMB,HHS,FDA 3/2/98
revised:MPlaisier 3/2/98
cleared:5:45 pmUSTR/SDerragh;USDA/GYoung
final clearance:7:10 pmOMB/WTaylor
concur:7:50pm USDA/MKelly

Qs & As

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

1. **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. In May, 1997, as part of the President's Food Safety Initiative, the Department of Health and Human Services (DHHS), the Department of Agriculture (USDA), and the Environmental Protection Agency (EPA) sent to the President a report that identified produce as an area of concern. The Secretary of Health and Human Services, in partnership with the U.S. Department of Agriculture and the agricultural community, was directed to develop 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. This second component of the President's Directive — voluntary guidance — is an important outreach and education effort, reflecting the Administration's commitment to direct resources toward improving food safety and the availability of food safety technologies.

   The President 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.

2. **Q. When you say good agricultural practices and good manufacturing practices, are you talking about mandatory GAPs and GMPs?**

   A. No, the GAP/GMP guidance is not mandatory; it is voluntary. The backbone of the fresh produce initiative is the "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables". We are developing this science-based guidance with technical assistance from USDA, states, and input from the agricultural and produce 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.

3. **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 early October, 1998.

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

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

5. Q. **The President's directive mentioned increasing FDA's overseas inspection capabilities. Does this mean that FDA will be inspecting farms overseas? Or increasing the number of inspections of plants or other establishments?**

A. FDA plans to provide countries exporting products to the U.S. with technical assistance and expertise, based on the evaluation of in-country growing, harvesting, processing and distributing operations, to promote application of the guidance. 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.

6. Q. **The President's directive also talked about new legislation to give FDA greater authority over imported foods. If the legislation is not passed by Congress, can the activities described in the report still be carried out?**

A. The President's directive has two components. The proposed legislation to give FDA greater authority over imported foods is separate from the second component which is the GAP/GMP guidance. The purpose of the legislation is to provide for improved safety of imported foods consistent with U.S. food safety requirements. The legislation will allow FDA to use its resources more effectively.

Additional Information: The legislation is an important tool for FDA to use in ensuring the safety of products imported into the U.S. However, the guidance, technical assistance and educational outreach, and research are all fundamental building blocks for food safety systems that reduce the risk of microbial contamination of fresh fruits and vegetables. Thus, the agencies will continue to work toward finalizing the guidance and providing the domestic and foreign industry with tools to apply the guidance, whether or not the legislation is enacted.

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

A. We envision involving a broad input from both the public and private sectors, including public health agencies, domestic and foreign industry groups, international organizations, and academia. We are in the process of developing a plan to provide the type of assistance and educational programs that will most benefit the users of the guidance after it is finalized in October. 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.

8. 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.

Talking Points:
Status Report on President's Fresh Produce Initiative

Purpose of the report:

Responds to the President's October 2, 1997 directive asking for a report on progress in activities to enhance the safety of fresh fruits and vegetables

What the report covers:

The report covers descriptions of activities and timelines for the following:

- Progress made toward providing industry with good agricultural practices (GAPs) and good manufacturing practices (GMPs) for fresh fruits and vegetables.
  - FDA, working with the U.S. Department of Agriculture and the agriculture community, states, academia, consumers, and others, is developing voluntary good agricultural practices/good manufacturing practices guidance for fresh fruits and vegetables that includes ways to prevent potential contamination.
- A plan for:
  - Providing technical assistance and educational outreach to the domestic industry and foreign countries to assist in appropriate application of the guidance.
  - Improving evaluation of the safety of domestic and imported fresh produce and verification of the appropriate application of the voluntary guidance by the domestic and foreign industry.
- Description of the accelerated research associated with fresh produce.
  - FDA initiated interagency review of research on fresh produce; a public meeting was held in October, 1997, to determine what research was underway in private industry and to determine research priorities of industry, academia, and consumers.
  - An interagency, coordinated research plan has been developed and will be available in early 1998.

Who is involved in the activities described in the report:

GAP/GMP guidance: FDA, working with USDA, EPA, the Department of Labor (OSHA) the agricultural community, states, consumers, industry

Technical assistance and educational outreach:

USDA (CSREES, FAS), FDA, CDC, EPA, the U.S. State Department

Inspections and verification of application of guidance: FDA

Research: FDA, USDA agencies, CDC, EPA, CDC, National Institutes of Health, Department of Defense, Department of Energy, National Science Foundation, and others

FINAL

cms pro-food safety - fruits + veg's

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.

Enhanced FDA Oversight for Imported Foods. The President will call on Congress to pass the food safety legislation to be introduced today in the Senate to give the FDA greater authority over imported foods. This legislation will ensure that the FDA halts imports of fruits, vegetables, and other food products from any foreign country with food safety systems that do not provide the same level of protection required for U.S. products. The legislation also permits the FDA to consider refusal of inspection as a factor in halting imports from a country or facility. 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 in order to implement this legislation. 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 on how the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in cooperation with the agricultural community, will develop guidance on good agricultural and manufacturing practices. This report outlines the progress already made -- and the measures that must still be taken -- to develop guidance for the growing, processing, shipping, and marketing of fruits and vegetables by October 1998. The guidance -- the first-ever specific safety standards for fruits and vegetables -- will address potential food safety problems throughout the production and distribution system and help ensure the sanitation and safety practices of all those seeking to sell produce in the U.S. market. 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.

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.

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

*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 foodborne disease outbreaks quickly and to improve prevention systems further.

*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 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 4, 1998

Q: What did the President announce today?

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

Q: Why is your Administration proposing these actions?

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

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

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

Q: Are you saying that imported produce is unsafe?

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

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

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

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

Questions on Food Safety Legislation

Q: What does the legislation do?

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

Q: How is this different from current authority?

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

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

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

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

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

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

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

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

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

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

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

Questions Related to Report on Guidance

Q: Why has this report been prepared?

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

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

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

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

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

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

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

Q: What is the status of the Guatemalan raspberries?

A: On November 20, 1997, FDA notified the Guatemalans that fresh raspberries will not be allowed entry into the U.S. during the period of March 15 through August 15, 1998. However, if the source of *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.

Clinton pro - food safety - fruits + vegs

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 the introduction of food safety legislation in the Senate that will 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 a roadmap for the Secretary of Health and Human Services, in cooperation with the Secretary of Agriculture and the agricultural community, 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

are taking today are adding additional layers of protection. We am 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 provides the FDA 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 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.

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. 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.

Clinton pro-food safety - talking points

THE WHITE HOUSE

WASHINGTON

March 3, 1998

FOOD SAFETY EVENT

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

I. PURPOSE

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

II. BACKGROUND

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

You will be making the following announcements:

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

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

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

III. PARTICIPANTS

Briefing Participants:
The Vice President
Secretary Shalala
Secretary Glickman
Bruce Reed or Elena Kagan

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

Standing on stage, but not speaking:
Secretary Shalala
Secretary Glickman
Lead Deputy Commissioner, FDA Michael Friedman
Congresswoman Eshoo and other Members of Congress

IV. PRESS PLAN

Open Press.

V. SEQUENCE OF EVENTS

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

VI. REMARKS

Remarks Provided by Speechwriting.

Clinton pro - food safety - fruits/vegs

Total Pages: 13

LRM ID: RJP177

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

URGENT

Friday, January 2, 1998

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: Janet R. Foragren (for) Assistant Director for Legislative Reference
OMB CONTACT: Wendy A. Taylor
PHONE: (202)395-4815 FAX: (202)395-6974
SUBJECT: **HHS/USDA Report on Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables**

DEADLINE: **10 AM Thursday, January 8, 1998**

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. **Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.**

COMMENTS: HHS/USDA draft report to the President is in response to his October 2, 1997, Directive on the progress made to date on ensuring the safety of imported and domestic fruits and vegetables.

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LRM ID: RJP177 **SUBJECT:** HHS/USDA Report on Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables

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RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:
(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

TO: Wendy A. Taylor Phone: 395-4815 Fax: 395-6974
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-7316

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this response sheet

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

Background

While American consumers enjoy the safest food supply in the world, in the last several years there have been increasing incidents of foodborne illness outbreaks associated with both domestic and imported fresh fruits and vegetables. On October 2, 1997, President Clinton announced an "Initiative to Ensure the Safety of Imported and Domestic Fresh Fruits and Vegetables". The initiative specified that FDA seek legislation to extend its existing authority to provide increased coverage of imported foods, that future budget requests include activities in this initiative, and that FDA and USDA develop a series of activities focused on assisting the domestic and foreign produce industries to improve the safety of fresh fruits and vegetables.

FDA and USDA have identified the funding necessary to carry out the domestic and international activities associated with the fresh fruits and vegetables initiative. Full implementation in FY99 is contingent upon receiving adequate funds. As part of the overall food safety initiative, the agencies are making plans for the most efficient use of funds, for example, by participating in a research coordination working group organized by Dr. John Gibbons, Science Adviser to the President, under the auspices of the National Science and Technology Council.

Status of the Legislation: A bill, the Safety of Imported Food Act of 1997 (H.R. 3052), was introduced in the House of Representatives on November 13, 1997. No comparable bill has yet been introduced in the Senate. If enacted, this proposed legislation would amend the Federal Food, Drug, and Cosmetic Act to expand FDA's authority to assure the safety of imported foods by providing FDA with authorities more comparable to those of USDA.

This Report

The President directed the Secretaries of HHS and Agriculture to submit a report on progress made in development of Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs), as well as other elements of the initiative. GAPs and GMPs guidance are interrelated in that some procedures may overlap. GAPs/GMPs primarily focus on production practices including growing, harvesting, handling, and transportation. GMPs can include harvesting and transportation, but also include other practices such as processing and packaging. Because of this overlap, the terms "GAP/GMP" and "GAPs/GMPs", as appropriate, will be used throughout the document.

The United States produce industry, as well as some countries exporting fresh fruits and vegetables to the U.S., have already taken significant steps to develop and implement improved agricultural practices and guidelines. Activities in this initiative, particularly development of GAP/GMP guidance, recognize this effort and build on it.

This report discusses the progress made on development of GAPs/GMPs and plans to accomplish the other elements of the initiative. This report also describes interdependent activities that will enhance the successful adoption of GAP/GMP guidance by the industry. For example, effective adoption of GAP/GMP guidance will depend on U.S. agencies providing technical assistance to the domestic industry and to countries exporting produce to the U.S. Education and outreach efforts will be provided to both the domestic and foreign industry and all of these activities will be based on a strong, underlying, accelerated research program. The cooperative efforts described in this report represent a comprehensive approach to improving the safety of fresh fruits and vegetables. Current resources have been redirected to these efforts, however, the overall level of effort will be determined by the resources provided in the FY 99 budget and thereafter.

1. Good Agricultural Practices/Good Manufacturing Practices Guidance

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

FDA and USDA sponsored a series of public meetings from mid-November to mid-December, 1997 in which the agricultural community, the international trade community, consumers, and the scientific community participated. The purpose of these meetings was to give participants the opportunity to offer their perspective on the working draft Guide and to provide comments, technical information, and suggested modifications to the draft guidance. The National Advisory Committee on Microbiological Criteria for Foods' Fresh Produce Subcommittee (a USDA/FDA

advisory committee) was present at the first public meeting. Based on information exchanged at that first public meeting and Subcommittee members' expertise, the Subcommittee provided recommendations that were incorporated into the draft guidance document. The revised document was subsequently used as the basis of discussion at a series of meetings targeted to the agricultural community. These "grassroots" meetings were held at six regional locations around the country during December. The agencies also presented the draft guidance to representatives of embassies and individuals associated with importing produce into the U.S. at an international meeting in December.

Timeline: FDA will publish draft GAP/GMP guidance, incorporating comments and information from the public meetings, in the Federal Register by early March, 1998. A 45-day comment period will be provided for public review and further comment. A public meeting may also be held. It is anticipated that finalized GAP/GMP guidance will be available at the end of July, 1998.

Supporting Information: The draft guidance represents the best advice of FDA and USDA, builds on current industry and scientific practice, and will incorporate information provided by the agricultural community, consumers, academicians, individuals involved in international trade, states' representatives, and other interested parties. Development of the final guidance will draw on fundamental information that describes the fresh fruit and vegetable industry domestically and in countries exporting products to the U.S.

Timeline: To complement data and information being developed domestically, comparable data and country information, such as copies of food safety legislation and regulation affecting production, handling, and storage of produce for selected countries which export produce to the U.S. will be compiled by mid-July, 1998.

II. Technical Assistance and Education and Outreach

Technical Assistance: GAP/GMP guidance alone cannot be effective in improving the safety of fresh fruits and vegetables if technical resources to adopt all or even parts of the guidance do not exist. The guidance is most effective when all the essential components that apply to a particular commodity or production operation are adopted, ensuring use of practices that bolster safety at every step in the process, from in-field operations through distribution to the consumer. U.S. government agencies, FDA and USDA in particular, will work with appropriate U.S. and foreign government public health and agricultural agencies, as well as with industry groups, to provide technical assistance needed to support adoption of the GAPs/GMPs by the produce industry. Working with foreign and U.S. agencies to provide assistance is not only beneficial to the industry but also to the health of American consumers. If a foreign government is interested in learning more about the U.S. guidelines and systems for assuring the safety of domestically produced and imported fresh fruit and vegetables or when, in order to provide requested technical assistance, it

becomes necessary for FDA investigators or scientists to visit foreign operations to ascertain the source of problems that may pose a safety hazard in produce exported to the U.S , USDA and the State Department overseas personnel will collaborate as necessary to facilitate these visits.

USDA and FDA plan to work with a broad spectrum of representatives from the public and private sector in foreign countries and in the U.S. to promote adoption of GAPs/GMPs and improve production and processing practices. These include officials from the health and agriculture agencies in foreign countries, the Food and Agriculture Organization, the World Health Organization, and subsidiary organizations (e.g., Pan American Health Organization), as well as exporter associations. In the U.S., the agencies will work with appropriate land grant colleges and universities, state agencies, and industry associations. In working with domestic and foreign groups, it is critical that in addition to technical assistance, we provide clear guidance on the legal requirements for offering fresh food for sale in the U.S. With this understanding, the foreign and domestic government, industry, and academic groups can guide producers' decisions about what, if any, modifications of current practices are appropriate for industry to satisfy U.S. legal standards. As part of this effort, USDA and FDA will share new technologies as they are developed to enhance the safety of fresh fruits and vegetables, such as improved manure treatment methods, more sensitive analytical methods, and post-harvest treatments to reduce levels of or eliminate pathogens on produce.

Timeline: During FY'98 the groundwork is being laid for providing technical assistance, pending finalization of the GAP/GMP guidance.

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

CSREES, through its partnership with State Cooperative Extension Services in the United States, will provide leadership for the Directive's producer outreach and educational strategy. USDA and FDA will plan a national food safety scientific and education conference for early 1998 to share current scientific and educational information on fruits and vegetables, to apprise scientific experts and extension professionals with the voluntary general guidance document, and to discuss methods. States may want to consider incorporation of the President's directive into ongoing State extension programs. State and local extension agents can play a vital role in the successful adoption of the guidance, since they are knowledgeable about on-farm production practices and can provide expert advice on how producers can incorporate interventions recommended in the guidance to reduce the risk of microbial contamination at the farm level.

CSREES will also disseminate the guidance and incorporate it into ongoing federal food safety extension programs.

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

We anticipate that education and outreach activities will reach beyond the immediate needs of the produce industry to ancillary industries, such as wholesale and retail, and to the consumer. Expanded education efforts will be directed to increasing awareness of public health concerns about fresh fruits and vegetables, as well as about use of safe practices for handling and storing fresh produce.

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

In the international arena, FAS will be instrumental in facilitating the development of education and training programs, either through their staff or the State Department. The FAS' International Cooperation and Development group can facilitate development of cooperative training programs on the GAP/GMP guidance, in collaboration with other agencies capable of providing funding for these activities. FAS will also explore mechanisms to obtain the resources and expertise from other international organizations, such as the FAO and the Inter-American Institute for Cooperation of Agriculture, in order to facilitate discussions on produce safety issues. FDA and USDA will evaluate the scope of GAP/GMP education programs and materials needed to educate foreign governments and organizations.

Timeline: Preliminary steps have been taken to determine mechanisms for providing information and assistance to the domestic industry in adopting GAP/GMP guidance. Likewise, preliminary steps will be taken to develop a program targeted to foreign producers.

III. Specific Guidance

The general GAP/GMP guidance is a requisite to ensure the safety of all produce. This general guidance is essential as a foundation for a host of more specific guidance for various commodities, hazards and pathways of contamination, or pathogens. As we consider the broad spectrum of a food safety system, general guidance is usually the first consideration. However, specific GAPs/GMPs are very appropriate and often essential for those foods or systems where individual HACCP programs are not warranted. Specific guidance for individual commodities can provide tailored guidance for reducing the potential for microbial contamination, e.g., the minimum time between manure application and produce harvest, appropriate manure treatment technologies to eliminate or significantly reduce levels of pathogens in manures, the best type of irrigation system to use, specific harvesting practices (e.g., picking berries or melons), or recommendations for transporting specific commodities. Likewise, specific guidance can be designed for minimizing microbial contamination through particular pathways, such as control of water quality, worker sanitation and health, field and facility sanitation, and transportation and handling of produce. Some pathogens may be appropriate subjects for specific guidance that would apply to all foods in which the risk of contamination with that pathogen exists.

Supporting Information: Domestic commodity data provided by USDA includes specific commodities produced, the form (whole or processed) and the quantities produced. FAS has available, as part of its ongoing trade reporting system, data on fruits and vegetables imported into the U.S. and some commodity specific reports for selected countries. Information about the current agricultural practices, about currently used handling and transportation practices, processing and packaging techniques, and about products associated with foodborne illness outbreaks will also be used. Both USDA and FDA have some data on current agricultural and manufacturing practices which they will provide. Country information (such as copies of food safety legislation and regulation affecting production, handling, and storage of produce) useful in identifying current production and processing practices in foreign countries will be provided by FAS. This information will be used to direct and support decisions to develop more specific guidance documents, as appropriate.

Selection of commodities, or hazards, or pathways of contamination, or pathogens: Options are being explored for the most efficient way to provide the industry with guidance that is effective and that yields the most benefit from the resources expended. Among the options under consideration are:

- Industry organizations could voluntarily work with FDA and USDA to develop specific guidance for commodities produced by their members.

- The subject of specific guidance for a commodity, or hazard, or pathway of contamination, or pathogen could be determined through a public process. FDA could publish a notice in the Federal Register announcing our intention to develop more specific guidance and proposed criteria to be used in the selection. This notice could ask for information to guide the selection of subjects.

- The competitive grant mechanism available through CSREES could be used to fund development of commodity-specific GAPs/GMPs by academic institutions in different regions of the country.

- Other approaches that could provide targeted guidance to the produce industry in a timely manner, including a combination of the options listed here, a combination of these options with other options.

- A decision not to develop any type of specific guidance.

Whichever options are chosen, some basic factors will be considered in selecting the subject of the guidance. These include the potential hazards associated with the commodity and whether or not microbe-specific methods (e.g., identification, detection, enumeration, and/or sampling technique) exist to ensure an appropriate level of public health protection. The potential public health impact of the commodity, based on the volume of the commodity produced and the primary consumer group (e.g., young children, the elderly, the population in general), are other factors that will be considered. A careful analysis will be conducted in selecting the subject of specific guidance (i.e., a commodity, or hazard, or pathway of contamination, or pathogen). This analysis will consider the value of any public health improvements that may result from specific guidance. It will also consider the total cost to society of foodborne illnesses (e.g., medical costs and productivity losses) associated with the subject, and the costs to the industry or consumers of implementing specific guidance that will reduce human health risks. On the basis of this information, a cost/benefit ratio can be estimated to assist in determining future actions. Another approach is to use epidemiological data, specifically data about the severity of illnesses, the potential magnitude of an outbreak of foodborne illness, and the frequency of occurrence of outbreaks. A combination of these two approaches may be most useful.

In any event, a FDA/USDA committee will oversee and direct development of the specific guidance documents which will undergo scrutiny in the FDA public review process. This process entails publication of the draft documents in the Federal Register, receipt and evaluation of comments, revision of the documents incorporating information from the comments, and publication as a final guidance document.

Timeline: It is anticipated that proposed specific guidance will be available to the produce industry during 1998. If the CSREES grant process is used for development of the specific guidance documents, it is anticipated that the grant process will begin in May, 1998 and conclude with grant awards in October, 1998. Draft documents will be developed during 1999 and will undergo the FDA public review process beginning in 2000.

IV. Focused Inspections and Monitoring Adoption Of GAP/GMP Guidance

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

FDA will continue its fresh fruit and vegetable inspection and testing program at current levels for domestic and imported produce. Additional resources will be focused particularly on sampling products from areas, in the U.S. and abroad, where there is evidence that a potential hazard exists and GAP/GMP guidance has not been adopted.

Monitoring: Monitoring and evaluating the effectiveness of GAP/GMP guidance and/or specific guidance will provide assurances to consumers, producers, and processors that following the guidance will result in reducing risks. The USDA and FDA will use survey techniques to determine the effectiveness of the GAP/GMP program and the extent of adoption of the guidance by both the domestic and foreign industry. The first survey will be conducted to determine current practices, specifically those practices that have the most impact on public health and those that are covered in the general GAP/GMP guidance. This baseline information will be augmented with information from other sources, such as foreign governments and state agencies, on current practices. A second, more thorough, survey on practices will be conducted at a later date. This information — from the surveys and other sources — will be used to monitor adoption of the GAP/GMP guidance and to make necessary adjustments in the GAP/GMP program, including the guidance.

Timeline: FDA's inspection and sample collection and analysis activities are ongoing. Increased inspection and testing efforts are budget dependent and would be desirable to help monitor the effectiveness of general and specific GAP/GMP guidance. The monitoring activity may begin in FY98.

V. Accelerated Food Safety Research

Successful implementation of this initiative relies heavily on adequate scientific research targeted to assessment of risk to public health posed by microbial contamination. The overall research goal identified in this initiative is development of intervention and prevention strategies to reduce the incidence of foodborne illness. Research will also support development of improved detection methods useful in a variety of environments. These methods will be used to conduct long-term surveillance and monitoring of both domestic and imported produce, to support development of control and prevention strategies that augment use of GAP/GMP, and to develop guidance that accommodates specific needs imposed by environmental factors (e.g., water quality, manure management including development of appropriate manure treatment technologies to eliminate or significantly reduce pathogens in manure, worker hygiene).

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

FDA and USDA are individually and collectively reviewing their respective FY98 research projects related to fresh fruits and vegetables to identify specific research that can be accelerated. USDA and FDA have held research planning meetings with other agencies conducting food safety related research, including the EPA, DoD, the Department of Energy, the National Science Foundation, and NIH. In addition, the agencies have met with industry and consumer representatives to determine what food safety research is currently ongoing or in the developmental stages outside the government and to identify research needs from this outside perspective.

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

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

Timeline: The process of reviewing research related to safety of fresh fruits and vegetables was initiated in September, 1997. A research plan will be available in early 1998 that will identify fresh fruit and vegetable-related research.

VI. Participants in this Initiative

The following agencies are contributing to this initiative: the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS); the Agricultural Marketing Service (AMS), the Agricultural Research Service (ARS), the Animal and Plant Health Inspection Service (APHIS), the Cooperative State Research, Education, and Extension Service (CSREES), the Economic Research Service (ERS), the Foreign Agricultural Service (FAS), the Food Safety and Inspection Service (FSIS), the National Agricultural Statistics Service (NASS), the Natural Resources Conservation Service (NRCS), and the Office of Risk Assessment and Cost Benefit Analysis (ORACBA) in the U.S. Department of Agriculture (USDA); the Environmental Protection Agency (EPA); the Department of Labor's (DoL) Occupational Safety and Health Administration (OSHA); and the Department of Defense's U.S. Army-Natick Research Development and Engineering Center are also working on segments of the initiative.

— Cons pro - food safety —
Fruits + vegs

EK -
Here's the back & forth between EB & USDA on labeling.
Tom

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

OCT 23 1997

MEMORANDUM TO THE CHIEF OF STAFF

FROM: SECRETARY DAN GLICKMAN Dan Glickman

Subject: Country of Origin Labeling

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

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

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

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

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

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

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

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

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

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

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

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

BOB GRAHAM
FLORIDA

COMMITTEES:
FINANCE
ENVIRONMENT AND PUBLIC WORKS
VETERANS AFFAIRS
SELECT COMMITTEE ON INTELLIGENCE
ENERGY AND NATURAL RESOURCES

United States Senate

WASHINGTON, DC 20510-0903

October 23, 1997

Mr. Erskine Bowles
Chief of Staff
Executive Office of the President
White House
Washington, D.C. 20500

Dear Erskine:

I am pleased that President Clinton has recently elevated the food safety issue to the national agenda. This is a welcomed development.

I am writing to bring to your attention legislation Senator Craig and I have introduced which goes hand-in-hand with the Administration's overall goal of increasing the safety of food Americans purchase. Our bill, S. 1042, would require agricultural commodities imported into the United States to be labeled as to country of origin at the time of sale to the final consumer.

Giving American consumers the ability to make informed, educated decisions on the food they serve their families is a simple first step in assuring food safety. To illustrate, last year when the Centers for Disease Control (CDC) announced that Americans should avoid raspberries from Guatemala, there was no way for the residents of 49 states to comply with the CDC's directive.

Fortunately, the residents of Florida have had the ability to make informed decisions relative to the produce they buy since 1979. The Florida Statute is a simple, straight-forward model for what S. 1042 would provide all Americans no matter where they live.

I urge you to include our country of origin labeling bill in the food safety initiative the Administration is assembling. Should you or your staff have any questions or need more information please do not hesitate to contact me or Tom Greene or my staff at 224-0734.

Thank you in advance for your consideration of this important consumer information, food safety issue.

With warm regards,

Sincerely,

United States Senator

BG/tag
Enclosure

II

105TH CONGRESS
1ST SESSION

S. 1042

To require country of origin labeling of perishable agricultural commodities imported into the United States and to establish penalties for violations of the labeling requirements.

IN THE SENATE OF THE UNITED STATES

JULY 21, 1997

Mr. CRAIG (for himself, Mr. GRAHAM, and Mr. JOHNSON) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

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A BILL

To require country of origin labeling of perishable agricultural commodities imported into the United States and to establish penalties for violations of the labeling requirements.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the "Imported Produce Labeling Act of 1997".

SEC. 2. INDICATION OF COUNTRY OF ORIGIN OF IMPORTED PERISHABLE AGRICULTURAL COMMODITIES.

(a) DEFINITIONS.—For purposes of this section, the terms "perishable agricultural commodity" and "retailer" have the meanings given the terms in section 1(b) of the Perishable Agricultural Commodities Act, 1930 (7 U.S.C. 499a(b)).

(b) NOTICE OF COUNTRY OF ORIGIN REQUIRED.—A retailer of a perishable agricultural commodity imported into the United States shall inform consumers, at the final point of sale of the perishable agricultural commodity to consumers, of the country of origin of the perishable agricultural commodity.

(c) METHOD OF NOTIFICATION.—

(1) IN GENERAL.—The information required by subsection (b) may be provided to consumers by means of a label, stamp, mark, placard, or other clear and visible sign on the imported perishable agricultural commodity or on the package, display, holding unit, or bin containing the commodity at the final point of sale to consumers.

(2) LABELED COMMODITIES.—If the imported perishable agricultural commodity is already individually labeled regarding country of origin by the packer, importer, or another person, the retailer

shall not be required to provide any additional information to comply with this section.

(d) VIOLATIONS.—If a retailer fails to indicate the country of origin of an imported perishable agricultural commodity as required by subsection (b), the Secretary of Agriculture may impose a monetary penalty on the retailer in an amount not to exceed—

(1) $1,000 for the first day on which the violation occurs; and

(2) $250 for each day on which the same violation continues.

(e) DEPOSIT OF FUNDS.—Amounts collected under subsection (d) shall be deposited in the Treasury of the United States as miscellaneous receipts.

(f) APPLICATION OF SECTION.—This section shall apply with respect to a perishable agricultural commodity imported into the United States after the end of the 6-month period beginning on the date of the enactment of this section.

○

SUPPORTER OF S. 1042: THE IMPORTED PRODUCE LABELING ACT

American Agriculture Movement of Arkansas

American Agriculture Movement/ American Corn Growers Association Of Illinois

American Farm Bureau Federation

American Corn Growers Association

California Agricultural Commissioners & Sealers Association

California Citrus Mutual

California Farm Bureau

California Women in Agriculture

Coalition of Labor, Agriculture and Business

Dade County Farm Bureau

Desert Grape Growers Association

Florida Citrus Mutual

Florida Farmers & Suppliers Coalition

Florida Fruit & Vegetable Association

Florida Tomato Exchange

Georgia Fruit & Vegetable Growers Association

George Peanut Producers Association

Grower-Shipper Vegetable Association

Grown in the U. S. A.

Indian River Citrus League

International Brotherhood of Teamsters

Made in the U. S. A. Foundation

Michigan Asparagus Advisory Committee

National Association of Farmer Committeemen

National Farmers Organization, Iowa

National Farmers Union

National Peach Council

National Onion Association

National Watermelon Council

Riverside County Farm Bureau

South Carolina Tomato Association

Texas Corn Growers Association

U. S. Business & Industrial Council

Western Growers Association

Cons pro-food safety - fruits + vegs

Mary L. Smith
12/19/97 04:43:48 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Thomas L. Freedman/OPD/EOP

cc: Laura Emmett/WHO/EOP
Subject: Food Safety Ninety-Day Report

The report on the good manufacturing practices and good agricultural practices is due January 2. Wendy Taylor from OMB called and said that they would like an extension of a week in order to properly analyze it. They have some concerns and since many people will be out of the office for the holidays, they would like a little extra time. I think it would be fine, what do you think? Mary

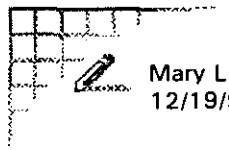
Tom/Mary—

This is fine. Do we have a draft? know what it's going to say? Is there anything to announce publicly here?

Elena

Box 7 Folder 17 DPC

Cmts pro-food safety - fruits + vegs



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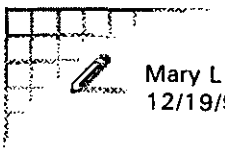
This is fine. Do we have a draft? know what it's going to say? Is there anything to announce publicly here?

Elena

Box 7 Folder 17 DPC

Cons pro-food safety - fruits + vegs



Mary L. Smith
12/19/97 04:43:48 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Thomas L. Freedman/OPD/EOP

cc: Laura Emmett/WHO/EOP
Subject: Food Safety Ninety-Day Report

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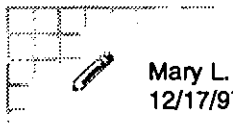
Cms pro - food safety - fruits + vegs



Mary L. Smith
12/17/97 03:06:24 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Thomas L. Freedman/OPD/EOP

cc: Laura Emmett/WHO/EOP
Subject: Principals' Meeting on Food Safety at USDA

I attended the principals' meeting on Food Safety at USDA today. There were three basic topics: (1) reports from public meetings; (2) timing of the report to the President; and (3) meeting on the Hill scheduled for Monday.

1. **Reports from public meetings.** The comments in the 6 public meetings with the growers and the state health departments were pretty favorable. In fact, it was emphasized that not one of the growers was opposed to the development of the gudiance in general. The comments were just that the timing seemed like it was happening very quickly; that the growers hoped that they could actively participate and that it would be a bottom-up process rather than a top-down process; and that, to the extent that we develop product-specific guidance, that they want to contribute to this process. It seems that the concern regarding the product-specific guidance is addressed adequately, at this initial stage in the process, in the draft report.

On the international front, there was a public meeting in Washington that staff of many of the embassies attended. The international community seems fine with it as well, but, again, they would like to participate and would like to conduct more research.

One other item that growers asked about was the President's position on country of origin labeling.

2. **Report to the President.** The report on the progress of the development of the Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) is due to the President on January 2, 1997. I am sending you an outline of the report as well as a draft to the report. It looks like HHS, FDA, and USDA are on track to get this to the White House by January 2, 1997. However, there were some rumblings that because of holidays, etc., they might not be able to send over the final draft until January 3 or 4. I emphasized that they should keep on track for the January 2, and that is the plan now. The timing could be emphasized again in the Food Safety meeting you have scheduled for tomorrow at 5 p.m.

3. **Hill Briefing.** Some Senate staff want a briefing on the entire food safety initiative, including the legislation and the guidance. This meeting is scheduled for Monday, December 22 at 1 p.m. HHS, USDA, and FDA are sending people to the meeting.

Thanks, Mary,

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

I. Introduction

II. Good Agricultural Practices Guidance

A. Status

1. Preparation of draft guidance: "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables"

2. Public meeting, National Advisory Committee on Microbiological Criteria for Foods meeting, grassroots meetings, international meeting

Timeline: FDA will publish draft GAP guidance, incorporating comments and information from the public meetings, in the Federal Register at the end of February or in early March, 1998. A 45-day comment period will be provided for public review and further comment. A public meeting may also be held. It is anticipated that finalized GAP guidance will be available at the end of July, 1998.

B. Supporting information

1. Data/ information describing fresh fruit and vegetable industry domestically an in countries importing into U.S.

Timeline: Data and information covering up to 40 country/commodity combinations will be compiled by mid-July, 1998. These data will provide a profile of each country's current growing, harvesting, handling, and transportation practices for the variety of products offered for import into the U.S.

III. Technical Assistance and Education and Outreach

A. Technical Assistance to support adoption of GAPs/GMPs - application

1. FDA and USDA work with appropriate government public health and agricultural agencies; WHO, FAO, and subsidiaries; and industry and exporter groups abroad and in the U.S.; landgrant colleges and universities.

Timeline: During FY'98 the groundwork is being laid for providing technical assistance, pending finalization of the GAP guidance. FY99 funding will determine the extent of the program.

B. Education for industry, consumers - understanding principles

1. Domestic

a. Producers and processors

b. CSREES will be the primary domestic source of GAP/GMP outreach and educational activities for producers.

National food safety scientific and education conference for early 1998 to provide colleges and universities background on GAP guidance for incorporation into their academic programs.

c. Expanded education efforts to ancillary industries, such as wholesale and retail, to the consumer - budget dependent

d. Other agencies and industry to provide education and outreach

2. Multi-lingual materials for domestic and foreign use

FDA and USDA will work with industry and foreign governments to provide translations - budget dependent

3. International:

a. FAS will be instrumental in facilitating the development of education and training programs, either through their staff or the State Department.

Timeline: Preliminary steps have been taken to determine mechanisms for providing information and assistance to the domestic industry in adopting GAP guidance. Likewise, preliminary steps will be taken, as funding permits, to develop a program targeted to foreign growers.

IV. Good Agricultural and Good Manufacturing Practices Guidance for Specific Commodities

A. Purpose: Augment general guidance with guidance tailored to unique aspects of a commodity to reduce the potential for microbial contamination

B. Supporting Information

C. Selection of Commodities

1. Options are being explored

a. Industry organizations will voluntarily work with FDA and USDA to develop specific GAPs/GMPs as guidance for commodities produced by their members.

b. Use public process. FDA will publish a notice in the Federal Register announcing our intention to develop guidance for specific commodities and the criteria to be used in the selection. This notice will ask for information to guide the selection of commodities.

c. CSREES competitive grant mechanism to fund development of commodity-specific GAPs/GMPs by academic institutions in different regions of the country.

d. Other approaches

D. Factors to consider in selecting commodities:

1. Health-related factors and availability of methods to ensure an appropriate level of public health protection.

E. Process

1. FDA/USDA committee will oversee and direct development of the guidance documents

2. Documents undergo public review process

Timeline: It is anticipated that development of the specific guidance by the agencies will be available to the produce industry during 1998. If the CSREES grant process is used for development of the specific guidance documents, it is anticipated that the grant process will begin in May, 1998 and conclude with grant awards in October, 1998. Draft documents will be developed during 1999 and will undergo the FDA public review process beginning in 2000.

V. Focused inspections of production and processing operations and testing on areas of highest risk and monitoring adoption of GAP/GMP guidance.

A. Inspection and Testing

FDA will continue its fresh fruit and vegetable inspection and testing program at current levels for domestic and imported produce.

B. Monitoring

1. Initial and follow-up survey to determine effectiveness and extent of adoption of guidance - USDA and FDA - budget dependent

Timeline: FDA's inspection and sample collection and analysis activities are ongoing. Increased inspection and testing efforts are budget dependent. The monitoring activity may begin in FY98, dependent on funds available.

VI. Accelerated food safety research.

A. FDA and USDA reviewing current research to identify projects for fast-track

Interagency meetings and meetings with industry and consumer representatives

b. Coordinated research plan being developed

1. Scheduled to be available in early 1998

2. Focus: Research on preventive technologies and to develop intervention strategies

Timeline: The process of reviewing research related to safety of fresh fruits and vegetables was initiated in September, 1997. A research plan will be available in early 1998 that will identify fresh fruit and vegetable-related research .

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

Introduction

While American consumers enjoy the safest food supply in the world, in the last several years there have been increasing incidences of foodborne illness outbreaks associated with fresh fruits and vegetables from both domestic and imported sources. On October 2, 1997, President Clinton announced an "Initiative to Ensure the Safety of Imported and Domestic Fresh Fruits and Vegetables". The initiative specified that FDA seek legislation to increase its authority over imported foods, that budget requests include activities in this initiative, and that FDA and USDA develop a series of activities focused on assisting the domestic and foreign produce industries to improve the safety of fresh fruits and vegetables.

The United States (U.S.) produce industry, as well as some countries importing fresh fruits and vegetables into the U.S., have already taken significant steps to develop and implement improved agricultural practices and guidelines. Activities in this initiative, particularly development of good agricultural practices and good manufacturing practices guidance, recognize this effort and build on it.

A bill, the Safety of Imported Food Act of 1997 (H.R. 3052), was introduced in the House of Representatives on November 13, 1997. No comparable bill has been introduced in the Senate. If passed by Congress, this proposed legislation will amend section 402 (adulterated food) of the Food, Drug, and Cosmetic Act to expand FDA's authority to assure the safety of imported foods. This will provide FDA with authorities more comparable to those of USDA over imported foods. FDA's and USDA's budget requests for FY99 includes funding for activities associated with the fresh fruits and vegetables initiative. The budget requests have been submitted to the Office of Management and Budget. As part of the overall food safety initiative, the agencies are making plans for the most efficient use of funds, for example, by participating in a research coordination working group organized by Dr. John Gibbons, Science Adviser to the President, under the auspices of the National Science and Technology Council.

The President directed the Secretaries of HHS and Agriculture to submit a report on progress made in development of Good Agricultural (GAPs) and Good Manufacturing Practices (GMPs) and other elements of the initiative. GAPs and GMPs guidance are interrelated in that some procedures may overlap. GAPs primarily focus on production practices and include growing, harvesting, handling, and transportation. GMPs can include harvesting and transportation, but also include other practices such as processing and packaging.

This report discusses the progress made on development of GAPs/GMPs and plans to accomplish the other elements of the initiative. This report also describes interdependent activities that will

enhance the successful adoption of GAP/GMP guidance by the industry. As an example, effective adoption of GAP/GMP guidance will depend on U.S. agencies providing technical assistance to the domestic industry and to countries importing produce. Education and outreach efforts will be provided to both the domestic and foreign industry and all of these activities will be based on a strong, underlying, accelerated research program.

Agencies contributing to this initiative are: the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS). U.S. Department of Agriculture (USDA) agencies include: the Agricultural Marketing Service (AMS), the Agricultural Research Service (ARS), the Animal and Plant Health Inspection Service (APHIS), the Cooperative State Research, Education, and Extension Service (CSREES), the Economic Research Service (ERS), the Foreign Agricultural Service (FAS), the Food Safety and Inspection Service (FSIS), the National Agricultural Statistics Service (NASS), the Natural Resources Conservation Service (NRCS), and the Office of Risk Assessment and Cost Benefit Analysis (ORACBA). The Environmental Protection Agency (EPA) and the Department of Labor's (DoL) Occupational Safety and Health Agency (OSHA), and the Department of Defense's Natick Labs (get full name) are also working on segments of the initiative.

I. Good Agricultural Practices Guidance

Status: FDA, working with USDA, is in the process of preparing a general Good Agricultural Practices (GAP) guidance document to be published as a proposal. This "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables" describes good agricultural practices that farmers and producers may use for water quality, manure management, sanitation (both field and facility sanitation, as well as worker hygiene), and transportation and handling. The guide also describes use of producer identification and information on the flow of the product through distribution channels. This information facilitates source identification, should a commodity be associated with a foodborne illness outbreak. This guidance can be used by both domestic and foreign fresh fruit and vegetable producers to help ensure the safety of their produce. The GAP guidance will be consistent with World Trade Organization guidelines and will not impose undue restrictions or barriers on either domestic or foreign producers.

A series of public meetings were held from mid-November to mid-December, 1997 in which the agricultural community, the international trade community, consumer, and the scientific community participated. The purpose of these meetings was to give these parties the opportunity to offer their perspective on the working draft Guide and to provide pertinent information, comments, technical information, and suggested modifications of the draft guidance. The first public meeting was held with the National Advisory Committee on Microbiological Criteria for Foods' Fresh Produce Subcommittee (an USDA/FDA advisory committee) in attendance. The

Subcommittee provided recommendations that were incorporated into the working draft guidance document used as the basis of discussion at a series of meetings targeted to the agricultural community. Six "grassroots" meetings were held around the country in December. The agencies also presented the proposed guidance to representatives of embassies and individuals associated with importing produce into the U.S. at an international meeting.

Agencies Responsible: Lead: FDA
Support: USDA (CSREES, AMS, ARS, FSIS, ERS, NASS, FAS), EPA, DoL (OSHA), CDC

Timeline: FDA will publish draft GAP guidance, incorporating comments and information from the public meetings, in the Federal Register at the end of February or in early March, 1998. A 45-day comment period will be provided for public review and further comment. A public meeting may also be held. It is anticipated that finalized GAP guidance will be available at the end of July, 1998.

Supporting Information: The draft guidance represents the best advice of FDA and USDA which builds on current industry and scientific practice and will incorporate information provided by the agricultural community, consumers, academicians, individuals involved in international trade, states, and other interested parties. Development of the final guidance will draw on fundamental information that describes the fresh fruit and vegetable industry domestically and in countries importing products into the U.S.

Agencies Responsible: Lead: USDA (ERS, NASS, FAS) and FDA
Support: USDA (CSREES, AMS),

Timeline: Data and information covering 40 country/commodity combinations will be compiled by mid-July, 1998. These data will provide a profile of each country's current growing, harvesting, handling, and transportation practices for the variety of products offered for import into the U.S.

II. Technical Assistance and Education and Outreach

Technical Assistance: GAP/GMP guidance, alone, cannot be effective in improving the safety of fresh fruits and vegetables if a lack of technical resources to adopt all or even parts of the guidance exists. The guidance is most effective when all the essential components of the guidance that apply to a particular commodity or production operation are adopted, ensuring use of practices that bolster safety at every step in the process from in-field operations to distribution to the consumer. U.S. government agencies, FDA and USDA in particular, will work with the appropriate public health and agricultural government agencies abroad and in the U.S. to provide technical assistance needed to support adoption of the GAPs/GMPs by the produce industry.

Working with foreign and U.S. agencies to provide assistance is not only beneficial to the industry, but to the health of American consumers. Successful adoption of GAP guidance by the industry will greatly enhance the safety of fresh fruits and vegetables. When it becomes necessary for FDA investigators or scientists to visit foreign operations to ascertain the source of problems that may pose a safety hazard in produce imported into the U.S., FAS and State Department officials will facilitate these visits. (The FY99 budget request includes funding for additional resources to carry this program out.)

USDA and FDA will work with a broad spectrum of representatives from the public and private sector in foreign countries and in the U.S.. These include officials from the health and agriculture agencies in foreign countries, the World Health Organization and the Food and Agriculture Organization and subsidiary organizations (e.g., PAHO), as well as exporter associations. In the U.S., the agencies will work with appropriate landgrant colleges and universities, state agencies, and industry associations. In working with these groups, it is critical that we not only provide technical assistance but that they have a clear understanding of the requirements for importing foods into the U.S. and meeting U.S. legal requirements. Equally important, is an appreciation for the U.S. consumers' perception of food safety. With this understanding, these groups can guide industry's determination of what, if any, modifications of current practices are needed for industry to satisfy U.S. legal and consumer expectations. FDA and USDA will provide technical advice and assistance to the domestic industry and to governments of countries importing products into the U.S. to aid in the adoption of GAPs/GMPs, as well as to improve production and processing practices in any other way. As part of this effort, USDA and FDA will share new technologies as they are developed to enhance the safety of fresh fruits and vegetables, such as improved manure treatment methods, more sensitive analytical methods, post-harvest treatments to reduce or eliminate pathogen levels on produce.

Agencies Responsible: Lead: FDA and USDA (FAS, FSIS, APHIS)

Timetable: During FY'98 the groundwork is being laid for providing technical assistance, pending finalization of the GAP guidance. FY99 funding will determine the extent of the program.

Education: Education and outreach programs are essential to successful adoption of GAP/GMP guidance by the domestic and international fresh fruit and vegetable industry. These programs are pivotal to the industry understanding the essential principles of GAP/GMP guidance, as well as the scientific and practical reasons for adoption of the guidance as everyday production and processing practice. Others in the distribution chain from the fruit and vegetable producers to the final user - the consumer - must be reached in these programs in order to assure that the care taken to prevent microbial contamination in growing, harvesting, processing, and transporting is not thwarted by mishandling later. (The extent of efforts in this area will be

contingent on additional funding in the FY99 budget.)

CSREES, through its existing network of agricultural extension service agents located in the U.S. farming community, will be the primary domestic source of GAP/GMP outreach and educational activities for producers. USDA and FDA will plan a national food safety scientific and education conference for early 1998 to provide colleges and universities background on GAP guidance for incorporation into their academic programs. The Extension agents play a vital role in the successful adoption of GAPs because they are knowledgeable about on-farm assessments and can provide advice to individual farmers on potential problem areas in their operations and how to improve practices. CSREES will disseminate the GAP guidance and incorporate it into the ongoing programs for domestic fruit and vegetable growers. Where necessary and funding is provided, the existing Extension Service-farm infrastructure will be strengthened to facilitate communication in the agricultural community.

In reaching the produce industry workforce, the GAP guidance and associated educational materials must be available in native languages and terms understood by this diverse community. Multi-lingual materials are also needed for use in foreign countries. To meet these needs, the GAP/GMP guidance documents, as well as associated training and information materials will be translated into appropriate languages as quickly as possible as they are finalized and funding permits.

We anticipate that education and outreach activities will reach beyond the immediate needs of the produce industry to ancillary industries, such as wholesale and retail, to the consumer. Expanded education efforts (contingent upon additional FY99 funding) will be directed to increasing awareness of public health concerns about fresh fruits and vegetables, as well as about use of safe practices for handling and storing fresh produce vegetables.

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

In the international arena, FAS will be instrumental in facilitating the development of education and training programs, either through their staff or the State Department. The FAS' International Cooperation and Development group can facilitate development of cooperative training programs on the GAP guidance, in collaboration with other agencies capable of providing funding for these activities. FAS will also explore mechanisms to obtain the resources and expertise from other international organizations, such as the FAO and the Inter-American Institute for Cooperation of Agriculture in order to facilitate discussions on produce safety issues. FDA and USDA will

provide governments and organizations in foreign countries with multilingual GAP/GMP education programs and materials (as funding permits) for presentation to their industries.

Agencies Responsible: Lead: FDA and USDA (CSREES, NAPLAP, NRCS, FSA)
Support: EPA, OSHA

Timetable: Preliminary steps have been taken to determine mechanisms for providing information and assistance to the domestic industry in adopting GAP guidance. Likewise, preliminary steps will be taken in late FY98 to develop a program targeted to foreign growers.

III. Good Agricultural and Good Manufacturing Practices Guidance for Specific Commodities

The general GAP guidance that is being developed cannot be expected to provide the specificity needed to ensure safe produce. This general guidance is essential as a foundation for more specific GAP/GMPs for various commodities. As we consider the broad spectrum of a food safety system, general guidance is usually the first consideration. However, specific GAPs/GMPs are very appropriate and often essential for those foods where individual HACCP systems are not warranted. GAP/GMPs for individual commodities can provide tailored guidance for reducing the potential for microbial contamination, e.g., the minimum time between manure application and harvest, the best type of irrigation system to use, specific harvesting practices (e.g., picking berries or melons), or recommendations for transporting specific commodities. So, additional GAP/GMP guidance documents will be developed that are tailored to reducing the risk of specific commodities.

Supporting Information: Domestic commodity data provided by USDA includes specific commodities produced, the form (whole or processed) and the quantities produced. FAS has available, as part of its ongoing trade reporting system, data on fruits and vegetables imported into the U.S. and some commodity specific reports for selected countries. Information about the current agricultural practices, about currently used handling and transportation practices, as well as processing and packaging techniques, and information about products associated with foodborne illness outbreaks will also be used. Both USDA and FDA have some data on current agricultural and manufacturing practices which they will provide. Country information (such as copies of food safety legislation and regulation affecting production, handling, and storage of produce) useful in identifying current production and processing practices in foreign countries will be provided by FAS. This information will be used to direct and support decisions to develop specific GAP/GMP guidance documents.

Selection of Commodities: Options are being explored for the most efficient way to provide the

industry with guidance that is effective, and yields the most benefit from the resources expended. Among the options under consideration are:

- Industry organizations will voluntarily work with FDA and USDA to develop specific GAPs/GMPs as guidance for commodities they represent.

- Commodities for which specific GAPs/GMPs will be developed will be selected through a public process. FDA will publish a notice in the Federal Register announcing our intention to develop guidance for specific commodities and the criteria to be used in the selection. This notice will ask for information to guide the selection.

- The competitive grant mechanism available through CSREES will be used to provide funding for academic institutions in different regions of the country to develop commodity-specific GAPs/GMPs.

- Other approaches that will provide targeted guidance to the produce industry in a timely manner.

Whichever option is chosen for development of specific GAP/GMP guidance, some basic factors will be considered in selecting the commodities. These include the potential hazards associated with the commodity and whether or not microbe-specific methods (e.g., identification, detection, enumeration, and/or sampling technique) exist to ensure an appropriate level of public health protection. With these criteria, *Cyclospora* is not an appropriate choice for a specific GAP. The potential public health impact of the commodity, considering points such as the volume of the commodity produce, and the primary consumer group (e.g., young children, the elderly, the population in general).

Regardless of the option chosen for selecting commodities for which to develop individual GAP/GMP guidance, a FDA/USDA committee will oversee development of the documents which will undergo scrutiny in the FDA public review process. This process entails publication of the draft documents in the Federal Register, receipt and evaluation of comments, revision of the documents according incorporating information in the comments, and publication as a final guidance document.

Agencies Responsible: Lead: FDA
Support: USDA (CSREES, AMS, ARS, NRCS, NASS, ERS), EPA, DoL (OSHA), CDC

Timeline: It is anticipated that development of the specific guidance by the agencies will be available to the produce industry during 1998. If the CSREES grant process is used for development of the specific guidance documents, it is anticipated that the grant process will begin in May, 1998 and conclude with

grant awards in October, 1998. Draft documents will be developed during 1999 and will undergo the FDA public review process beginning in 2000.

IV. Focussed inspections of production and processing operations and testing to areas of highest risk and monitoring adoption of GAP/GMP guidance.

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

FDA will continue its fresh fruit and vegetable inspection and testing program at current levels for domestic and imported produce. Additional resources (additional funding from the FY99 budget) will be focussed on sampling products from producers that have not adopted GAP/GMP guidance, domestic or foreign.

Monitoring: The USDA and FDA will use survey techniques to determine the effectiveness of the GAP/GMP program and the extent of adoption of the guidance in both the domestic and foreign industry. The first survey will be conducted to determine current practices, specifically those practices that have the most impact on public health and those that are covered in the general GAP guidance. This baseline information will be augmented with information from other sources, such as foreign governments and state agencies, on current practices. A second, more thorough, survey on practices will be conducted at a later date. All of this information - from the surveys and other sources - will be used to monitor adoption of the GAP/GMP guidance and to make necessary adjustments in the GAP/GMP program, including the guidance. (The extent of this work is contingent on additional funding in the FY99 budget.)

Agencies Responsible: Lead: FDA
Support: USDA (ORACBA, ERS, FSIS, ARS, AMS, FAS), EPA, CDC

Timetable: FDA's inspection and sample collection and analysis activities are ongoing. Increased inspection and testing efforts are budget dependent. The monitoring activity will begin in FY98, dependent on funds available.

V. Accelerated food safety research.

Successful implementation of an initiative, such as this, relies heavily on scientific research to develop intervention and prevention strategies to prevent foodborne illness. Research will

support development of improved detection methods useful in a variety of environments to conduct longterm surveillance and monitoring of both domestic and imported produce, development of control and prevention strategies to augment use of GAP/GMP, and to develop GAP guidance that accommodates specific needs imposed by environmental factors (e.g., water quality, manure management, worker hygiene).

FDA and USDA both have extensive research programs in areas related to development of pathogen detection and quantification methodology, as well as development of control and prevention interventions. EPA and USDA also have research programs underway focused on water quality and manure management.

FDA and USDA are individually and collectively reviewing their respective FY98 research projects related to fresh fruits and vegetables to identify specific research that can be accelerated. USDA and FDA have held research planning meetings with other agencies conducting food safety related research, including the Department of Defense, the Department of Energy, the National Science Foundation, and the National Institutes of Health. In addition, the agencies have met with industry and consumer representatives to determine what food safety research outside the government is currently ongoing or in the developmental stages and, from this outside perspective, identify research needs.

The agencies are developing a coordinated research plan for reducing microbial risk in produce. The research plan is scheduled to be available in early 1998. Four specific areas for research focus have been identified as: Improved detection methods, resistance to traditional preservation techniques, antibiotic resistance, and development of intervention strategies. Research is currently underway in all these areas. Among the areas to be further investigated are: packaging, storage, and preservation technologies; production practices, in particular manure management and maintenance of water quality; and use of post-harvest treatments, such as antimicrobial agents in wash water, to reduce levels of unavoidable microbial contamination. NIH will put out a call for research proposals in these and other related areas.

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

Agencies Responsible: Lead: FDA and USDA (ARS, CSREES, ERS)

Support: EPA, NIH, DoD (Natick Labs)

Timetable: The process of reviewing research related to safety of fresh fruits and vegetables was initiated in September, 1997. A research plan delineating fresh fruit and vegetable-related research being accelerated, will be available in early 1998 .

Cmi pro- food safety – fruits + vegs

PIFSI: Status

Produce and Imported Food Safety Initiative Status Report - Outline

Summary

In his October 2 Directive to the Secretaries of Health and Human Services and the Department of Agriculture, the President requested the Secretaries to report back within 90 days (January, 1998) with a complete schedule for developing "standards" to ensure the safety of fresh produce within a year and a comprehensive plan to improve the monitoring of food safety programs abroad, to help foreign countries upgrade their safety precautions, and to toughen food inspections at the border. This report describes the timeline developed by FDA, in cooperation with USDA and other participating agencies, for publication of broad-scope good agricultural practices (GAPs) and good manufacturing practices (GMPs) for all fresh fruit and vegetables and GAPs/GMPs for additional, specific fruits and vegetables. The report also lays out the agencies' strategy for:

- Improved monitoring of domestic and foreign agricultural practices
- Improved monitoring of manufacturing practices
- Providing technical assistance to foreign countries
- Targeting inspection and testing to highest risk areas
- Education and outreach to domestic and foreign growers
- Accelerating supporting food safety research

Background

While American consumers enjoy the safest food supply in the world, there have been increasing incidences of foodborne illness outbreaks associated with fresh fruits and vegetables from both domestic and imported sources. In an effort to enhance the safety of fresh produce from all sources, on October 2, 1997, President Clinton announced steps to further ensure the safety of the nation's food supply. The directive, entitled "Initiative to Ensure the Safety of Imported and Domestic Fresh Fruits and Vegetables" is geared toward increasing assurances that fruits and vegetables, whether produced domestically or imported, are safe.

Elements of the directive include:

- Legislation will be requested from Congress giving FDA the authority to halt imports unless importing countries have in place food safety systems that offer the same level of protection as the U.S. system.
- The Administration will request FY'99 funds to increase coverage of importing countries
- FDA develop inspection system for foreign inspections
- HHS and USDA will issue, by October 1, 1998, guidance on good agricultural practices (GAPs) and good manufacturing practices (GMPs) for fresh fruits and vegetables
- GAPs and GMPs should take into account differences in crops and growing regions and address potential risks throughout the food distribution and marketing system.
- Develop coordinated outreach and educational activities
- Accelerate food safety research necessary to support these activities.

Status Report Outline

FDA, in cooperation with USDA, CDC, EPA, and Department of Labor, will plan and implement the following operations in order to carry out the President's October 2, 1997 Directive e. (A draft report on the plans and timetable for accomplishing these goals will be prepared by December 1.)

I. Issue broad guidance, from which will flow more specific Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) documents.

A. Strategy

A single broad-scope good agricultural practices (GAPs) and good manufacturing practices (GMPs) document is being prepared for publication during FY'98. This "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables" is intended to be guidance only. The guide does not bind the agencies, nor does it create or confer any rights, privileges, or benefits for, or on, any person. This guide will represent the best advice of FDA and USDA. Industry and public input will be sought and incorporated into these documents.

This broad-scope guide will be used as a model for developing individual documents for specific fruits and vegetables deemed to be at high risk of microbial contamination. The agencies plan to issue these additional GAPs and GMPs in the near future. These guidance documents will discuss microbial hazards and good management practices specific to individual fresh market crops and regions. Where applicable for a particular crop, the specific documents will include guidance on minimizing microbial food safety hazards at subsequent steps in the food production system beyond those covered in this general guidance document. These detailed guidance documents will be accompanied by extensive educational and outreach programs for the fresh produce industry and consumers.

B. Agencies Responsible

1. Lead: FDA

2. Support: USDA (AMS, CSREES, ARS, FSIS), EPA, Department of Labor

C. Timetable

1. FY'98

a) Broad-scope GAP/GMP document

11/17/97: Draft broad-scope GAP/GMP document to Produce Subcommittee of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) for review.

Public meeting to introduce draft broad-scope GAP/GMP document and solicit input from representatives from the food industry and consumer advocates.

I. Issue broad guidance, from which will flow more specific Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) documents. (cont.)

12/1-12/97: Six domestic and one international grassroots meetings will be held to introduce the draft broad-scope GAP/GMP and solicit input from growers, handlers, and processors of produce.

1/16/98: Revised draft broad-scope GAP/GMP delivered to the Produce Subcommittee, NACMCF, for review.

1/30/98: Final approval of draft broad-scope GAP/GMP by FDA/CFSAN.

2/28/98: Publication of draft broad-scope GAP/GMP in Federal Register; 45-day comment period.

4/15/98: End of comment period on draft broad-scope GAP/GMP.

4/98: Possible second public meeting.

5/31/98: Approval of final broad-scope GAP/GMP by FDA/CFSAN.

6/30/98: Public notice of availability of final broad-scope GAP/GMP.

b) Individual commodity GAP/GMPs

12/97: Four commodities will be selected for development of individual GAP/GMP documents; these will be chosen based on judgements about their relative risk of microbial contamination

4/98-5/98: Publication in Federal Register of four draft individual GAPs/GMPs, one for each commodity selected during 1997

4/98-5/98: Additional commodities identified as suitable for individual GAP/GMP development.

2. FY'99

12/98: Final approval of second set of individual GAP/GMPs by FDA/CFSAN.

II. Identify ways to improve monitoring of agricultural practices, foreign and domestic.

A. Strategy

An international Food Safety Program will be established to monitor domestic and foreign agricultural practices. FDA investigators, available using increased resources, will work with USDA personnel to monitor domestic (USDA, CSREES, AMS involvement) and foreign (APHIS, FAS) operations. GAP/GMP documents developed under item I. will be used as a guide to survey importing countries and develop a baseline of potential problem areas.

II. Identify ways to improve monitoring of agricultural practices, foreign and domestic. (cont.)

B. Agencies Responsible:

1. Lead: FDA and USDA (FAS, NRCS, FSA, ERS, NASS, AMS, APHIS)

C. Timetable

1. FY'98

11/97:	FAS will provide a timeline for developing country profiles
Summer '98:	Develop international Food Safety Program

2. FY'99

III. Identify ways to improve monitoring of manufacturing practices.

A. Strategy

An international Food Safety Program will be established to monitor manufacturing practices in domestic and foreign operations. FDA investigators, available using increased resources, will work with USDA personnel to monitor domestic (USDA CSREES, AMS involvement) and foreign (APHIS, FAS) operations. GAP/GMP documents developed under item I will be used as a guide against which to evaluate the practices.

B. Agencies Responsible

1. Lead: FDA and USDA (NASS, ERS, FAS, AMS)

C. Timetable

1. FY'98

2. FY'99

IV. Provide technical assistance to foreign countries.

A. Strategy

USDA will document known measures and practices affecting the safety of U.S. food imports or targeted problem regions. Working cooperatively with FDA, USDA will establish country profiles assessing the in-country safety parameters and likelihood of meeting U.S. entry requirements for fresh produce. Based on the country profiles, FDA will target inspection and testing to areas of highest risk. USDA and FDA will work with all affected parties to communicate GAPs and GMPs for fresh fruits and vegetables.

FDA and FAS will expand foreign training and technical assistance directed towards countries that import produce into the U.S.

IV. Provide technical assistance to foreign countries. (cont.)

B. Agencies Responsible

1. Lead: FDA and USDA (FAS, FSIS, APHIS)

C. Timetable

1. FY'98

FDA has met with USDA and has provided FAS preliminary information on country profiles.

2. FY'99

V. Develop methods to target inspection and testing to areas of highest risk.

A. Strategy

Based on country profiles compiled by USDA, FDA will evaluate growing, harvesting, handling, transportation, and production operations in foreign countries. Models will be developed to assess the risks associated with different types of commodities, geographic regions, and growing conditions. FDA/CFSAN, with support from USDA, will develop risk assessments based on volume of production, the particular agricultural and handling practices associated with each commodity, and profiles of countries from which the U.S. imports.

FDA will collect and analyze approximately 1000 additional samples to determine the status of products offered for entry into the U.S. As a first step, FDA will collect and analyze samples of prepared cut vegetable salad items to obtain information on current sanitation practices used by the industry and evaluate correlation between these practices and analytical results.

A federal-state communications system will be expanded, enabling states to inform federal agencies of problems found with imported products in their jurisdictions.

B. Agencies Responsible

1. Lead: FDA

2. Support: USDA (ORACBA, ERS, FSIS, ARS, AMS), EPA, CDC

C. Timetable

1. FY'98

11 /97: Draft FDA Field assignment for sampling and analysis of foods from fresh cut manufacturers

1 /98: Field assignment for fresh cut manufacturers issues.

V. Develop methods to target inspection and testing to areas of highest risk. (cont.)

2. FY'99

FDA budget request for resources to do microbiological survey of fresh cut produce. NACMCF will develop criteria for this survey.

VI. Develop strategy for education and outreach to growers (domestic and foreign).

A. Strategy

FDA and USDA will expand communications about fresh fruits and vegetables GAPs and GMPs to appropriate audiences. USDA Cooperative State Research, Education and Extension Service (CSREES), with its existing network of contacts within the U.S. farming community, will provide access points for disseminating the GAPs and GMPs and for providing further education to support their implementation.

USDA APHIS and FAS, with their networks in foreign countries, will provide access points for producers handlers of produce outside the U.S.

B. Agencies Responsible

1. Lead: FDA and USDA (CSREES, NAPLAP, NRCS)

2. Support: EPA, OSHA

C. Timetable

1. FY'98

A meeting is scheduled with USDA for November 10, 1997 to develop an outreach education plan.

2. FY'99

VII. Accelerate food safety research to support these activities.

A. Strategy

FDA and USDA are individually reviewing their respective FY'98 research projects for produce to identify areas for future research to reduce microbial risk. The agencies have met with industry and consumer representatives to determine what research is currently ongoing or in the developmental stages, as well as determining research needs for reducing microbial contamination from fresh produce.

B. Agencies Responsible

1. Policy Direction: NSTC

2. Lead: FDA and USDA (ARS, CSREES, ERS)

3. Support: EPA

VII. Accelerate food safety research to support these activities. (cont.)

C. Timetable

1. FY'98-'99

9/26/97:	CFSAN meeting with ARS
10/7-8/97:	ARS meeting at USDA/ARS, Philadelphia
10/23/97:	FDA/industry meeting
11/30/97:	FDA draft FY'98 research plan for fresh produce
11/6/97:	Interagency meeting on "Research Needs and Research Being Conducted" cosponsored by ARS and FDA; attended by DOD, USDA, EPA, NIOSH
1/98:	Research plan for FY'98 available

2. FY'99

pifsi3 outline

Cms 720 - food safety - fruits + vegs

Wendy A. Taylor 11/04/97 06:18:03 PM

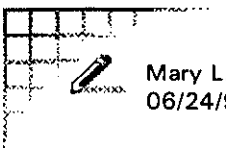
Record Type: Record

To: Robert J. Pellicci/OMB/EOP

cc: laura emmett/who/eop, toby donenfeld/ovp @ ovp
Subject: Re: HHS draft bill on Safety of Imported Food Act

Elena carefully crafted the compromise language with the agencies which OIRA supports. We will defer to her on the timing of its release.

Cen pw - food safety - limits + regs



Mary L. Smith
06/24/98 07:24:18 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Bruce N. Reed/OPD/EOP

cc: Thomas L. Freedman/OPD/EOP, Laura Emmett/WHO/EOP
Subject: Dingell food safety bill

Elena asked about the Dingell food safety bill and why he was offering a separate bill instead of the Administration bill, sponsored by Eschoo. One of the main reasons Dingell offered the bill was to provide a method for paying for the President's food safety initiative. Dingell has proposed authorizing FDA to collect a user fee on imported food which would raise approximately $50 million. (Of the Administration's $96 million food safety initiative for USDA and FDA, we received only $16.8 million in the House full committee and only $2.6 million in the Senate full committee. FDA received $7 million in the House and nothing in the Senate.)

USTR is very adamant that because the user fees were only against imports and not domestic foods, they would violate the GATT. Therefore, OMB is not sending comments on the bill because of the trade problem. In the event that we actually do comment on the bill, OMB will circulate the comments.

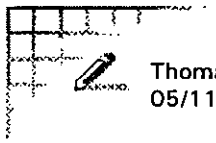
Here are some of the main provisions of the bill:

1. **Import Inspection User Fees.** The Dingell bill authorizes FDA to collect a user fee of $20 per line item of imported food.

2. **Country of Origin Labeling.** The Dingell bill mandates country-of-origin labeling of imported food subject to FDA regulation at the point such food is offered for retail sale.

3. **Refusal of imports.** One of the main differences between the Dingell bill and the Administration bill is that the Dingell bill mandates the refusal of imports if a country does not allow FDA inspections. Our bill ensures that FDA halts imports of fruits, vegetables, and other food products from any foreign country with food safety systems that do not provide the same level of protection required for U.S. products. Our bill only permits FDA to consider the refusal of inspections as one factor in deciding whether to halt imports.

Cam pa - food safety -
Smith recs



Thomas L. Freedman
05/11/98 08:14:20 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP

cc: Mary L. Smith/OPD/EOP, Laura Emmett/WHO/EOP, Michelle Crisci/WHO/EOP
Subject: Imported food

The network coverage if you missed it, ranged from ok (CBS mentioned the legislation, showed a clip of Clinton, and its Friedman interview) to bad, ABC (edited Friedman in mid-sentence so he doesn't say anything about the legislation) to ugh, NBC (alarmist, just says Congress and the Administration blame each other.)

The next test on this issue is Collins' hearing Thursday. The topic is the GAO report and she'll have GAO and a former FDA investigator who may describe how the safety system can be cheated. So far, Collins has not invited FDA to testify, though they made clear they would be available.

Without FDA, it becomes more likely the story stays on the problem, and Collins avoids stories saying that a bill is pending and Congress should act. I wonder if we shouldn't more formerly press to testify and put her in the position of refusing to have administration testimony. Any ideas?

FDA has sent me some material on further legislation they would like on in this area on civil penalties which I will pass along. They suggested they could ask for this additional tool this week prior to the hearings, but it seems a little small. We need a way to focus on the languishing legislation.

main stds
are food neces
[illegible] standards

Food safety - fruits + vegs

Mexico Delegation re Food Safety

1. Perception issues -
   like to participate in drafting, etc. - guidelines
   timetable is key

2. New agency? (Fazio)
   also support from CA.
   what are the possibs for this?

Huslaud: (NAS examination) →

3. irradiation? FDA/USDA opinion?

4. Enforcement / monitoring of agricultural practices?
   certification system?

In addition to equivalency:
stds must be nec to ensure safety; take costs into acct

need to know in advance so we can work w/ our own producers.