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.

Background

American consumers enjoy among the safest and most plentiful food supplies in the world. However, over the last several years there have been increasing incidents of reported outbreaks of serious foodborne illness caused by 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 and Services, the Department of Agriculture, and the Environmental Protection Agency sent to the President a report that identified produce and imported foods as areas 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. Specifically, the President called on Congress to give the Food and Drug Administration the authority to stop the importation of fruits, vegetables, and other foods from countries whose safety precautions do not meet American standards. This new law would provide FDA authority similar to the authority already provided USDA to keep unsafe, imported meat and poultry out of our stores. The President also announced that his next budget will provide enough funds to ensure that FDA can fully implement this new law by dramatically expanding its international food inspection force.

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 specific safety standards for the growing, processing, shipping, and selling of fruits and vegetables. These standards will address potential food safety problems throughout the production and distribution system, and they will improve the sanitation and safety practices of all those seeking to sell produce in the United States market. Finally the President asked the two Secretaries to report back to him within 90 days with a plan and schedule for developing these standards within a year.

Status of the Legislation: On the Administration sent to the Congress legislation to amend the Federal Food, Drug, and Cosmetic Act to expand FDA's authority to ensure the safety of imported fruits, vegetables, and other foods by providing FDA with authority comparable to that already provided USDA. On November 13, 1997, Representatives Eshoo and Pallone introduced the "Safety of Imported Foods Act of 1997 (H.R. 3052), incorporating the Administration's proposal. The bill was referred to the House Committee on Commerce. A comparable bill has not yet been introduced in the Senate.

This Report

This report presents the progress made to develop specific safety standards for the growing, processing, shipping, and selling of fruits and vegetables, and presents 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 Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) for produce. GAPs will address production practices including growing, harvesting, handling, and transportation. GMPs will primarily address harvesting and transportation, but will also include other parts 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 adopt GAP/GMP guidance. For example, the domestic and foreign industry will depend on technical assistance from U.S. agencies to effectively adopt GAP/GMP 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. The White House Office of Science and Technology Policy will help coordinate the needed research planning.

The U.S. produce industry 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 developing GAP/GMP guidance, recognize this effort and build on it.

(Wendy -- For now I have left out the part on budget -- identifying the funds and the need for adequate funds in FY99 -- for the reasons we discussed. But if it can be explained clearly I would add it to the end of the last paragraph. Thanks.)

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.

I. 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 *Cyclaspora* 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.

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. Forsgren (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**

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.

Background

American consumers enjoy among the safest and most plentiful food supplies in the world. However, over the last several years there have been increasing incidents of reported outbreaks of serious foodborne illness caused by 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 and Services, the Department of Agriculture, and the Environmental Protection Agency sent to the President a report that identified produce and imported foods as areas 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. Specifically, the President called on Congress to give the Food and Drug Administration the authority to stop the importation of fruits, vegetables, and other foods from countries whose safety precautions do not meet American standards. This new law would provide FDA authority similar to the authority already provided USDA to keep unsafe, imported meat and poultry out of our stores. The President also announced that his next budget will provide enough funds to ensure that FDA can fully implement this new law by dramatically expanding its international food inspection force.

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 specific safety ~~standards~~ guidance for the growing, processing, shipping, and selling of fruits and vegetables. ~~These standards~~ guidance will address potential food safety problems throughout the production and distribution system, and they will improve the sanitation and safety practices of all those seeking to sell produce in the United States market. Finally the President asked the two Secretaries to report back to him within 90 days with a plan and schedule for developing these standards within a year.

Status of the Legislation: On the Administration sent to the Congress legislation to amend the Federal Food, Drug, and Cosmetic Act to expand FDA's authority to ensure the safety of imported fruits, vegetables, and other foods by providing FDA with authority comparable to that already provided USDA. On November 13, 1997, Representatives Eshoo and Pallone introduced the "Safety of Imported Foods Act of 1997 (H.R. 3052), incorporating the Administration's proposal. The bill was referred to the House Committee on Commerce. A comparable bill has not yet been introduced in the Senate.

This Report

This report presents the progress made to develop specific safety standards for the growing, processing, shipping, and selling of fruits and vegetables, and presents 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 Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) for produce. GAPs will address production practices including growing, harvesting, handling, and transportation. GMPs will primarily address harvesting and transportation, but will also include other parts 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 adopt GAP/GMP guidance. For example, the domestic and foreign industry will depend on technical assistance from U.S. agencies to effectively adopt GAP/GMP 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. The White House Office of Science and Technology Policy will help coordinate the needed research planning.

The U.S. produce industry 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 developing GAP/GMP guidance, recognize this effort and build on it.

(Wendy -- For now I have left out the part on budget -- identifying the funds and the need for adequate funds in FY99 -- for the reasons we discussed. But if it can be explained clearly I would add it to the end of the last paragraph. Thanks.)

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

FAX COVER SHEET

Pages: _____ Date: _____

To: Jerry Mande

Agency: _____

Office Phone Number: _____

Fax Number: 66027

- -

From: Wendy Taylor [redacted]
Special Assistant to the Administrator or OIRA

Phone Number: 202-395-1247

Fax Number: 202-395-3047

- -

Comments:

Here are the first 2 pages. The earlier the better but, if possible, by 2:30 or 3:00 ??

Thanks!

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

Background

While American consumers enjoy among the safest food supply in the world, in the last several years there have been increasing incidents of reported 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~~ Assistant for Science and Technology 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 and 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 guidance 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.

I. 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

EXECUTIVE OFFICE OF THE PRESIDENT
NATIONAL SCIENCE AND TECHNOLOGY COUNCIL
WASHINGTON, D.C. 20502
November 25, 1997

MEMORANDUM FOR DONNA E. SHALALA, HHS
DAN GLICKMAN, USDA
CAROL M. BROWNER, EPA

FROM: JOHN H. GIBBONS

SUBJECT: NSTC FOOD SAFETY RESEARCH PLAN

Acting on the President's commitment to improve the safety of our nation's food supply and in keeping with the Government Performance and Results Act, I am establishing an Interagency Working Group (IWG) on Food Safety Research under the auspices of the National Science and Technology Council (NSTC) Committee on Science. In your May 1997 interagency report to the President, you highlighted the opportunities for better research coordination across the federal government. Therefore, this new IWG will develop a coordinated federal food safety research plan, which will extend to our research partners in states, industry, and academia.

The following agencies play a significant role in addressing the research needs associated with ensuring the safety of our nation's food supply: ARS, CSREES, FSIS, and ERS in USDA; FDA, NIH, and CDC in HHS; and EPA. Under the IWG, these agencies will conduct an in-depth review of all federal research related to microbiological aspects of food safety as well as research related to natural toxins and tissue residues of veterinary drugs. Based on this review, the IWG will make recommendations for future coordinated research. The first step in this process will be devising a review structure and mapping all research onto that structure so that an organized picture of the existing federal research portfolio can be created. This will be followed by an assessment that will identify unnecessary duplicative efforts, jurisdictional issues, research gaps, and other information pertinent to designing a more coordinated research plan. The IWG's work should serve as the basis for an ongoing interagency process for coordination of food safety research. A detailed terms of reference will be prepared in consultation with the IWG. In order to support your FY2000 budget submissions, this work should be completed by May 29, 1998.

Since time is short, we need to initiate the work of the IWG immediately. Please submit names of your agencies' representatives to Dr. Clifford Gabriel by December 5, 1997. In addition, I would like USDA and HHS to each designate a policy level individual who can serve as an IWG co-chair. The IWG will hold its first meeting in early December. Dr. Gabriel can be reached at: cgabriel@ostp.eop.gov, 202-456-6130 (voice), or 202-456-6027 (fax).

cc: Adrienne Erbach, OMB
Lisa Grove, OMB
Angela Phillips-Diaz, NSTC ✓

NSTC IWG Food Safety Research Roster

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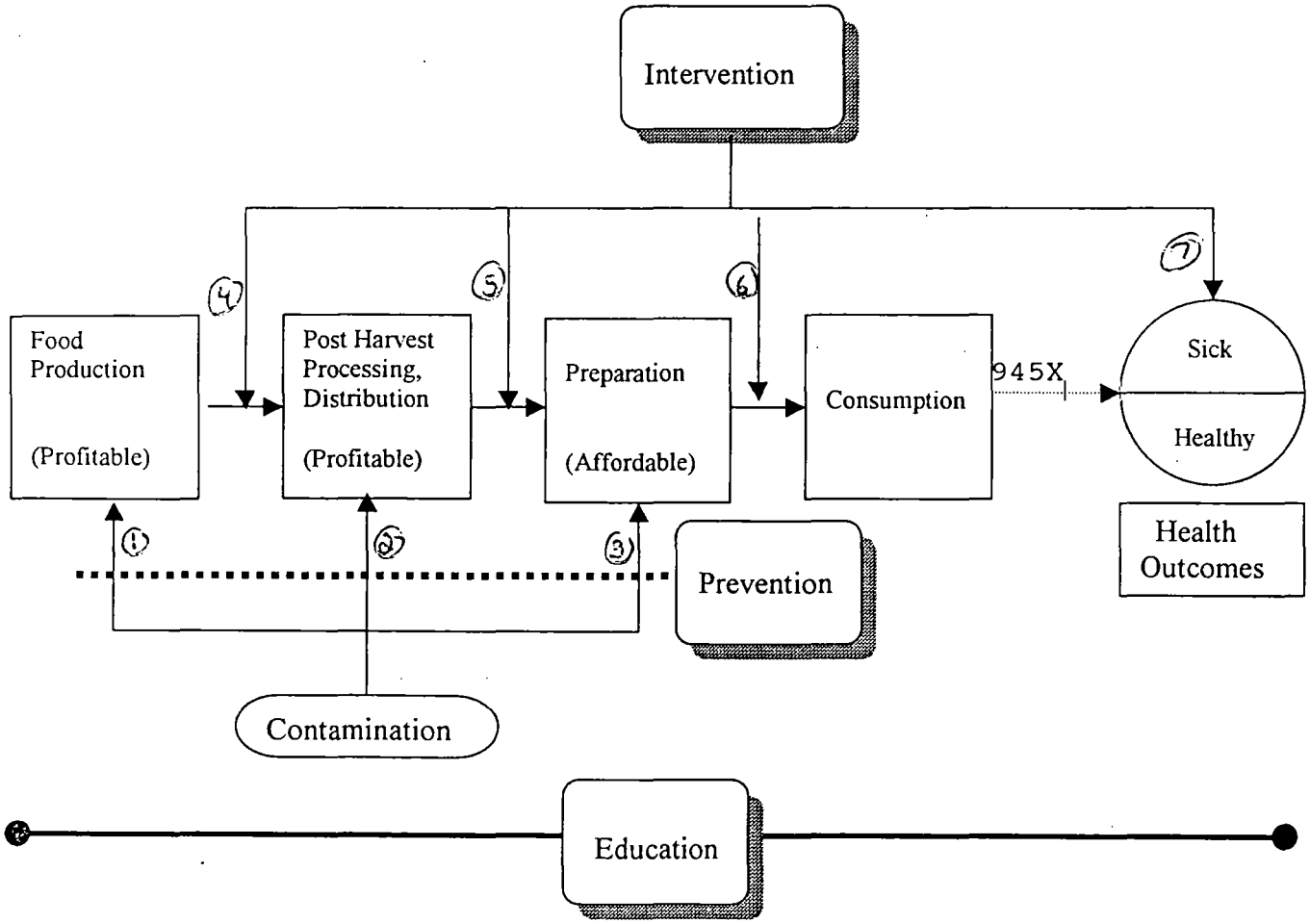
Food Safety Research and Education Framework



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 .