Food safety one

Mary L. Smith
11/24/98 09:23:54 PM

Record Type: Record

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

cc:

Subject: Charter and Action Memos for Food Safety Council

I will send you a copy of the charter for the Food Safety Council and four decision memoranda that will be discussed at the first Council meeting, which is tentatively set for December 16. The action memos are on the following: (1) Assessment of the NAS report; (2) Process for developing a strategic plan; (3) Process for developing coordinated food safety budgets and a unified food safety initiative budget; and (4) Scope of the food safety strategic plan.

The agencies are seeking comments by November 30. If you have any comments before November 30, let me know. Thanks, Mary

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

SUBJECT: President's Council on Food Safety Clearance Documents

TO: See Distribution List

FROM: Joan Mondshein
Confidential Assistant to the Administrator
Food Safety and Inspection Service

20 NOV 1998

Charles Danner
Director, Planning Staff
Food Safety and Inspection Service

Attached for your final review are the most recent charter and decision memoranda (4) drafts which, when finalized, will be discussed by the President's Council on Food Safety at its first meeting in early December.

The final charter will provide general direction to the Council. Comments received on the earlier draft of this document have been incorporated in the attached version.

The decision memoranda define important food safety issues that were addressed in the President's Executive Order establishing the Council. Discussion of the issues contained in the papers and approval of the charter will form the major portion of the agenda for the first meeting.

Please review the attached documents and forward your comments to Charles Danner by COB Monday, November 30, 1998. You may telephone, fax or email your comments to:

Phone: 202-720-4745
Fax: 202-690-1742
Email: charles.danner@usda.gov

Attachments

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(Draft 11/2)

PRESIDENT'S COUNCIL ON FOOD SAFETY
CHARTER

Article I: Purpose.

On August 25, 1998, the President, by Executive Order, No. 13100, established the President's Council on Food Safety ("Council") to improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs. The purpose of the Council is to develop and update periodically a comprehensive strategic plan for Federal food safety activities, to make recommendations to the President on how to implement the comprehensive strategy and enhance coordination among Federal agencies, State, local and tribal governments, and the private sector, to advise Federal agencies in setting priority areas for investment in food safety, to oversee research efforts of the Joint Institute for Food Safety Research, and to evaluate and make recommendations to the President on the proposals contained in the National Academy of Sciences report on food safety.

This Charter provides the basis for collaboration among the members of the Council in carrying out the responsibilities of the Council as set forth in the Executive Order.

Article II: Membership

Council membership shall comprise:

1. Secretary of Agriculture,
2. Secretary of Commerce,
3. Secretary of Health and Human Services,
4. Administrator of the Environmental Protection Agency,
5. Director of the Office of Management and Budget,
6. Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy,
7. Assistant to the President for Domestic Policy, and
8. Director of the National Partnership for Reinventing Government.

Each member may designate a senior Federal employee, subject to the approval of the co-chairs, to serve as an alternate representative to perform the duties of the Council member.

Article III: Co-Chairs

The Secretaries of Agriculture and of Health and Human Services and the Assistant to the

President for Science and Technology/Director of the Office of Science and Technology Policy, or their designated alternates, shall serve as co-chairs of the Council.

The co-chairs shall provide leadership and direction to the Council, and coordinate the formation and schedule of standing committees. Each meeting will be led by one co-chair and this responsibility shall rotate quarterly among the co-chairs.

Article IV: Staff Support Services

Staff support services for the activities of the Council will be provided by the Co-Chairs through a Secretariat, which will consist of a senior Federal employee from each of the following: the Department of Agriculture, Department of Health and Human Services, and the Office of Science and Technology. Other members may provide additional staff support services, as necessary. The Secretariat will facilitate planning, coordination, and communication among Council members.

Article V: Meetings

The Council shall meet on a quarterly basis at a time and location chosen by the co-chairs. Additional meetings may be held at the call of the co-chairs or at the request of a majority of the members.

A majority of the Council membership shall constitute a quorum for the transaction of business. All decisions made by the Council at the meetings shall be by general agreement.

The Secretariat will prepare a summary report of each meeting of the Council for distribution to the membership and make each report available for public inspection and copying and on the Council Internet web site.

The Council may prepare a report for submission to the President on October 1 of each year. The report will contain, at a minimum, a description of the Council's activities and accomplishments during the preceding fiscal year and a description of the planned activities for the coming year, and a review of strategic planning objectives and progress made toward accomplishing those objectives.

Article VI: Duties and Responsibilities

The specific responsibilities of the Council are to:

1. Develop and update periodically a comprehensive strategic Federal food safety plan ("plan") to reduce the annual incidence of acute and chronic foodborne illness by further enhancing the safety of the nation's food supply. The plan will address public health, resource, and management questions facing Federal food safety agencies and will focus on the full range of food safety issues, including the needs of regulatory agencies, and the actions necessary to ensure the safety of the food Americans use and consume. The planning process will consider both

short-term and long- term issues including new and emerging threats to the nation's food supply and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council will take into consideration the findings and recommendations of the National Academy of Sciences report "Ensuring Safe Food from Production to Consumption" and the review of Federal food safety research by the interagency working group under the auspices of the National Science and Technology Group.

The final plan will help set priorities, improve coordination and efficiency, identify gaps in the current system and ways to fill those gaps, enhance and strengthen prevention and intervention strategies, and identify reliable measures to indicate progress.

The Council will conduct public meetings to engage consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process.

2. Advise Federal agencies of priority areas for investment in food safety and ensure that the member agencies develop annual coordinated food safety budgets for submission to the Office of Management and Budget (OMB) to sustain and strengthen priority activities on food safety, eliminate duplication, and ensure the most effective use of resources for achieving the goals of the plan.

3. Oversee the Joint Institute for Food Safety Research (JIFSR). The Council will evaluate the reports from JIFSR on food safety research activities and give direction to JIFSR on research needed to establish the most effective possible food safety system.

4. Evaluate and report to the President on the National Academy of Sciences (NAS) report, "Ensuring Safe Food from Production to Consumption". After providing opportunity for public comment, including public meetings, the Council will, by February 21, 1999, report to the President on the Council's response to and recommendations concerning the NAS report and appropriate additional actions to improve food safety.

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Article VII: Committees

The co-chairs, after consultation with Council members, may establish committees of Council members, their alternates, or other Federal employees, as they deem necessary, to facilitate and carry out effectively the responsibilities of the Council. Such committees shall report to the Council.

The following committees shall be established by the co-chairs:

1. Strategic Planning Committee

The Committee shall develop a comprehensive strategic Federal food safety plan ("plan") that will review public health, resource and management issues facing Federal food safety agencies and will focus on the full range of issues and the actions necessary to ensure the safety of the

food Americans use and consume. The Committee will conduct public meetings to engage consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process. The plan will include a comprehensive strategy for the enhancement of coordination among Federal agencies, State, local and tribal governments, and the private sector on food safety issues.

The Committee will provide the plan to the Council that will help set priorities, improve coordination and efficiency, identify gaps in the current system including legal authorities, and ways to fill those gaps, and enhance and strengthen prevention and intervention techniques.

2. Budget Committee

The Committee will examine all Federal food safety related budgets to identify priority areas for investment in food safety and ensure that resources are used effectively and to eliminate duplication.

3. JIFSR Executive Research Committee

The Committee will evaluate the reports from the JIFSR on its efforts to coordinate food safety research and make recommendations to the Council regarding research needed to establish the most effective possible food safety system.

4. NAS Report Review Committee

The Committee shall prepare a response to the NAS report, after providing for public comment, and shall submit the report to the Council by January 21, 1999.

Article VIII: Web Site

The Council shall establish an Internet web site. The Department of Agriculture shall be the system owner of the web site and shall be responsible for maintaining it. The Council website will provide links to websites of federal agencies having food safety responsibilities.

Article IX: Effective Date

This Charter shall become effective on the latest date affixed below and may be modified with supplemental agreements signed by the members of the Council.

Secretary of Agriculture

Secretary of Commerce

Secretary of Health
and Human Services

Administrator of Environmental
Protection Agency

Director of Office
of Management and Budget

Assistant to the President for Science
and Technology/Director of the
Office of Science and Technology
Policy

Assistant to the President
for Domestic Policy

Director of the National Partnership
for Reinventing Government

November 16, 1998

MEMORANDUM FOR THE PRESIDENT'S COUNCIL ON FOOD SAFETY

FROM: INTERAGENCY FOOD SAFETY WORKING GROUP

SUBJECT: Assessment of NAS Report "Ensuring Safe Food from Production to Consumption"

ACTION: Approval of plan to provide the President with an assessment of the NAS Report "Ensuring Safe Food from Production to Consumption."

BACKGROUND: In the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1998, funds were provided to the Agricultural Research Service to support the NAS to "1) determine the scientific basis of an effective food safety system, 2) assess the effectiveness of the current food safety system in the United States, 3) identify scientific needs and gaps within the current system, and 4) provide recommendations on the scientific and organizational changes in federal food safety activity needed to ensure an effective science-based food safety system."

The NAS established their study committee under the auspices of both the Institute of Medicine and the National Research Council and held three meetings (from March through June 1998) obtaining input from Federal agencies and other stakeholders of the Federal food safety system. The NAS issued their report on August 20, 1998. Attached is a summary of its findings and recommendations.

Congress viewed this study as part one of a possible two-part process. Should the NAS recommend that a single Federal food safety agency is required to achieve adequate performance and levels of public health protection, Congress planned to appropriate additional funds to support a second NAS study, which would focus on how such an agency should function. The NAS Committee did not explicitly recommend the establishment of a single Federal food safety agency, and funds for part two were not appropriated for fiscal year 1999.

On August 25, 1998, the President issued a directive tasking the Council on Food Safety to provide him with an assessment of the NAS report in 180 days (by February 21, 1999). Specifically, the President directed:

> "...the Council to review and respond to this report as one of its first orders of business. After providing opportunity for public comment, including public

meetings, the Council shall report back to me within 180 days with its views on the NAS's recommendations. In developing its report, the council should take into account the comprehensive strategic Federal food safety plan that it will be developing."

Four public meeting have been scheduled to solicit stakeholder input (October 2, in Arlington, VA; October 20, in Sacramento, CA; November 10, in Chicago, IL; and December 8 in Dallas, TX).

RECOMMENDATION: The Interagency Food Safety Working Group recommends that the Council establish a task force consisting of one representative from each of the following agencies: OSTP, HHS, USDA, EPA, and DOC. This 5 person task force will systematically assess the NAS report by providing 1) an analysis of the report's findings, including whether we agree or disagree with the findings and why; 2) an assessment of the strengths and weaknesses of each recommendation as they relate to the findings that are determined to have merit; and 3) recommendations on whether to incorporate particular elements of the NAS report into the Council's comprehensive strategic plan. If appropriate, the task force should identify barriers (e.g., legal) to implementation and recommend ways to overcome them. Each task force representative will be responsible for coordinating input from within his or her own agency. The task force will be chaired by OSTP and provide a draft report to the Council by February 5, 1999. Once the report is submitted to the President by February 21, 1999, the Council will seek additional public input on its assessment of the NAS report's recommendations.

MEMORANDUM FOR THE PRESIDENT'S COUNCIL ON FOOD SAFETY

FROM; INTERAGENCY FOOD SAFETY WORKING GROUP

SUBJECT: Process for developing a Food Safety Strategic Plan for all Federal food safety agencies

ACTION: Approval of a process for preparing a food safety strategic plan

BACKGROUND: On January 25, 1997, the President announced a new food safety initiative. He directed the Secretaries of Agriculture and Health and Human Services and the Administrator of the Environmental Protection Agency to identify specific steps to improve food safety. Those agencies held public meetings with consumers, producers, industry, states, universities, and the public, and reported back to the President. The Report, issued in May 1997, was entitled *Food Safety from Farm to Table, A National Food-Safety Initiative*. In that report, the Federal agencies involved in food safety recommended a longer-term strategic planning effort to consider how to best address important challenges and make the best use of the agencies' limited resources. The agencies made a commitment to involve all public and private stakeholders in the process.

The President's Council on Food Safety will be responsible for development of a 5-year Federal food safety strategic plan. A coordinated food safety strategic planning effort is needed to build on common ground and to tackle some of the difficult public health, resource, and management questions facing Federal food safety agencies. The strategic plan will focus on not just microbial contamination but the full range of issues that are discussed in the scope of food safety decision paper. It will also identify actions necessary to ensure the safety of the food Americans consume. The charge is to develop a comprehensive strategic long-range plan that addresses the steps necessary to achieve a seamless food safety system including key public health, resource, and management issues regarding food safety. The plan will be used to help set priorities, improve coordination and efficiency, identify gaps in the current system and mechanisms to fill those gaps, continue to enhance and strengthen prevention and intervention strategies, and develop performance measures to show progress. Each agency will incorporate the relevant parts of the strategic plan into its Government Performance and Results Act (GPRA) strategic plan, commensurate with its budget.

The food safety agencies have already taken the first steps in developing the food safety strategic plan, by participating in interagency strategic planning sessions and developing a draft vision statement for the U.S. food safety system and the roles of all those involved in food safety. The vision statement establishes the essential characteristics of an effective food safety system:

> Consumers can be confident that food is safe, healthy and affordable. We work within a seamless food safety system that uses farm-to-table preventive strategies and integrated research, surveillance, inspection, and enforcement. We are

vigilant to new and emergent threats and consider the needs of vulnerable populations. We use science-based and risk-based approaches along with public/private partnerships. Food is safe because everyone understands and accepts their responsibilities.

During early 1997, the federal food safety agencies engaged a wide range of stakeholders in discussions about food safety issues through a series of public meetings and through written comments to public dockets. At four additional meetings, held between October and December 1998, the food safety agencies engaged consumers, producers, industry, food service providers, retailers, health professionals, State and local governments, Tribes, academia, and the public in the strategic planning process. Participants commented on the draft vision statement as well as the strategic planning process. They were also asked to discuss goals and critical steps and to identify potential barriers to achieving those goals.

Additionally, at the request of Congress, the National Academy of Sciences (NAS) conducted a study of the current food safety system to: (1) determine the scientific basis of an effective food safety system; (2) assess the effectiveness of the current system; (3) identify scientific and organizational needs and gaps at the federal level; and (4) provide recommendations. The NAS released its findings, conclusions, and recommendations in an August 20th report, *Ensuring Safe Food from Production to Consumption.* The report stated that "changes in statutes or organization should be based on a rational, well-developed national food safety plan formulated by current federal agencies charged with food safety efforts and with representation from the many stakeholders involved in ensuring safe food."

RECOMMENDATION: The Interagency Food Safety Working Group recommends that the President's Food Safety Council convene a task force to develop a comprehensive food safety strategic plan based on the recommendations and comment received from its various constituencies. The task force will consist of representatives from each of the following agencies: HHS (CFSAN, CVM, NIH, CDC), USDA (FSIS, ARS, CSREES, ORACBA), and EPA.

The task force will first conduct a content analysis of the transcripts and dockets of the 1998 meetings and the input received through the notice and comment process to determine the major themes, issues, and subject areas that emerged during the public outreach phase. This will identify what stakeholders want in a food safety strategic plan. The task force will also consider the conclusions and recommendations of:

The National Academy of Sciences' report on *Ensuring Safe Food from Production to Consumption,*

The review of Federal food safety research and the research plan currently being developed by an interagency working group under the auspices of the National Science and Technology Council,

Input from the 50-State meeting on state/local issues and recommendations, and

Input from the agencies involved.

The task force will then develop a proposed set of strategic goals and objectives and present a draft strategic plan to the President's Food Safety Council. Following Council review, the draft food safety strategic plan will then be presented to the public for review.

After a suitable period of further public comment, the task force will prepare a final draft of the strategic plan with specific recommendations on needed changes and steps to achieve a seamless food safety system including resource needs, roles, and barriers to implementation, and submit it to the Council for approval.

Discussion Paper: Coordinated Food Safety Budget Process

For Consideration by the President's Council on Food Safety

Action Required: Approval of a process to develop coordinated food safety budgets and a unified food safety initiative budget submission.

Background

Executive Order 13100 established the President's Council on Food Safety, to "advise agencies of priority areas for investment in food safety and ensure that Federal agencies annually develop coordinated food safety budgets for submission to the Office of Management and Budget (OMB) that sustain and strengthen existing capacities, eliminates duplication, and ensure the most effective use of resources for improving food safety." The President further directed the Council to "ensure that the Federal agencies annually develop a unified budget for submission to OMB for the President's Food Safety Initiative and such other Food Safety issues as the Council determines appropriate."

Timetable for the Federal Budget Process

The Federal agency budget process begins no later than the spring of each year, at least 9 months before the budget is transmitted to Congress. In the spring and summer, the process focuses on the review of program performance, as well as ways to ensure efficient Government resources and successful implementation of programs and policies. Beginning in early fall, Executive branch departments and agencies submit initial materials to OMB in accordance with a schedule developed by OMB. Initial due dates for submitting material may differ between agencies, but final OMB action on budget decisionmaking is the same. OMB reviews agency budget requests, based on Presidential priorities, program performance, and budget constraints. A complete set of budget proposals is presented to the President by early December for approval. After this process is complete, agencies revise their budget requests to bring them into accord with the President's decisions. Under current law, the budget must be submitted to Congress no later than the first Monday in February.

The Federal Budget Process

The budget process is governed by OMB Circular No. A-11, "Preparation and Submission of Budget Estimates," which provides detailed instructions and guidance on the preparation and submission of agency budget requests and related materials, including the development of strategic plans and annual performance plans. Policy guidance is given to agencies for the upcoming budget year and out-years to provide initial guidelines for preparation of agency budget requests. OMB works with agencies to identify major issues for the upcoming budget; undertakes the analysis

necessary to provide the context for decisionmaking; identifies major options; and develops and implements plans for analysis of future issues.
During the OMB review process, major issues and options are prepared for consideration by the President, organized around major Administration themes and cross-cutting issues. The A-11 requires data for cross-cutting issues in addition to agency budget submissions to analyze individual agency budgets, make Government-wide resource allocation decisions, and prepare unified budget presentations. Contributing agencies submit detailed budget schedules and narrative information that describes agency functions and provides budget justifications. The narrative justifications include evidence of cooperative development of complementary requests among the major agencies involved. OMB utilizes the information to make crosscutting comparisons between agencies and to make Government-wide resource allocation decisions.

One example of a cross-cutting activity is for research and development. Agencies are required to report cross-cutting data for the specific areas of research identified by the National Science and Technology Council (NSTC). Prior to the beginning of the budget process, NSTC identifies a set of research and development areas that are important national efforts requiring coordinated investments across several agencies. These priorities, and other guidance, are provided to participating agencies to consider during the development of agency budgets. The agencies utilize this information to justify proposed changes in research and development activities addressed by NSTC. The A-11 also identifies other cross-cutting areas such as drug control programs and violent crime control programs.

Current Interagency Budget Planning Process

Currently, a formal process for coordinating the budget for food safety functions has not be established as it has been for other cross-cutting functions. In the absence of specific guidance, the Department of Heath and Human Services (HHS), and the Department of Agriculture (USDA) have coordinated a multi-agency effort to present a unified budget for the President's Food Safety Initiative. This process began with and is based on the May 1997 report to the President, entitled, *Food Safety from Farm-to-Table: A National Food Safety Initiative*. The report recognized microbial foodborne illness as an emerging public health hazard that requires aggressive government action. The report recognizes that only through joint planning can Federal resources be maximized and the greatest improvements in food safety be achieved. The farm-to-table strategy developed in the May 1997 report identifies critical gaps in the food safety system for controlling or eliminating foodborne pathogens from the food supply and proposes a strategy for closing those gaps.

The involved agencies have worked collaboratively to present a unified food safety initiative budget to OMB and the Congress for 1998 and 1999. However, the process for coordination and joint planning has not been initiated until the completion of individual agency budget decisionmaking. The result is inclusion of food safety initiative budget requests in individual agency budget submissions to OMB and preparation of a unified budget submission "after the fact".

The Council's Role in Food Safety Budget Planning

A primary responsibility of the Council is the development of a comprehensive Federal food safety strategic plan with the goal of a "seamless," science-based food safety system (e.g., a system that is an integrated Federal, State, and local system). The plan will contain specific recommendations on needed changes, including measurable outcome goals, steps necessary to achieve the goal, and key food safety public health, resource, and management issues. In developing the strategic plan, the Council will consult with all interested parties and will consider both short-term and long-term issues including new and emerging threats, and the special needs of vulnerable populations such as children and the elderly.

The strategic plan will provide a solid basis for coordinated food safety budget planning and resource requests. The Council will also ensure that the agencies submit a unified food safety initiative budget that includes other food safety issues, as determined appropriate by the Council.

Preparation of a Coordinated Food Safety Budget Planning Process

Developing a coordinated budget process for food safety activities includes a number of key factors. The first key factor is the development of guidance by the Council for food safety agencies to consider during the preparation of their budgets. In order for this guidance to be most useful, the Council should make it available to the agencies by late February to coincide with the beginning of the budget planning process of the involved agencies. A second major factor is the collection of budget data necessary for coordinating food safety budgets and recommending government-wide resource allocations. A third factor is establishing a process for agencies to submit relevant budget information to the Council and OMB for use in evaluating agency budget submissions.

Recommendation: Form a task force composed of representatives from the budget and program planning staffs of HHS, USDA, and EPA to work with the Council to develop a coordinated budget process for food safety activities similar to other cross-cutting issues. The team will work throughout the budget process to assure coordination of activities and resource requests. The task force should conduct the following functions:

- Review the strategic plan and Council budget guidance to identify budget data and other information that will be necessary to plan and evaluate agency budget submissions;
- Design a uniform format for presenting food safety initiative budget components for use in both agency and the unified budget submissions;
- Develop necessary guidance to facilitate submission of a unified food safety initiative budget and any other agencies deemed appropriate by the Council;
- Develop a timetable for submitting information to the Council that accommodates the various agencies budget processes.

DRAFT - 11/20/98

MEMORANDUM TO PRESIDENT'S COUNCIL ON FOOD SAFETY

FROM: Interagency Food Safety Working Group

SUBJECT: Scope of the Council's Comprehensive Strategic Food Safety Plan

ACTION: Decision on the scope -- what's in and what's out – of the Council's initial actions and comprehensive strategic Federal food safety plan.

BACKGROUND: On January 25, 1997, the **President issued a directive** to the Secretaries of USDA and HAS and the Administrator of EPA to work with stakeholders and the public to identify ways to further improve the safety of the food supply, and to report back to him in 90 days. The Federal food safety agencies (HAS, USDA and EPA) initially focused on the goal of reducing illnesses caused by microbial contamination of food and water. The plan for meeting this goal was presented to the President in May, 1997 in "Food Safety From Farm to Table: A National Food Safety Initiative"(FBI).

To implement the plan, USDA and HAS submitted **joint budget requests** for pathogen research, surveillance, risk assessment, inspection and education for F, F, and F. Microbial contamination of water and biomedical research are included within the scope of the FBI, and NH and EPA participated in the Initiative; however, support for NH and EPA programs have not been included in the joint budget submissions.

The May, 1997 report made a commitment to prepare a comprehensive 5-year **strategic plan**, with the participation of all concerned parties. The President's Council on Food Safety was established in August, 1998 under E.G. 13100 and is now responsible for development of this strategic food safety plan. The first steps to lay the groundwork for development of the strategic plan have already been taken by drafting a vision statement for the U.S. food safety system along with a series of questions designed to elicit the public's view on the vision, goals and critical steps as well as potential barriers to achieving that vision. In developing the vision, the agencies assumed that the scope of the strategic plan would be broadened beyond the FBI to include chemical hazards in the food supply.

Independently, the **National Academy of Sciences** (AS) was charged by Congress with: 1) determining the scientific basis of an effective food safety system; 2) assessing the effectiveness of the current food safety system; 3) identifying scientific needs and gaps; and 4) providing recommendations on the scientific and organizational changes needed to ensure an effective system. The AS released its findings and recommendations in August, 1998 in "Ensuring Safe Food from Production to Consumption". In the report, AS broadly defined food safety as "not only the avoidance of foodborne pathogens, chemical toxicants, and physical hazards, but also issues such as nutrition, food quality, labeling, and education". While the scope of the study included all these components, the report focused primarily on microbial, chemical and physical hazards from "substances that can cause adverse consequences" in domestically-produced and imported foods, including additives, agricultural chemicals and animal drug residues.

For the Council's purposes in **defining "food safety"** and determining the scope of the strategic plan, this paper identifies two categories of activities: "core food safety activities" and "collateral" or related activities. "Core food safety activities" includes programs or activities that enhance the safety of the nation's food supply and protect public health by reducing the annual incidence of acute and chronic foodborne illness. "Collateral activities" are related to and have implications for food safety but are undertaken to serve another primary purpose or mission, such as insuring fishable, swimmable waters. Specific food safety research or regulatory actions may need to be coordinated with these collateral activities, and vice versa, but they will not be included in the initial strategic plan. Collateral activities will be identified as appropriate for coordination or integration, and could be brought in the future within the scope of the strategic plan and the Council's work.

This framework is designed to allow the Council to focus on the important, "core" activities that directly impact food safety. Once developed, the strategic plan should assist the agencies to address the important food safety challenges by identifying priorities and making the best use of limited resources. This paper does not, therefore, determine priorities within the initial scope for Federal attention and resources, but rather leaves those decisions to the strategic planning process. Further, activities within the scope may not all be addressed in the same depth or at the same time depending on our assessment of the public health risks and potential benefits of action.

RECOMMENDATION: It is recommended that the Council and the strategic plan focus first on "core food safety activities" defined as microbial hazards, physical hazards, and chemical substances. Other "collateral activities" that are less directly related to the safety of the food supply will be considered for collaborative efforts or enhanced coordination on a specific, targeted basis as needed. Included in this second category are: miscellaneous food constituents, the nutrition programs, and waterborne hazards. *[Note: USDA and FDA recommended water be in the core.]*

Table 1: Recommended Scope of Food Safety Strategic Plan

	Core	Collateral
Microbial Hazards	X	
Chemical Substances	X	
Misc. Food Constituents		X
Nutrition Programs		X
Physical Hazards	X	
Waterborne Hazards		X

The remainder of this paper defines the categories above and examines the pros and cons for inclusion of each category within the scope of the Council's comprehensive food safety strategic plan. Table 2 (attached) provides information on "core" and "collateral activities" at the food

safety agencies.

OPTIONS: Building federal capacity to prevent, reduce and respond to microbial hazards in the food supply will continue to be a priority issue addressed by the Council and in the strategic plan. This includes not only known and emerging problems due to human pathogens in imported and domestic food (from farm to table) and antibiotic resistance in pathogens, but also some naturally-occurring toxicants (e.g., mycotoxins). Federal programs for microbial research, monitoring, surveillance, regulation and prevention (including irradiation of food), voluntary and mandatory certification and inspection, and enforcement as well as labeling and education (e.g., Fight BAC) that encourage proper food handling to avoid microbial contamination will be part within the scope of the plan.

This paper examines options for expanding the scope of the strategic plan beyond pathogens. Several categories of work have been identified which, separately or in combination, would broaden the scope and make the plan more comprehensive:

Option 1: Chemical Substances
Option 2: Miscellaneous Food Constituents
Option 3: Nutrition Programs
Option 4: Physical Hazards
Option 5: Waterborne Hazards

Option 1: Chemical Substances *[Note: This section is still under discussion, and may be revised.]* Food itself is a complex collection of "naturally-occurring" and added (inadvertently or for a specific purpose) chemicals with nutritive and other properties. "Added chemicals", including synthetic chemicals and metals, are sometimes inadvertently introduced into foods (e.g., industrial contaminants) and/or are present at unauthorized levels, while others are intentionally added and present in food, in most cases, at or below legal and "safe" levels.

The category includes a diverse set of substances: environmental contaminants (e.g., methyl mercury in fish, lead in baby food); industrial contamination (e.g., dioxin in chicken feed, polybrominated biphenyls in animal feed); pesticides (both residues in/on food and antimicrobials used to control pathogens); sanitizers; components of packaging materials (e.g., fungicide treated fruit and vegetable wraps); animal drugs (including residues in meat and/or milk); byproducts of manufacturing and process-induced components of foods (e.g., nitrosamines and pyrolysis products). Among the chemical substances of concern are naturally-occurring and added substances in dietary supplements (particularly herbals and botanicals, such as ephedrine alkaloids in ma huang and *Digitalis lanata* in a plantain-containing supplement). Similarly, nutrients present in either low or high levels may pose health risks to vulnerable populations in products specifically designed to meet their needs (e.g., infant formula, medical foods, and foods for special dietary purposes). Another area of concern included in the category are genetically modified plants and products used in food or animal production. This category also includes food and feed additives (e.g., coloring agents, preservatives, food packaging waxes), flavors, enzymes, and vitamins and minerals (including high levels of substances such as Selenium and Vitamin D). Because of broad public concern about the risks posed by chemicals, they have

historically been the subject of Federal attention and regulation.

Under this option, all FDA, USDA, EPA and CDC chemical-related food safety responsibilities, including those aimed at ensuring "safe" and lawful levels of chemicals in food, would be considered in the strategic plan. The plan would address chemical/pesticide research (including research on preventive controls and intervention strategies), monitoring/surveillance (food and human diseases), regulation and related voluntary programs, inspection, enforcement, education and outreach.

There are several reasons to include chemical substances as "core food safety activities" in the comprehensive strategic plan.

- Food safety involves protecting consumers from a wide range of potential hazards including the risks posed by chemicals.
- Significant Federal programs/resources at HAS, EPA and USDA are devoted to protecting the public's health from chemical hazards in food; since the mission of these programs is to ensure safe food, they should be part of the food safety strategic plan.
- Some resource efficiencies in surveillance and enforcement efforts could likely be achieved by integrating work on pathogens and chemicals.
- There is broad public concern about the safety of pesticide residues, food additives, and other chemical hazards in food.
- The plan will be perceived by the public as deficient if chemical substances are left out.
- The AS report specifically cited the need to include chemical hazards in any discussion of food safety and called for development of a comprehensive strategic plan for food safety; there would be a significant gap if chemical hazards were not considered in developing the plan.
- Some chemical substances present new and important challenges for the food safety system (e.g., endocrine disruption, protections for vulnerable populations) that should be considered in the strategic plan.
- There is a direct link between certain chemicals and our ability to control microbial contamination. For example, antimicrobials, pesticides and food additives play a role in controlling microbial contamination of food.
- There is growing interest in dietary supplements; some supplements, including herbal products, may pose a risk of adverse health effects because they contain a toxic constituent. The Dietary Supplements Health and Education Act exempted dietary supplements from Federal premarket approval of their safety, so effective post-market approaches are needed.
- There is public concern about the safety of products from genetically modified plants and animals.
- Including chemicals broadens the spectrum of programs included in the Initiative and the stakeholders, and should bring additional opportunities for improvements to the food safety system.

On the other hand, there are some reasons to exclude chemical substances from the "core".

- Some may argue that the urgency of the problem with pathogens warrants a focus on

microbial contamination alone.

- There are legal, scientific, regulatory and organizational distinctions that make chemical issues different from microbes; it may be an awkward blend and create challenges in terms of balancing competing priorities.
- The potential risks associated with this diverse group of substances varies widely in scope and severity. Some believe that including all chemical hazards may broaden the scope of the strategic plan beyond what is manageable.
- Some chemicals may not be priorities, and thus may not need to be included initially. For example, there are classes of pesticides (e.g., plant growth regulators with no toxic mode of action) that are addressed differently from those with a toxic mode of action. Similarly, risks posed by regulated food/feed additives are generally well characterized and addressed in terms of science and regulation.
- Pesticide residues are being extensively addressed due to the recent legislation, and these activities can be supported through other mechanisms.

Recommendation: All chemical substances in food should be included within the scope of the Council's efforts and its strategic plan, and potentially the annual coordinated budgets. This does not mean, however, that because these substances are in the same category for purposes of this paper that they pose public health risks of the same magnitude, or that they will all be a priority in the strategic plan or for budget initiatives; their inclusion does provide opportunities for better coordination, integration, and resource efficiencies. Further, continued progress on goals and objectives for microbial hazards can be ensured by adding chemical hazard activities slowly on a priority basis to the budget, so that they can be absorbed into the overall FBI work in an orderly fashion (exact timing for budget inclusion to be determined by the Budget Task Force).

Option 2: Miscellaneous Food Constituents There are a number of miscellaneous constituents such as artificial sweeteners, fat substitutes, and other "naturally occurring" substances that serve various functions when added to food. These constituents are not typically considered "chemical hazards", but as components of food products are a candidate for inclusion within the scope.

Reasons to include these miscellaneous food constituents within the "core activities" of the strategic plan are provided below.

- Food processors are examining "new" sources of ingredients (e.g., gums and fibers) for more conventional functional properties and adding them to food; the use of these ingredients raises safety questions.
- Food processors are utilizing macronutrient substitutes (e.g., non-nutritive sweeteners and fat substitutes); since quantities of these substitutes in the diet may be larger than traditional food additives, there are questions about the effect of their use on the quality of the American diet.

Reasons to exclude these miscellaneous constituents from the "core activities" are the following.

- Some may argue that the urgency of the problems with pathogens and chemicals warrants a focus on those hazards; inclusion of these miscellaneous constituents would broaden the scope beyond what may be practical.

- These areas are not likely to be priorities in the plan, and may not need to be addressed at this time.
- Although there are concerns about the effect of these constituents in the American diet, the primary purpose of programs dealing with them is not to reduce foodborne illnesses.

Recommendation: Include this category in the" collateral activities", but do not consider it in developing the strategic plan (and budget) at this time. Although related to food safety, Federal programs dealing with these constituents are not focused on reducing the incidence of acute or chronic foodborne illness due to these products in the food supply. The issue can always be revisited if significant food safety issues arise.

Option 3: Nutrition Programs There are several HAS and USDA programs as well as public-private partnerships designed to define and educate the American people on the benefits of a healthy, nutritious diet. USDA and FDA have developed the food pyramid, which recommends daily quantities of fruits, vegetables, meat and grains. Both agencies also have labeling programs designed to inform the public on the caloric and nutritional content of food. These programs are important in encouraging the consumption of a healthy, nutritious diet which can help to reduce the incidence of both acute and chronic disease.

Some feel that these nutrition programs are aligned with food safety and should be part of the "core activities" for the following reasons.

- The Federal government cannot ensure a healthy and affordable food supply, as outlined in the vision, without consideration of the nutrition programs.
- This would provide an opportunity to develop public health messages about both the nutritional benefits and the infectious/toxicologic hazards associated with various foods.
- Nutrition information could send a positive, constructive message to the American people, making food safety about more than just food contamination and poisoning. Food safety could also be about eating a wholesome, balanced diet to reduce the risk of disease, particularly chronic diseases (e.g., some cancers), and malnutrition.

On the other hand, the nutrition programs might not be considered "core activities" for several reasons.

- Some would argue that the urgency of the problems with pathogens and chemicals warrants a focus on these hazards; consideration of the nutrition programs would broaden the scope beyond what is practical and include areas that do not need attention or funding.
- Inclusion of the nutrition programs could dilute FBI efforts on infectious and toxicologic hazards to the point of ineffectiveness.
- The intent of these programs is to promote healthy eating habits by the American people and reduce the incidence of chronic disease; their primary purpose is not to enhance the safety of the food supply.

Recommendation: Federal programs to define and promote a healthy diet should be considered "collateral activities". They can support and help to implement the vision of a safe, healthy and affordable food supply, but are not designed to ensure food safety.

Option 4: Physical Hazards This includes a diverse set of "foreign" physical hazards in food that can cause serious harm if consumed, including stones, bones, metal chips or parts, and glass. Included also in this category are insect and rodent infestations (e.g., insects in flour, rat droppings). For purposes of this paper, tampering is included here although it is recognized that tampering may include the addition of biological and microbiological agents, as well as chemical or other agents, to foods to intentionally harm the consumer. This category was included in AS' definition of food safety concerns, but received little attention in the report.

Incidents of contamination of food with physical hazards can have significant adverse consequences. Reasons for inclusion in the "core food safety activities" include the following.

- Some physical hazards can result in significant harm to individuals.
- The public perceives contamination with physical hazards as part of the food safety issue.
- USDA and FDA legislation covers control and prevention of physical hazards, and USDA has substantial resources devoted to inspecting for physical hazards.
- These hazards are relatively easy to detect and may be easy to mitigate with limited Federal attention and/or resources.

Reasons to not include physical hazards in the "core activities" are as follows.

- Some may argue that the urgency of the problem with pathogens and chemicals warrants a focus on them.
- Food processors and handlers have numerous safeguards in place to protect against physical hazards and tampering in order to avoid liability and other costs as well as the harmful publicity associated with incidents of easily-detected physical materials in food.
- Partly for the reason cited above and because these hazards generally do not pose a wide-spread threat to public health, some food safety agencies have paid less attention to these hazards. Expanding the scope to include them seems unnecessary and would divert Federal resources from more significant public health problems.
- The food safety system for controlling these hazards is perceived by some to not be broken, with the exception of dealing with tampering and bioterrorism, and thus does not warrant increased attention at this time.

Recommendation: Physical hazards should be included in the "core food safety activities", and addressed in the strategic plan.

Option 5: Waterborne Hazards Water is an essential component of food production, processing and preparation; food production and processing are also a significant source of contamination to the nation's waters. Public water suppliers provide a majority of the drinking water used for washing and final preparation of food, including for use in reconstituted food products available in restaurants and the home. Waterborne hazards include: pathogens in irrigation and other waters used on farms and ranches and that can contaminate food -- sometimes as a result of poor farming practices, in particular mismanagement of animal wastes; pathogens and chemicals in surface or groundwater from point and non-point sources that can contaminate food; microbes and chemicals in public and private water supplies used for food processing and preparation; as well as chemicals and especially pathogens in drinking water

consumed by the public (*Cryptosporidium* in Milwaukee; *E Coli* in Alpine, Wyoming).

There are several reasons to include waterborne hazards as "core" activities in the strategic plan.

- Drinking water is part of the diet and an important component of many final food products (6 of the top 10 foods consumed by Americans are mixed with water before consumption *Is this correct?*).
- Water is used in most food production and manufacturing processes and drinking water is used in food preparation and consumption; use of potable water is a fundamental requirement of all regulations and guidance (GMPs, GAP/GMP guidance for produce, HACCP regulations, and recommended codes -- e.g., Pasteurized Grade A milk code, Food Code).
- Some programs to reduce pathogen contamination of water are already included in the President's Food Safety Initiative, and EPA's research on pathogens to support its water program is in the OSTP research Inventory -- i.e., microbial contamination of water is already in the FBI.
- Inclusion within the scope would provide attention to the important role of irrigation and processing water in food safety.
- There may be public health benefits that can be achieved by inclusion of EPA's water programs within the "core"' scope, since:
  - There is a need to coordinate across the government on research on emerging pathogens in order to ensure efficiency and non-duplication of Federal research (e.g., the agencies share mutual objectives in the areas of risk assessment, health effects, dose response, and analytical methods for pathogens whether in food or water);
  - Irrigation water and animal manures can be a pathway for contamination of food by pathogens; several acute disease outbreaks have occurred from this route (e.g., *Cryptosporidium* in apple juice), and there is a need for coordination of surveillance and inspections; and
  - Several commonly waterborne pathogens are sometimes transmitted by the foodborne route.
- EPA develops fish advisories for locally-caught fish, while FDA develops action levels for commercial seafood; inconsistencies in the action levels/fish advisories might be addressed through these joint efforts.
- Water, whether for consumption by humans or animals, is considered "food" under the Federal Food, Drug, and Cosmetic Act.

However, there are also significant reasons why waterborne hazards should not be included in the "core" activities.

- The purpose of EPA's water programs is to insure fishable, swimmable surface waters and safe tap water for drinking, and not to enhance food safety by reducing acute or chronic illnesses.
- Inclusion of these programs in the food safety initiative could divert EPA from its primary responsibilities under SDWA and CWA, including meeting statutory and judicial deadlines, and may expand the scope beyond what is manageable.

- Tap water that is safe for drinking is also safe for food production, processing and consumption.
- EPA does not regulate water in food production, processing, preparation and consumption, and it has not been a primary concern for EPA.
- The issues related to animal manures and irrigation water would not only bring into the strategic plan a large range of EPA activities but also a suite of programs managed by USDA and the Department. of Interior.
- We already coordinate on regulatory issues via the President's Clean Water Action Plan and via the Animal Feeding Operation Strategy; duplicative coordination is inefficient.
- It will be extremely difficult, if not impossible, to separate EPA's regulation/enforcement water program budget for food safety from the budget for the entire water program.

Recommendation: Water safety should be considered a "collateral activity" which is related to food safety but whose primary mission is not to reduce foodborne illnesses. Collaboration to avoid duplication of research efforts and ensure adequate EPA input into development of FDA and USDA guidelines (e.g., Good Agricultural Practices, Good Manufacturing Practices and the Food Code) is critical but can be accomplished without water being a part of the initial strategic plan.

TABLE 2
FEDERAL ACTIVITIES RELATING TO FOOD SAFETY

Federal Agency	Other Agencies Involved	Activity	Type of Activity	Issues Addressed	Core or Collateral Activity
USDA (Food Safety Activities)					
Food Safety & Inspection Service	FDA EPA CDC	Sets standards for meat, poultry and egg shells shipped interstate; inspects domestic and imported meat and poultry and enforces standards; recalls adulterated products.	Regulation, Inspection, & Enforcement	Pathogens Chemical residues Physical hazards Food quality	Core
Agricultural Marketing Service	EPA	Pesticide data program to monitor and collect pesticide residue information for EPA risk assessment; microbial data program surveillance and monitoring; manages voluntary quality certification program.	Regulatory Support, Monitoring, & Risk Assessment	Pesticides Pathogens Food quality	Core
Agricultural Research Service	EPA FDA	Research (basic) on elimination, mitigation and detection of hazards	Research, & Regulatory Support	Pathogens Chemicals	Core
Cooperative State Research, Education & Extension Service	EPA FDA	Research (applied), outreach, and education on elimination, mitigation, and detection of hazards.	Research, & Regulatory Support	Pathogens Chemicals	Core
Animal & Plant Health Inspection Service	EPA FDA	Regulation of biotechnology and irradiation, methods.	Regulation, Inspection, & Enforcement	Biotechnology Irradiation	Core
Economic Research Service	EPA FDA	Data Interpretation.	Regulatory Support, Guidance, & Risk Assessment	Pesticide uses Chemicals	Core
National Agricultural Statistical Service	EPA FDA	Data collection and monitoring	Regulatory Support, & Risk Assessment		Core

Federal Agency	Other Agencies Involved	Activity	Type of Activity	Issues Addressed	Core or Collateral Activity
Grain Inspection, Packers & Stockyards Administration		Inspect for toxins (e.g., aflatoxin)	Inspection	Toxins	
Office of Risk Assessment & Cost Benefit Analysis	EPA FDA	Data interpretation, guidance, and risk assessment	Regulatory Support, & Guidance		Core
Office of Pest Management Policy	EPA FDA	Data collection, interpretation, guidance, and risk assessment	Regulatory Support, & Guidance	Pesticides	Core
Food & Drug Administration					
Center for Food Safety & Applied Nutrition	USDA EPA CDC		Regulation, Inspection, Enforcement	Pathogens Chemicals Nutrition	Core
Center for Veterinary Drugs	USDA CDC			Animal Drugs	Core
Centers for Disease Control & Prevention					
Centers for Disease Control & Prevention	USDA FDA EPA	Investigates outbreaks of foodborne illness; monitors and collects information on food- and waterborne illnesses; conducts nationwide surveillance for food- and waterborne diseases; designs and implements surveillance systems; performs research on diagnostic and subtyping methods; and training and education.	Surveillance, Monitoring, Research, Training, & Education	Food- and waterborne pathogens FoodNet and PulseNet Infectious disease outbreaks Chemical hazards	Core
U.S. Environmental Protection Agency					

Federal Agency	Other Agencies Involved	Activity	Type of Activity	Issues Addressed	Core or Collateral Activity
Office of Prevention, Pesticides & Toxic Substances	USDA FDA CDC	Regulation of pesticide uses, residues in/on food and antimicrobials for control of pathogens. Supports investigations of certain chemical contamination incidents and regulates chemicals.	Regulation, & Risk Assessment	Pesticides Chemicals	Core
Office of Water	USDA CDC FDA	Regulates drinking water quality and biosolids; establishes discharge standards for facilities. Provides criteria for ambient water contamination, watershed controls, and other pathogen elimination/protection authorities.	Regulation, Guidance, Research & Risk Assessment	Pathogens in water Chemicals in water Animal wastes Other agricultural wastes	Collateral
Office of Research & Development	OSTP USDA FDA	Responsible for research on pesticide testing methods, chemical monitoring methods development, and risk assessment issues; provides technical and scientific advice on risk assessment, and testing and monitoring methods.	Research, Guidance, & Risk Assessment	Chemicals Pesticides Pathogens?	Core (pesticides)
Office of Enforcement & Compliance Assurance	FDA USDA	Ensures that pesticides used on crops/food are registered, are not adulterated, and are used correctly. Ensures that data used to support pesticides registration is not fraudulent. Referrals for possible illegal residues. Collects pesticide production information.	Inspections, Enforcement, Referrals, Regulation, & Risk Assessment Support	Product inspections Use inspections Lab Inspections Pesticide misuse Recalls	Core (pesticides)
Department of Commerce					
National Marine Fisheries Service	FDA	Voluntary inspection program for seafood quality.	Inspection		

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
October _, 1998

Guidance for Industry

Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables

U.S. Department of Health and Human Services
Food and Drug Administration
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GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS FOR FRESH FRUITS AND VEGETABLES

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Guidance for Industry[1]

GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS FOR FRESH FRUITS AND VEGETABLES

PREFACE

Fresh fruits and vegetables are important to the health and well being of the American consumer. Consumers enjoy one of the safest supplies of fresh produce in the world. However, over the last several years, the detection of outbreaks of foodborne illness associated with both domestic and imported fresh fruits and vegetables has increased. In a January 1997 radio address, President Clinton announced a Food Safety Initiative to improve the safety of the nation's food supply (Ref. 1). In May of 1997, as part of the President's Food Safety Initiative, the Department of Health and Human Services, the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA) sent to the President a report that identified produce as an area of concern (Ref. 2). On October 2, 1997, President Clinton announced a plan entitled "Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables" (produce safety initiative) to provide further assurance that fruits and vegetables consumed by Americans, whether grown domestically or imported from other countries, meet the highest health and safety standards (Ref. 3). As part of this initiative, the President directed the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue guidance on good agricultural practices (GAPs) and good manufacturing practices (GMPs) for fruits and vegetables (Ref. 3).

In response to this directive, the FDA and USDA are issuing "Guidance for Industry -- Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." This guidance document ("the guide") addresses microbial food safety hazards and good agricultural and management practices common to the growing, harvesting, washing, sorting, packing, and transporting of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (raw) form. This voluntary, science-based guidance can be used by both domestic and

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[1]This document has been prepared as guidance by the Food and Drug Administration (FDA) and the USDA. This guidance represents the current thinking of FDA and USDA on a number of microbial food safety hazards and on good agricultural and management practices common to the growing, packing, and transport of most fresh fruits and vegetables. It does not create or confer any rights for or on any person and does not operate to bind FDA or USDA or the public. The agencies encourage growers, packers, and shippers to use the general recommendations in this guidance to tailor food safety practices appropriate to their particular operations. An alternative approach may be used if such approach would effectively serve to reduce microbial hazards that could result in foodborne illness and if such approach satisfies applicable statutes and regulations.

foreign fresh fruit and vegetable producers to help ensure the safety of their produce. The voluntary guidance is consistent with U.S. trade rights and obligations and will not impose unnecessary or unequal restrictions or barriers on either domestic or foreign producers.

The produce guide is guidance and it is not a regulation. As guidance and if applied as appropriate and feasible to individual fruit and vegetable production operations, the guide will help to minimize microbial food safety hazards for fresh produce. Because it is guidance, and not a regulation, the guide does not have the force and effect of law and thus is not subject to enforcement. Operators should use the general recommendations in this guide to tailor food safety practices appropriate to their particular operations. In no case do the recommendations in this guide supercede applicable Federal, state, or local laws or regulations for U.S. operators. Operators outside of the U.S. should follow corresponding or similar standards, laws or regulations.

The guide is one of the first steps under the President's produce safety initiative to improve the safety of fresh produce as it moves from the farm to the table. The guide focuses on the production and packing of fresh produce. However, the food safety initiative is not limited to the farm. It will focus on all stages of the farm-to-table food chain. For example, FDA's Food Code provides advice and information to state and local agencies about safe food handling practices in grocery stores, institutions, restaurants, and other retail establishments (Ref. 4). FDA is also actively seeking assistance from the Conference for Food Protection (a consortium of state, local and Federal agencies, academia, and consumer and industry representatives) in identifying practical interventions that may assist in reducing or eliminating microbial contamination of fresh produce at the retail level. In addition, as part of the President's food safety initiative, educational outreach programs, such as the recently initiated "Fight Bac" campaign, will promote improved safe food handling by consumers.

Identifying and supporting research priorities designed to help fill gaps in food safety knowledge is another focus of the food safety initiative.[2] In the longterm, research and risk assessment on fresh produce will be incorporated in the multi-year food safety initiative research planning process. The overall goal of research 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 targeted to sources of contamination.

Growers, packers, and shippers are urged to take a proactive role in minimizing food safety hazards potentially associated with fresh produce. Being aware of, and addressing, the common risk factors outlined in this document will result in a more effective, cohesive response to emerging concerns about the microbial safety of fresh fruits and vegetables. Furthermore, operators should encourage the adoption of safe practices by their partners along the farm-to-table food chain, including transporters of produce, such as distributors, exporters, importers, retailers, food service operators, and consumers, to ensure that each individual effort will be enhanced.

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[2]FDA and USDA, "Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables: Status Report," February 24, 1998.

INTRODUCTION

The importance and influence of the diet on health is undisputed. Several chronic diseases of major public health concern in the U.S., such as coronary heart disease and some types of cancer, are associated with dietary excess or imbalance. Current dietary guidelines from Federal government agencies and nationally recognized health professional organizations recommend decreased consumption of fats (especially saturated fat) and cholesterol, maintenance of desirable body weight, and increased consumption of fruits and vegetables (five or more servings daily) and grain products (six or more servings daily). Recognition of the importance of routine fruit and vegetable consumption, together with the marked increase in the year-round availability of fresh produce from a global market, has contributed to the substantial increase in consumption of fresh fruits and vegetables in the United States over the past two decades.

Whereas the health benefits associated with regular consumption of fresh fruits and vegetables have been clearly demonstrated, an increasing– though still small– proportion of reported outbreaks of foodborne illness are traced to fresh produce (Ref. 15). Recent outbreaks of foodborne illness associated with produce, including *E. coli* O157:H7 in mesclun mix lettuce and *Cyclospora* in imported raspberries, have raised concerns regarding the potential safety of fruits and vegetables that are not subsequently processed to reduce or eliminate pathogens. However, no estimates are available on the incidence and prevalence of foodborne infection associated with the consumption of fresh produce.

Use of This Guide

Because of the diversity of agricultural practices and commodities, practices recommended to minimize microbial contamination will be most effective when adapted to specific operations.

This guide is intended to assist the U.S. and foreign produce industry in enhancing the safety of domestic and imported produce by addressing common areas of concern in the growing, harvesting, sorting, packing, and distribution of fresh produce. The guide identifies the broad microbial hazards associated with each area of concern, the scientific basis of that concern, and good agricultural and management practices for reducing the risk of microbial contamination in fresh produce.

The scientific basis for reducing or eliminating pathogens in an agricultural setting is evolving and not yet complete. Thus, the examples of good agricultural practices and good management practices presented in the guide may not apply to all types of fresh and minimally processed produce and are intended to be implemented where appropriate by all industry operators. Therefore, the examples are intended to build broad industry understanding and awareness of those practices that individual growers, packers, and shippers may consider and incorporate in their own operations. Because of the diversity of agricultural production practices and commodities, procedures recommended to minimize microbial contamination will be most

effective when these general concepts are adapted to specific operations.

Government agencies recognize that the agricultural community has made a significant effort to adjust and adopt good agricultural practices to help minimize microbial food safety hazards in produce. Several fresh fruit and vegetable trade organizations, universities, state and local government agencies, and countries exporting produce to the United States have taken strong leadership roles in assisting growers, packers, and shippers in identifying potential hazards associated with their operations. These efforts have included the development of quality assurance programs, good manufacturing practices, and good agricultural and management practice guidance documents; funding of agriculture research studies; and sponsoring educational initiatives. The intent of the guide is to build on those earlier and continuing efforts and to develop national guidelines to enhance the consistency and scientific basis of food safety initiatives throughout the country.

This document represents generally accepted, broad-based agricultural guidance, developed from current knowledge of food safety practices of FDA, USDA, and others. It was developed in cooperation with experts from several Federal and state government agencies and the fresh produce industry. The guide cannot address all microbiological hazards potentially associated with fresh produce, but it can provide the framework for identifying and implementing appropriate measures most likely to minimize risk on the farm, in the packinghouse, and during transport.

There are several important considerations to remember when using this guide.

1) The guide focuses on microbial hazards for fresh produce. The guide does not specifically address other areas of concern to the food supply or the environment (such as pesticide residues or chemical contaminants). In evaluating the recommendations in this guide that are most appropriate for reducing microbial hazards in their individual operations, growers, packers, and shippers should strive to establish practices that do not inadvertently increase other risks to the food supply or the environment (e.g., excessive packaging or improper use and disposal of antimicrobial chemicals).

2) The guide focuses on risk reduction not risk elimination. Current technologies cannot eliminate all potential food safety hazards associated with fresh produce that will be eaten raw.

3) The guide provides broad, scientifically based principles. Operators should use the guide to help assess microbiological hazards within the context of the specific conditions (climatic, geographical, cultural, economic) that apply to their own operation and implement appropriate and cost effective risk reduction strategies.

4) As new information and technological advances expand the understanding of those factors associated with identifying and reducing microbial food safety hazards, the agencies will take steps (such as revising this guide or providing supplements or additional guidance documents, as appropriate) to update the recommendations and information contained in this guide.

Operators are encouraged to seek additional advice from their state and local Departments of Public Health, Environment, Agriculture, extension services and Federal agencies.

Basic Principles

> ***Use the general recommendations in this guide to develop the most appropriate good agricultural and management practices for your operation.***

This guidance document is based upon certain basic principles and practices associated with minimizing microbial food safety hazards from the field through distribution of fresh fruits and vegetables.

By identifying basic principles of microbial food safety within the realm of growing, harvesting, packing, and transporting fresh produce, users of this guide will be better prepared to recognize and address the principal elements known to give rise to microbial food safety concerns.

Principle 1. Prevention of microbial contamination of fresh produce is favored over reliance on corrective actions once contamination has occurred.

Principle 2. To minimize microbial food safety hazards in fresh produce, growers, packers, or shippers should use good agricultural and management practices in those areas over which they have control.

Principle 3. Fresh produce can become microbiologically contaminated at any point along the farm-to-table food chain. The major source of microbial contamination with fresh produce is associated with human or animal feces.

Principle 4. Whenever water comes in contact with produce, its source and quality dictates the potential for contamination. Minimize the potential of microbial contamination from water used with fresh fruits and vegetables.

Principle 5. Practices using animal manure or municipal biosolid wastes should be managed closely to minimize the potential for microbial contamination of fresh produce.

Principle 6. Worker hygiene and sanitation practices during production, harvesting, sorting, packing, and transport play a critical role in minimizing the potential for microbial contamination of fresh produce.

Principle 7. Follow all applicable local, state, and Federal laws and regulations, or

corresponding or similar laws, regulations, or standards for operators outside the U.S., for agricultural practices.

Principle 8. Accountability at all levels of the agricultural environment (farm, packing facility, distribution center, and transport operation) is important to a successful food safety program. There must be qualified personnel and effective monitoring to ensure that all elements of the program function correctly and to help track produce back through the distribution channels to the producer.

I. DEFINITIONS

The following definitions are applicable to this guidance document.

Agricultural water refers to water used in the growing environment (for example, field, vineyard, or orchard) for agronomic reasons. It includes water used for irrigation, transpiration control (cooling), frost protection, or as a carrier for fertilizers and pesticides. Occasionally a more specific term may be used, such as "irrigation water." Typical sources of agricultural water include flowing surface waters from rivers, streams, irrigation ditches, open canals, impoundments (such as ponds, reservoirs, and lakes), wells, and municipal supplies.

Adequate means that which is needed to accomplish the intended purpose in keeping with good practice.

Clean means that food or food-contact surfaces are washed and rinsed and are visually free of dust, dirt, food residues, and other debris.

Composting refers to a managed process in which organic materials, including animal manure and other wastes, are digested aerobically or anaerobically by microbial action.

Control means (a) to manage the conditions of an operation in order to be consistent with established criteria, and (b) to follow correct procedures and meet established criteria.

Control measure means any action or activity that can be used to prevent, reduce, or eliminate a microbiological hazard.

Facility means the buildings and other physical structures used for or in connection with the harvesting, washing, sorting, storage, packaging, labeling, holding, or transport of fresh produce.

Food-contact surfaces are those surfaces that contact fresh produce and those surfaces from which drainage onto the produce or onto surfaces that contact the produce may occur during the normal course of operations. "Food-contact surfaces" includes equipment, such as containers and conveyor belts that contact fresh produce, used in harvesting, post harvesting, and packing

operations. It would not include tractors, forklifts, handtrucks, pallets, etc. that are used for handling or storing large quantities of contained or packed fresh produce and that do not come into actual contact with the food.

Fresh fruits and vegetables refers to fresh produce that is likely to be sold to consumers in an unprocessed or minimally processed (i.e., raw) form. Fresh produce may be intact, such as strawberries, whole carrots, radishes, and fresh market tomatoes, or cut during harvesting, such as celery, broccoli, and cauliflower. The guidance in this document is also applicable to "fresh cut" produce, such as pre-cut, packaged, ready-to-eat salad mixes. However, some fresh produce specialty items, such as fresh cut produce, may be subject to additional processing steps and/or handling that may warrant consideration of specific good manufacturing practices in addition to the good agricultural and management practices covered in this guidance document.

Good management practices refers to general practices to reduce microbial food safety hazards. The term may include both "good agricultural practices" used in growing, harvesting, sorting, packing, and storage operations and "good manufacturing practices" used in sorting, packing, storage, and transportation operations.

Microorganisms includes yeasts, molds, bacteria, protozoa, helminths (worms), and viruses. Occasionally, the term "microbe" or "microbial" is used instead of the term "microorganism."

Microbial hazard means occurrence of a microorganism that has the potential to cause illness or injury.

Municipal biosolids (biosolids) are the by-product of human waste treatment by local government that may be used as fertilizer or as a soil amendment.

Operator means the person or persons who have day-to-day responsibility for the production, harvesting, washing, sorting, cooling, packaging, shipping, or transportation of fresh fruits and vegetables, and responsibility for management of all employees who are involved in each of these activities.

Pathogen means a microorganism capable of causing disease or injury.

Pest refers to any animal or insect of public health importance including, but not limited to, birds, rodents, cockroaches, flies, and larvae, that may carry pathogens that can contaminate food.

Processing water means water used for post-harvest treatment of produce, such as washing, cooling, waxing, and product transport.

Sanitize means to treat clean produce by a process that is effective in destroying or substantially reducing the numbers of microorganisms of public health concern, as well as other undesirable microorganisms, without adversely affecting the quality of the product or its safety for the

consumer.

Sanitize (food contact surfaces) means to adequately treat clean food-contact surfaces by a process that is effective in destroying or substantially reducing the numbers of microorganisms of public health concern, as well as other undesirable microorganisms, without adversely affecting the quality of the involved product or its safety for the consumer. It means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to reduce populations of representative microorganisms by 5 log or 99.999% (Ref. 4).

Transporter means the operator of a conveyance such as a truck, railcar, vessel, or aircraft used to transport fresh produce from grower to market.

II. WATER

Wherever water comes into contact with fresh produce, its quality dictates the potential for pathogen contamination.

Water use in crop production involves numerous field operations including irrigation, applications of pesticides and fertilizers, cooling, and frost control. Post-harvest uses include produce rinsing, cooling, washing, waxing, and transport. Water of inadequate quality has the potential to be a direct source of contamination and a vehicle for spreading localized contamination in the field, facility, or transportation environments. Wherever water comes in contact with fresh produce, its quality dictates the potential for pathogen contamination. If pathogens survive on the produce, they may cause foodborne illness.

A. Microbial Hazard

Water can be a carrier of many microorganisms including pathogenic strains of *Escherichia coli*, *Salmonella* spp., *Vibrio cholerae*, *Shigella* spp., *Cryptosporidium parvum*, *Giardia lamblia*, *Cyclospora cayetanensis*, *Toxiplasma gondii*, and the Norwalk and hepatitis A viruses. Even small amounts of contamination with some of these organisms can result in foodborne illness.

As discussed in Section V. (Traceback), it is often difficult to identify with certainty the source of microbial contamination for fresh produce. It is not currently known what proportion of produce may become contaminated by water used in agricultural or packing facility operations. However, research has shown that the use of contaminated irrigation water can increase the frequency of pathogen isolation from harvested produce (Refs. 5 and 6). In 1990 and 1993, two outbreaks, involving at least 300 cases in four states attributed to *Salmonella* species, were linked to consumption of fresh tomatoes (Refs. 7 and 8). Tomatoes from both outbreaks were traced back to a single packing facility where a water-bath appeared to be the likely source of contamination. Growers and packers are urged to take a proactive role in minimizing those microbial hazards over which they have some control.

B. Control of Potential Hazards

In general, the quality of water in direct contact with the edible portion of produce may need to be better than the quality of water in which contact with the edible portion of the plant is minimal.

The quality of water, how and when it is used, and the characteristics of the crop influence the potential for water to contaminate produce. In general, the quality of water in direct contact with the edible portion of produce may need to be of better quality compared to uses where there is minimal contact. Other factors that influence the potential for contact with waterborne pathogens, and their likelihood of causing foodborne illness, include the condition and type of crop, the amount of time between contact and harvest, and post-harvest handling practices. Produce that has a large surface area (such as leafy vegetables) and that with topographical features (such as rough surfaces) that foster attachment or entrapment may be at greater risk from pathogens, if they are present, especially if contact occurs close to harvest or during post-harvest handling. Some sectors of the produce industry use water containing antimicrobial chemicals to maintain water quality or minimize surface contamination.

Operators should consider the following issues and practices when assessing water quality and in applying controls to minimize microbial food safety hazards. Not all of the following recommendations will be applicable or necessary for all operations. Rather, growers and packers should select practices, or combinations of practices, appropriate to their operations and the quality of their water supply, to achieve food safety goals.

1.0 Agricultural Water

Water quality should be adequate for its intended use. Where water quality is unknown or cannot be controlled, growers should use other good agricultural practices to minimize the risk of contamination.

Agricultural water quality will vary, particularly surface waters that may be subject to intermittent, temporary contamination, such as waste water discharge or polluted runoff from upstream livestock operations. Ground water that is influenced by surface water, such as older wells with cracked casings, may also be vulnerable to contamination. Practices to help ensure adequate water quality may include ensuring that wells are properly constructed and protected, treating water to reduce microbial loads, or using alternative application methods that reduce or avoid water-to-produce contact. The feasibility of these and other practices will depend on available water sources, the intended water use and the needs and resources of the particular produce operation.

1.1 General considerations

- **Identify the source and distribution of water used and be aware of its relative potential for being a source of pathogens.**
  Typical sources of agricultural water include flowing surface waters from rivers, streams, irrigation ditches, and open canals; impoundments such as ponds, reservoirs, and lakes; groundwater from wells; and municipal supplies. It is generally assumed that groundwater is less likely to be contaminated with high levels of pathogens than surface water. Under certain conditions, shallow wells and improperly constructed or older wells may be under the influence of surface water and thus more likely to be susceptible to contamination.

- **Growers with older wells (e.g., wells constructed 30 – 40 years ago, and especially wells constructed before 1925), or who have other reasons for concern about the condition of their well and possible contamination, may want to have their well examined by a water quality expert.** Programs available from County Extension Offices, and state and local Public Health and Environmental Protection Agencies may help growers determine the condition of their wells.

- **Review existing practices and conditions to identify potential sources of contamination.**
  Agricultural water can become contaminated, directly or indirectly, by improperly managed human or animal waste. Human contamination may occur from improperly designed or malfunctioning septic systems and sewage treatment facility discharges such as combined sewer overflows and storm sewer overflows. Examples of on-site sources of contamination from animal waste are animal pasturing in growing areas; manure storage adjacent to crop fields; leaking or overflowing manure lagoons; uncontrolled livestock access to surface waters, wells, or pump areas; and high concentrations of wildlife. These and other potential sources of water contamination should be assessed and controlled to the extent feasible to minimize microbial food safety hazards.

- **Be aware of current and historical use of land.**
  Agricultural water is frequently a shared resource. In some regions, agricultural water comes from surface waters that travel some distance before reaching the produce growing area. While growers may not have control over factors that affect the watershed, awareness of potential problems helps determine which control options are most appropriate. In assessing water quality, operators should consider what affects their portion of the watershed. Growers may consider questions such as:

  -What is the prevalence of animal production in the region?
  - Do feedlots, animal pastures, and dairy operations in the region use fences or other barriers to minimize animal access to shared water sources?
  - Is manure applied to land by many farms in the region?
  - Do local rainfall patterns and topography impact the likelihood of contaminated runoff from these operations reaching surface waters?

- Are controls generally in place to minimize contamination of agricultural waters from other farm or animal operations?

At the individual field, orchard, or vineyard level, the topography of the land and current and historical use of adjacent lands all affect the potential for water to become contaminated, if pathogens are present, and for spreading pathogens to fruits and vegetables. Growers should evaluate their production areas in terms of their proximity to surrounding land uses that pose a potential for polluted runoff from heavy rainfall.

- **Consider practices that will protect water quality.**
  As mentioned above, growers may not have control over factors that affect the watershed. However, where a potential source of microbial contamination can be identified and controlled, growers should consider practices to protect the quality of agricultural water. Good agricultural practices may include protecting surface waters, wells, and pump areas from uncontrolled livestock or wildlife access to limit the extent of fecal contamination. Soil and water conservation practices such as grass/sod waterways, diversion berms, runoff control structures, and vegetative buffer areas may help prevent polluted runoff water from contaminating agricultural water sources and produce crops.

- **Irrigation water quality and use.**
  There is general scientific agreement that irrigation practices that expose the edible portion of plants to direct contact with contaminated water may increase microbial food safety risks (Ref 10 NACMCF white paper), especially for those crops and regions where irrigation is likely to occur close to harvest. To the extent feasible, growers should follow good agricultural practices that minimize the potential for contaminated water to contact the edible portion of the crop .

  Irrigation needs will vary with crop and region. Growers should first concentrate on protecting and maintaining water quality. However, where water quality is unknown or cannot be controlled, growers may want to consider irrigation practices that minimize contact between water and the edible portion of the crop. Where available and appropriate, growers may want to consider low volume sprays, drip, furrow, or underground irrigation as part of their overall program. Alternative approaches may also be used. Conversely, if knowledge or testing indicates water quality is good (such as water from properly constructed wells or municipal water supplies), the risk of water serving as a direct source of microbial contamination is low, regardless of the type of irrigation system used. Further, for some crops, such as root crops or low growing crops, it may not be possible to effectively minimize contact between irrigation water and the edible portion of the crop.

1.2 Microbial testing of agricultural water.

There are a number of gaps in the science upon which to base a microbial testing program for agricultural water and microbial testing of agricultural water may be of limited usefulness. Growers concerned about water quality should first focus their attention on good agricultural

practices (such as manure management and runoff controls) to maintain and protect the quality of their water sources. Growers interested in testing the microbial quality of agricultural water sources may want to consider the following:

- Growers may elect to test their water supply for microbial contamination on a periodic basis, using standard indicators of fecal pollution, such as *E. coli* tests, which may be performed by commercial, State, or local government laboratories. However, bacterial safety of water does not necessarily indicate the absence of protozoa and viruses.

- Where agricultural water comes from public sources, information on microbial analysis of the water may be available from the local water authority.

- Water quality, especially surface water quality, can vary with time (e.g., seasonally or even hourly), and a single test may not indicate the potential for water to be contaminated. Furthermore, testing water may not reveal specific pathogens if they are present in low numbers. However, appropriate microbiological testing may be useful for confirming water quality concerns in extreme situations (e.g., polluted water source) and in assessing the effectiveness of certain control programs (e.g., clean-up of well water).

- Growers can consult local water quality experts, such as state or local Environmental Protection or Public Health agencies, extension agents or land grant universities, for advice appropriate for individual operations.

2.0 Processing Water

Processing water should be of such quality that it does not contaminate produce.

Water used during the post-harvest handling of fruits and vegetables often involves a high degree of water-to-produce contact. Although water is a useful tool for reducing potential contamination, it may also serve as a source of contamination or cross-contamination. Reusing processing water may result in the build-up of microbial loads, including undesirable pathogens from the crop. Operators should institute practices to ensure that water quality is adequate for its intended use, both at the start and at the end of all post-harvest processes.

2.1 General Considerations

- **Follow good manufacturing practices to minimize microbial contamination from processing water.**

- Water quality needs may vary depending on where the water use falls within the series of processes and whether a particular process is followed by additional cleaning processes. For example, water quality needs may be greater for water used for a final rinse before packaging compared with water in a dump tank where field soil from arriving produce quickly mixes with the water.

- Water quality consistent with U.S. EPA requirements for drinking water, or similar standards, is recommended (Currently, the Total Coliform Rule and the Surface Water Treatment Rule, See Appendix 2 for information on obtaining copies of EPA rules and regulations). While water quality management may vary throughout all operations, packers should follow good manufacturing practices to minimize the potential for the introduction or spread of pathogens via processing water. Water that meets the microbial standards for drinking water is considered "safe and sanitary."

- Where water is reused for a series of processes, it is recommended that whenever possible, water flow counter to the movement of produce through the different unit operations. For example, water might be used first in a final rinse then reused in an earlier unit operation, such as a dump tank.

- Good Manufacturing Practices (GMPs) for water used for food and food contact surfaces in processing facilities are in Title 21 of the Code of Federal Regulations (CFR), sections 110.37(a) and 110.80(a)(1). 21 CFR 110.19 provides an exemption from the requirements in 21 CFR part 110 for establishments engaged solely in the harvesting, storage, or distribution of raw agricultural commodities. However, U.S. operators using water for post-harvest operations in the field or packing facility are encouraged to consider those good manufacturing practices in part 110, that are applicable to their operations. Foreign operators are encouraged to consider corresponding or similar provisions. (See Appendix 2 for information on how to order copies of the CFR.)

- **Consider practices that will ensure and maintain water quality.**
Such practices may include:

- Perform periodic water sampling and microbial testing;

- Change water as necessary to maintain sanitary conditions. Consider developing SOPs (standard operating procedures or sanitary operating plans), including water change schedules, for all processes that use water;

- Clean and sanitize water contact surfaces, such as dump tanks, flumes, wash tanks, and hydrocoolers, as often as necessary to ensure the safety of produce;

- Install backflow devices and legal air gaps, as needed, to prevent contamination of clean water with potentially contaminated water (such as between potable water fill lines and dump tank drain lines; and

- Routinely inspect and maintain equipment designed to assist in maintaining water quality, such as chlorine injectors, filtration systems, and backflow devices, to ensure efficient operation.

Prevention of contamination is preferred over application of antimicrobial chemicals after contamination occurs.

2.2 Antimicrobial Chemicals

Prevention of contamination is preferred over corrective actions once contamination has occurred. However, antimicrobial chemicals in processing water are useful in reducing microbial build-up in water and may reduce microbial load on the surface of produce. Thus, antimicrobial chemicals may provide some assurance in minimizing the potential for microbial contamination.

The effectiveness of an antimicrobial agent depends on its chemical and physical state, treatment conditions (such as water temperature, acidity [pH], and contact time), resistance of pathogens, and the nature of the fruit or vegetable surface. Chlorine, for example, is commonly added to water at 50 - 200 ppm total chlorine, at a pH of 6.0 - 7.5, for post-harvest treatments of fresh produce, with a contact time of 1 - 2 minutes.

Ozone has been used to sanitize wash and flume water in packinghouse operations. Ultraviolet radiation may also be used to disinfect processing water. Chlorine dioxide, trisodium phosphate, and organic acids (such as lactic and acetic acids) have been studied for use as antimicrobial agents in produce wash water, although more research needs to be done. Operators should consider options for water sanitation most appropriate for their individual operations.

- All chemical substances that disinfect wash water and contact food must be used in accordance with FDA and EPA regulations. Operators outside the U.S. should follow corresponding or similar national or regional laws or regulations. (See Appendix 2 for information on obtaining copies of FDA and EPA regulations.)

- Operators should carefully read antimicrobial chemical labels, regulations, and other relevant information. Operators should follow manufacturers' directions for correct mixing of antimicrobial chemicals to obtain effective concentrations and to minimize safety hazards. Operators should not exceed recommended levels and must not exceed allowable levels of antimicrobial chemicals in wash water. Excessive concentrations of antimicrobial chemicals (such as chlorine) can damage equipment, reduce produce quality, be harmful to worker health, and may pose a hazard to consumers.

- Antimicrobial chemical levels should be routinely monitored and recorded to ensure that they are maintained at appropriate concentrations. Other parameters (such as pH, temperature, and oxidation reduction potential [ORP]) that indicate levels of active agents or that affect the effectiveness of the antimicrobial used, should also be monitored and recorded. Operators should establish SOPs for monitoring, recording, and maintaining antimicrobial chemical levels.

- As organic materials and microbial load increases in wash water, the efficacy of antimicrobial chemicals decreases, rendering them inactive against microorganisms. For some operations, filtering recirculating water or using a net to scoop plant material or debris from tank surfaces, may help reduce the build-up of organic material.

-Surface treatments with some antimicrobial chemicals may need to be followed by a clean water rinse to remove any treatment residues.

-Operators should contact chemical companies that sell antimicrobial chemicals for additional technical assistance.

2.3 Wash Water.

Washing fresh produce (also known as surface treatment) can reduce the overall potential for microbial food safety hazards. This is an important step since most microbial contamination is on the surface of fruits and vegetables. If pathogens are not removed, inactivated, or otherwise controlled, they can spread to surrounding produce, potentially contaminating a greater proportion of the produce.

A number of post-harvest processes, such as hydrocooling, use of dump tanks, and flume transport, involve a high degree of water-to-produce contact. Packers should follow good manufacturing practices to maximize the potential for these processes to assist in cleaning produce.

- **Use appropriate wash methods.**

  - Vigorous washing of produce not subject to bruising or injury may increase the likelihood of pathogen removal. Brush washing is more effective than washing without brushes. Brushes used in brush washing must be cleaned frequently.

  - Different methods are used to wash different types of produce, including submersion, spray, or both. Spray wash treatments may be less likely to directly spread microbial contaminants. However, spray wash treatments may spread pathogens by splashing or by aerosol, or on food contact surfaces, such as brushes and utensils. Further, if water is contaminated during washing and then reused, it can be a vehicle for spreading contamination. Therefore, regardless of wash method used, operators are encouraged to follow good management practices that ensure and maintain adequate water quality.

- **Maintain the efficacy of wash treatments.**
  Wash water, even with antimicrobial chemicals, likely reduces but may not eliminate pathogens on the surface of produce. Antimicrobial washes generally reduce microbial populations by 10- to 100-fold. Operators should adopt practices to maintain the efficacy of wash treatments.

  -For some operations, a series of washes may be more effective than a single wash. For example, packers may consider using an initial wash treatment to remove the bulk of field soil from produce followed by additional washes and/or a sanitizing dip and a final fresh, clean water rinse.

- **Consider the wash water temperature for certain produce.**
  - Removing field heat is a primary consideration in maintaining the quality of many types of produce. However, for some types of produce (apples, celery, tomatoes) the temperature of wash water should be greater than that of the produce or a pressure differential results that can cause water to be pulled into the plant material, causing pathogens that may be present on the produce surface or in the water to be internalized. If pathogens are pulled into the produce, washing is unlikely to reduce these pathogens (Refs. 9 and 10). Denser products (such as carrots) do not appear to be affected by water temperature differences. For products that may be susceptible to internalization of pathogens, the recommended temperature differential may be achieved either by heating water or by air cooling produce before immersion.

  - When it is not practical to expose produce to warmer water temperatures, good manufacturing practices to minimize pathogens in the water or on the surface of produce are especially important. Such practices may include using antimicrobial chemicals in the wash water, using spray-type wash treatments instead of submerging produce, and ensuring that both produce and water are clean before produce is submerged.

- **Consider alternative treatments for water-sensitive produce.**
  - Dry cleaning (e.g., brushing, scraping, blowing air) may be used with some produce that cannot tolerate water. In these cases, periodic equipment clean up and sanitation will reduce the potential for cross-contamination.

  - Treatment of produce with ionizing radiation at doses up to 1 kGy (1 kiloGray or 100 krad) is permitted for inhibition of ripening or sprouting, and for insect control (21 CFR 179.26). At these doses, there would also be some reduction in pathogens that may be present. The extent of any reduction will be dependent on the radiation sensitivity of the particular pathogen as well as the actual dose used. For example, doses needed to achieve a 10-fold reduction in Salmonella are typically higher than those needed to achieve the same reduction in *E. coli* O157:H7. The actual effectiveness of any low-dose radiation treatment in pathogen control will, in addition, be strongly dependent on the load initially present.

2.4 Cooling Operations

Various methods are available for cooling produce, including water, ice, and forced air. The method used depends on the fruit or vegetable and the resources of the operator. In most instances, cooling with air (such as vacuum coolers or fans) will pose the lowest risk.

Water and ice used in cooling operations should be considered a potential source of pathogenic contamination. Further, reuse of water to cool continuous loads of produce increases the risk of cross-contamination. For example, contaminated produce from a single container going through a cooling process may result in the build-up of pathogens over time in the cooling water supply. Operators should follow good management practices to ensure that chilling does not introduce food safety hazards. Practices may include the following.

- **Maintain temperatures that promote optimum produce quality.**
  The benefits of chilling to remove field heat and the temperature requirements for optimum keeping quality vary for different types of produce. Adequate refrigeration, in conjunction with crop characteristics, such as pH, is an important safeguard against many pathogens. Further, good quality, intact produce is most resistant to microbial contamination and growth. Thus, maintaining temperatures that promote optimum product quality may reduce the risk of microbial hazards.

- **Maintain air cooling equipment and cooling areas.**
  Air cooling equipment and cooling areas should be periodically cleaned and inspected. Potential sources of contamination should not be located near air intakes.

- **Consider the use of antimicrobial chemicals in cooling water.**
  Antimicrobial chemicals in cooling water may reduce the potential for microbial contamination of produce.

- **Keep water and ice clean and sanitary.**
  Consider periodic microbial testing of chilling water and water used to make ice. Operators should contact ice suppliers for information about the source and quality of their ice. Water in hydrocoolers should be changed as needed to maintain quality.

- **Ice should be manufactured, transported, and stored under sanitary conditions.**

- **Equipment should be clean and sanitary.**
  Chilling equipment, such as hydrocoolers, and containers holding produce during chilling operations should be clean and sanitary. Field soil should be removed as much as possible from produce and containers prior to chilling. Interiors of hydrocoolers should routinely be cleaned and sanitized.

III. MANURE AND MUNICIPAL BIOSOLIDS

Growers should follow good agricultural practices for handling animal manure or biosolids to minimize microbial hazards.

Properly treated manure or biosolids can be an effective and safe fertilizer. Untreated, improperly treated, or recontaminated manure or biosolids used as a fertilizer, used to improve soil structure, or that enters surface or ground waters through runoff, may contain pathogens of public health significance that can contaminate produce. Crops in or near the soil are most vulnerable to pathogens which may survive in the soil. Low growing crops that may be splashed with soil during irrigation or heavy rainfall are also at risk if pathogens in manure persist in the soil. Produce where the edible portion of the crop generally does not contact soil is less at risk of contamination provided that produce that does contact the ground (e.g., windfalls) is not harvested. As with agricultural water, physical characteristics of produce that foster entrapment or attachment also affect risk.

Growers using manure or biosolids need to follow good agricultural practices to minimize microbial hazards. Growers also need to examine their specific growing environment to identify obvious sources of fecal matter that could be a source of contamination.

A. Microbial Hazard

Animal manure and human fecal matter represent a significant source of human pathogens. A particularly dangerous pathogen, *Escherichia coli* O157:H7, is known to originate primarily from ruminants such as cattle, sheep and deer, which shed it through their feces. In addition, animal and human fecal matter are known to harbor *Salmonella, Cryptosporidium,* and other pathogens. Therefore, the use of biosolids and manures, including solid manure, manure slurries, and manure tea, must be closely managed to limit the potential for pathogen contamination.

Growers must also be alert to the presence of human or animal fecal matter that may be unwittingly introduced into the produce growing and handling environments. Potential sources of contamination include use of untreated or improperly treated manure; nearby composting or manure storage areas, livestock, or poultry operations; nearby municipal wastewater or biosolids storage, treatment, or disposal areas; and high concentrations of wildlife in the growing and harvesting environment (such as nesting birds in a packing shed or heavy concentrations of migratory birds, bats, or deer in fields). (See also Sections IV and V regarding worker hygiene and sanitary facilities in produce growing and packing environments.)

B. Control of Potential Hazards

Good agricultural practices for the use of animal manure or biosolids include treatments to reduce pathogens and maximizing the time between application to production areas and harvest of the crops.

1.0 Municipal Biosolids

On July 18, 1991, the Environmental Protection Agency (EPA) published a notice in the **Federal Register** outlining the U.S. policy statements on the beneficial use of biosolids on Federal land, including its use on food crops (56 FR 33186). Requirements for the use of biosolids are set out in Title 40 of the Code of Federal Regulations, part 503 (40 CFR part 503). Part 503 requires either elimination of pathogens or significant reduction of pathogens along with certain restrictions (such as minimum times between the application of biosolids and the harvest of different food or feed crops). Some states also have requirements for the use of biosolids. Growers using biosolids must first meet the requirements of Part 503 and then comply with any additional state requirements. Since animal manure may contain equal or higher levels of certain pathogens, some of which are infectious to humans, growers may want to consider some of the principles behind the Part 503 requirements and consider the appropriateness of adapting these practices to the land application of manure. (See Appendix for information on obtaining 40 CFR part 503.)

The use of biosolids on fields used to produce food crops involves a number of concerns in addition to microbial risk factors (e.g., potentially toxic heavy metals and organic compounds) that are beyond the scope of this document (which focuses on microbial hazards). However, these concerns are addressed in the Part 503 regulation.

Growers may obtain guidance on proper agronomic methods for the use of biosolids from USDA's Natural Resources Conservation Service (NRCS) (formerly the Soil Conservation Service), and Cooperative State Research, Education, and Extension Service (CSREES). For additional technical information on the use of biosolids or manure in crop production, including fruits and vegetables, growers may consult the resources at the end of this section.

2.0 Good Agricultural Practices for Manure Management

Growers should follow good agricultural practices for handling animal manure to reduce the introduction of microbial hazards to produce. Such practices include processes, like composting, that are designed to reduce possible levels of pathogens in manure. Good agricultural practices may also include minimizing direct or indirect manure-to-produce contact, especially close to harvest.

Examples of good agricultural practices for growers to consider are discussed below.

2.1 Treatments to Reduce Pathogen Levels

A variety of treatments may be used to reduce pathogens in manure and other organic materials. Treatment may be performed by the grower using organic materials generated on the

farm or by a supplier. Choice of treatment will depend on the needs and resources of an individual grower or supplier. Treatments may be divided into two groups, passive and active.

2.1.1 Passive treatments.

Passive treatments rely primarily on the passage of time, in conjunction with environmental factors, such as natural temperature and moisture fluctuations and ultraviolet (UV) irradiation, to reduce pathogens. To minimize microbial hazards, growers relying on passive treatments should ensure manure is well aged and decomposed before applying to fields. Holding time for passive treatments will vary depending on regional and seasonal climatic factors and on the type and source of manure. Passive treatments such as aging should not be confused with actively managed treatments such as composting.

2.1.2 Active treatments.

Active treatments generally involve a greater level of intentional management and a greater input of resources compared with passive treatments. Active treatments include pasteurization, heat drying, anaerobic digestion, alkali stabilization, aerobic digestion, or combinations of these.

Composting is an active treatment commonly used to reduce the microbial hazards of raw manure. It is a controlled and managed process in which organic materials are digested, aerobically or anaerobically, by microbial action. When composting is carefully controlled and managed, and the appropriate conditions are achieved, the high temperature generated can kill most pathogens in a number of days. Thus, the risk of microbial contamination from composted manure is reduced compared to untreated manure.

Composting should not be confused with simpler passive treatments such as aging. In general, passive treatments, such as aging, will require a significantly longer period of time to reduce microbial hazards compared to active treatments which expose pathogens to lethal conditions, such as high temperature or high pH. In addition, much of the research on the composting of manure and application of manure to field crops has focused on the effects of different practices on soil fertility and crop quality. Research on pathogen survival in untreated manure, treatments to reduce pathogen levels in manure, and assessing the risk of cross-contamination of food crops from manure under varying conditions is largely just beginning. Some pathogens tolerate higher temperatures than others. In addition, management practices required to achieve the time and temperature necessary to eliminate or reduce microbial hazards in manure or other organic materials may vary depending on seasonal and regional climatic factors (such as ambient temperature and rainfall) and on the specific management practices of an individual operation.

While the agencies do not have sufficient data to make specific time and temperature recommendations that would apply to all composting or other manure treatment operations, good agricultural practices, as discussed below, may reduce the risk of microbial contamination of fresh produce by manure.

2.2 Handling and Application

Review existing practices and conditions to identify potential sources of contamination.

- **Manure storage and treatment sites should be situated as far as practicable from fresh produce production and handling areas.**
  Minimize contamination of produce from manure in open fields, compost piles, or storage areas. Manure storage or treatment sites close to fresh produce fields or packinghouses increase the risk of microbial contamination. Thus, manure storage and treatments sites should be situated as far as practicable from fresh produce production and handling areas. The minimum distance necessary will depend on many factors, including farm layout and the slope of the land, what runoff controls are in place, the likelihood of wind-spread or heavy rainfall, and the quantity of manure and how it is contained.

- **Consider barriers or physical containment to secure manure storage or treatment areas where contamination from runoff, leaching, or wind spread is a concern.**
  Physical containment may include concrete block, soil berms, pits, or lagoons. Practices such as storage on concrete slabs or in clay lined lagoons may reduce the potential of leachate entering groundwater.

- **Consider good agricultural practices to minimize leachate from manure storage or treatment areas contaminating produce.**
  Rainfall onto a manure pile can result in leachate, potentially containing pathogens. Growers may want to consider covering manure piles, such as storing manure under a roof or covering piles with an appropriate covering. Alternatively, growers may consider collecting water that leaches through manure that is being stored or treated. Collecting leachate allows the grower to control its disposal (e.g., on a vegetative grassway) or use (e.g., to control moisture during composting). Leachate may pose a microbial hazard similar to the manure from which it originates. Growers using manure leachate or manure tea in fresh produce production areas should follow good agricultural practices, such as maximizing time between application and harvest, to minimize microbial hazards.

- **Consider practices to minimize the potential of recontaminating treated manure.**
  -Treated manure can be recontaminated by birds and rodents. Covered storage and reducing nearby harborage, like tall grass and debris, may reduce the potential for recontamination.

  -Equipment, such as tractors, that come into contact with untreated or partially treated manure and are then used in produce fields can be a source of contamination. Equipment used to turn compost, and other multiple use equipment that contacts manure, should be cleaned (such as with high pressure water or steam sprays) before it contacts fresh produce. Growers should also be aware of other factors, such as farm layout and traffic flow, that may allow a tractor to drive through manure before entering a produce field.

2.2.1 Untreated Manure

Use of untreated (raw) manure on food crops carries a greater risk of contamination compared with the use of manure that has been treated to reduce pathogens. Growers using untreated manure may need to consider the following good agricultural practices:

- **Consider incorporating manure into the soil prior to planting.**
  Competition with soil microorganisms may reduce pathogens. Incorporating manure into the soil (e.g., prior to planting) may reduce microbial hazards.

- **Applying raw manure, or leachate from raw manure, to produce fields during the growing season prior to harvest is <u>not</u> recommended.**

- **Maximize the time between application of manure to produce production areas and harvest.**
  - In general, the shorter the time between application of raw manure to a production area and harvest of the crop, the greater the risk of pathogens being present in manure or soil and contaminating the crop. Although no one knows for sure how long pathogens can survive in the field or on produce, some researchers have reported that, depending on conditions, pathogens may survive in raw manure for as much as a year or longer (Ref. 11 and 12). Growers should maximize, to the greatest extent possible, the time between application of manure to produce production areas and harvest.

  - Good agricultural practices to maximize the time between manure application and harvest of produce for the fresh market include, but are not limited to, post-harvest application and incorporation, applying raw manure to a fall cover crop to minimize nutrient loss, planning crop rotations where manure is applied to agronomic crops, or to fields planted with crops that are to be cooked or properly heat-processed prior to being delivered to consumers.

  - Additional research is needed to determine how pathogens in manure may spread in the field. However, for some operations, drift, flooding, or runoff from adjacent fields may result in microbial hazards. Growers may consider scheduling application of raw manure on adjacent fields to maximize the time between manure application to those fields and harvest of fresh market produce. Growers may also consider establishing field plans where the fields closest to fresh produce crops are planted with crops that do not receive raw manure.

- **Where it is not possible to maximize the time between application and harvest, such as for fresh produce crops which are harvested throughout most of the year, raw manure should not be used.**

2.2.2 Treated Manure

Natural fertilizers, such as composted manure, and fertilizers containing natural components, should be processed and handled in a manner to reduce the likelihood of introducing pathogens into produce production areas. Composting, appropriate aging, and other treatments may reduce but might not eliminate pathogens in manure. Furthermore, it is unknown to what extent pathogens that survive treatment may regrow in treated manure that is stored before use. Therefore, growers using treated manure may want to consider some of the recommendations made for untreated manure, such as maximizing time between application and harvest. Additional good agricultural practices for handling and application of treated manure follow.

- **Avoid contamination of fresh produce from manure that is in the process of being composted or otherwise treated.**

- **Apply good agricultural practices that ensure that all materials receive an adequate treatment.**
  - The specific requirements of any treatment to reduce pathogens depend on many factors, including types of organic materials being treated, pH, moisture content, process management, the carbon/nitrogen balance of the organic materials, and even climatic factors such as rainfall and temperature.

  - Whatever parameters are selected, growers and manure suppliers should apply good agricultural practices that ensure that all materials receive an adequate treatment, such as thorough mixing and turning outside edges into the center of a compost pile. Cold spots or other pockets that do not receive an adequate treatment can recontaminate the rest of the batch.

- **Growers purchasing manure should obtain a specification sheet from the manure supplier for each shipment of manure containing information about the method of treatment.**

- **Growers should contact state or local manure handling experts for advice specific to their individual operations and regions.** Assistance may be available through agricultural colleges or cooperative extension services.

3.0 Animal Manure

Animal manure is a known source of pathogens that can cause foodborne illness.

While it is not possible to completely exclude all animal life from all fresh produce production areas, many field programs include elements to protect crops from animal damage. Growers should review existing practices and conditions to assess the prevalence and likelihood of significant amounts of uncontrolled deposits of animal feces coming into contact with crops. Good agricultural practices for minimizing hazards from livestock include:

- **Domestic animals should be excluded from fresh produce fields, vineyards, and orchards during the growing season.**
  Depending on the operation, good management practices may include keeping livestock confined (e.g., in pens or yards) or preventing their entry into fields by using physical barriers such as fences.

- **Where necessary, growers should consider measures to ensure that animal waste from adjacent fields or waste storage facilities does not contaminate the produce production areas.**
  Growers should determine whether surrounding fields and farms are used for animal production. Growers may need to consider measures to ensure that animal waste from adjacent fields or waste storage facilities does not contaminate the produce production areas during heavy rains, especially if fresh produce is grown in low-lying fields or orchards. Measures might include physical barriers, such as ditches, mounds, grass/sod waterways, diversion berms, and vegetative buffer areas.

In addition, high concentrations of wildlife (such as deer or waterfowl in a field) may increase the potential for microbial contamination. Control of wild animal populations in the field may be difficult, especially where crop production areas are adjacent to wooded areas, open meadows, and waterways. Federal, state, or local animal protection requirements must also be considered. However, to the extent possible, where high concentrations of wildlife are a concern, growers should consider establishing good agricultural practices to deter or redirect wildlife to areas with crops that are not destined for the fresh produce market.

Helpful Resources:

The NRCS Conservation Practice Standard 317, "Composting Facility" sets out standards for on-farm composting (USDA, SCS, December 1990).

NRCS AWMFH 651.1004(F), Rynk et al., "On Farm Composting Handbook," NRAES-54 North Regional Agricultural Engineering Svc, Cooperative Extension.

R.T. Haug, 1993, "The Practical Handbook of Compost Engineering," Tachnomics Publishing Co., Inc, Lancaster, PA.

"Domestic Septage Regulatory Guidance - A Guide to the EPA 503 Rule," EPA 832-B-92-005, September, 1993.

US EPA, "A Plain English Guide to the EPA Part 503 Biosolids Rule," EPA 1832-R-93-003, Washington DC, 1994.

Environmental Regulation and Technology Control of Pathogens and Vector Attraction Reduction, EPA 1625/1-92/013, December 1992.

IV. WORKER HEALTH AND HYGIENE

Be aware of existing state and Federal regulations regarding standards for worker health, hygiene and sanitation practices during the growing, packing, holding, and transport of human food.

Operators should be aware of and follow applicable standards for protecting worker health established under the Occupational Safety and Health Act. In addition, the U.S. Code of Federal Regulations (CFR) Title 21, Section 110.10 (21 CFR 110.10) prescribes worker health and hygienic practices within the context of GMPs in the manufacturing, packing, or holding of human food. The standards in this section should be considered when establishing hygienic practices appropriate for the agricultural environment (field, packing facility, and transport operations). Operators outside of the U.S. should follow corresponding or similar standards, regulations, or laws for protecting worker health.

A. Microbial Hazards

Infected employees who work with fresh produce increase the risk of transmitting foodborne illnesses.

Past outbreaks of foodborne illness associated with fresh and minimally processed produce have usually been the result of produce becoming contaminated with fecal material. Therefore, operators should place a high priority on ensuring the use of agricultural and management practices that minimize the potential for direct or indirect contact between fecal material and fresh fruits and vegetables. In addition, infectious diseases, accompanied by diarrhea or open lesions, that include boils, sores, or infected wounds, are a source of disease-causing microorganisms.

The importance of food workers understanding and practicing proper hygiene cannot be overemphasized. Workers can unintentionally contaminate fresh produce, water supplies, and other workers, and transmit foodborne illness if they do not understand and follow basic hygienic principles. For example, in 1994, there was a community hepatitis A outbreak in New York among individuals who had consumed bakery foods (Ref. 13). The source of the infection was a baker who contaminated baked goods while applying sugar glaze. In 1995, a foodborne outbreak, culture-confirmed for *Salmonella typhimurium*, occurred in a Minnesota nursing home (Ref. 14). Data from the investigation indicated that the *Salmonella* was likely transmitted by the consumption of mechanically softened foods, possibly contaminated by an infected employee.

B. Control of Potential Hazards

Train all employees to follow good hygienic practices.

1.0 Personal Health and Hygiene

It is important to ensure that all personnel, including those indirectly involved in fresh produce operations, such as equipment operators, potential buyers and pest control operators, comply with established hygienic practices. Operators should consider the following practices.

- **Establish a training program.**
  - All employees, including supervisors, full time, part time and seasonal personnel, should have a good working knowledge of basic sanitation and hygiene principles. The level of understanding needed will vary as determined by the type of operation, the task, and the assigned responsibilities.
  - Each producer should develop a sanitation training program for their employees. Depending on the situation, formal presentations, one-on-one instruction, or demonstrations (example, handwashing) may be appropriate. Depending on the workers' job requirements, periodic refresher or follow-up training sessions may be needed. (Also, see section 2.0 below on training.)
  - If a formalized training program is not practical, such as for part time and seasonal field personnel, the operator or the supervisor should verbally instruct and demonstrate to newly hired workers proper health and hygiene practices, such as proper handwashing techniques.

- **Become familiar with typical signs and symptoms of infectious diseases.**
  - The pathogens *Salmonella typhi*, *Shigella* species, *E. coli* O157:H7, and hepatitis A virus have a high infectivity, which is the ability to invade and multiply in the body, and virulence, which is the ability to produce severe disease. Any worker showing symptoms of an active case of illness that may be caused by any of these pathogens should be excluded from work assignments that involve direct or indirect contact with fresh produce. Workers with diarrheal disease and symptoms of other infectious diseases should not work with fresh produce or the sorting and packing equipment in the packing facility. See the Appendix 1 for more information on symptoms of infectious diseases that can contaminate food. Operators may also want to consult FDA's Food Code (Ref. 4).

  - Operators should instruct employees to report any active case of illness to their supervisor before beginning work. Supervisors should be familiar with the symptoms of infectious diseases so that if symptoms are evident, the supervisor can take appropriate steps.

- **Provide protection from a lesion.**
  A lesion that contains pus, such as a boil or infected wound that is open or draining and that is located on parts of the body that might have contact with produce or produce harvesting, sorting, or packing equipment, increases the risk of contaminating fresh produce. If a worker has a lesion that cannot be effectively covered in such a way to prevent contact with fresh produce or related equipment, the employee should not be working in any aspect with fresh produce, utensils, or other food contact surfaces of equipment.

- **Consider alternative good hygienic practices.**
  Single-service disposable gloves can be an important and effective hygienic practice in combination with handwashing in some circumstances. If gloves are used, be sure they are used properly and do not become another vehicle for spreading pathogens. The use of gloves in no way lessens the need or importance of handwashing and proper hygienic practices.

- **Ensure good hygienic practices are followed by visitors to the farm, packing, or transport facilities whenever they come into contact with fresh produce.**
  Operators should require that product inspectors, buyers, and other visitors comply with established hygienic practices when inspecting produce.

2.0 Training

When providing training for employees, the requirements under the Occupational Safety and Health Act (29 CFR 1910.141, subpart J, and 29 CFR 1928.110) that are applicable to worker health and training should be considered. See Appendix 2 for information on how to obtain a copy of these regulations. Operators outside of the U.S. should follow corresponding or similar standards, regulations, or laws for protecting worker health. Other areas of training to consider include, but are not limited to, the following:

- **The importance of good hygiene.**
  All personnel should understand the impact of poor personal cleanliness and unsanitary practices on food safety. Good hygiene not only protects the worker from illness, but it reduces the potential for contaminating fresh produce which, if consumed by the public, could cause a large number of illnesses.

- **The importance of handwashing.**
  Thorough handwashing before commencing work with produce and after using the toilet is very important. Many of the diseases that are transmissible through food may be harbored in the employee's intestinal tract and shed in the feces. Contaminated hands can also transmit infectious diseases.

- **The importance of proper handwashing techniques.**

Don't assume that workers know how to wash their hands properly. Teach proper handwashing techniques which include the following:

- Handwashing with water. Warm water is more effective than cold water for washing hands;

- Use of soap; and

- Thorough scrubbing (including cleaning under fingernails and between fingers), rinsing, and drying of the hands. Common, or shared, towels should be not be used.

- **The importance of using toilet facilities.**
  Teach all employees the importance of using toilet facilities connected to a sewage disposal system, or properly constructed on-site sanitary pit privies, or latrines to reduce the potential for contaminating fields, produce, other workers, and water supplies. See section V. (Sanitary Facility) for additional information about toilet facilities.

3.0 Customer-Pick Operations and Road-Side Produce Stands

Growers who have a customer-pick operation should consider the good agricultural practices presented in this guide regarding water quality and the use of manure. Growers who allow the public to pick their own fruits or vegetables in the field or who sell their own produce directly to customers should also consider the following good agricultural practices.

- **Promote good hygienic practices.**
  Encourage customers to wash hands. Provide convenient, properly equipped handwashing stations in the field. Handwashing stations should be equipped with a basin, water, liquid soap, sanitary hand drying devices (such as single-use paper towels), and a waste container.

- **Provide clean, properly supplied, and convenient toilets for customer use.**
  Provide an adequate supply of toilet paper.

- **Promote good handling/processing practices.**
  Encourage all customers to thoroughly wash all fruits and vegetables to be eaten raw.

V. SANITARY FACILITIES

A. Microbial Hazards

Operations with poor management of human and other wastes in the field or packing facility can significantly increase the risk of contaminating produce.

B. Control of Potential Hazards

Operators should operate their facilities or farms in accordance with the laws and regulations that describe field and facility sanitation practices. The field sanitation laws prescribed under the Occupational Safety and Health Act 29 CFR 1928.110, subpart I, describe the appropriate number of toilets to the number of workers, proper handwashing facilities, maximum worker-to-restroom distance, and how often such facilities should be cleaned. Good field sanitation helps reduce the potential for contaminating produce and ensures that employees and consumers are protected from foodborne diseases.

OSHA standards under 29 CFR 1910.141, subpart J, provide regulations relative to toilet facilities and other sanitation issues. Enclosed packing facilities come under these regulations.

In addition, the CFR prescribes current good manufacturing practices for buildings and facilities, equipment, and production and process controls for foods (21 CFR 110.20 to 110.93), and is a good resource to guide the development of mitigation programs. Packers should also consider application of food service type standards, such as found in FDA's Food Code (Ref. 4), in packing facility environments.

Operators outside of the U.S. should follow corresponding or similar standards, regulations, or laws regarding field and facility sanitation practices. See appendix 2 for information on how to obtain copies of the OSHA and FDA regulations.

1.0 Toilet Facilities and Handwashing Stations

- **Toilet facilities should be accessible.**
  The more accessible the facilities, the greater the likelihood that they will be used. Workers should always have the opportunity to use the facilities when they need to, not only when they are on break. This helps reduce the incidence of workers in the field or outside packing areas relieving themselves elsewhere (such as in fields).

- **Toilet facilities should be properly located.**
  Toilet facilities in the field should not be located near a water source used in irrigation or in a location that would subject such facilities to potential runoff in the event of heavy rains. Runoff from improperly constructed and located toilet facilities has the potential to contaminate soil, water sources, produce, animals, and workers.

- **Toilet facilities and handwashing stations should be well supplied.**
  Provide an adequate supply of toilet paper. Handwashing stations should be equipped with a basin, water, liquid soap, sanitary hand drying devices (such as disposable paper towels), and a waste container.

- **All facilities should be kept clean.**
  Toilets and handwashing stations, whether attached to the toilet facility or located near it, should be cleaned on a regular basis. Containers used to transport or store water for handwashing should, on a routine basis, be emptied and thoroughly cleaned, sanitized, and refilled with potable water.

2.0 Sewage Disposal

Improper disposal of human waste from toilets could lead to water, soil, animal, crop, or worker contamination. Systems and practices should be in place to ensure safe management and disposal of waste from permanently installed or portable toilets to prevent drainage into the field. Operators should follow EPA regulations for the use or disposal of sewage sludge, 40 CFR Part 503, or refer to EPA's "Domestic Septage Regulatory Guidance: A Guide to the EPA Part 503 Rule," or corresponding or similar standards, regulations, or laws for international operators. See Appendix 2 for information on how to obtain a copy of U.S. regulations. Examples of good practices to consider are as follows:

- **Use caution when servicing portable toilets.**
  Waste water from portable toilet facilities that may drain into a field can contaminate fresh produce. Sewage transport trucks need direct access to toilet facilities to ensure proper collection and disposal of wastes through a municipal sewage system or a sub-surface septic tank system.

- **Have a plan for containment and treatment of any effluent in the event of leakage or a spill.**
  Operators should be made aware and be prepared in the event of any incidence of leakage or spillage of effluent in a field. Refer to 40 CFR Part 503 for additional guidance.

VI. FIELD SANITATION

Poor management of human and other wastes in the field can significantly increase the risk of contaminating produce.

A. Microbial Hazards

Microbial contamination or cross-contamination of fresh produce during pre-harvest and harvest activities may result from contact with soils, fertilizers, water, workers, and harvesting equipment. Any of these may be a source of pathogenic microorganisms.

Sections II and III of this guidance document address the concerns associated with water quality and use of manure and municipal biosolids. Sections IV and V address the importance of worker health and hygiene and sanitary facilities. Section VII provides general guidance for packing facilities.

B. Control of Potential Hazards

1.0 General Harvest Considerations

- **Clean harvest storage facilities prior to use.**
  Facilities used to store fresh produce should be cleaned and, as necessary, disinfected prior to harvest. These facilities should also be inspected for evidence of pests, such as rodents, birds, and insects. (See section VII. B 3.0 for guidance on pest control.)

- **Discard damaged containers that are no longer cleanable in an effort to reduce possible microbial contamination of fresh produce.**

- **Clean containers or bins before using to transport fresh produce.**
  Containers used to transport ready-to-eat produce should be routinely cleaned and sanitized.

- **Ensure that produce that is washed, cooled, or packaged in the field is not contaminated in the process.**
  Contact with manure or biosolids, poor quality water, workers with poor hygiene, and unclean packaging or packing boxes greatly increases the risk of contaminating fresh produce with pathogenic microorganisms.

- **Remove as much dirt and mud as practicable from the produce before it leaves the field.**
  Removing mud from fresh produce when fields are muddy may not be practical. At such times, adhering mud would have to be removed at the packing facility prior to sorting, grading, and packing.

2.0 Equipment Maintenance

Field equipment, such as harvesting machinery, knives, containers, tables, baskets, packaging materials, brushes, buckets, etc., can easily spread microorganisms to fresh produce. Operators should consider the following guidelines:

- **Use harvesting and packing equipment appropriately and keep it as clean as practicable.**
  Any equipment used to haul garbage, manure, or other debris should not be used to haul fresh produce or contact the containers or pallets that are used to haul fresh produce without first being carefully cleaned and sanitized.

- **Keep harvest containers clean to prevent cross-contamination of fresh produce**
  Harvest containers used repeatedly during a harvest should be cleaned after each load is delivered and prior to reuse. If the containers are stored outside, they should be cleaned and sanitized before being used to haul fresh produce.

- **Assign responsibility for equipment to the person in charge.**
  The person with assigned responsibility needs to know how equipment is being used during the day, ensure that it is functioning properly, and take steps to ensure proper cleaning and sanitizing of equipment when needed.

VII. PACKING FACILITY SANITATION

It is important to maintain buildings, fixtures, and other physical facilities, and their grounds, in good condition to reduce the potential for microbial contamination of produce.

A. Microbial Hazard

Operations with poor sanitation in the packing environment can significantly increase the risk of contaminating fresh produce and water used on produce. Pathogenic microorganisms may be found on the floors and in the drains in the packing facility and on the surfaces of sorting, grading, and packing equipment. Without good sanitary practices, any of these surfaces that come in contact with fresh produce could be a potential source of microbial contamination. Packers should employ good sanitation practices as a standard operating procedure to maintain control throughout the packing operation.

B. Control of Potential Hazards

1.0 General Packing Considerations

- **Remove as much dirt and mud as practicable from fresh produce outside of packing facilities or packing areas.**
  Take additional care to protect fresh field-packed produce from possible contamination because of possible exposure to manure and animal fecal material in the soil. Operators of open packing facilities should also be aware of potential contamination from airborne contaminants from any nearby livestock or poultry areas or manure storage or treatment facilities.

- **Repair or discard damaged containers.**
  Inspect containers for damage on a regular basis. Because damaged container surfaces may harbor pathogenic microorganisms and cause damage to the surface of fresh produce, they should not be used.

- **Clean pallets, containers or bins before using to transport fresh produce.**
  Operators might set aside an area in the receiving yard to clean pallets and containers used for whole fresh fruits and vegetables. Containers used for ready-to-eat fresh produce should be cleaned and sanitized. Care must be taken when packing produce in the field not to contaminate containers or bins by exposure to soil and manure.

- **Protect unused cleaned and new packing containers from contamination when in storage.**
  Packing containers and other packing materials that are not used right away should be stored in a way that protects them from contamination by pests (such as rodents), dirt, and water condensing from overhead equipment and structures. If packing containers are stored outside the packing facility, they should be cleaned and sanitized before use.

2.0 General Considerations for Facility Maintenance

Packing and storage facilities should always be maintained in a clean condition. Equipment used in sorting, grading, and packing fresh produce should be of such material and workmanship as to be adequately cleanable. The design, construction, use, and general cleanliness of equipment can help reduce the risk of cross contamination of produce. Operators or growers should consider the following practices:

- **Keep equipment or machinery that comes in contact with fresh produce as clean as practicable.**
  All sorting, grading, and packing equipment that makes contact with fresh produce may serve as a vehicle for spreading microbial contamination. Remove mud and debris from processing equipment daily. Equipment such as knives, saws, blades, boots, gloves, smocks, and aprons should be cleaned, inspected for defects that make them uncleanable on a regular basis, and replaced as needed.

- **Clean packing areas at end of each day.**
  As necessary, clean and sanitize the washing, grading, sorting, and packing lines to reduce the potential for microbial contamination of fresh produce.

- **Maintain the cooling system to ensure proper functioning of the equipment.**
  Inspect all cooling equipment daily, remove all debris, and clean as necessary when in use.

- **Clean product storage areas regularly.**
  Remove, as much as practicable, all visible debris, soil, dirt, and unnecessary items from product storage areas on an ongoing basis. Clean these areas on a regularly scheduled and "as needed" basis and take steps to minimize free-floating dust and other airborne contaminants.

3.0 Pest Control

All animals, including mammals, birds, reptiles, and insects, are potential sources of contamination in produce environments because they harbor, or could be a vector for, a variety of pathogenic agents, such as *Salmonella*. In general, pest problems can be minimized by taking precautions, such as:

- **Establish a pest control system.**
  For all facilities, establish a pest control program to reduce the risk of contamination by rodents and other animals. The program should include regular and frequent monitoring of affected and treated areas to accurately assess the program's effectiveness.

- **Maintain the grounds in good condition.**

- Grounds in the immediate vicinity of all packing areas should be kept clear of waste, litter, and improperly stored garbage. Keep all grasses cut to discourage the breeding, harboring, and feeding of pests, such as rodents and reptiles.

- Remove any unnecessary articles, including old and inoperative equipment that is no longer used, to eliminate areas that harbor rodents and insects.

- Clean daily to remove product or product remnants that attract pests in and around the packing facility and any other packing facility where product is handled or stored.

- Maintain adequate surface drainage to reduce breeding places for pests.

- **Monitor and maintain facilities regularly.**
  - Regularly inspect all facilities to check for evidence of pest populations or animal contamination. Minimize the availability of food and water to pests.

  - Remove dead or trapped birds, insects, rodents, and other pests promptly to ensure clean and sanitary facilities and to avoid attracting additional pests.

  - As much as practicable, ensure that potential nesting or hiding places for pests have been eliminated.

  - Clean surfaces soiled by birds or other wildlife.

- **Block access of pests into enclosed facilities.**
  Exclude pests by blocking areas, such as holes in walls, doors, flooring, etc., and vents that allow entrance into the facility. Consider the use of screens, wind curtains, and traps.

- **Use a pest control log.**
  Maintain a pest control log that includes dates of inspection, inspection report, and steps taken to eliminate any problems. Establish frequent monitoring of affected and treated areas to determine the effectiveness of the treatment applied.

VIII. TRANSPORTATION

The proper transport of fresh produce from farm to market will help reduce the potential for microbial contamination.

Operators and others involved in the transport of fresh produce are encouraged to scrutinize product transportation at each level in the system, which includes transportation from the field to the cooler, packing facility, and on to distribution and wholesale terminal markets or

retail centers. The proper transport of fresh produce helps reduce the potential for microbial contamination. An active and ongoing discussion with personnel responsible for transportation is essential for ensuring the success of any management program designed to deliver safe foods to the consumer.

A. Microbial Hazard

Microbial cross-contamination from other foods and nonfood sources and contaminated surfaces may occur during loading, unloading, storage, and transportation operations.

B. Control of Potential Hazards

Wherever produce is transported and handled, the sanitation conditions should be evaluated. Transporters should separate fresh produce from other food and nonfood sources of pathogens in order to prevent contamination of the produce during transport operations.

1.0 General Considerations

- **Workers involved in the loading and unloading of fresh produce during transport should practice good hygiene and sanitation practices.**
  See Section IV for more information about good hygienic practices.

- **Product inspectors, buyers, and other visitors should comply with established hygienic practices, such as thoroughly washing their hands before inspecting produce.**

2.0 General Transport Considerations

Growers, packers, shippers, brokers, exporters, importers, retailers, wholesalers and others involved in the transport of fresh produce should help ensure that sanitation requirements for trucks or other carriers are met at the different steps within the transportation chain. Some specifics to consider are:

- **Inspect trucks or transport cartons for cleanliness, odors, obvious dirt or debris before beginning the loading process.**

- **Keep transportation vehicles clean to help reduce the risk of microbial contamination of fresh produce.**
  Operators should be aware of prior loads carried in a transport vehicle and take this information into consideration when determining use of a vehicle. Trucks that were recently used to transport animals or animal products, for example, would increase the risk of contaminating fresh produce if the trucks were not cleaned before loading produce. Consult local or state agencies or universities to determine the most appropriate cleaning and sanitization methods for individual operations.

- **Maintain proper temperatures to help ensure both the quality and safety of fresh produce.**
  Operators should work with transporters to ensure adequate control of transport temperatures from the loading dock to the receiving dock. Transporters should be aware of temperature requirements for produce being hauled and avoid delivery of mixed loads with incompatible refrigeration requirements.

- **Load produce in trucks or transport cartons in a manner that will minimize damage.**
  All fresh produce should be carefully loaded in trucks or transport cartons in a manner designed to minimize physical damage to the produce and to reduce the potential for contamination during transport. Produce should also be loaded so as to allow proper refrigerated air circulation.

IX. TRACEBACK

The ability to identify the source of a product can serve as an important complement to good agricultural and management practices intended to minimize liability and prevent the occurrence of food safety problems.

Traceback is the ability to track food items, including fresh produce, back to their source (growers, packers, etc.). A system to identify the source of fresh produce cannot prevent the occurrence of a microbiological hazard that may lead to an initial outbreak of foodborne disease. However, the ability to identify the source of a product through traceback can serve as an important complement to good agricultural and management practices intended to prevent the occurrence of food safety problems. Information gained from traceback investigation may also be useful in identifying and eliminating a hazardous pathway.

Overview of the traceback process

Food items suspected of causing outbreaks of illness are typically identified through epidemiological studies. Once an outbreak is suspected, public health officials begin scientific studies to determine common food items consumed during the period of infection for the pathogen. If these epidemiological studies implicate a particular food product and hazard analysis shows that other contributing causes were not to blame (for example, cross-contamination, ill food workers, other sources of infectious agent, etc.), health officials attempt to obtain the following information:

1. At the Point of Service establishment (where the product was sold or prepared), pertinent product identifying information, including product types, packaging, labeling, and lot numbers, if applicable, is obtained. Health officials also determine when the product was

purchased or prepared, and determine receiving, stock rotation, inventory, handling and shipping procedures. Records are collected about suppliers and shipments of the implicated product to the Point of Service over the shelf life of the implicated product.

2. Data relating to distribution of the implicated product is charted and analyzed. This analysis is accomplished either by tracing lot numbers, if they are available; or using a Shipment Delivery Time Line to identify suspect shipments, based on knowledge about the time period when the implicated product is useable and salable during the infection period.

3. Distributor interview, data collection, and analysis are repeated for each level of distribution until health officials identify the source of the product.

Depending on the pathogen involved, and the suspected food source, there can be wide variations in the reliability of the data obtained from such studies. In most instances in the fresh produce industry, lot numbers/grower identifications are not commonly used or recorded on receipt/shipping records. Public health investigators must rely on record review and interviews. This method increases the time and resources necessary to trace an implicated product back to its source. Further, review of records that may not be complete and interviews with people whose memories may be imperfect make it more difficult to narrow down the cause(s) of an outbreak.

Challenges facing the produce industry

Fresh produce with a relatively short shelf life is often gone by the time an outbreak is reported, making it extremely difficult to identify the item causing foodborne illness. If fresh produce is linked to an outbreak, current industry practices in the marketing and distribution systems, such as using recycled shipping crates and co-mingling during distribution or at retail, make a direct identification of the source of a product very difficult. If an implicated source (for example, a field or packing facility) is identified, the source of contamination may no longer be present when investigators arrive on the scene. This variability and lack of a direct determination of cause have resulted in a high degree of uncertainty, and, in some cases, false associations. The economic burden of a false association is especially troublesome for those industry segments that may later be proven not to have been involved in the actual outbreak.

Advantages of an effective traceback system

Despite the best of efforts by food industry operators, food may never be completely free of microbial hazards. However, an effective traceback system, even if only some items carry identification, can give investigators clues that may lead to a specific region, packing facility, even field, rather than an entire commodity group. Narrowing the potential scope of an outbreak could lessen the economic burden on those industry operators not responsible for the problem.

From a public health perspective, improving the speed and accuracy of tracing implicated food items back to their source may help limit the population at risk in an outbreak. Rapid and effective traceback can also minimize the unnecessary expenditure of valuable public health resources and reduce consumer anxiety. Tracing implicated food items may also help public

health officials to determine potential causes of contamination, thereby providing data for growers, shippers, and others for identifying and minimizing microbial hazards.

Instituting effective traceback systems

Because of the diversity of handling practices throughout the produce distribution and marketing chain, a traceback system may be more easily implemented for some commodities. For example, traceback systems may be more easily implemented for larger operations that have more direct control over a greater number of steps in the growing/packing/distribution chain. However, industry associations, growers, and operators are encouraged to consider ways to provide this capability, where feasible.

Operators should examine current company procedures and develop procedures to track individual containers from the farm, to the packer, distributor, and retailer, in as much detail as possible. At a minimum, an effective traceback system should have documentation to indicate the source of a product and a mechanism for marking or identifying the product that can follow the product from the farm to the consumer. Documentation should include:

a. Date of harvest,

b. Farm identification, and

c. Who handled the produce from grower to receiver.

Many growers, especially smaller operations, have little control over what happens to produce after it enters the distribution and marketing chain. Therefore, it is critical that growers, packers, and shippers work with their partners in transportation, distribution, and retail to develop technologies that allow grower/packing facility identification to follow fresh produce from the grower to the retailer and consumer. Some industry trade groups are developing technologies (such as bar codes, stamps, stickers, tags, etc.) to identify the source of produce and software to assist retailers in providing more accurate traceback to the grower/packer level.

X. CONCLUSION

Once good agricultural practices are in place, it is important to ensure that the process is working correctly.

Protecting the safety of the U.S. food supply requires a comprehensive and coordinated effort throughout the food production and transportation system. The responsibility to safeguard our food supply is shared by everyone involved, from the grower to the consumer. This includes growers, farm workers, packers, shippers, transporters, importers, wholesalers, retailers, government agencies, and consumers.

This guidance document provides some basic principles and recommended practices for operators to consider that will help minimize microbial food safety hazards in the production, packing, and transport of fresh fruits and vegetables. While research is ongoing and will continue to provide new information and improved technologies, the industry is urged to take a proactive role to minimize those microbial hazards over which they have control. Operators are encouraged to utilize this guide to evaluate their own operations and assess site-specific hazards

so they can develop and implement reasonable and cost effective agricultural and management practices to minimize microbial food safety hazards.

As outlined in this guide, analyzing the risk of microbial contamination includes a review of five major areas of concern. These involve: 1) water quality, 2) manure/municipal biosolids, 3) worker hygiene, 4) field, facility, and transport sanitation, and 5) traceback. Growers, packers, and shippers should consider the variety of physical characteristics of produce and practices that affect the potential sources of microbial contamination associated with their operation, and decide on which combination of good agricultural and management practices are most cost effective for them.

Once good agricultural and manufacturing practices are in place, it is important that the operator ensure that the process is working correctly. Operators should followup with supervisors or the person in charge to be sure that regular monitoring takes place, equipment is working, and good agricultural and management practices are being followed. Without accountability to ensure the process is working, the best attempts to minimize microbial food safety hazards in fresh fruits and vegetables are subject to failure.

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Appendix 1

A wide range of communicable disease and infections may be transmitted by infected employees to consumers through food or food utensils. An important part of an on-going program to ensure the safety of fresh produce is to institute a system of identifying employees who present a risk of transmitting foodborne pathogens to fresh produce or to other employees. Below is a partial list of infectious and communicable diseases that are transmitted through food.

Pathogens Often Transmitted by Food Contaminated by Infected Employees*

1. Hepatits A virus	Fever, Jaundice
2. *Salmonella typhi*	Fever
3. *Shigella* species	Diarrhea, Fever, Vomiting
4. Norwalk and Norwalk-like viruses	Diarrhea, Fever, Vomiting
5. *Staphylococcus aureus*	Diarrhea, Vomiting
6. *Streptococcus pyogenes*	Fever, Sore throat with fever

The symptoms of diarrhea, fever, and vomiting are also symptoms of several other pathogens occasionally transmitted by food contaminated by infected employees.

*1997 Food Code (Ref. 4)

Appendix 2

Helpful Information

1. How to obtain FDA regulations

Title 21, Code of Federal Regulations: 21 CFR 100-169 and 21 CFR 170-199

Sections of Title 21, such as 21 CFR 110.10, that are referenced in the guide can be viewed and printed from the WWW at the following address: www.access.gpo.gov/nara/cfr/.

You may purchase 21 CFR 100-169 or 21 CFR 170-199 from the U.S. Government Printing Office or by telephone purchase at (202) 512-1800. FDA regulations may also be purchased at local branches of the U.S. Government Printing Office Bookstores. Information on location of regional branches is available on the WWW at the following address: http://vm.cfsan.fda.gov/~lrd/ob-reg.txt.

2. How to obtain OSHA standards

OSHA General Industry standards, Title 29 CFR 1910, and OSHA Agricultural Industry standards, Title 29 CFR 1928, may be purchased through a U.S. Government Printing Office or by telephone purchase at (202) 512-1800. 29 CFR 1910.141 and 29 CFR 1928.110, that are referenced in the guide may be viewed and printed from the WWW at the following address: http://www.osha-slc.gov/OshStd_toc/OSHA_Std_toc.html.

3. How to obtain EPA regulations

EPA regulations may be obtained by contacting the U.S. EPA/NCEPI, P.O. Box 42419, Cincinnati, OH 45242-2419. Telephone: 1-800-490-9198; FAX (513) 489-8695. You must give the EPA catalog number for the publication (see below).

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Mr. Gore's Phone Calls—Again

ATTORNEY GENERAL Janet Reno has, once again, opened a 90-day preliminary investigation under the independent counsel law related to Vice President Gore's spree of dialing-for-dollars from his White House office. To be exact, she now is examining whether Mr. Gore made false statements concerning the 1995 phone solicitations the last time she conducted a preliminary investigation to determine whether an independent counsel should examine the matter.

The issue the last time around hinged, to some extent, on what kind of money Mr. Gore had solicited. The law against soliciting campaign contributions on federal property does not apply to unregulated "soft money" donations, which are technically not federal campaign contributions at all. So as long as Mr. Gore was raising only soft money, he was in the clear even if—as subsequently happened—some of that money ended up being diverted by the Democratic National Committee into hard-money accounts.

Mr. Gore, who was interviewed by investigators during the last preliminary investigation, insisted that he believed he was raising only soft money. And in December, Ms. Reno declined to appoint an independent counsel when she found that there was "clear and convincing evidence" that he had not asked for hard money. But Ms. Reno went further, noting that even if he had, it wouldn't, *in itself*, be prosecutable: "[T]he established policy of the Department of Justice requires the presence of aggravating circumstances before a prosecution of [this type] is warranted, and there is no evidence of any such circumstance here."

The recent disclosure of a memorandum suggesting Mr. Gore may have known he was bringing in hard money does not appear to have caused the Justice Department to reexamine the phone calls themselves. The vice president's possible misstatements alone may not constitute an "aggravating circumstance," so Mr. Gore could well be safe from further trouble on the question of which phone can be used to raise what money from whom.

But the issue of lying to investigators is never trivial. It is one the Justice Department has had some trouble settling definitively in other preliminary investigations in the past. Unless the department can show clear and convincing evidence that Mr. Gore did not knowingly make false statements, the matter will have to be resolved by an independent counsel.

Ms. Reno received quick criticism for lopping off a piece of the campaign finance matter for further review under the independent counsel law. In our judgment, she did the right thing. Whatever one thinks about whether the whole campaign finance imbroglio should be handled outside of her department, the question of whether Mr. Gore made false statements to investigators is a separate matter that can and should be examined on its own terms.

Who's Watching the Beef?

FOOD SAFETY inspection always has been a patchwork of programs and agencies. As the food supply becomes more global, as new bacteria emerge and as American eating habits get more varied, the patchwork keeps getting messier. A new report from the National Academy of Sciences on the food safety system counts 35 major statutes and 12 "primary" agencies involved in keeping food safe, including the Food and Drug Administration, the Centers for Disease Control and parts of the Agriculture, Commerce and Health and Human Services departments.

Partly in response to this confusion, the president has just issued an executive order creating a President's Council on Food Safety—chaired by HHS Secretary Donna Shalala, Agriculture Secretary Dan Glickman and science adviser Neal Lane—that will try to pull all these threads together and maybe even reallocate their famously lopsided and overlapping budgets. But the president has another reason for pushing ahead on food safety issues: They have repeatedly proved to be a political winner, one of those areas where virtually no public sentiment can be detected for weakening or dismantling government protections.

On the contrary, with periodic news of tragedies such as the new E. coli strain that can contaminate uncooked hamburgers, there are signs of support even for cautious expansion in food safety, at least if it's done in a way that solves, rather than exacerbates, the underlying tensions that impede cooperation. One longstanding complaint is the built-in conflict between promoting and regulating the meat and poultry issues at the Agriculture Department, which has by far the most resources for inspection; the FDA, with a more varied industry to police, has fewer.

In its budget this year, the administration asked for a chunk of new money that the FDA and others could use for food safety research and modernization. House and Senate appropriations committees rebuffed the proposal, but the Senate, in another surprise showing of the issue's appeal, added $66 million of a requested $100 million in floor debate. Whether or not new money comes through, the presidential council could offer some guideposts for the more scientifically based system the science academy's report calls for. U.S. food inspection, it says, "has many of the attributes of a highly effective system"; it just needs a better grounding in science-based tools and consistent risk analysis, and it needs to cut down on archaic and conflicting practices and on overlaps between different agencies' inspections. These are prescriptions too sensible to be treated as partisan.

The Washington Post

FRIDAY, AUGUST 28, 1998

Saddam Wins

TWENTY-TWO DAYS have now passed without United Nations inspections of Saddam Hussein's weapons-making capabilities. That is 22 days during which he could work unimpeded to develop chemical, biological and nuclear arms. This is a dictator who has used chemical weapons, on his own people and on his enemies, and who would use them again. Yet his defiance of the United States and the United Nations goes unchallenged. On Tuesday one of the most tenacious U.N. inspectors, Scott Ritter, resigned rather than participate in what he called "the illusion of arms control." And for most of a year, we now know, the Clinton administration has been working to rein in the inspectors.

The United States, in other words, has abandoned a policy, in place since the end of the Persian Gulf War, of insisting on aggressive arms inspections to deny Iraq's dictator his weapons of mass destruction. The new policy, although the Clinton administration will not openly acknowledge it as such, seems to be one of deterrence and containment. In other words, as Defense Secretary William Cohen said, "if he [Saddam Hussein] takes any action to reconstitute his weapons of mass destruction, or disrupts the stability or peace in the region," then the United States reserves the right to use force.

The search for a new policy, after last winter's standoff, is understandable. Few analysts inside or outside the government then were sanguine about the ability to achieve U.S. goals through the use of force. Allied support was minimal. But the new policy inevitably raises questions. Without inspections, can the United States know when Saddam Hussein is "reconstituting his weapons of mass destruction"? The record is highly discouraging in this regard. Does not Saddam Hussein's victory over the United Nations, and his ability now to rebuild his arsenal, send a message to neighbors and others that in itself "disrupts the stability" of the region? And if Saddam Hussein now manages to acquire nuclear weapons, would U.S. threats really serve to deter, for example, another invasion of Kuwait? Deterrence depends on credibility.

President Clinton himself provided answers to these questions last February. "What if he fails to comply and we fail to act, or we take some ambiguous third route, which gives him yet more opportunities to develop this program of weapons of mass destruction? ... Well, he will conclude that the international community has lost its will. He will then conclude that he can go right on and do more to rebuild an arsenal of devastating destruction. And some day, some way, I guarantee you he'll use the arsenal."

Back those six long months ago, the Clinton administration insisted that Saddam Hussein could not wiggle out of an agreement that U.N. Secretary General Kofi Annan personally negotiated. This time the international community would certainly rise up in indignation if he tried. Yet today, the U.S. government is using international apathy as an excuse to do nothing, and Mr. Annan seems astonishingly sanguine about Saddam Hussein's assault on his own authority.

What might the consequences be, in Iraq and around the world, of such appeasement? Back in February, Mr. Clinton had an answer to that question, too. "In this century, we learned through harsh experience that the only answer to aggression and illegal behavior is firmness, determination and, when necessary, action. ... If we fail to respond today, Saddam, and all those who would follow in his footsteps, will be emboldened tomorrow by the knowledge that they can act with impunity, even in the face of a clear message from the United Nations Security Council, and clear evidence of a weapons of mass destruction program."

The Washington Post

FRIDAY, AUGUST 28, 1998

Food Safety

Food Safety: Enhancing a Fragmented Regulatory System

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Of course we accept full responsibility for any inaccuracies or misperceptions taken from our interviews and consultation.

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EXECUTIVE SUMMARY

Most observers agree that our current federal food safety system works relatively well at minimizing the risk of food-related morbidity and mortality. However, with an estimated 6 - 33 million morbidities and 9,000 mortalities per year that result from foodborne causes, there is certainly room for improvement. Many policy analysts contend that food safety is compromised by the fragmented nature of the federal food regulatory system.

(DIS)ORGANIZATION OF FEDERAL FOOD SAFETY AGENCIES

As the General Accounting Office (GAO) has documented, there are at least 12 federal agencies involved in implementing at least 35 statutes that regulate food safety and quality. There are three primary federal agencies involved in the regulation of food safety. Generally, the USDA's Food Safety and Inspection Service (FSIS) regulates meat[1] and poultry[2]; the Food and Drug Administration (FDA) regulates non-meat and processed foods through its Center for Food Safety and Applied Nutrition (CFSAN)[3]; and the Environmental Protection Agency's (EPA) Office of Pesticides Programs (OPP) registers and sets pesticide tolerances for enforcement by FDA and FSIS.[4] Appendix B contains an outline of food safety statutes and responsibilities across the bureaucracy. Moreover, the states enforce their own food safety statutes in the areas of agriculture, consumer protection, restaurant regulation, and food adulteration and misbranding.

TWO POLICY PROBLEMS: UNNECESSARY ILLNESS AND INEFFICIENCY

The fragmented federal food safety system causes two broad categories of policy problems. First, the disorganized structure and allocation of resources that we outline increases the number of food-related morbidities and mortalities. Second the fragmented system increases regulatory inefficiency by raising the costs per unit of health or inspection. The fragmented nature of food safety regulation has increased the risk of food-related illnesses—at least marginally—by hampering regulatory cooperation in mitigating foodborne illness risks that transcend jurisdictional boundaries. The organizational structure of the food safety system has also caused higher degrees of inefficiency by increasing the costs of necessary coordination and information-transfer. Consequently, several interest groups and members of Congress have proposed the consolidation of all or some of the federal food safety agencies.

CONSOLIDATION IS NOT THE ANSWER

However, a major consolidation of the food safety agencies would not necessarily guarantee that food safety would improve significantly, and it would most likely entail significant costs. A bureaucratic consolidation of food safety agencies—whether placed in HHS, USDA, EPA or in a new independent agency—could result in several significant benefits, such as:

- a single management and regulatory planning structure;
- reduced workforce requirements in the long-term due to the realization of synergies;
- a unified, multidisciplinary inspection force; and
- the ability to request resources in a coherent, risk-based manner.

Each of these benefits is important and could lead to decreased incidence of food-related illnesses and deaths and a more efficient use of resources.

However, the creation of a single food agency would entail substantial costs. Many of these costs are quite real, yet unquantifiable, such as the resistance to new organizational procedures. Some of the costs of consolidation include:

- Inspection and enforcement lapses, as agencies adapt to consolidation and employees face job uncertainty;
- Loss of political capital to effect changes to statutorily mandated risk standards, inspection requirements, and enforcement powers; and
- Lost productivity due to bureaucratic and cultural adjustment.

These costs could result in increased incidence of foodborne illness and greater levels of inefficiency in the short-term, as the factors mentioned above increase the costs per unit of health or inspection.

In the end, the bureaucratic and political costs of consolidation must be justified by the decreased risks of food-related illness, enhanced regulatory efficiency, and political feasibility. It is unlikely that bureaucratic reorganization without significant changes in the underlying authorizing statutes of the food safety agencies will substantially decrease illness or enhance efficiency. Moreover, there is little doubt that a consolidation proposal would spark serious jurisdictional clashes among the several congressional committees that appropriate, authorize, and oversee the federal agencies. The political capital that members of Congress would expend to wrest legislative oversight from other members and committees would diminish the chances of implementing the substantial changes in the underlying statutes that are necessary to enhance health and efficiency most effectively.

ENHANCED COORDINATION STRUCTURES AS THE SECOND BEST ALTERNATIVE

Rather than supporting a full-scale consolidation of food-safety agencies, we advocate the development of permanent coordination structures at the headquarters and field levels to improve the planning and resource allocation of the major federal food agencies. Therefore, we provide the following short-term and long-term recommendations to help FSIS and other policy makers respond to the problems posed by regulatory fragmentation of the federal food safety system:

- **Congress should not merge the major food safety agencies at this time.** The marginal health and efficiency benefits that we predict are not likely to justify the costs of large-scale consolidation. Moreover, as we discuss below, the food safety agencies can achieve many of the coordinative benefits of consolidation through the adoption of enhanced, permanent communication mechanisms at the headquarters and field levels.
- **The President should establish by Executive Order an interagency Food Safety Working Group chaired by a White House-appointed food safety coordinator**. Upper-level managers of FDA (CFSAN), USDA (Undersecretary for Food Safety, FSIS), EPA (OPP), CDC, and other relevant food safety agencies should meet frequently for purposes of organizing multi-agency food safety initiatives, investigations, and enforcement actions; enhancing cooperation and information- sharing; improving field-level communication; and implementing risk-based budgetary planning.
- **The food safety agencies should implement enhanced coordination mechanisms at the field level, including the establishment of regional interagency working groups and the consolidation of consumer affairs offices into one federal food safety information service.** Improved interagency information-sharing at the regional level can offer significant health and efficiency benefits at limited cost. Moreover, the establishment of a unified food safety

consumer affairs office would enhance consumer convenience and facilitate field-level cooperation. The budget savings that would result from the synergy gains of combining food safety public liaison activities could be used to fund increased public education of safe food handling and farm-based food safety.

- **Congress and the food safety agencies should continue to enhance monitoring and risk assessment mechanisms such as FoodNet in accordance with the President's Food Safety Initiative.** More accurate data on the extent of foodborne illnesses and the greatest risks to health are necessary for Congress and the food safety agencies to marshal federal resources to attack the greatest foodborne risks most efficiently.

- **FSIS should continue to upgrade the skills of its inspectors for the purpose of expanding science-based inspection and leaving behind carcass-by-carcass, organoleptic inspection methods.** A broad consensus of food safety experts has determined that the inspection methods of the early 20th century will not serve the citizenry in fighting pathogens that cannot be seen, smelled, or touched. The risks of visible animal diseases—the harms that organoleptic inspection was created to fight—are no longer the most substantial threats to human health. As scientific advancement continues to improve our ability to detect the most serious pathogenic risks to food, the citizenry will demand a meat and poultry inspection force that mitigates those threats at every point from farm to table. FSIS should anticipate the eventual move away from inefficient and largely superficial carcass-by-carcass inspection and continue to prepare its inspectors accordingly.

- **Congress should amend the underlying food safety statutes to allow agencies to regulate in a risk-based manner and provide a statutory mandate to allow the FDA to meet its inspection obligations.** To that end, Congress should dismantle the carcass-by-carcass pre-and post-slaughter inspection system and instead give FSIS the option to perform random sampling with detailed, risk-based analyses on each sampled animal. Moreover, FDA requires a resource anchor, such as a quota to visit a certain portion of its regulated facilities annually, to meet its food safety monitoring and inspection obligations.

INTRODUCTION

As food safety regulation in the United States has evolved from mere visual inspection to state-of-the art assessments involving biological and chemical analyses, federal food safety responsibilities have been scattered throughout the bureaucracy.[5] Consequently, the minimization of food safety risks is not only a scientific challenge, it is also a problem of resource allocation within a structure of shared authority.

One common complaint about the nature of our federal food safety regulatory apparatus is that the system is altogether too fragmented, uncoordinated, and inconsistent. As a result, similar risks are treated dissimilarly throughout the food supply. Perhaps the most well-known example of this phenomenon is the case of frozen pizza. While USDA inspects plants that produce pepperoni pizza daily, FDA typically inspects plants that produce cheese pizza on the average of once every ten years.[6] As a response to the health and efficiency costs of regulatory fragmentation, some policy makers have advocated the consolidation of all or some of the more than 12 federal agencies that hold jurisdiction over food quality or safety.

At the request of Margaret O'K. Glavin, Deputy Administrator for Policy, Program Development, and Evaluation of the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), we have evaluated options to enhance the fragmented federal food safety system. In Chapter I, we provide an overview of the federal food safety system; in Chapter II, we define the policy problems that regulatory fragmentation poses; in Chapter III, we summarize five policy options for responding to the problems of our fragmented regulatory system; in Chapter IV, we summarize our criteria for policy success and analyze consolidation and other policy options through the lenses of health, efficiency, and political feasibility; and in Chapter V, we conclude with our policy recommendations. The Appendices contain data and case studies that support our analyses and recommendations.

FSIS senior managers have recently taken important steps—such as implementing Hazard Analysis and Critical Control Point (HACCP) protocols for meat and poultry inspection—to modernize the USDA's food safety regulation. We hope that the recommendations of this report can aid in the critical effort to enhance and modernize federal food safety regulation.

I. BACKGROUND: AN OVERVIEW OF FEDERAL FOOD SAFETY EFFORTS

With over $2 billion spent on various federal food safety and quality programs annually, the protection of the nation's food supply is a substantial public health responsibility.[7] However, since the inception of the Federal Food and Drugs Act of 1906 and the Federal Meat Inspection Act of 1907, responsibility for food safety research, standard-setting, monitoring, inspection, and enforcement has been scattered throughout the federal bureaucracy by statutorily defined food categories.[8] This report examines the costs and benefits of policy options that respond to the health and efficiency problems caused by organizational fragmentation. This initial chapter provides an overview of the federal food safety system and begins to highlight the disadvantages of regulatory fragmentation.

FOOD-RELATED ILLNESS

The U.S. food supply is commonly recognized as one of the safest in the world. However, an estimated 9,000 people die each year due to illness caused by foodborne pathogens (0.003% of the current population and 0.4% of all deaths); while food poisoning is notoriously underreported, 6.5 - 33 million illnesses are believed to be caused by food annually.[9] Significantly, levels of foodborne illness have risen in recent years, with new threats posed by emerging pathogens and increased incidence of agricultural cross-contamination.[10] According to the Centers for Disease Control and Prevention (CDC), bacterial pathogens are the most common causes of foodborne morbidity and mortality in the U.S,[11] and contaminated meat and poultry are believed to be the most common food sources of these pathogens.[12]

The USDA's Economic Research Service (ERS) has estimated that the seven most common foodborne pathogens cause illnesses that result in $6.5 - $13.3 billion of lost wages and health costs annually (1995 dollars).[13] ERS has also estimated that the total cost of illness plus the implied value of lives lost due to these pathogens is between $19.7 - 34.9 billion per year.[14] Table 1.1 below provides ERS' estimates of incidence as well as illness and death costs of six common foodborne ailments.

Table 1.1
Selected Foodborne Pathogens: Estimated Incidence and Illness / Death Costs

Pathogen	Morbidities	Mortalities	Cost of Illnesses & Deaths ($bil)
Campylobacter	1,375,000 - 1,750,000	110 - 511	$0.6 - $1.0
Clostridium	10,000	100	0.1
E. coli 0157:H7	8,000 - 16,000	160 - 400	0.2 - 0.6
Listeria	1,526 - 1,767	378 - 485	0.2 - 0.3
Salmonella	696,000 - 3,840,000	696 - 3,840	0.6 - 3.5
Staph. Aureus	1,513,000	1,210	1.2
TOTAL	3,603,526 - 7,130,767	2,654 - 6,546	$2.9 - $6.7

Source: JEAN C. BUZBY, ET AL., BACTERIAL FOODBORNE DISEASE: MEDICAL COSTS & PRODUCTIVITY LOSSES 70 (1996).

As the table above implies, eating and drinking can entail many risks. Some of the many food hazards include: bacterial contamination, chemical residue toxicity, parasitic contamination, viral contamination, pest and filth impurity, and inherent food toxicity. Between 1988 and 1992, CDC monitored 77,373 cases of foodborne disease, a small fraction of the estimated outbreaks.[15] Of these cases, bacterial pathogens caused 90% of illnesses, with Salmonella causing the largest number of illnesses and deaths (most due to eating undercooked, infected eggs).[16] The remainder of morbidities were caused by chemical agents (2%), parasites (1%), and viruses (6%).[17] In most bacterial foodborne disease outbreaks, the food was stored at improper holding temperatures; the second most commonly reported practice that led to foodborne disease was poor personal hygiene of food handlers.[18] In Appendix C, we provide a table that shows the primary and secondary sources of foodborne contamination for the six pathogens listed in Table 1.1.

As a result of the imprecision of food safety morbidity and mortality data, the CDC, in conjunction with FDA and USDA, has established FoodNet, an active monitoring network in several locations around the country. FoodNet targets seven common foodborne pathogens as those with the greatest risks to public health: Campylobacter; E. coli 0157:H7; Salmonella; Listeria; Shigella; Vibrio; and Yersinia.[19] FoodNet's total monitoring sites encompass areas that contain approximately 15 million people.[20] Table 1.2 summarizes FoodNet's laboratory-confirmed cases of CDC's seven targeted foodborne pathogens for 1996.

Table 1.2
1996 FoodNet Pathogen Detection[21]

Pathogen	Rate per 100,000	Total Cases	Deaths
Campylobacter	24.7	3,267	3
Salmonella	16.2	2,142	16
Shigella	9.5	1,251	2
E. coli 0157	2.9	384	2
Yersinia	1.0	135	0
Listeria	0.5	63	9
Vibrio	0.1	17	1
TOTAL		7,259	33

Source: FOOD SAFETY AND INSPECTION SERVICE, U.S. DEP'T OF AGRIC., THE ESTABLISHMENT AND IMPLEMENTATION OF AN ACTIVE SURVEILLANCE SYSTEM FOR BACTERIAL FOODBORNE DISEASES IN THE UNITED STATES (1997).

As the preceding table illustrates, even the most common foodborne illnesses do not seem to entail prevalent risks. For example, based on the first year of FoodNet data (which is not necessarily generalizable), the risk of dying from Salmonella in 1996 (16/14.7 million FoodNet population) was approximately one in a million: the estimated risk of dying in an airliner crash.[22] On the other hand, the rates per 100,000 of contracting Campylobacter and Salmonella are especially high, given that much of this risk can be eliminated by low-cost activities such as proper food refrigeration, washing, and cooking.[23] Yet while these risks seem low, Americans seem to regard *any* death from a lapse of food safety to be unacceptable.[24]

Sources of food risk other than bacterial and other microbial pathogens do not seem to entail significant measurable food risks. For example, it has been estimated that the risk of death due to cancer caused by *all* food additives is less than 1% of all cancer deaths.[25] Thus, of the approximately 2.2 million Americans who die each year, less than 5,000 of them die from food additive carcinogens—a risk of less than 2 per 100,000. While there are certainly measurement difficulties that are unique to long-term food exposure risks, the CDC data indicate that bacterial pathogens present the greatest risk to food safety in terms of morbidity and mortality.

Due to the high value our society places on safe food, and because individuals are commonly not equipped to detect whether the food they consume is adulterated, the federal government has assumed the responsibility for ensuring a safe food supply. However, in order to minimize morbidity and mortality risks and regulate in a cost-effective manner, it is critical that the federal government marshal its resources wisely.

(DIS)ORGANIZATION OF FEDERAL FOOD SAFETY AGENCIES

There are three primary federal agencies involved in the regulation of food safety. Generally, the USDA's Food Safety and Inspection Service (FSIS) regulates meat[26] and poultry[27]; the Food and Drug Administration (FDA) regulates non-meat and processed foods through its Center for Food Safety and Applied Nutrition (CFSAN)[28]; and the Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP) registers and sets pesticide tolerances for enforcement by FDA[29].

However, there are at least a dozen other agencies involved in food safety regulation, including: the USDA's Agricultural Marketing Service; the USDA's Grain Inspection, Packers and Stockyards Administration (GIPSA); the Commerce Department's National Marine Fisheries Service (NMFS); the USDA's Agricultural Research Service (ARS); the USDA's Animal and Plant Inspection Service (APHIS); USDA's Cooperative State Research, Education, and Extension Service (CSREES); USDA's Economic

Research Service (ERS); the Treasury Department's Bureau of Alcohol, Tobacco and Firearms (ATF); CDC; the Federal Trade Commission (FTC); and the U.S. Customs Service.[30]

Table 1.3
Federal Safety Responsibilities for Selected Food Products

Food	Regulator(s)	Comments
Alcoholic Beverages	ATF	ATF licenses and inspects breweries/distilleries.
Eggs	FDA, AMS, FSIS, APHIS	FDA has lead jurisdiction over shell eggs. FSIS continuously inspects egg products. AMS operates a voluntary grading program. APHIS monitors animal health.
Fruits and Vegetables (includes genetically enhanced varieties)	FDA, EPA, USDA	EPA and USDA share pesticide regulation responsibilities.
Grain	FDA, GIPSA, EPA	GPSA establishes and enforces identity standards through inspection.
Meat and Poultry	FSIS, FDA	FDA technically holds regulatory authority once meat leaves the slaughtering or manufacturing plant.
Processed Foods	FDA	FDA is responsible for most non-meat products.
Seafood	FDA, NMFS	NMFS runs a voluntary inspection service.
Water	FDA, EPA	EPA regulates tap water, FDA bottled water.

As Table 1.3 indicates, several common food varieties are subject to regulation by multiple agencies. For example, grain, the ubiquitous American commodity has many overseers. Identity standards for grain are established and enforced by GIPSA[31]; pesticide residues on crops are regulated by both FDA and EPA; and grains in processed food are regulated by FDA.[32] Similarly, staples such as seafood and eggs also have multiple regulators.[33] And while meat is traditionally a USDA concern, meat that is part of a processed food falls under FDA's jurisdiction once the products have left the plant.[34] Such fragmentation can be confusing to consumers who commonly call the wrong federal agency with food safety complaints.[35] With such dispersion of federal responsibilities for food safety oversight, lapses of communication and coordination can result in increased illness, death, and federal waste.

Recently, the federal government—primarily through President Clinton's Food Safety Initiative—has taken important steps to enhance coordination at the highest levels of the food safety system. For example, last year, representatives of the CDC, FDA, EPA, and FSIS formed the Foodborne Outbreak Response Coordinating Group (FORCG) to strengthen interagency coordination during food-related emergencies.[36] Furthermore, FSIS and the White House Office of Science and Technology Policy have recently convened interagency meetings to create a unified food safety research agenda.[37] However, there is no guarantee that these informal coordination mechanisms will remain in the long-term.

IMPLEMENTING MANY FOOD SAFETY STATUTES

One of the principal explanations of our fragmented food safety system is the existence of individual—yet often related—authorizing statutes for the regulation of distinct foods. For example, there are separate statutes that establish distinct inspection regimes for meat, poultry, eggs, and other, non-meat processed foods. Moreover, several food safety agencies are responsible for administering overlapping authorizing statutes. Thus, the three primary food safety regulators—FDA, USDA, and EPA—administer 15 principal food safety statutes, including: the Federal Food, Drug and Cosmetic Act (FDCA)[38]; the Federal Meat Inspection Act (FMIA)[39]; the Poultry Products Inspection Act (PPIA)[40]; the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[41]; and the Public Health Service Act.[42] (See Appendix B for a more complete list of federal food safety statutes.) Due to the fragmented allocation of federal responsibility for food safety, agency jurisdiction can seem haphazard.

One example of different levels of regulatory scrutiny based on underlying statutory authority is the distinction between meat and non-meat foods. Because the FMIA and the PPIA call for inspection of every meat and poultry carcass before and after slaughter, there must be at least one FSIS inspector in every slaughtering plant, visually inspecting every carcass, every day.[43] FSIS also must inspect every meat or poultry processing plant (post-slaughter) at least once per day.[44] The FDA, on the other hand, has no legislative mandate for continuous in-plant inspection. Due to FDA's budgetary constraints and non-continuous style of regulation, plants that produce foods that do not contain meat or poultry are inspected, on average, once every ten years.[45] Thus, although there should be no significant difference in health risk, meat and poultry plants regulated by FSIS are inspected every day, while "game meats" such as rabbit and venison that are within FDA's jurisdiction have plants that are inspected once every three to five years.[46] While the volume of game meat production is small relative to beef or chicken, the animals pose similar bacterial threats.

THE COSTLY INSPECTION OF MEAT AND POULTRY

As the most expensive feature of federal food safety inspection and a management mechanism for the greatest health risks, meat and poultry oversight deserves special scrutiny. FSIS spends approximately 88% of its personnel budget, or $318 million in 1997, on meat and poultry inspection.[47] In-plant, carcass-by-carcass slaughter inspection consumes approximately 47% of the FSIS personnel budget, $170 million in 1997.[48] The continuous inspection mandates of the FMIA and PPIA thus become "resource anchors"[49] for FSIS, since any meat or poultry that is not subjected to continuous inspection is considered adulterated.[50]

Yet, simply put, sight-and-smell, carcass-by-carcass inspection of meat and poultry is an ineffective regulatory method for mitigating risks that cannot be monitored by the naked eye.[51] President Clinton's recent remark about the dated nature of our meat and poultry inspection methods, while perhaps overstating the case, is telling: "I was literally stunned when I came here to find out that we were inspecting meat in the United States in the same way we had inspected it since 1910—and in the same way that dogs inspect it today, by smelling it and touching it. We're doing a little better now."[52] While the implementation of Hazard Analysis and Critical Control Point (HACCP) protocols will enable industry and the federal government to focus on mitigating the greatest production risks of meat and poultry, the inefficient statutory requirement of carcass-by-carcass pre- and post-slaughter inspection will remain.

The current meat and poultry inspection processes can be traced back decades. Congress imposed traditional organoleptic carcass-by-carcass inspection of meat in 1907 and bird-by-bird inspection of poultry in 1957.[53] Significantly, organoleptic inspection originated as a method of detecting visible animal diseases. Despite USDA's frequent efforts to modernize its meat and poultry inspection methods,[54] however, the National Academy of Sciences in 1987 concluded that "the present system of inspection does very little to protect the public against microbial hazards in young chicken."[55] As microbial pathogens present the highest foodborne risks to human health, only regulatory methods that reduce such risks are acceptable. Hence, it is not surprising that FSIS' meat and poultry inspection regime has encountered substantial scientific criticism from the NAS, GAO, and others.[56]

As most food safety experts agree, one important method of enhancing meat and poultry inspection is the adoption of HACCP protocols.[57] HACCP is a preventive regulatory system that requires food producers and transporters to identify significant food risks (e.g., bacterial contamination) throughout food production, transport, and storage; specify validated processes to control significant risks (e.g., refrigeration); and establish record-keeping and monitoring procedures to verify effectiveness and detect errors.[58] New regulations require all meat and poultry plants to create and implement a HACCP program that specifically addresses all major hazards, including microbial pathogens.[59] FSIS must continue its carcass-by-carcass inspection by statutory mandate, but it will also monitor the effectiveness of plants' HACCP systems. Therefore, implementing HACCP will not allow FSIS to rationalize the enormous resources dedicated to meat and poultry inspection, since HACCP is not intended to supplant carcass-by-carcass inspection.

USDA's adoption of HACCP principles for meat and poultry regulation is an important step in the right direction. However, as long as FSIS continues to inspect each meat and poultry carcass individually—

often at line speeds of approximately two seconds per animal[60]—then it is likely that resources are being allocated inefficiently at the expense of other valuable government programs.

BUDGETARY IMBALANCE?

A cursory examination of the federal budget for food safety agencies reveals the extraordinary resources that are devoted to USDA's carcass-by-carcass inspection of meat and poultry products. In 1997, most of the FSIS budget of $570 million funded the salaries of over 8,000 inspectors in approximately 6,000 meat, poultry, and egg plants. These inspectors visually examined over 40,000 meat carcasses, 44,000 poultry carcasses, and 3,100 egg products last year.[61] Added together, USDA's food safety and related research budget exceeded $2 billion in 1997—approximately 2/3 of the entire federal food safety budget.[62]

By contrast, the FDA's 1997 total budget for food-related activities—including research—totaled just $191 million.[63] While FDA has jurisdiction over 53,000 establishments that produce or store food—almost *nine times* the number of FSIS-regulated plants—the agency employs only 770 food safety inspectors nationwide.[64] In fact, the USDA's Agricultural Research Service employs almost as many workers (7,318 FTE's in 1997) as the FDA does for *all* of its programs (8,359 FTE's in 1997 including drug, medical device, blood, and cosmetic programs).[65] In recognition of the relative disparity of FDA's food safety budget in relation to USDA, the President's FY 1999 budget calls for the hiring of an additional 250 FDA food safety personnel and a budget increase of $50 million to fund programs such as enhanced imported fruit and vegetable surveillance.[66] However, even with these additional funds, the USDA budget for meat, poultry, and egg inspection will still be over three times greater than FDA's budget for inspection *and* research relating to almost all non-meat foods, including seafood and produce. See Appendix D for a summary of major federal food safety agency funding.

Due to the fact that meat and poultry products seem to account for the most prevalent and severe risks of foodborne disease, perhaps the current allocation of resources is justified. However, it is important to recognize that meat and poultry are not the only sources of foodborne pathogens. In fact, FSIS has estimated that meat and poultry account for approximately 50 - 75% of foodborne illness caused by six prevalent pathogens. As the table below indicates, USDA regulates products that cause from one to three times the number of illnesses and death compared to FDA-regulated products. However, USDA's food safety budget (inspection and research included) is *ten times* greater than FDA's: approximately $2 billion versus $200 million.

Table 1.4
Estimated Costs of Death and Illness: Meat and Non-Meat Products ($ Billions)

Pathogen	Total Illness/ Death Costs (a)	% Caused by Meat/Poultry (b)	% Caused by Non-Meat	Costs for Meat/Poultry	Costs for Non-Meat
Campylobacter	$0.6 - $1.0	75 - 75	25 - 25	$0.5 - $0.8	$0.2 - $0.3
Clostridium	0.1	50 - 50	50 - 50	0.1 - 0.1	0.1 - 0.1
E. coli 0157:H7	0.2 - 0.6	75 - 75	25 - 25	0.2 - 0.5	0.1 - 0.2
Listeria	0.2 - 0.3	50 - 50	50 - 50	0.1 - 0.2	0.1 - 0.2
Salmonella	0.6 - 3.5	50 - 75	50 - 25	0.3 - 2.6	0.3 - 0.9
Staph. aureus	1.2	50 - 50	50 - 50	0.6 - 0.6	0.6 - 0.6
TOTAL	$2.9 - $6.7			$1.7 - $4.6	$1.3 - $2.1

(a) JEAN C. BUZBY, ET AL., BACTERIAL FOODBORNE DISEASE: MEDICAL COSTS & PRODUCTIVITY LOSSES 70 (1996).
(b) STEVE CRUTCHFIELD, ET AL., AN ECONOMIC ASSESSMENT OF FOOD SAFETY REGULATIONS: THE NEW APPROACH TO MEAT AND POULTRY INSPECTION 11 (1997).

While Table 1.4 seems to present evidence that regulation of non-meat food risks is underfunded, such a conclusion is not necessarily warranted. Because mitigation of meat and poultry risks may be more expensive than mitigation of non-meat risks, Table 1.4 merely illustrates the extensive estimated costs of illnesses caused by non-USDA-regulated foods.

CONGRESSIONAL OVERSIGHT

The fragmented nature of the federal food safety agencies is mirrored and exacerbated by the fragmented congressional committee structure that holds jurisdiction over the respective agencies. Since committees typically hold food safety hearings that focus on their own respective specialties (e.g., health versus agriculture), a committee will rarely conduct a multi-faceted style of oversight that is appropriate for the multi-dimensional problems of food safety. As we illustrate in Appendix B, the web of food safety agencies is overseen by an even larger thicket of congressional committees. Because congressional committees traditionally guard their jurisdictions jealously, any serious effort to reorganize any or all of the federal food safety agencies will have to loosen the tight grip that several congressional committees and their respective chairmen have on each agency.

BUREAUCRATIC HISTORY

Each of the federal food safety agencies has its own distinct bureaucratic culture. While FDA was originally a part of the USDA, the two agencies split in 1940. FDA became a bureau of the Federal Security Agency until 1953, when it was placed in the Department of Health, Education, and Welfare, the precursor to HHS.[67] Since its inception, USDA has traditionally focused on agricultural promotion and food safety from a farming and veterinary perspective. Thus, many of USDA's inspectors are veterinarians, while a significant number of FDA inspectors hold graduate degrees in chemistry or other pure sciences. Similarly, EPA scientists typically approach food safety problems from a perspective that focuses on long-term chemical exposure. The research methods that EPA scientists typically utilize are often distinct from those of pesticide experts at USDA. Moreover, each agency is associated with distinct constituencies. For example, USDA's primary constituency is farmers, while EPA's constituency is composed primarily of environmentalists. In assessing solutions to the problem of regulatory fragmentation, it is critical to address the challenges posed by these differences of organizational culture.

STATE AND INTERNATIONAL ISSUES

Finally, one must consider the food safety agencies from both a federalist and international perspective. While the federal agencies typically inspect and regulate all food production facilities, there are literally hundreds of state and local health and agricultural organizations that inspect plants, restaurants, supermarkets, and slaughterhouses. Any solution to the problem of regulatory fragmentation must consider improving links to state and local agencies. Moreover, any consolidation or change of food safety inspection or risk standards will have international implications. As free trade agreements such as GATT increasingly utilize independent international arbitrators such as the WTO, federal agencies must justify their food safety regulation with the best-available science. Thus, an important consideration in addressing fragmentation is the scientific justification for any inspection or risk-standard adjustments.

In this chapter we have outlined the difficulties that regulatory fragmentation presents in the current food safety system. These organizational, structural, and contextual conditions define the policy problems we detail in Chapter II.

II. PROBLEM DEFINITION: UNNECESSARY ILLNESS AND INEFFICIENCY

The fragmented federal food safety system causes two broad categories of policy problems. First, the disorganized structure and allocation of resources outlined in the previous chapter increases the number of food-related morbidities and mortalities. Second, the fragmented system increases regulatory inefficiency. The frequent inability of food safety agencies to allocate resources based on risk is both a health and an efficiency problem. The lack of regulatory risk-prioritization is an efficiency problem, because a system that does not allocate resources based on risk cannot systematically achieve the highest health benefits at the lowest cost. Moreover, lack of risk-based regulation is a health problem. As Mary Douglas and Aaron Wildavsky have written, individuals' perception of the government's risk management affects their behavior and susceptibility to risk:

> If some degree of risk is inevitable, suppressing it in one place often merely moves it to another. Shifting risks may be more dangerous than tolerating them, both because those who face new risks may be unaccustomed to them and because those who no longer face old ones may become more vulnerable when conditions change.[68]

Therefore, to the extent that the federal food safety system suppresses smaller risks at the expense of more serious risks, it decreases citizens' aggregate level of health.

THE HEALTH RISKS OF REGULATORY FRAGMENTATION

The fragmented federal food safety system increases the risk of foodborne illness—at least marginally—in two ways. First, by creating separate institutions and regulatory standards for different food categories, the system often does not allocate resources that minimize the most serious health risks. Second, the fragmented bureaucratic organization of the food safety system hinders cooperation in fighting disease. The institutional and statutory orientation of the food safety system does not allow the Executive Branch to funnel resources to the highest risks. Because Congress has scattered responsibility for food safety to many agencies with distinct inspection methods and priorities, the risks of foodborne morbidity and mortality may differ by seemingly arbitrary food categories. For example, as previously noted, plants that produce non-meat processed foods may be inspected once per decade, while a plant that makes similar food that contains meat or poultry receives continuous inspection. While meat may present higher risks than non-meat products, such differences would not seem to present an infinitely higher amount of risk that is suggested by the government's legally-mandated inspection practices.

First, risk standards differ by food category even within the same agencies and authorizing statutes. For example, the infamous Delaney Clause of the FDCA mandates a zero risk standard for carcinogenic additives,[69] while additives that are "generally recognized as safe" (GRAS), are exempted from the FDCA's additive pre-market approval protocol altogether.[70] Therefore, as a result of statute-driven resource allocation, some risks—such as carcinogens—seem to be overregulated and relatively costly to contain, while other risks—such as caffeine, a GRAS substance—may be underregulated. Similarly, as a result of Congress' mandated and costly continuous inspection of meat and poultry, precious federal funding is kept from other, potentially more valuable activities. By allocating scarce resources in a manner that is not always risk-driven, the food safety system does not protect the citizenry as effectively as it could.

Second, the fragmented bureaucratic organization of food inspection and monitoring hinders the government-wide fight against foodborne illness. As the GAO has documented, several of the food safety agencies commonly refer enforcement matters that are outside of their statutory authority to other relevant agencies.[71] For example, both the NMFS and the AMS, which operate voluntary inspection programs—for seafood plants and egg producers, respectively—have policies to notify FDA of unsanitary conditions found during inspections; FDA holds statutory authority for assuring the sanitary conditions of seafood and shell egg plants. Yet because inspectors and managers were often unaware of these referral requirements, NMFS failed to refer to FDA 198 seafood plants that failed NMFS' sanitation inspection between 1988 and 1991.[72]

As the GAO and the Center for Science in the Public Interest (CSPI) have documented, USDA's shell egg graders and inspectors have often failed to notify FDA of high-risk sanitation and contamination findings.[73] In one example that CSPI has described, APHIS investigated a Salmonella-contaminated chicken flock and did not notify FDA of its results until almost one month after the inspection; by then it was too late for FDA to attempt to recall the Salmonella-ridden eggs.[74] Since the fragmented organizational structure of the food safety system makes coordination difficult, the government is unable to protect health as effectively as it might in a more unified system.

It is important to note, however, that while regulatory fragmentation most likely increases food-related illness and death, we are not empirically certain. Since we cannot test the current system with a control group (other countries with different food safety standards and monitoring mechanisms provide no true comparison to our own), and since we presently have relatively inaccurate estimations of foodborne disease incidence, we cannot be certain that de-fragmentation would improve health. However, we should be suspect of any illness caused by a product that is regulated by two or more agencies, since lack of coordination, communication, or accountability between or among agencies could explain lapses in federal inspection or enforcement. As former FSIS Administrator and FDA Associate Commissioner Michael Taylor has argued, the present federal food safety system lacks a centralized figure whose sole responsibility is the safety of all food.[75] The interagency referral problems that we discuss above demonstrate how this lack of centralized accountability puts the food supply at risk unnecessarily.

THE EFFICIENCY COSTS OF REGULATORY FRAGMENTATION

The second broad class of policy problems caused by the fragmented nature of federal food safety regulation are lapses of *efficiency*: increased cost per unit of health or regulated product. For example, since there is no formal centralized vetting process for federal food safety research, it is possible for two or more agencies to perform similar work simultaneously without knowing of the existence of the other agency's research. Fragmentation causes inefficiency costs, including: duplication of duties, interagency coordination costs, lost synergy opportunities, and the organizational costs that are inherent in shared regulation by a number of large, specialized agencies with deeply entrenched bureaucratic cultures.

The breadth of federal food safety responsibilities makes coordination extremely difficult. For example, at least 21 different agencies are currently spending over $1 billion on food-related research, but there is no formal priority-setting, coordination, or oversight process.[76] Furthermore, as we describe above, there are often enforcement and epidemiological investigations that involve more than one of the agencies. Since there is no statutorily-defined mechanism mandating inter-agency coordination, regulators have designed informal coordination mechanisms that are used during emergencies. Likewise, there is no central point in which regulatory proposals, budgetary appropriations, and potential enforcement conflicts are vetted. Thus, lack of coordination increases the cost of food safety regulation unnecessarily.

A second source of regulatory inefficiency is misallocation of budgetary and personnel resources. For example, while the FSIS budget is driven by the statutory mandate requiring at least one inspector in every meat or poultry plant,[77] FDA's food safety budget has no corresponding resource anchor. Rather, FDA's revenues are driven by the agency's more risk-driven inspection system and the relative dominance of drug regulation within the agency. Historically the FSIS budget has remained nearly constant in real terms; however the FDA's food safety budget has diminished as its responsibilities have increased.[78] Consequently, the FDA conducted approximately 16,000 food inspections in 1980, compared to approximately 5,000 in 1996.[79] Thus, while the risks of FDA-regulated foods have not decreased substantially in the past 17 years, FDA's ability to manage these risks through inspection has been hampered.[80] Moreover, FDA's food safety budget has suffered in recent years, as Congress has directed more resources toward drug and device approval. In fact, the agency's budget for drug and device approval is twice its food budget, and Congress, pursuant to the Prescription Drug User Fee Act of 1992, allows the agency to collect user fees to finance drug approval.[81] Congress has been reluctant to provide FDA with user fee funding for food safety programs, even though industry has supported certain measures.[82]

Any long-term food safety plan should link monetary and personnel resource allocation to the efficient mitigation of the most significant risks. Currently, federal food safety spending is dominated by

FSIS' carcass-by-carcass inspection of meat and poultry—a mechanism that dates back to the days following Upton Sinclair's publishing of *The Jungle*. As a result of the personnel costs necessary to implement often superficial carcass-by-carcass inspection, monetary resources may not be allocated to programs on the basis of managing the most significant risks most effectively and efficiently.

III. ADDRESSING REGULATORY FRAGMENTATION: POLICY ALTERNATIVES

There are several policy options available to address fragmentation of the federal food safety system. We focus on five alternatives, although there are variations and combinations of each: 1) maintaining the status quo; 2) consolidating all or some of the agencies; 3) changing statutory food safety standards and/or inspection regimes; 4) adjusting budgetary priorities; and 5) improving formal or informal communication.

A. STATUS QUO

Of all the options, maintaining the current system requires the smallest amount of monetary, bureaucratic, and political resources. Maintaining the status quo is preferred, if the most effective and efficient food safety regulation can be achieved through the current organization and statutes, or if the costs of change are too high.

B. CONSOLIDATION

1. Create a New Independent Food Agency

Under this option, Congress would create a new "super-agency" that alone would hold regulatory authority over all aspects of food safety. Adoption of this option is appropriate if centralization of agency functions is a significant cause of effectiveness and efficiency. Centralization of the food safety system into a new single agency would utilize existing resources while also requiring additional resources to implement change. This option would likely require the formation of new congressional committee jurisdictions at significant political cost.

2. Consolidate into an Existing Agency

Under this option, Congress would create a single food agency within a currently existing agency. For example, the food safety system could be collapsed into USDA, HHS, or EPA. While this option reflects the view that centralization of functions is a key driver of health and efficiency, policy makers may feel that creating a new independent agency is either unnecessary or undesirable for political reasons.

C. CHANGE AUTHORIZING STATUTES

1. Change Authorizing Statutes "Wholesale"

A third policy option is to modify the existing authorizing statutes that underlie food safety regulation. The "wholesale" approach attempts to replace the set of antiquated and often burdensome statutes with a new legislative mandate. Adoption of this alternative would be appropriate if regulatory effectiveness and efficiency are hindered more by fragmented and inconsistent statutory authority than by institutional organization of existing agencies. An example of a "wholesale" change would be a merger of the FDCA, FMIA, and PPIA that would create one standard, one inspection force, and one set of enforcement tools and penalties. Such a change would likely have maximum health and efficiency effects of the options we have described, since the underlying statutes create risk standards, inspection requirements, and enforcement powers. As with consolidation, a wholesale re-writing of the food safety statutes would entail high political costs.

2. Change Authorizing Statutes Partially

These policy options partially modify the existing authorizing statutes that underlie the food safety system. Some of these options include:

- **One Risk Standard.** A "partial" statutory change might include revisiting the risk standards of each agency by mandating a single set of risk standards and/or inspection regimes.

- **Elimination of Carcass-by-Carcass and Continuous Inspection.** Congress could dismantle the labor-intensive carcass-by-carcass inspection method for meat and poultry and require random sampling with more intensive inspection of each food item for pathogenic hazards. Importantly, FSIS has already begun to utilize random sampling and statistical techniques in its inspection of imported meat products.[83]

- **Inspection Requirement for FDA.** Congress might establish a more stringent inspection mandate for FDA. This method would enable the agency to garner more resources during the federal budgetary appropriation process, since a legislative mandate would warrant increased resources. The President's Food Safety Initiative envisions the adoption of user fees to fund the hiring of more FDA inspectors.

- **Greater Enforcement Powers for FDA.** A legislative mandate might also grant FDA greater enforcement powers over its regulated industry. This would put the agency on par with the enforcement authority of its food safety counterpart USDA.

D. CHANGE BUDGETARY PRIORITIES WITHIN EXISTING INSTITUTIONS AND STATUTES

Under this policy option, Congress would modify budgetary priorities on two levels. First, at the federal level, appropriations would be allocated to address the greatest risks in the food supply chain most efficiently. Second, at the agency level, budgetary priorities would be adjusted to rationalize and allocate resources in a risk-based manner. While it is likely that agency leaders currently attempt to direct budgetary resources to mitigate the highest risks in their respective purviews, it is possible—as we discuss in the previous chapter—that Congress may not direct enough resources to FDA's food safety tasks.

E. ENHANCE COORDINATION WITHIN EXISTING INSTITUTIONAL INFRASTRUCTURE

Under this final policy option, agencies would improve formal or informal coordination efforts within the existing bureaucratic structure. Compared to the first three options, adoption of informal communication and coordination methods would result in decreased economic and political costs, but also decreased coordination benefits.

Adopting formal coordination mechanisms within the existing multi-agency environment has two key benefits. First, establishing formal coordination and communication mechanisms could provide a timely and systematic regulatory review of investigations, enforcement, and budgetary planning. Second, formal coordination mechanisms could centralize the locus of regulatory activity, thereby increasing the accountability of agency function to Congress, the President, and the public. There are several ways to enhance coordination formally, including:

- **Appoint a Czar.** The President could appoint a high-profile food safety coordinator to chair regular meetings with FDA, FSIS, EPA, and others. Such a coordinator would hold a role similar to the AIDS Czar and Drug Czar.

- **Establish an Advisory Committee.** The President or Congress could establish an advisory committee, that would be responsible for formal coordination and communication across agencies.

In this chapter we have highlighted possible solutions to the problem of regulatory fragmentation. In Chapter IV, we evaluate these policy options through the lenses of expected health, efficiency, and political costs and benefits.

IV. POLICY ANALYSIS: HEALTH EFFECTS, EFFICIENCY GAINS, AND POLITICAL FEASIBILITY OF DE-FRAGMENTATION OPTIONS

CRITERIA FOR POLICY SUCCESS

Since the two primary problems caused by fragmentation of the federal food safety agencies are decreased levels of health and efficiency, policy options should be evaluated on the basis of these two criteria. Additionally, any consolidation proposal must be politically feasible. Consequently, in evaluating proposals for organizational and statutory change, we ask the following questions in evaluating the given proposals:

1) Will the proposal significantly **decrease food-related morbidities and mortalities**?
2) Will the proposal significantly **enhance efficiency**? (Will there be lower cost per unit of health or decreased cost per unit of inspection); and
3) Is the proposal **politically feasible**? (Would the proposal likely pass congressional and presidential muster?)

A proposal that is politically feasible and significantly reduces food-related illness and/or significantly enhances efficiency would be a successful policy. As we imply in Chapter II, one sign that a policy enhances both health and efficiency is the degree to which that policy permits an agency the freedom to adjust its regulatory scrutiny based on an assessment of the relative risks presented by different products.

OVERVIEW OF POLICY ANALYSIS

In assessing proposals that respond to the fragmentation of the federal food safety agencies, it is important to weigh estimated costs and benefits through the lenses of health improvement, efficiency, and political feasibility. While many of the costs and benefits associated with these options are difficult to quantify, it is helpful to compare such costs to a benchmark: the status quo. Further, it is helpful to separate the costs and benefits of de-fragmentation into categories: short-term and long-term; relatively lower and higher costs and benefits; and costs and benefits to field staff as opposed to headquarters staff. In this chapter, we examine costs and benefits, relative to the status quo, of: consolidation; statutory change; shifts in budget priorities; and enhanced formal or informal coordination mechanisms.

The benefits that we estimate relative to the status quo are our policy goals: improved health and efficiency. Based on the interviews we have conducted, we assess the relative **health improvements** of each option by postulating how, if at all, each option would affect the federal government's ability to detect and counter foodborne illness. We also attempt to assess any **efficiency gains** through increased field performance and headquarters coordination of standard-setting, inspection, enforcement, and research activities. There may also be budgetary benefits due to de-fragmentation, such as: synergistic workforce reductions; lower telecommunications costs; and decreased travel expenses. Again, rather than attaching actual costs to these options, we assess benefits relative to the status quo.

We also estimate the potential health, efficiency, and political costs of each option relative to the status quo. Health costs entail any increased morbidity and mortality that results from de-fragmentation. Efficiency costs include **operational costs**, such as : *physical costs* (Property, Plant, and Equipment (PP&E); personnel costs, and training); *technology costs* (such as telecommunication and information technology (IT) costs); and *travel costs*. A second category of efficiency costs are **organizational costs** that are more intangible, including: *cultural costs* (such as employment uncertainty, morale, and bureaucratic tensions); *field-level communication costs*; and *headquarters' coordination costs*. Finally, **political costs** include: *jurisdictional costs* (such as congressional committee in-fighting to oversee any combined agency); *funding issues* (constituency fights over budgeting for preferred agencies); and *safety debate costs* (the political risk to legislators of debating the merits of controversial safety standards).

Summary of Findings

As Table 4.1 indicates, each policy option that we assess has its distinctive advantages and liabilities on the dimensions of health, efficiency, and political feasibility. Consolidation would entail higher short-term efficiency costs; as the government would expend the physical resources to create a new organization, and workers expended resources adapting to a new bureaucracy. However, consolidation would also provide long-term efficiencies through synergistic workforce reduction and greater ability to coordinate policies and activities. The health effects of a pure consolidation would probably be marginal; as merely shifting organization without adapting the underlying safety and inspection standards would do little to affect the government's research, monitoring, and inspection duties. Moreover, the political costs of consolidation would be high, since merger would entail either congressional committee turf battles to oversee a new agency or a disorganized multiple committee oversight system. Further, a drawn-out congressional battle over the organization of a new food safety agency would likely distract legislators from addressing statutory change of safety and inspection standards.

Changing the underlying food safety statutes would allow the highest potential health and efficiency effects. Two changes that could significantly enhance the government's ability to address the greatest risks most efficiently would be: 1) replacing FSIS' burdensome, carcass-by-carcass meat and poultry inspection system with a statute that allows FSIS to take large, random samples of meat and poultry and perform rigorous risk-based testing; and 2) requiring FDA to inspect a certain percentage of its regulated facilities annually. These changes would likely yield long-term health and efficiency gains by allowing FSIS to marshal its resources in a modern, scientific inspection program and by providing FDA with a statutory mandate to enhance its inspection resources. The likely costs of this option are high short-term efficiency losses within FSIS, as inspectors adapt to a new system, and high political costs, as legislators are forced to address controversial food safety standards and funding issues.

Changing budgetary priorities to increase FDA funding would allow the agency to meet the increased risk of emerging pathogens more effectively, especially risks posed by imported fruits and vegetables. Beyond the physical costs of enlarging budget and staffing, there would be high political costs in attempting to find resources under the constraints of recent budget agreements. Moreover, while additional FDA funding would most likely decrease the risk of foodborne illness by strengthening inspection and research capabilities, there would be no guarantee of enhanced efficiency.

The final option that we assess—adopting enhanced headquarters and field-level coordination mechanisms—features the lowest costs and high potential benefits. As the multi-disciplinary, farm-to-table approach to food safety emerges as the most appropriate method of managing the risks of emerging pathogens and agricultural cross-contamination, the federal government increasingly counts on the resources of many of its food safety agencies. Through the establishment of a permanent inter-agency committee chaired by a White House appointee, upper-level food safety regulators would have a regular forum to vet regulatory proposals; participate in creative group problem-solving; and coordinate and share research and enforcement plans. Recently, food safety regulators from across the government have enhanced their coordination, through emergency plans and White House/FSIS-sponsored research coordination. Yet the establishment by Executive Order of a permanent Food Safety Working Group would have the ability to yield long-term efficiency and health benefits at low health, efficiency, and political costs.

The matrix below summarizes our cost and benefit estimations of the four policy options we describe relative to the status quo. Following the matrix, we break out our analysis of each alternative.

Table 4.1
Summary of Major Costs and Benefits of
Food Safety De-Fragmentation Alternatives Relative to the Status Quo[a]

Costs	Consolidation[b]	Change Underlying Statutes[c]	Change Budget Priorities[d]	Improved Communication[e]
OPERATIONAL				
Physical	HIGH (ST)	LOW	SAME-HIGH	SAME
Technology	HIGH (ST)	SAME	SAME	SAME
Travel	LOW-SAME	LOW-SAME	SAME	SAME
ORGANIZATIONAL				
Cultural	HIGH (ST)	HIGH (ST)	SAME	SAME
Field Communication	HIGH (ST)	SAME	SAME	SAME
Hdqrtrs. Coordination	HIGH (ST)	SAME	SAME	SAME-HIGH
POLITICAL				
Jurisdictional	HIGH (ST)	SAME	SAME	SAME
Funding	HIGH (ST)	HIGH (ST)	HIGH (ST)	SAME
Safety Debate	SAME-HIGH	HIGH (ST)	SAME-HIGH	SAME
Benefits				
IMPROVED HEALTH[f]	SAME-HIGH	SAME-HIGH	SAME-HIGH	SAME-HIGH
IMPROVED EFFICIENCY[g]	HIGH (LT)	HIGH	SAME-HIGH	SAME-HIGH
Workforce Reduction Opportunities	HIGH	LOW-SAME	LOW-SAME	SAME
Field Communication	HIGH	SAME	SAME	SAME
Hdqrtrs. Coordination	HIGH	SAME	SAME	HIGH

NOTES:
[a] "LOW," "SAME," "HIGH" are relative to the status quo. "ST"=Short-term. "LT"=Long-term.
[b] Assumes consolidation of at least CFSAN, FSIS, and OPP.
[c] Assumes legislation that eliminates continuous inspection requirement, decreases number of FSIS inspectors, but calls for more rigorous testing through a large random sampling method. Also requires higher level of FDA inspection and increases enforcement powers.
[d] Assumes higher FDA food safety budget; USDA stays same or decreases to compensate for higher FDA budget.
[e] Assumes establishment of interagency coordination committee with meetings at least twice per month.
[f] Measure: a significant decrease in foodborne morbidities and mortalities.
[g] Measure: lower cost per unit of health or inspection.

Since we describe the food safety system as it currently stands (the status quo) in Chapter I, it is unnecessary for us to describe the costs and benefits of the present system further. Suffice it to say, CDC and FoodNet data indicate that the present system works relatively well in protecting Americans from food-related illness.[84] However, our food safety system could work more effectively and efficiently by decreasing the fragmentation that is a result of years of statutory layering. Each of the four policy options that we assess attempts to rectify the problems of fragmentation through organizational, coordinative, statutory, or budgetary means.

A. CONSOLIDATION

Theorists of government reorganization remain hopelessly divided in determining the success of agency mergers in achieving gains in efficiency or effectiveness.[85] Our study of the federal food safety system has exposed several deficiencies caused by fragmentation. However, we believe that the benefits of regulatory coordination can be bought at a much cheaper price than massive consolidation. In short, we agree with OMB's chief reorganization analyst under President Carter:

> Reorganization has traditionally focused on structural change, whose dominating principle is that related programs should be placed cheek by jowl within the same institution. But the issues government now addresses ... cause widely separated programs to be related, and each with different sets of others, depending on the issue. Structural change is far too difficult and slow-

> moving to manage such shifting and multiple relations. Processes of coordination, far more flexible, are the only devices that can serve.[86]

Our analysis of the option to consolidate some or all of the major federal food safety agencies, while not quantitatively precise, leads us to three conclusions:

- Most of the estimated costs related to consolidation are short-term; while most of the benefits are long-term;
- Many of the costs related to consolidation are substantial; while most of the benefits may impact health and efficiency only marginally; and
- Many of the benefits of consolidation can be attained through means less costly than full-scale consolidation.

We summarize our taxonomy of the costs and benefits of consolidation in Appendix E. As we discuss below, we believe that the predicted costs associated with any substantial consolidation of the federal food safety system would outweigh the potential health and efficiency benefits. However, the Canadian government—which has recently consolidated its food safety inspection force—may provide a convincing model for regulatory consolidation. We outline the Canadian reforms, as well as a British proposal to create a new, independent food safety agency, in Appendix F.

Health Benefits and Costs of Consolidation

Although the consolidation of some or all of the federal food safety agencies would lead to a more centralized planning and management mechanism in the long-term, it is unlikely that consolidation alone would have a significant impact on human health.

The underlying statutory structure of the federal food safety system provides clues that explain the limited ability of reorganization to improve health. The existing food safety statutes provide risk standards, and in some cases inspection requirements, for distinct classes of foods. These statutory mandates provide the foundation of food safety regulation regardless of the organizational structure of the agencies that implement the legal requirements. For example, even if FSIS were to be merged with FDA in a new independent agency, without changing the underlying statutes, meat and poultry inspectors would still be required to inspect visually individual carcasses before and after slaughter. Moreover, the new agency would still be required to implement the food additive pre-market approval requirements of the FDCA and apply its safety standard: that "there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."[87] Thus, absent significant changes to statutes such as the FMIA, PPIA, FIFRA, and FDCA, *and* absent substantial adjustments in budgetary resources, there would be very little impact on human health, because the various authorizing statutes—not the organizational structure—provide the basis for risk allocation.

While a merger is not likely to affect health significantly, there would probably be several marginal benefits to consolidation that would improve the government's ability to protect health:

- Improved budgetary flexibility to share resources between food classes, since it is easier for agencies to shift funds within departments than it is to transfer funds to other agencies;
- Enhanced ability to plan regulatory and enforcement priorities across food classes due to centralized management and single communications network (e.g., email) among field staff; and
- Better information-sharing and coordination in regulating items presently covered by more than one statute and organization.

Undoubtedly, a single or consolidated food agency would allow upper-level managers to discuss risk mitigation across the entire spectrum of food, rather than piecemeal. Moreover, a single agency could provide Congress with budget requests that consider all categories of food safety. Presumably, these budget requests would attempt to procure funds on the basis of most efficiently managing the greatest risks. However, absent significant statutory change, a consolidated food agency would still be tied to existing legislative mandates that dominate the regulation.

All reorganizations entail costs. While the benefits of consolidation would be long-term in nature, any health costs would be primarily short-term. However, if any reorganization resulted in negative net adjustments in overall resources devoted to food safety (after accounting for efficiency gains), there could be long-term costs as well. Aggregate health levels might decrease under consolidation due to:

- Inspection lapses, as field-level employees face the uncertainty of bureaucratic reorganization and possible firings;
- The possibility of decreased resources for research and enforcement in order to fund transition costs; and
- Distraction of legislators from addressing underlying statutory challenges involving risk standards and inspection requirements.

Efficiency Benefits and Costs of Consolidation

While it is difficult to estimate the health costs or benefits that may result from consolidation, it is just as difficult to estimate efficiency gains and losses. Such difficulties are not new; as even President Truman refused to estimate the "modest but worth-while economies" he predicted, when he proposed merging several agencies to form the Department of Health, Education, and Security (precursor to HHS).[88] As we have described, we estimate significant short-term efficiency costs as a result of uncertainty and bureaucratic cultural tensions. However, there would also be long-term efficiency gains.

The primary efficiency gains of consolidation would stem from synergistic workforce reductions and the ability to avoid duplicative regulatory activities such as risk assessment, monitoring, public affairs, and dual inspection. Moreover, consolidation would improve the federal government's ability to coordinate regulation with the states and to craft and present a unified food safety policy in the global arena. While we do not quantify these economy of scale savings, it is important not to overestimate them. For example, even though the agencies would be able to reduce workforce in certain administrative areas, a merger would also create a much larger bureaucracy whose very size could limit efficiency improvements. Furthermore, occasions when the food safety agencies must cooperate—through referrals or joint action—are often the exception rather than the rule. For the most part, FSIS and FDA inspectors act in independent jurisdictional spheres. A second set of efficiency gains would stem from the ability to rationalize overall resource allocation in one organization. Since the food safety organizations currently compete for resources in the budget cycle, there is limited incentive for any of them to limit budget requests. However, one organization, faced with one budget constraint, would be forced to prioritize all food safety activities within statutory constraints in a way that competing agencies with different budget constraints cannot do. Theoretically, one organization would be able to allocate resources more efficiently than many.

The costs of consolidation would likely have a negative effect on regulatory efficiency in the short-term. The physical costs of moving, adjusting telecommunications and IT systems, and establishing new administrative networks would certainly be higher than under the status quo. Such costs range from printing new stationary and creating new intra-agency manuals and directories to displacing thousands of agency workers. Moreover, the cultural tensions of consolidating separate bureaucracies could damage the quality of regulation in the short-term. Anxieties resulting from bureaucratic uncertainty would likely harm productivity, and early on, coordination between headquarters and the field may be impaired.