

Box 7

Homeless kids
Homeless vets
Home office tax deduction
Housing discrimination
Housing and tax
Hr 3052
Hud
Hud discrimination
Hunger
Immigration
Information privacy
Insurance for homecare providers
Interns
Internet
Internet gambling
Internet marketing
Internet smut
Internet tax
Investment scams
Invites
Imports
Israel
Italy
Jews
Jonas law
Juice labeling
Justice
Juvenile crime
Juvenile justice
Kenneth baer
Kids today
Kids and media
Latchkey kids
Lifetime probation
Literacy
Littletown
Livability
Liveable agenda
Long term strategy for science and tech
Lottery
Magazine report
Magazine report 2
Magazine report 3
Magazine report 4

Malaria
Mayors
Mcdonalds
Medals of freedom
Medicaid
Medicaid consumer issues
Medical practice management
Medical research
Medicare
Medicare reform
Mental health
Mikuta/hanson
Millennium
Millennium communities
Minimum wage
Minority access to college
Minorities in higher education
Minyon
Mit speech
Mom at home
Moms in prison
Motor voters
Movie ratings
Nanny registry
Nas report
Nasa
Nasa research
National endowment
National service

rights
critical

NAS

Could be
improving
Sept

Options the same

EW

Slam - dietary supplements & should reg'l.
ephedra

GDH more science

Limburg - human segs

mission differences promotional
vs.
reg'l.

epidemiological work

not env research

not env study.

milk - workers

food code universally adopted

need Nat'l food safety plan

one person should allocate resources
contact system can't so budget

Secret
food
will

- 10/1/73
- Seaford
- C99s
- drinking vs bottled water
- 1st Radiation
- Gove vs. non-Gove
- nuclear labels
- 1st strike

Council on Food Safety
Assessment of the NAS Report
Ensuring Safe Food from Production to Consumption

Americans have one of the world's safest food supplies. This is largely a result of sustained education and research efforts along the farm to table continuum as well as surveillance and regulatory programs. The federal food safety system is comprised of 12 agencies, is authorized by a diverse set of statutes, and is supported by numerous key partnerships with state, local, and tribal governments. Through this decentralized system, consumers have confidence in the wholesomeness of their food purchases.

As good as the nation's food safety system is, it must improved. Illnesses and deaths due to contaminated food continue to cause considerable human suffering and economic loss. That is why, at the very beginning of his first term, President Clinton set a course to strengthen the nation's food safety system. Under the President's leadership, surveillance and research have dramatically increased, programs are better coordinated, and regulations are more science based. But this is only the beginning. The Council on Food Safety, with the help of the public, will continue to identify problems and promote solutions.

The Council welcomes the input provided by the National Academy of Sciences in its August 1998 report *Ensuring Safe Food From Production to Consumption*. This report lays out a clear rationale for a national food safety plan, one that is based on science and risk.

- The Council supports recommendation I, which states that the food safety system should be based on science. In this assessment of the NAS report, the Council provides numerous examples of where this is already the case and examples of areas that need to be strengthened.
- The Council supports recommendation IIa, which calls for federal statutes to be based on scientifically supportable assessments of risk to public health. In this regard, the Council will conduct a thorough review of existing statutes and determine what can be accomplished with existing regulatory flexibility and what improvements will require statutory changes.
- The Council supports recommendation IIb, which calls for the production of a comprehensive national food safety plan. In fact, the development of such a plan is already well underway and one of the primary functions of the Council as specified in Executive Order 13100. A key component of the plan will be a comparative risk assessment of the nation's food supply.
- The Council supports the spirit behind recommendation IIIa. Here, the NAS calls for a new statute that establishes a unified framework for food safety programs with a single official with control over all federal food safety resources. The

report acknowledges that there may be many organizational approaches to achieving the goal of a “single voice” for federal food safety activities. As recommended by the NAS, the Council will conduct an assessment of structural models that would strengthen the federal food safety system through better coordination, planning, and resource allocation.

- The Council supports recommendation IIIb. This recommendation argues that agencies should have the legal partnering tools needed to unify their efforts with state and local governments. Fortunately, federal food safety agencies already have many of the tools identified by the NAS and have used them to establish extensive partnerships with state, tribal, and local governments. However, some tools are missing and much more needs to be done to better coordinate the federal government’s interactions with other levels of government. As part of the Council’s strategic plan, the National Integrated Food Safety System project will identify barriers to effective partnering and recommend ways to overcome them.

DRAFT FOR DISCUSSION PURPOSES ONLY

- I. Move food inspection and standard-setting/regulation for microbial, viral, and parasitic pathogens to FSIS (USDA), including seafood, eggs, milk, fruits and vegetables as well as FDA/State boards on milk, seafood, and the food code.
- II. CFSAN at FDA has responsibility over food additives, dietary supplements, biotechnology, chemical/pesticide/drug residues/standards, and food labeling under NLEA (?), including meat and poultry products. They are also given a budget increase. Consideration is given to promoting preemption, as USDA has for meats, and processor groups would prefer.
- III. Inspection Resources--move small number of field personnel i.e. imports, otherwise all inspection personnel remain for drugs, medical devices. Provide FSIS with base increase of XX million to ensure successful transition
- IV. USDA becomes U.S. Department of Food and Agriculture (Under Secretary for Public Health and Food Safety)
- V. Underlying Statutes (FFDCA, FMIA etc) remain intact. (Direct development of proposal to unify?)
- VI. Consider other measures to ensure independence from promotion, e.g. statutory advisory board, statutory reaffirmations.
- VII. Public Health and Ag. Committees share full jurisdiction over food safety.

NAS

DRAFT

2/17/99

**Council on Food Safety
Assessment of the NAS Report
Ensuring Safe Food from Production to Consumption**

Americans have one of the world's safest food supplies. This is largely a result of sustained education and research efforts along the farm to table continuum as well as surveillance and regulatory programs. The federal food safety system is comprised of 12 agencies, is authorized by a diverse set of statutes, and is supported by numerous key partnerships with state, local, and tribal governments. Together these agencies have created a system that has given U.S. consumers confidence in the safety of their food purchases.

As good as the nation's food safety system is, it must improved. Illnesses and deaths due to contaminated food continue to cause considerable human suffering and economic loss. That is why, at the very beginning of his first term, President Clinton set a course to strengthen the nation's food safety system. Under the President's leadership, surveillance and research have dramatically increased, programs are better coordinated, and regulations are more science-based. But this is only the beginning. The Council on Food Safety, with the help of the public, will continue to identify problems and promote solutions.

The Council welcomes the input provided by the National Academy of Sciences in its August 1998 report *Ensuring Safe Food From Production to Consumption*. This report lays out a clear rationale for a national food safety plan, one that is based on science and risk.

^ *with input*

- The Council supports **NAS recommendation I**, which states that the food safety system should be based on science. In this assessment of the NAS report, the Council provides numerous examples of where ~~this~~ is already the case and examples of areas that need to be strengthened. *Science based*
- The Council supports **NAS recommendation IIa**, which calls for federal statutes to be based on scientifically supportable assessments of risk to public health. In this regard, the Council will conduct a thorough review of existing statutes and determine what can be accomplished with existing regulatory flexibility and what improvements will require statutory changes.
- The Council supports **NAS recommendation IIb**, which calls for the production of a comprehensive national food safety plan. In fact, the development of such a plan is already well underway and one of the primary functions of the Council as specified in Executive Order 13100. A key component of the plan will be a comparative risk assessment of the nation's food supply.
- The Council supports the goal of **NAS recommendation IIIa**. Here, the NAS calls for a new statute that establishes a unified framework for food safety programs with a single official with control over all federal food safety resources.

The report acknowledges that there may be many organizational approaches to achieving the goal of a “single voice” for federal food safety activities. As recommended by the NAS, the Council will conduct an assessment of structural models that would strengthen the federal food safety system through better coordination, planning, and resource allocation.

- The Council supports **NAS recommendation IIIb**. This recommendation argues that agencies should have the legal partnering tools needed to unify their efforts with state and local governments. Fortunately, federal food safety agencies already have many of the tools identified by the NAS and have used them to establish extensive partnerships with state, tribal, and local governments. However, some tools are missing and much more needs to be done to better coordinate the federal government’s interactions with other levels of government. As part of the Council’s strategic plan, the National Integrated Food Safety System project will identify barriers to effective partnering and recommend ways to overcome them.

President's Council on Food Safety Assessment of the NAS Report: Ensuring Safe Food from Production to Consumption

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 on scientific and organizational changes needed to ensure an effective food safety system. To conduct this study, the NAS established a committee and obtained input from federal agencies and other stakeholders of the federal food safety system. The NAS issued its report on August 20, 1998.

On August 25, 1998, through Executive Order 13100, the President established the Council and charged it to develop a comprehensive strategic plan for federal food safety activities and to make recommendations to the President on how to implement the plan. Also on August 25, 1998, the President issued a directive tasking the Council to provide him with an assessment of the NAS report in 180 days. 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.”

In response to the President's directive, the Council established a task force consisting of representatives from the following departments and agencies: Departments of Agriculture (USDA), Health and Human Services (HHS), and Commerce (DOC), Environmental Protection Agency (EPA), Office of Science and Technology Policy (OSTP), and Office of Management and Budget (OMB). The

task force benefited from valuable input obtained at four public meetings (Arlington, VA; Sacramento, CA; Chicago, IL; and Dallas, TX) and from public comment dockets maintained by EPA, USDA Food Safety and Inspection Service (FSIS), and the Food and Drug Administration (FDA).

In general, the Council finds the NAS report a constructive contribution to its efforts to improve the effectiveness of the federal food safety system through strengthening science and risk assessment, strategic planning, and better federal integration with state and local governments. In particular, the NAS places appropriate weight throughout its report on applying science to the management of government food safety efforts. The Council believes that science based food safety surveillance and inspection are very important elements of the nation's food safety system.

The NAS report also recommends that the nation's food safety system should be based on risk. The Council agrees with the report's thesis that a food safety system that includes regulation, research and development, education, inspection and enforcement, and surveillance should be based on science and should use various risk analyses including quantitative and qualitative risk assessments and risk management principles to achieve such a system.

The Council recognizes that a food safety system comprised of 12 agencies with differing missions and statutory authority may increase the potential for uneven adoption and inconsistent application of regulatory philosophies based on science. However, the Council believes that through implementation of its strategic plan (including its assessment of existing statutes and structure) the potential for uneven adoption and inconsistent application among federal agencies will be reduced. The Council is committed to identifying further improvements that would result in a seamless science-based food safety system.

Recommendation I

Base the food safety system on science.

The NAS report notes that the United States has enjoyed notable successes in improving food safety and that with increasing knowledge, many rational, science-based regulatory philosophies have been adopted. The report suggests, however, that adoption of these regulatory philosophies has been uneven and difficult to ensure given the fragmentation of food safety activities, and the differing missions of the various agencies responsible for specific components of food safety. The greatest strides in ensuring food safety from production to consumption, the NAS argued, can be made through a scientific, risk-based system that ensures surveillance, regulatory, research, educational resources are allocated to maximize effectiveness.

Council Assessment

The Council strongly endorses this recommendation. Many federal food safety programs are already, or are being modified to be, science-based. The Council recognizes that scientifically robust programs will result in better identification of public health needs, determination of the most effective means of reducing public health risk including the most cost-effective opportunities for improvement, and improved priority setting.

The scientific information generated through surveillance, research, and risk assessment efforts will result in improved food safety only if there is a commensurate strong effort to translate that scientific information into practical, usable information at the working level, e.g., through guidance or education. This means there must be education for all those involved in producing, manufacturing, transporting, and preparing food as well as for those persons involved in government food safety regulatory activities.

The Council's goal is to ensure that science and risk based decision-making are central to the Administration's on-going efforts and its strategic plan. Fortunately, considerable improvements have been made over the past several years. The strong scientific underpinnings of the President's Food Safety Initiative, enactment of the Food Quality Protection Act (FQPA), restructuring of food safety agencies within USDA, and many individual agency activities, such as implementation of Hazard Analysis and Critical Control Points (HACCP) programs for meat, poultry, and seafood, have strengthened the overall science base of the food safety system.

The Council believes that the necessary elements of a science-based program—surveillance, outbreak response, risk assessment, research, inspection, and education of stakeholders—are largely in place, and that improvements planned for the next 5-10 years will enhance food safety. Specifically, the Council will consider in its strategic plan the following elements of a science-based food safety system:

- *Surveillance.* Food safety agencies will continue to develop more effective ways to achieve surveillance goals and to monitor the safety of the food supply. Although FoodNet (foodborne outbreak monitoring system), PulseNet (foodborne pathogen DNA fingerprinting system), and the National Antibiotic Resistance Monitoring System (NARMS) provide information never before available in the United States on foodborne illnesses and the occurrence of antibiotic resistant pathogens, enhanced quantitative data on the entire range of infectious and non-infectious foodborne hazards will require additional efforts.
- *Risk assessment.* Risk assessment is a valuable tool for setting priorities, allocation of resources, and regulatory decision-making. The development of a comparative risk assessment for hazards in the food supply will be an important aspect of both strategic planning and budgeting. As currently done for chemical hazards such as pesticide residues, the federal government needs to create and use a national microbial risk assessment capability as a means of identifying hazards and quantifying risk, and assist in creating similar capacities internationally. EPA will use risk assessment to determine acceptable levels of pesticides residues.

Under FQPA, this approach has been strengthened to further protect all consumers, and especially children, from the risks of pesticides in their diet.

- *Research.* Through the Joint Institute for Food Safety Research, a research infrastructure has been established to improve and coordinate food safety research activities across the federal government. The Institute will continue a critical review of the federally supported food safety research that was begun through the National Science and Technology Council. Future goals in the area of research include: coordination of research planning, budget development, and prioritization; scientific support of food safety guidance, policy, and regulation; enhanced communication and links among federal agencies; and enhanced communication and links with industry and academic partners through use of public-private partnerships and technology transfer mechanisms.
- *Education.* Food safety agencies will expand science-based education and training programs for producers, processors, distributors, food service workers, and consumers as well as those involved in regulatory activities. It is essential to include in these programs new scientific information on foodborne hazards and their control and effective food safety management strategies.
- *Inspection/Preventive Controls.* USDA and FDA will further improve and evaluate the effectiveness of inspections of domestically and internationally produced food and will continue to develop and implement science-based preventive controls such as HACCP systems and the Good Agricultural Practices. Where necessary, regulatory requirements will be established, such as additional performance standards for pathogen reduction that can be developed as more monitoring and surveillance data become available.
- *Consistency of Science-Based Standards.* USDA, FDA, and EPA will work toward clear food safety standards nationally and internationally. The Conference for Food Production brings together all 50 states for purposes of regulating retail establishments, and the Food Code is gaining wider adoption among the states. Internationally, the Codex Alimentarius Commission (CAC) is the primary mechanism through which these activities will take place. U.S. food safety

agencies should also become more active in providing technical assistance to developing countries.

- *Private Sector Incentives.* The federal and state regulatory agencies will work with the private sector to develop new technologies to further food safety and to encourage commercial scale-up applicable in large and small companies, and industry adoption. A research effort with industry, consumer, academic, and government participation could develop new technologies and evaluate them.
- *Evaluation.* Evaluating the effectiveness of science based regulatory programs continues to be critical. For example, *Salmonella* data from the first year of HACCP implementation in poultry facilities show a trend toward fewer contaminated products. Also, by providing important information on trends in the incidence of infections with foodborne pathogens, FoodNet assists in the evaluation of the effect of preventive controls. The effect of preventive controls implemented by the dairy industry on the reduction in the number of cases of listeriosis was readily apparent in a Center for Disease Control and Prevention (CDC)-conducted case-control study that was a forerunner of FoodNet.

Scientific Challenges

The Council faces a number of challenges in improving the scientific basis of the food safety system. A general challenge is that while food safety agencies must be guided primarily by science, the agencies must also consider other factors such as technical limitations, statutory mandates, policy considerations, budget constraints, practicality, and consumer assurances and societal preferences. Science must be advanced within the context of these competing interests. The following are a few examples of challenges that must be met to strengthen the scientific underpinnings of federal food safety efforts:

- Emerging new pathogens, changing food habits, a global food supply, and a changing population require new data that are difficult to predict and obtain in a timely way. An example is the impact of *E. coli* O157:H7, which was unknown

as a foodborne pathogen 20 years ago, but has been responsible for major outbreaks of foodborne illness in recent years.

- Gaps exist in our knowledge of microbial pathogens and in our ability to measure their impact on human health. For example, there are gaps in knowledge about the pathogens associated with fresh fruits and vegetables and the routes of contamination.
- Assessment of cumulative risk from multiple sources presents a major scientific challenge. Implementation of the new FQPA standards for pesticide residues requires EPA to assess aggregate risk from food, water, and residential exposure as well as cumulative risk from multiple pesticides.
- Gaps exist in our knowledge of monitoring and detection of food contaminants. For example, our current knowledge is insufficient to detect and monitor the presence of non-indigenous pathogens or unapproved pesticides on food.
- Gaps exist in our knowledge of effective interventions, prevention, and alternatives that minimize contamination of food. For example, the existing level of knowledge is insufficient to develop on-farm preventive controls and systems of testing. With the advent of FQPA, more research is also needed to develop safer pesticide alternatives or crop production techniques in order to ease the transition from older pest control techniques to newer, safer ones.
- Insufficient data exist on the entire range of infectious and non-infectious foodborne hazards. Even with the improvements made through FoodNet and PulseNet, enhancement of quantitative data on the entire range of infectious and non-infectious foodborne hazards will strengthen monitoring and surveillance programs for prevention, early identification, and prediction of emerging food safety problems.

Examples of Recent Changes that Strengthen the Federal Food Safety System Scientific Base

- USDA 1994 reorganization (separated public health from marketing functions)
- HACCP implementation (12/97 seafood and 1/98 meat and poultry)
- FQPA enactment and implementation
- FoodNet/PulseNet established
- FDA Fresh Produce Guidelines released
- Joint Institute for Food Safety Research created
- Research funding increased
- Food Safety Research Database initiated
- Annual Food Safety Research Conference held
- Interagency Risk Assessment Consortium established
- Risk Assessment Clearinghouse established

Recommendation IIa

Congress should change federal statutes so that inspection, enforcement, and research efforts can be based on scientifically supportable assessments of risks to public health.

The report identifies a need for a “national food law that is clear, rational, and comprehensive, as well as scientifically based on risk” as a major component of a model food safety system. The report concludes it is necessary to revise the current statutes on food safety to create a comprehensive national food law under which:

- Inspection, enforcement, and research efforts can be based on a scientifically supportable assessment of risks to public health. This means eliminating the continuous inspection system for meat and poultry and replacing it with a science-based approach that is capable of detecting hazards of concern.

- There is a single set of flexible science-based regulations for all foods that allows resources to be assigned based on risk, that permits coordination of federal and state resources, and that makes it possible to address all risks from farm to table.
- All imported foods come only from countries with food safety standards equivalent to U.S. standards.

The NAS report states that the laws—particularly what the report characterizes as the requirement that there be continuous inspection of meat and poultry production through sight, smell, and touch (“organoleptic”) inspection—create inefficiencies, do not allow resource use to reflect the risks involved, and inhibit the use of scientific decision-making in activities related to food safety, including the monitoring of imported food.

Council Assessment

The report’s recommendation that federal statutes provide agencies with authority to make decisions based on scientific assessments of risks to the public health is sound. Decisions based on public health risk assessments allow agencies to make effective use of science to set food safety priorities, allocate resources to higher risk areas, and instill consumer confidence that high-risk hazards are being addressed.

Since the federal food safety regulatory agencies operate under very different legislative authorities, the Council will conduct a full assessment of these statutes and evaluate the degree of regulatory flexibility that already exists. Therefore, the Council recommends that a legislative review be undertaken as part of the strategic planning process. The purpose of the review would be to: 1) examine the similarities and differences in federal food safety statutes; 2) identify the “best” statutory approaches for reducing foodborne illness; and 3) assess both gaps and statutory barriers to implementation of the plan. The need for statutory changes could then be determined, and, if necessary, legislative principles developed which would form the basis for discussions with stakeholders and Congress. For example, given the recent

overhaul of pesticide legislation, the Council believes that further statutory changes may not be needed for pesticides at this time.

In some cases, the NAS report overstates the problem with existing statutory requirements. For example, the report concludes that the statutes require the current method of organoleptic inspection of all carcasses. Even though the current law requires continuous inspection, it does not specify how this inspection mandate is to be carried out. The statutes do require appropriate examination of animals prior to slaughter and examination post-slaughter at all official slaughter and processing facilities. This continuous inspection requirement for animals is important to ensure use of the best sanitary dressing processes, prevention of fecal contamination (which harbors the pathogens that cause disease), reduction in the incidence of disease-causing pathogens, and prevention of meat from diseased animals from entering the food supply. Inspection of all animals and carcasses also serves to protect the public from diseases and other hazards to human health. Europe's experience with Bovine Spongiform Encephalopathy (BSE) should serve as a reminder that wholesale elimination of inspection of all animals and carcasses is not the most prudent course of action.

USDA has the flexibility to create, and in fact has begun to develop and test, a more risk-based inspection system by adopting regulations requiring that HACCP be implemented in all slaughter and processing plants. USDA is also studying how best to effect further inspection improvements in the future.

The food safety agencies have achieved and can continue to accomplish significant science-based improvements in their food safety programs under current authorities. However, new authorities that would improve the federal food safety system have been proposed by the President and are waiting action by Congress. Other new authorities have been identified and need further Executive branch discussion and clearance before a formal legislative proposal can be advanced for congressional

consideration. Further analysis of the statutes may result in additional proposed statutory modifications.

Current Legislative Challenges

Congress should pass:

- the Food Safety Enforcement Enhancement Act, forwarded by the Clinton Administration and introduced during the last Congress that increases the enforcement capabilities of USDA; and
- legislation that gives FDA increased authority to effectively assure the safety of food imports.

The Administration should also explore areas where regulatory jurisdiction is split between agencies or where resources could be more effectively shared between agencies. Examples include:

- developing a legislative proposal to improve the current system for the regulation of eggs and egg products;
- modifying statutes to permit FSIS inspectors not only to report their findings to FDA but actually to perform inspections and enforcement for that agency to increase interagency efficiencies; and
- developing a legislative proposal giving FSIS explicit authority to enter into cooperative agreements for food safety risk assessment.

Recent Advances in Applying Scientific Assessments Of Public Health Risks to Food Safety

- HACCP implemented
- FQPA tolerance reassessment based on aggregate exposure, cumulative risk, and vulnerable subpopulations.
- Single, risk-based pesticide standard for food established
- Tolerance setting focusing on the riskiest pesticides
- Priority registration given to “safer” pesticides
- Risk Assessment Consortium established
- FoodNet/PulseNet established
- Good Agricultural Practices guidance for fresh produce established
- Unpasteurized juice warning labels required

Recommendation IIb

Congress and the Administration should require development of a comprehensive national food safety plan. Funds appropriated for food safety programs (including research and education programs) should be allocated in accordance with science-based assessments of risk and potential benefit.

This recommendation contains two parts. The first part recommends that Congress and the Administration require preparation of a comprehensive, national food safety plan. The NAS report lists several essential features of such a plan, including a unified food safety mission; integrated federal, state and local activities; adequate support for research and surveillance; and increased efforts to ensure the safety of imported foods. The second part of the recommendation stresses that resources should be allocated on the basis of science-based assessments of risk and potential benefits.

Council Assessment

The Council agrees that a comprehensive national food safety strategic plan should be developed and the development of such a plan is underway. In fact, the President's Food Safety Initiative was an initial step toward a national food safety plan. The 1997 *Farm to Table* report was a means of leveraging federal food safety resources through coordinated planning and cooperative work to meet common needs such as development of surveillance data, response to outbreaks, research into preventive interventions, development of risk assessment techniques particularly for microbial risk assessments, and consumer education. This initial plan also took some steps toward extending food safety planning to the state and local level.

Strategic Planning

Picking up where the *Farm to Table* report left off, the Council will continue and expand the strategic planning process. One of the Council's primary purposes is to develop a comprehensive strategic plan for federal food safety activities that contains specific recommendations on needed changes, including goals with measurable outcomes. The plan's principal goal is to enhance the safety of the nation's food supply and protect public health through a seamless science- and risk-based food safety system. The plan will set priorities, improve coordination and efficiency, identify gaps in the current system and mechanisms to fill those gaps, continue to enhance and strengthen prevention strategies, and develop performance measures to show progress.

Preparation of the food safety strategic plan will be a public process, and will consider both short- and long-term issues including new and emerging threats and the special needs of vulnerable populations such as children and the elderly. Once the plan is sufficiently complete, the Council will advise agencies of priorities for investing in food safety and ensure that federal agencies annually submit coordinated food safety budgets to OMB to sustain and strengthen existing capacities. In short,

the President's Council on Food Safety will develop a national food safety plan and make budget recommendations to accomplish what the NAS report recommends.

The Council has defined the scope of future federal level food safety strategic planning and a process for interagency planning and public participation. An interagency task force anticipates having a draft plan ready for public review and discussion in January 2000. Even while developing this plan, the task force intends to continue its consultations with stakeholders. The following is the draft vision statement for the Council's strategic plan:

“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 subpopulations. We use science- and risk-based approaches along with public/private partnerships. Food is safe because everyone understands and accepts their responsibilities.”

The President's Council on Food Safety held four public meetings in the Fall of 1998 in Arlington, VA; Sacramento, CA; Chicago, IL; and Dallas, TX to solicit comments on this draft vision for food safety and to identify a strategic planning process, goals and critical steps as well as potential barriers to achieving that vision.

The Council's strategic planning task force is analyzing the transcripts of the 1998 public meetings and the input received through the notice and comment process to determine the major themes, issues, and subject areas. The task force will also consider the conclusions and recommendations of the NAS report, input from the federal, state, and local government National Integrated Food Safety System project, and input from the agencies involved. The task force will then develop a proposed set of strategic goals and objectives and present a draft plan to the President's Council on Food Safety. Following Council review, the draft plan will be provided to the public

for formal review and comment. After public comment, the task force will prepare a final 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 this final plan to the Council for approval.

The planning process will build upon common ground and provide the forum to tackle some of the difficult public health, resource, and management questions facing the federal food safety agencies and our state, tribal and local government partners. The plan will identify areas for enhanced coordination and efficiencies, determine whether legislative changes would be beneficial, and clarify federal, state, and local government roles and responsibilities in the national food safety system (see discussion under recommendation IIIb).

Allocation of Resources

The NAS report recommendation goes a step further than a national plan by urging that resources be allocated according to science-based assessments of risk and potential benefits. As stipulated in Executive Order 13100, the Council will develop annual budget recommendations consistent with the strategic plan. The Council will develop guidance for food safety agencies to consider during the preparation of their individual budgets. The Council has created a budget task force that will:

- work with the strategic planning task force and review the draft and final strategic plans and Council budget guidance on priority areas for investment to identify budget data and other information that will be necessary to plan and coordinate agency budget submissions to OMB;
- design a uniform format for presenting food safety initiative budget components in the OMB budget process for use in both individual agencies and the unified budget submissions;

- develop necessary guidance to facilitate submission of a unified food safety initiative budget and any other food safety issues deemed appropriate by the Council;
- establish a timetable for developing coordinated food safety budget requests and for submitting information to the Council that accommodates the various agencies' budget planning processes; and
- consider the issue of whether to amend OMB Circular No. A-11 (OMB guidance to agencies on budget structure and reporting elements) to include food safety as a budget cross-cut.

Comparative Risk Assessment

An important part to both risk-based planning and resource allocation will be the development of a comprehensive comparative risk assessment of the food supply. The Council has requested the Interagency Food Safety Risk Assessment Consortium, which consists of EPA, FDA, CDC, and USDA, to consider how to develop a comparative risk analysis for food safety strategic planning.

The Council believes that various steps may need to be taken to evaluate risks including: a ranking of foodborne pathogen risks based on CDC surveillance and economic data; consideration of a broader range of food safety hazards including not only microbial risks, but also pesticides and chemicals; and finally selection of highly ranked hazards, an evaluation of control measures, and an evaluation of net benefits. The Council must avoid applying risk assessment that is too strict, rigorous, or inflexible. Instead, the assessment must be used to prioritize the known greatest risks at the current time, with the understanding that scientific risk estimates can, and will likely, change frequently over time.

Challenges in Planning

The Council faces the following challenges in developing a comprehensive food safety strategic plan and allocating resources based on risk:

- Developing and successfully implementing a national plan will require strong cooperation, coordination, and communication, since each federal, state, and local agency has unique mandates, authorities, history, culture, and operating procedures.
- The diversity of stakeholders in food safety is enormous. It will be difficult, but imperative, that all stakeholders are represented in the Council's planning process.

Progress in Strategic Planning

- President's 1997 Farm to Table Food Safety Initiative
- President's Fresh Produce and Imported Food Safety Initiative
- Establishment of the Joint Institute for Food Safety Research
- Establishment of the President's Council
- Input from the National Academy of Sciences, Council of Agricultural Science and Technology, and other organizations
- National Integrated Food Safety System project meetings
- Input from multiple public meetings

Recommendation IIIa

To implement a science-based system, Congress should establish by statute a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities, including outbreak management,

**standard-setting, inspection, monitoring, surveillance, risk assessment,
enforcement, research, and education.**

The NAS report finds that the current regulatory structure for food safety in the United States is not well equipped to meet current challenges. Specifically, it points out that the system is facing tremendous pressures with regard to:

- emerging pathogens and ability to detect them;
- maintaining adequate inspection and monitoring of the increasing volume of imported foods, especially fruits and vegetables;
- maintaining adequate inspection of commercial food services and the increasing number of larger food processing plants; and
- the growing number of people at high risk for foodborne illnesses.

The report cites the strengths of the current food safety system, including the advent of FoodNet and PulseNet, HACCP implementation, and the Partnership for Food Safety Education. It also identifies deficiencies, which it attributes partly to “the fragmented nature of the system.” The report attributes the fragmentation largely to a lack of adequate integration among the various federal agencies involved in the implementation of the primary statutes that regulate food safety, and observes that this lack of adequate integration occurs also with state and local activities. The report notes that 12 primary federal agencies are involved in key food safety functions and references more than 50 memoranda of agreement between various agencies related to food safety.

The NAS report attributes the lack of adequate integration among federal, state and local food safety authorities in part to the absence of “focused leadership” that has the responsibility, the authority and the resources to address key food safety problems. The report presents several examples of possible organizational structures to create a single federal voice for food safety. These include:

- a Food Safety Council with representatives from the agencies with a central chair appointed by the President, reporting to Congress and having control of resources;
- designating one current agency as the lead agency and having the head of that agency be the responsible individual;
- a single agency reporting to one current cabinet-level secretary; and
- an independent single agency at cabinet level.

Although the report indicates many of the NAS committee's members believe that a single, unified agency headed by a single administrator is the most viable structure for implementing the "single voice" concept, the report recognizes that there may be many other models that would be workable.

Council Assessment

The Council agrees with the goal of the NAS recommendation--that there should be a fully integrated food safety system in the U.S. The food safety agencies are committed to this goal, and the Council is confident that its comprehensive strategic plan will be a major step toward creating a seamless system. The Council will conduct, through a public process, a thorough assessment of structural and organizational options before recommending major legislative or administrative actions on reorganization. The Council will identify and analyze existing models in government for achieving mutual and truly national food safety goals. Some of these models might address structure, and some might address facilitating mechanisms.

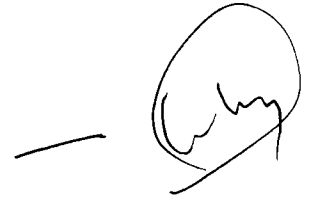
The Council's strategic plan ^{see 16} will bring agreement on the vision, goals, and actions needed to enhance the safety of the nation's food supply and protect public health by reducing the annual incidence of acute and chronic foodborne illness. It will also clarify the roles and responsibilities of each food safety agency as well as those of our state, tribal, and local government partners.

While the Council recognizes that certain models of reorganization may improve coordination and allow for a better allocation of resources, any reorganization of food safety activities must recognize the non-food-safety-related responsibilities of each agency and how these relate to the food safety responsibilities. Reorganization must not be done at the expense of these responsibilities and activities. The Council is concerned that, if not done carefully, separating food safety from non-food safety activities in each agency could act to weaken consumer protection overall.

The Council also recognizes that expertise and knowledge, particularly expertise in state-of-the-art science and technology, provides a resource to food safety activities. For example, analytical methods for detection and quantification on economic adulterants in foods may be adapted to detection of chemical contaminants that threaten public health. Expertise in non-food safety regulatory science and legal procedures are critical when warnings are required on food labels to assure safety. In addition, reorganizations must avoid interfering with the public health framework established to identify and respond to infectious and non-infectious public health threats whether they are foodborne or not. Thus, in its strategic planning the Council will be cognizant of the interplay between the food safety and non-food safety activities of each agency and how they strengthen each other.

The Council believes that there are programs that can benefit from immediate reorganization. For example, during the last two years, FDA and NOAA have been developing a proposal to transfer the NOAA Seafood Inspection Program to FDA as a Performance Based Organization (PBO) in order to operate the voluntary Seafood Inspection Program on a more business-like basis. The PBO would be formed under the umbrella of FDA and would include all seafood inspection activities now carried out by NOAA. The fiscal year 2000 budget proposes to transfer the existing Seafood Inspection Program from NOAA to FDA. This action will fully consolidate federal seafood inspection activities within one agency thereby increasing the efficiency and effectiveness of seafood oversight. It will also enhance the overall safety and

wholesomeness of seafood products. Funds are provided to cover the costs of transition, including training and education activities.



Factors to Consider in Organizational Restructuring

The Council assessment of structural and organizational options must take into consideration the following factors:

- Many food safety issues can only be dealt with through collaboration and partnerships between agencies. For example, BSE is an animal health issue and a human health issue. Foodborne disease problems are also waterborne disease problems. *Salmonella enteritidis* in shell eggs is not only a food safety issue but also an animal health and a marketing issue.
- Research and education programs for food safety do not operate as separate activities within the agencies, but rather draw significant strength from one another. For example, any attempt at placing “pure” food safety research and education in one agency could actually jeopardize the ability to deliver improved food safety to consumers. While some projects are entirely focused on food safety, the food safety research portfolio includes many other projects in such areas as animal health and animal genetics. Similarly, scientific expertise and endeavors should always inform regulatory activities. Each regulatory agency must have a cadre of trained and involved scientists to facilitate communications and cooperation with the research/education agencies. Thus, any restructuring must ensure continued coordination and communication between food safety programs and non-food safety functions that strengthen these programs.
- The Council should build upon existing successful partnerships. For example, CSREES FSIS, FDA, CDC and other private and governmental organizations now participate in the Partnership for Food Safety Education. This group serves to coordinate food safety educational programs among private and governmental agencies, and is a key element of the Food Safety Initiative. Yet this and other partnerships would not be possible without relying on the many effective working

relationships developed among the participants over the years, including joint projects on residue control and nutrition labeling. Any reorganization needs to recognize the importance of existing partnerships.

- Food safety standards at the federal, state, local, and international levels need to be consistent. Mechanisms such as the Codex Alimentarius for international standards and the Conference for Food Protection for federal and state standards are in place to reduce inconsistency, but better integration at all levels is needed and viewed as a long-range project.

**Recent Steps Taken to Create a Unified
Federal Food Safety System**

- 1997 President's Food Safety Initiative implemented
- JIFSAN/Interagency Risk Assessment Consortium created
- President's Fresh Produce plan implemented
- FORC-G established
- President's Council on Food Safety established
- Restructuring of seafood inspection proposed
- Partnership for Food Safety Education created

Recommendation IIIb

Congress should provide the agency responsible for food safety at the federal level with the tools necessary to integrate and unify the efforts of authorities at the state and local levels to enhance food safety.

The NAS report recommends that federal, state, and local governments function as an integrated enterprise, along with their partners in the private sector. The report identified five statutory tools required to integrate federal, state, and local food safety activities into an effective national system:

- authority to mandate adherence to minimal federal standards for products or processes;
- continued authority to deputize state and local officials to serve as enforcers of federal law;
- funding to support, in whole or in part, activities of state and local officials that are judged necessary or appropriate to enhance the safety of food;
- authority given to the Federal official responsible for food safety to direct action by other agencies with assessment and monitoring capabilities; and
- authority to convene working groups, create partnerships, and direct other forms and means of collaboration to achieve integrated protection of the food supply.

This recommendation acknowledges the “equally critical roles” of state and local government entities with those of the federal government in ensuring food safety, and suggests that changes in federal authorizing and appropriating legislation may be necessary to achieve better integration of federal, state, and local activities.

Council Assessment

The Council agrees that the roles of state, tribal, and local governments in the food safety system are critical and supports steps taken toward the development of a more fully integrated national food safety system. While more needs to be done to optimize and develop new partnerships, the federal food safety agencies have already established extensive interactions with state and local regulatory agencies. In fact, a critical factor for the Council to consider is the manner in which existing federal/state or local activities are integrated and coordinated. The Council believes that its strategic planning process provides a fresh opportunity for their non-federal partners to participate as primary and equal partners in the development of the future food safety system.

Some overlap occurs among federal, state, and local food safety efforts. Neither federal food safety agencies nor state and local agencies have sufficient resources to

carry out a comprehensive food safety program, but all these agencies have expertise and resources that, when combined in an integrated program, would significantly enhance the impact of food safety programs.

The Council also agrees that the five statutory tools identified by the NAS are critical for ensuring good coordination between the federal government and state and local agencies. Fortunately, the federal food safety regulatory agencies (FDA, FSIS, and EPA) already have many of the statutory tools recommended by NAS.

The Council recognizes and agrees with the report's conclusion that the lack of integration among federal, state, and local authorities often complicate the administration of regulatory programs. We need to utilize available mechanisms to leverage resources and expertise from government, industry, academia, and consumers to expand the nation's food safety capabilities beyond what any one group can accomplish. Increased awareness and knowledge of food safety in each segment of the food safety community reduces the need for extensive regulation of industry and decreases the incidence of contamination at every point in the food safety system in order to protect public health.

National Integrated Food Safety System (NIFSS) Project

HHS, USDA, and EPA are working with state and local officials in a National Integrated Food Safety System (NIFSS) project to identify appropriate roles and to develop mutually supporting common goals for all levels of government in the U.S. food safety system. This work is considered integral to the Council's strategic plan and coordinated budget recommendations and will be the basis for improved integration with state, tribal and local governments.

Under the leadership of the FDA, the current project is proceeding under existing federal, state, and local laws although all levels of government recognize that changes in some of the federal and state laws will be necessary to achieve an integrated

system. The project began with a meeting of state and local officials from public health and agriculture agencies and state laboratories representing all 50 states, Puerto Rico, and the District of Columbia, CDC and USDA in Kansas City in September 1998. In December 1998, six work groups and an 18 member Coordinating Committee composed of federal, state and local officials met in Baltimore, Maryland to begin to develop plans for implementing recommendations and overcoming the obstacles identified at the Kansas City meeting. The next meeting is planned for late winter or early spring, 1999. The group estimates that a fully integrated federal/state/local food safety system will take approximately 10 years to build. The Association of Food and Drug Officials, which is an organization of state and local public health officials and regulators, endorses the concept of a NIFSS.

Challenges to Developing a National Integrated Food Safety System

Even though there is some uniformity between federal and state standards (e.g., standards associated with the intrastate shipment of meat or poultry), the Council recognizes the following challenges to building an integrated food safety system:

- Integrated federal, state, and local food safety systems will help build a more consistent, uniform level of safety assurance across the nation. To accomplish this, however, clear, national standards are needed, together with uniform food safety messages and enhanced training, capability, and technical assistance to meet all levels of regulatory, industry, academic, and consumer need.
- Consumers are concerned that the economic interests of industry within states may be a source of conflict if those states have an expanded food safety role that includes activities thought to be primarily a federal responsibility (e.g., firm inspections).
- Industry is concerned that food safety regulation will be inconsistent among the states if systems are integrated without adequate preparation of the state agencies to step into the expanded food safety role.

- In order for integration to work, it is crucial that state and local governments have access to high quality scientists and health care professionals. The strategic plan will explore incentives for education and training of epidemiologists, laboratory workers, public health nurses, and environmental sanitarians.

Examples of Federal/State/Local Cooperation

- Milk Sanitation Program - Pasteurized Milk Ordinance
- Retail Food Safety Program - Food Code
- National, Integrated Food Safety System Project
- Interstate Shellfish Sanitation Program
- States conduct 5,000 inspections of FDA-regulated plants
- FDA maintains more than 100 state partnerships
- Conference for Food Protection
- FoodNet/Emerging Infections Program
- PulseNet
- Epidemiology and Laboratory Cooperative Agreements
- Appropriate delegation of pesticide responsibility to states
- Partial funding of states for implementation of some pesticide programs and for most compliance programs
- State FIFRA Issues Research and Evaluation Group
- State and local government involvement in FORC-G
- State conducts inspections in 250 FSIS regulated plants
- FSIS oversees and supports 26 state "equal to" meat and poultry inspection programs
- FSIS supports animal production food safety outreach projects involving 11 states
- FSIS supports animal production food safety workshops
- HACCP based enhancement of state labs, computer capabilities, and state training
- Partnership for Food Safety Education "Fight BAC!" campaign

NAS
Sept

NATIONAL ACADEMY OF SCIENCES
2101 Constitution Avenue, N.W. Washington, D.C. 20418

FOOD AND NUTRITION BOARD
INSTITUTE OF MEDICINE
Phone: (202) 334-1732
FAX: (202) 334-2316

BOARD ON AGRICULTURE
NATIONAL RESEARCH COUNCIL
Phone: (202) 334-3062
FAX: (202) 334-1978

Embargoed; Not for public release until
Thursday, August 20, 1998, 12:00 Noon EDT

ENSURING SAFE FOOD
From Production to Consumption

Committee to Ensure Safe Food from Production to Consumption

Conclusions:

- I. An effective and efficient food safety system must be based in science.**
- II. To achieve a food safety system based on science, current statutes governing food safety regulation and management must be revised.**
- III. To implement a science-based system, reorganization of federal food safety efforts is required.**

Recommendations:

- I. Base the food safety system on science.**
- IIa. Congress should change federal statutes so that inspection, enforcement, and research efforts can be based on scientifically supportable assessments of risks to public health.**

Changes in federal statute that would foster and enhance science-based strategies:

- eliminate continuous inspection system for meat and poultry and replace with a science-based approach which is capable of detecting hazards of concern;
- mandate a single set of science-based inspection regulations for all foods;
- mandate that all imported foods come from only countries with food safety standards deemed equivalent to US standards.

- IIb: Congress and the administration should require development of a comprehensive national food safety plan. Funds appropriated for food safety programs (including research and education programs) should be allocated in accordance with science-based assessments of risk and potential benefit.**

The National Food Safety Plan should:

- include a unified, science-based food safety mission;
 - integrate federal, state, and local food safety activities;
 - allocate funding for food safety in accordance with science-based assessments of risk and potential benefit;
- provide adequate and identifiable support for the research and surveillance needed to:
- monitor changes in risk or potential hazards created by changes in food supply or consumption patterns, and
 - improve the capability to predict and avoid new hazards;
- increase monitoring and surveillance efforts to improve knowledge of the incidence, seriousness, and cause-effect relationships of foodborne diseases and related hazards;
 - address the additional and distinctive efforts required to ensure the safety of imported foods;
 - recognize the burdens imposed on state and local authorities that have primary front-line responsibility for regulation of food service establishments; and
 - include a plan to address consumers' behaviors related to safe food-handling practices.

IIIa: To implement a science-based system, Congress should establish, by statute, a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.

IIIb: Congress should provide the agency responsible for food safety at the federal level with the tools necessary to integrate and unify the efforts of authorities at the state and local levels to enhance food safety.

The statutory tools required to integrate local and state activities regarding food safety into an effective national system:

- authority to mandate adherence to minimal federal standards for products or processes,
- continued authority to deputize state and local officials to serve as enforcers of federal law,
- funding to support, in whole or in part, activities of state and local officials that are judged necessary or appropriate to enhance the safety of food,
- authority given to the federal official responsible for food safety to direct action by other agencies with assessment and monitoring capabilities, and
- authority to convene working groups, create partnerships, and direct other forms and means of collaboration to achieve integrated protection of the food supply.

Executive Summary

NAS report

Adequate, nutritious, safe food is essential to human survival, but food can also cause or convey risks to health and even life itself. Although estimates vary widely, there is agreement that foodborne illness is a serious problem. In the United States, as many as 81 million illnesses (Archer and Kvenberg, 1985) and up to 9,000 deaths (CAST, 1994) per year have been attributed to food related hazards. Estimates of the annual cost of medical treatment and lost productivity vary widely, from \$6.6 billion to \$37.1 billion from seven major foodborne pathogens (Buzby and Roberts, 1997).

The nation's agriculture and food marketing systems have evolved to provide food to a growing and increasingly sophisticated population. Complex processes built on advances in science and technology have been developed to evaluate and manage the risks associated with the changing nature of the food supply. Well-established systems control many food risks, but serious hazards to public health remain.

PURPOSE AND SCOPE OF THE STUDY

As a result of the continuing concern about the food safety system in the United States, Congress commissioned the National Academy of Sciences, through the Agricultural Research Service of the US Department of Agriculture (USDA), to undertake the study that resulted in this report. The charge to the committee was twofold. The committee was asked to (1) assess the effectiveness of the current system to ensure safe food, and (2) provide recommendations on scientific and organizational changes needed to increase the effectiveness of the

food safety system. Over a 6 month period, the committee held three meetings as well as two open forums where agency representatives and relevant stakeholders discussed the food safety system. The committee reviewed many documents, including reports on how other countries are reshaping their systems.

This report summarizes the committee's review of food safety in the United States by (1) describing the current US system for food safety and the changing nature of concerns which it encounters, (2) outlining an effective food safety system, (3) identifying the ways in which the current food safety system is inadequate, and (4) providing recommendations to move toward the scientific foundation and organizational structure of a more effective food safety system.

Protecting the safety of food requires attention to a wide range of potential hazards. Food safety is not limited to concerns related to foodborne pathogens, toxicity of chemical substances, or physical hazards, but may also include issues such as nutrition, food quality, labeling, and education. While the scope of this study includes all of these components, this committee's immediate concern focuses on food related hazards.

1. The Current US Food Safety System

The US food supply is abundant and affordable and is judged by many to present an acceptable level of risk to health. The system has evolved from one that provided consumers with minimally processed basic commodities that were predominantly for home preparation to today's system of highly processed products designed either to be ready-to-eat or to require minimal preparation in the home. As a result of many technological advances, the food system has progressed dramatically from traditional food preservation processes such as salting and curing to today's marketplace with frozen ready-to-eat meals and take-out foods. Likewise, distribution systems for foods have changed greatly.

While these developments have provided the American consumer with a wide array of food products with a high degree of safety, a more diverse food supply carries additional risks as well as benefits. The availability of new food choices such as "minimally processed" vegetable products (for example, prebagged and chopped leaf lettuce mixes) presents new risks for microbial contamination. The globalization of the food system brings food from all parts of the world into the US marketplace, and with it the potential for foodborne infection or other hazards not normally found in the United States.

The current US food safety system has many of the attributes of an effective system. The nature of food safety concerns has changed due to past successful efforts to control the use of unidentified or misrepresented food ingredients and problems with the appearance and wholesomeness of food products; microbiological and chemical hazards now present new and in some cases increasingly serious challenges which cannot be detected using traditional inspection methods. The introduction of Hazard Analysis Critical Control Point (HACCP) monitoring systems in meat, poultry, and seafood products is an

example of the introduction of science-based process control methodology into food safety regulation and enforcement.

Many Americans now eat in ways that increase risk, including consuming more raw or minimally processed fruits and vegetables and eating fewer home-prepared meals. A smaller number of food processing and preparation facilities provide food to increasingly larger numbers of US consumers, enhancing the extent of harm that can arise from any one incident. Simultaneously, increasing numbers of Americans have compromised immune systems because of age, illness, or medical treatment. The development of genetically modified foods and modified macronutrients are two examples of new products or technologies that require new ways of evaluating the safety of substances added to the food supply.

The federal government has usually addressed these developments by adding new structures and processes or adjusting old ones. These incremental adjustments have created a number of inefficiencies and apparent conflicts within the system. Some have been addressed (for example, pesticides have been exempted from the Delaney clause's ban on carcinogens), but others remain. USDA is obligated by statute to maintain the system of continuous on-site factory inspection by government inspectors that has been the hallmark of meat and poultry regulation. The Food and Drug Administration (FDA), meanwhile, with a more varied industry to regulate, has relied on selective monitoring, in which far fewer inspectors periodically visit settings where food is produced, processed, or stored to verify compliance with or to uncover violations of its requirements. A result is that in some cases inspectors from these two agencies oversee food processing in the same processing facility at the same time due to the different enabling statutes. Agencies are at times precluded by statute from implementing monitoring or enforcement practices that are based in science.

The size and complexity of the US food system require significant involvement of government at all levels—federal, state, and local; of the food industry—ranging from the producer to food server; of universities; of the news media; and, most importantly, of the consumer, to address adequately the multitude of issues that arise in ensuring safe food. At the federal level, the efforts are currently fragmented, with at least 12 agencies¹ involved in the key functions of safety: monitoring, surveillance, inspection, enforcement, outbreak management, research, and education. Efforts to coordinate federal activities have intensified over the last two years with the National Food Safety Initiative. There are over 50 memoranda of agreement between various agencies related to food safety. The recent proposal to create a Joint Food Safety Research Institute

¹The major federal agencies involved include: the Agricultural Marketing Service, the Animal and Plant Health Inspection Service, the Agricultural Research Service, the Cooperative State Research, Education and Extension Service, the Economic Research Service, the Food Safety and Inspection Service, and the Grain Inspection, Packers and Stockyards Administration of the United States Department of Agriculture; the Centers for Disease Control and Prevention, the Food and Drug Administration, and the National Institutes of Health of the Department of and Human Services; the National Marine Fisheries Service of the Department of Commerce; and the Environmental Protection Agency.

between USDA and FDA is an obvious outgrowth of such efforts. Notwithstanding these relatively recent activities, however, there still exist significant barriers to full integration.

Summary Findings: The Current US System for Food Safety

- has many of the attributes of an effective system;
- is a complex, inter-related activity involving government at all levels, the food industry from farm and sea to table, universities, the media, and the consumer;
- is moving toward a more science-based approach with HACCP and with risk based assessment;
- is limited by statute in implementing practices and enforcement that are based in science;
- is fragmented by having 12 primary federal agencies involved in key functions of safety: monitoring, surveillance, inspection, enforcement, outbreak management, research, and education; and
- is facing tremendous pressures with regard to:
 - emerging pathogens and ability to detect them;
 - maintaining adequate inspection and monitoring of the increasing volume of imported foods, especially fruits and vegetables;
 - maintaining adequate inspection of commercial food services and the increasing number of larger food processing plants; and
 - the growing number of people at high risk for foodborne illnesses.

2. An Effective Food Safety System

Mission

The committee defines safe food as food that is wholesome, that does not exceed an acceptable level of risk associated with pathogenic organisms or chemical and physical hazards, and whose supply is the result of the combined activities of Congress, regulatory agencies, multiple industries, universities, private organizations, and consumers. The mission of a food safety system should be stated as an operational charge that uses and reflects that definition. After reviewing the missions presented by some of the lead federal agencies involved in the US food safety system, the committee defined an overall mission as follows:

The mission of an effective food safety system is to protect and improve the public health by ensuring that foods meet science-based safety standards through the integrated activities of the public and private sectors.

Attributes of an Effective Food Safety System

The attributes of a model food safety system can be summarized in five major components. First, it should be science-based, with a strong emphasis on risk analysis, thus allowing the greatest priority in terms of resources and activity to be placed on the risks deemed to have the greatest potential impact (see Box ES-1). Adjusting effort to risk depends on being able to identify hazards, evaluate the dose-response characteristics of the hazards, estimate or measure exposures, and then determine the likely frequency and severity of effects on health resulting from estimated exposure. Hazards are properties of substances that can cause adverse consequences. Hazards associated with food include microbiological pathogens, naturally occurring toxins, allergens, intentional and unintentional additives, modified food components, agricultural chemicals, environmental contaminants, animal drug residues, and excessive consumption of some dietary supplements. In addition, improper methods of food handling and preparation in the home can contribute to increases in other hazards.

The limited resources available to address food safety issues direct that regulatory priorities be based on risk analysis, which includes evaluation of prevention strategies where possible. This approach enables regulators to estimate the probability that various categories of susceptible persons (for example, the elderly, or nursing mothers) might acquire illness from eating specific foods and thereby allows regulators to place greater emphasis and direct resources on those foods or hazards with the highest risk of causing human illness. Risk analysis provides a science-based approach to address food safety issues. Comprehensive human and animal disease surveillance must be an integral part of any risk analysis in order to estimate exposure.

The second component in a model system is to have a national food law that is clear, rational, and comprehensive, as well as scientifically based on risk. Scientific understanding of risks changes, so federal food safety efforts must be carried out within a flexible framework. US regulatory agencies are moving toward science-based HACCP programs². This is a major step toward a science-based system, but other steps remain critical. An ideal system would be preventive and anticipatory in nature, and thus designed with integrated national surveillance and monitoring along with education and research required to support these activities woven into the fabric of the system. A reliable and accurate system of data collection, processing, evaluation, and transfer is the foundation for scientific risk analysis. Research should have both applied and basic components and be targeted at the needs of producers, processors, consumers, and regulatory decision-makers and other scientists.

² The implementation of the science-based HACCP strategy is perhaps the most notable recent advance. In contrast to the traditional reactive food safety strategies, the HACCP system focuses on preventing hazards that could cause foodborne illness by applying science-based control processes at each step, from raw material to finished product.

Box ES-1. What is the Meaning of Science-Based?

A science base for ensuring safe food encompasses many elements. When utilized, these elements improve the ability to identify, reduce, and manage risks; minimize occurrence of foodborne hazards; gather and utilize information; enhance knowledge; and improve overall food safety. Several examples of science-based actions that have been implemented in the US food safety system that are readily recognized as positive elements of the system include:

- implementation of low-acid canned food processing technology, which reduces the risk of botulism;
- implementation of HACCP systems and risk assessment in decision-making;
- approval of irradiation technology for use in spices, pork, beef, poultry, fruits and vegetables;
- prohibition of the use of lead-based paints on utensils that come in contact with food;
- estimation of maximum allowable exposure levels to pesticides;
- development of standards for allowable practices associated with transport of foods following transport of pesticides in the same containers;
- use of labeling as a device to warn consumers who are sensitive to potential food allergens of the content of the allergen; and
- requirements that meat and poultry products at the retail level carry consumer information related to safe food handling practices.

While the approaches above are important successful science-based tools in food production and processing, these are only examples of implementation of the scientific basis for food safety. An effective food safety system also integrates science and risk analysis at all levels of the system, including food safety research, information and technology transfer, and consumer education.

Third, a model food safety system should also have a unified mission and a single official who is responsible for food safety at the federal level and who has the authority and the resources to implement science-based policy in all federal activities related to food safety. This would allow for effective and consistent regulation and enforcement. Similar risks require similar planning, action, and response. Thus the intensity, nature, and frequency of inspection should be similar for foods posing similar risks. A central voice is critical to effective marshaling of all aspects of the food safety system to create a coordinated response to foodborne disease outbreaks. Control of resources is also critical in order to encourage movement toward science-based food safety provisions and

to ensure that research and education are targeted toward efforts that will produce the greatest benefit for a given cost of improving food safety.

The fourth essential feature of an ideal federal food safety system is that it be organized to be responsive to and work in true partnership with nonfederal partners. These include state and local governments, the food industry, and consumers. The food safety system must function as an integrated enterprise. It must be agile, fluid, connected, integrated, and transparent, with well defined accountability and responsibility for each partner in the system. It must frame approaches to risk management that recognize the importance of public perception of risks as well as assessments conducted by experts.

Finally, an effective food safety system must be supported by funding adequate to carry out its major functions and mission—to promote the public's health and safety. Moving toward science-based risk analysis as the underpinning of the system should allow reallocation of resources to areas identified as critical to an integrated, focused effort to ensure safe food.

Summary Findings: An Effective Food Safety System

- should be science-based with a strong emphasis on risk analysis and prevention thus allowing the greatest priority in terms of resources and activity to be placed on the risks deemed to have the greatest potential impact;
- is based on a national food law that is clear, rational, and scientifically based on risk;
- includes comprehensive surveillance and monitoring activities which serve as a basis for risk analysis;
- has one central voice at the federal level which is responsible for food safety and has the authority and resources to implement science-based policy in all federal activities related to food safety;
- recognizes the responsibilities and central role played by the non-federal partners (state, local, industry, consumers) in the food safety system; and
- receives adequate funding to carry out major functions required.

3. Where Current US Food Safety Activities Fall Short

Statutory revision is essential to the development and implementation of an effective and efficient science-based food safety system. Major aspects of the current system are in critical need of attention in order to move toward a more effective food safety system. Food safety in the United States lacks integrated Congressional oversight, allocation of funding based on science, and sustained political support. Statutory impediments interfere with implementation of a more effective food safety system. More than 35 primary statutes regulate food safety. Statutory revision is essential to the development and implementation of an effective and efficient science-based food safety system. The meat and poultry inspection laws mandate a form of compliance monitoring that is largely

unrelated to the magnitude or the types of risks that are now posed by those foods. This diverts efforts and perhaps resources from actual risks and other hazards. Inconsistent food statutes often inhibit the use of science-based decision making in activities related to food safety, including lack of jurisdiction to evaluate food handling practices in countries of origin for some types of imported foods.

The federal government response to food safety issues is too often crisis-driven. Management decisions, emphasis, and agency culture are driven by the primary concerns of each agency and special initiatives. One result is fragmentation, which causes a lack of coordination and consistency among agencies in mission, food safety policies, regulation, and enforcement. The fact that some agencies have dual responsibilities (regulation of the quality of food products while marketing them via promotional activities) makes their actions more vulnerable to criticism regarding possible conflicts of interest and may bias their approach to food safety.

In addition to fragmented and overlapping authorities, federal activities are not well integrated with state and local activities. This results in overlapping responsibilities, gaps in responsibilities, and inefficiencies. Although FDA recommended minimum food handling standards in a Food Code issued in 1993, the Code has not been adopted in its entirety by most state and local authorities. Surveillance efforts currently in place (such as FoodNet) have been designed to provide data representative of national trends with regard to seven indicator foodborne pathogens yet are not designed to identify trends within smaller geographic areas or communities. Similarly, there are conflicts between US requirements and those of other nations and international bodies. These inadequacies have serious implications for both food imports and food exports.

The multi-faceted federal framework of the US food safety system lacks direction from a single leader who can speak for the government when confronting food safety issues and providing answers to the public. There is no single voice in the government to communicate with stakeholders regarding food safety issues. The lack of clear leadership at the federal level impedes the federal role in the management of food safety. Leadership is needed to set priorities, deploy resources, and integrate a consistent policy into all levels of the system.

A significant impediment to moving toward a science-based food safety system is the lack of adequate emphasis on and integration of surveillance activities that provide timely information on current and potential foodborne disease and related hazards. This timely information is critical if the food safety system is to move from a mode of reaction to prevention. FDA's lack of resources to maintain adequate inspection and monitoring of commercial food facilities and of fresh fruits and vegetables, both domestic and imported, using statute-driven methods of monitoring and enforcement, increases the threat of foodborne disease and related hazards in the food supply.

The committee found that the resource base for research and surveillance was not adequate to achieve the goals identified as necessary for an effective system. Furthermore, there is not an adequately coordinated effort on the scale

required to analyze risk and respond to the challenges of the changing nature of American food hazards related to increases in consumption of imported foods and of food eaten outside the home.

With respect to consumer education, the committee found two major problems: in some instances, consumer knowledge is inadequate or erroneous; and even where knowledge is adequate, it often fails to influence behavior.

Summary Findings: Where the US Food Safety System Falls Short

- inconsistent, uneven and at times archaic food statutes that inhibit use of science-based decision making in activities related to food safety, including imported foods;
- a lack of adequate integration among the 12 primary agencies that are involved in implementing the 35 primary statutes that regulate food safety;
- inadequate integration of federal programs and activities with state and local activities;
- absence of focused leadership: no single federal entity is both responsible for the government's efforts and given the authority to implement policy and designate resources toward food safety activities;
- lack of similar missions with regard to food safety of the various agencies reviewed;
- inadequate emphasis on surveillance necessary to provide timely information on current and potential foodborne hazards;
- resources currently identified for research and surveillance inadequate to support science-based system;
- limited consumer knowledge, which does not appear to have much impact on food handling behavior; and
- lack of nationwide adherence to appropriate minimum standards.

4. Conclusions and Recommendations Needed to Improve the US Food Safety System

Given the concerns outlined above, the committee came to three primary conclusions:

- I. An effective and efficient food safety system must be based in science.
- II. To achieve a food safety system based on science, current statutes governing food safety regulation and management must be revised.
- III. To implement a science-based system, reorganization of federal food safety efforts is required.

To accomplish these objectives, the committee recommends that the following measures be taken regarding the scientific and organizational changes needed to improve the US food safety system:

Recommendation I:

Base the food safety system on science.

The United States has enjoyed notable successes in improving food safety. One example is the joint government-industry development of low-acid canned food regulations, based on contingency microbiology and food engineering principles, that has almost eliminated botulism resulting from improperly processed commercial food. Similarly, the passage of the 1958 Food Additives Amendment to the Food, Drug, and Cosmetic Act of 1938 was a "technology forcing" event that improved the evaluation of the safety of added and natural substances and reduced the risks associated with the use of food additives. In a like manner, the Delaney clause of that amendment resulted in increased attention to carcinogenic substances in the food supply. With increasing knowledge, many rational, science-based regulatory philosophies have been adopted, some of which rely on quantitative risk assessment. Adoption of such a science-based regulatory philosophy has been uneven and difficult to ensure given the fragmentation of food safety activities, and the differing missions of the various agencies responsible for specific components of food safety. This philosophy must be integrated into all aspects of the food safety system, from federal to state and local.

Recommendation IIa:

Congress should change federal statutes so that inspection, enforcement, and research efforts can be based on scientifically supportable assessments of risks to public health.

Limitations on the resources available to address food safety issues require that food safety activities operate with maximal efficiency within these limits. This does not require full-scale, cost-benefit analysis of each issue, but it does require that costs, risks, and benefits be known with some precision. Thus, where feasible, regulatory priorities should be based on risk analysis which includes evaluation of prevention strategies where possible. The greatest strides in ensuring food safety from production to consumption can be made through a science-based system that ensures that surveillance, regulatory, and research resources are allocated to maximize effectiveness. This will require identification of the greatest public health needs through surveillance and risk analysis, and evaluation of prevention strategies. The state of knowledge and technology

defines what is achievable through the application of current science. Public resources can have the greatest favorable effect on public health if they are allocated in accordance with the combined analysis of risk assessment and technical feasibility. However, limiting allocation of resources to *only* those areas where high priority hazards are known can create a significant problem: other hazards with somewhat lower priority but with a much greater probability of reduction or elimination might not be addressed due to limited resources. Thus both the marginal risks and marginal benefits must also be considered in allocating resources.

Not all agencies responsible for monitoring the safety of imported food are authorized to enter into agreements with the governments of exporting countries in order to reciprocally recognize food safety standards or inspection results. Uniform or harmonized food safety standards and practices should be established, and officials allowed to undertake research, monitoring, surveillance, and inspection activities within other countries. This should permit inspection and monitoring efforts to be allocated in accordance with science-based assessments of risk and benefit. Changes in federal statute that would foster and enhance science-based strategies are shown in Box ES-2.

Box ES-2. Changes in Federal Statute that Would Foster and Enhance Science-based Strategies:

- eliminate continuous inspection system for meat and poultry and replace with a science-based approach which is capable of detecting hazards of concern;
- mandate a single set of science-based inspection regulations for all foods; and
- mandate that all imported foods come from only countries with food safety standards deemed equivalent to US standards.

Recommendation IIb:

Congress and the administration should require development of a comprehensive national food safety plan. Funds appropriated for food safety programs (including research and education programs) should be allocated in accordance with science-based assessments of risk and potential benefit.

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. Such a plan, as shown in Box ES-3, should serve as the blueprint for strategies designed to determine priorities for

funding, to determine what the needs are, and to ensure that they are incorporated into activities and outcome evaluation.

Box ES-3. The National Food Safety Plan should:

- include a unified, science-based food safety mission;
- integrate federal, state, and local food safety activities;
- allocate funding for food safety in accordance with science-based assessments of risk and potential benefit;
- provide adequate and identifiable support for the research and surveillance needed to:
 - monitor changes in risk or potential hazards created by changes in food supply or consumption patterns, and
 - improve the capability to predict and avoid new hazards;
- increase monitoring and surveillance efforts to improve knowledge of the incidence, seriousness, and cause-effect relationships of foodborne diseases and related hazards;
- address the additional and distinctive efforts required to ensure the safety of imported foods;
- recognize the burdens imposed on state and local authorities that have primary front-line responsibility for regulation of food service establishments; and
- include a plan to address consumers' behaviors related to safe food-handling practices.

Recommendation IIIa:

To implement a science-based system, Congress should establish, by statute, a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.

The committee was asked to consider organizational changes that would improve the safety of food in the United States. During the 6 months of active review of information and deliberation, the committee identified characteristics needed in an organizational structure that would provide for an improved focus for food safety in the United States. The committee found that the current fragmented regulatory structure is not well equipped to meet the current challenges. The key recommendation in this regard is that in order for there to be a successful structure, one official should be responsible for federal efforts in food safety and have control of resources allocated to food safety.

This recommendation envisions an identifiable, high-ranking, presidentially-appointed head, who would direct and coordinate federal activities and speak to the nation, giving federal food safety efforts a single voice. The structure created, and the person heading it, should have control over the resources Congress allocates to the food safety effort; the structure should also have a firm foundation in statute and thus not be temporary and easily changed by political agendas or executive directives. It is also important that the person heading the structure should be accountable to an official no lower than a cabinet secretary and, ultimately, to the President.

Many members of the committee are of the view that the most viable means of achieving these goals would be to create a single, unified agency headed by a single administrator—an agency that would incorporate the several relevant functions now dispersed, and in many instances separately organized, among three departments and a department-level agency. However, designing the precise structure and assessing the associated costs involved are not possible in the time frame given the committee, nor were they included in its charge. The committee did discuss other possible structures; while it ruled out some, it certainly did not examine all possible configurations and thus the examples provided in Box ES-4 are only illustrative of possible overall structures that could be considered.

Box ES-4. Some Examples of Possible Organizational Structures to Create a Single Federal Voice for Food Safety:

- a Food Safety Council with representatives from the agencies with a central chair appointed by the President, reporting to Congress and having control of resources,
- designating one current agency as the lead agency and having the head of that agency be the responsible individual,
- a single agency reporting to one current cabinet-level secretary, and
- an independent single agency at cabinet level.

Note: These examples are provided for illustrative purposes and many other configurations are possible. It is strongly recommended that future activities be directed toward identifying a feasible structure that meets the criteria outlined.

The committee does not believe that the type of centralized focus envisioned can be achieved through appointment of an individual with formal coordinating responsibility but without legal authority or budgetary control for food safety, a model similar to a White House-based 'czar'. Nor, in the committee's view, can this goal be achieved through a coordinating committee similar to that currently provided via the National Food Safety Initiative. In evaluating possible structures, the committee realized that past experience with other structures or

reorganizations, including the creation of new agencies, such as the Environmental Protection Agency (EPA), should inform any final judgment. Further, it is quite possible that other models may now exist in government that can serve as templates for structural reform. Whether or not a single agency emerges, the ultimate structure must provide for not just delegated responsibility, but also for control of resources and authority over food safety activities in the federal government.

Recommendation IIIb:

Congress should provide the agency responsible for food safety at the federal level with the tools necessary to integrate and unify the efforts of authorities at the state and local levels to enhance food safety.

This report specifically addresses the federal role in the food safety system, but the roles of state and local government entities are equally critical. For integrated operation of a food safety system, officials at all levels of government must work together in support of common goals of a science-based system. The federal government must be able to ensure nationwide adherence to minimal standards when it is deemed appropriate. The work of the states and localities in support of the federal mission deserves improved formal recognition and appropriate financial support. Statutory tools required to integrate state and local activities regarding food safety into an effective national system are shown in Box ES-5.

Box ES-5. The Statutory Tools Required to Integrate Local and State Activities Regarding Food Safety into an Effective National System:

- authority to mandate adherence to minimal federal standards for products or processes,
- continued authority to deputize state and local officials to serve as enforcers of federal law,
- funding to support, in whole or in part, activities of state and local officials that are judged necessary or appropriate to enhance the safety of food,
- authority given to the federal official responsible for food safety to direct action by other agencies with assessment and monitoring capabilities, and
- authority to convene working groups, create partnerships, and direct other forms and means of collaboration to achieve integrated protection of the food supply.

MOVING TOWARD A MODEL SYSTEM

It is recognized that these recommendations will need significant review and discussion. The committee focused on the need for a centrally managed federal system to ensure coordination and direction in food safety programs and policy, and to serve as a single voice with authority and resources to suggest and implement legislation. It had insufficient time to review all the possible organizational structures that could accomplish this goal. A successor study could focus on this. Of critical importance, though, are the first two recommendations: the first, to base the system on science, and the second, that of rewriting the current patchwork of federal food statutes that in many cases do not serve to ensure a scientifically supportable and risk-based food safety system, and certainly prevent it from being more cost effective.

Regardless of the organizational structure chosen, a revamped federal food statute is critical to being able to reallocate resources toward risks that have or will have the greatest significance to the public's health. Implementation of these recommendations should not be looked at as a cost-cutting measure, but rather as a way to design a well-defined integrated system to ensure safe food. This system may well be able to demonstrate effectively a need for additional resources to address important and specific problems. Although the National Food Safety Initiative properly seeks to alleviate problems inherent in the present decentralized structure, experience indicates that any ad hoc administrative adjustments and commitments to coordination will not suffice to bring about the vast cultural changes and collaborative efforts needed to create an integrated system.

Changing hazards associated with food and changing degrees of acceptance of risk are factors that impact the nation's ability to protect public health and ensure safe food. Risk acceptance and foodborne hazards will continue to change and evolve with new technologies and consumer demands. Federal food safety efforts must be designed to deal with those changes. This report is not a comprehensive and all-inclusive discussion of these issues. Adoption of the recommendations in this report will not end the effort to make food safer. They should, however, contribute to ensuring the safety of our food while providing a blueprint for a truly integrated system.

00/20/90 10:04 1AA
THE WHITE HOUSE
WASHINGTON

NK3
Sept.

From the Office of:

The Domestic Policy Council

**Elena Kagan
Deputy Assistant to the President
for Domestic Policy**

TO: Tom

FAX: 67431

PHONE: _____

PAGES: 2

MESSAGE: _____

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



Thomas L. Freedman
07/22/98 12:33:25 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Michelle Crisci/WHO/EOP
cc: Mary L. Smith/OPD/EOP, Laura Emmett/WHO/EOP
Subject: Update: NAS Report and Single Food Agency/ ignore the last e-mail.

1. In mid-August, the prestigious National Academy of Science is supposed to release a report on the utility of a single food agency. We are starting to get rumors of what it will say. It is likely to get some attention.

2. The report is likely to be very critical of the current food safety regulatory structure, particularly that USDA has a lot of money but little authority and FDA little money, but much authority.

3. The report will suggest four options: 1. create a WH food czar who puts out a single food safety budget; 2. put either USDA or FDA in charge; 3. create a single food agency like EPA; or 4. designate one agency as the lead on the issue.

4. We have been pushing the agencies to come up with some more movement on creating a "virtual food agency" that could be announced in August-- advances like the research institute the President announced that combine FDA and USDA in other areas. Already there is a working group on the budget which it might make sense to institutionalize in a formal structure and require a formal annual plan. Is there any interest in option of "1" of the NAS report -- creating a coordinating food safety czar?

Tom -
I think we have to try + preempt
this with as large an announcement
as possible (rel. e.s., what we did
on nursing homes last week). Let's
set up a time to talk ASAP. You
should come in with ideas.
Elena

cc: Bruce

NAS ref-

Date: 01/29/1999 11:21 am (Friday)
From: Eric Olsen
To: Caren Wilcox; Cathie Woteki; Tom Billy
Subject: Today's Mtg

I will not be able to attend (meeting with Sec about budget presentation monday). My key issues: and feel free to invoke Secretary's office:

The draft is much too negative on structural shifts: I don't mean to understate the negatives, but there are positives as well, and this draws too deep a line in the sand against a shift. We need to maintain the position advocated by the Secretary i.e. rolling into strategic plan, with policy subgroup, leaving open possibility of moving. I would rather not preview the arguments in support of my outline, but I do want to be personally involved in the policy level subgroup. Rather, our position, as stated by the Secretary, should not be a hard line in support of the status quo. We need to actively evaluate the substantive and policy merits of any shift, which we have not done to date, and this report should not lock us into either the status quo or a change. As you recall, he was also strong that "science" is not the only guiding factor....OMB or OSTP may try to change some of that, and I do not think we should give ground on this if that is the case

And the 50 state initiative. This HAS to be rolled into Council. The way it is drafted only has recommendations being reviewed by Council. This will only lead to expectations, possibly being frustrated, by state partners. Entire process needs to be rolled into Council. No further actions until Council approves of strategy and approach.

My guess is OMB will push a hard line in support of risk assessments for all actions and try to quash any references to future regulatory actions. I think we should strongly resist this, particularly the latter. I have briefly discussed with the Secretary a focus on achieving 2-3 more significant regulatory initiatives in the next 2 years, and he is supportive of this. DPC is likely to support microtesting regime etc. If OMB balks at specific language or pushes a hard line, I would suggest we list several options with general language on risk and revisit with specific strategies and approaches e.g. campy, cranking down salmonella, ingesta, listeria....This is a good time to push for policy level approval of additional regulatory measures, and it would probably be good to use this report to foreshadow those, particularly since it does not take a position on the structural issues e.g. shows ongoing actions and commitments. I do not think we should accept utilizing this report as a way of watering down of future regulatory actions, or hamstringing with specific commitments on quantitative risk assessments. I would want to review any such changes.

I'll be around if you want to discuss this or any other thoughts/concerns you have. Sorry I won't be at the meeting.

NAS
Report

Need for
Fed's response
to Unif. Structure
2. ↑ Struc.
3. ↑ Resour.

A SSESSMENT OF THE NAS REPORT ENSURING SAFE FOOD
Findings of the NAS Report and Draft Responses

Chapter 2. The Current US System for Food Safety

- a. *Has many of the attributes of an effective system*
- b. *Is a complex, inter-related activity involving government at all levels, the food industry from farm and sea to table, universities, the media, and the consumer*
- c. *Is moving toward a more science-based approach with HACCP and with risk based assessment*
- d. *Is limited by statute in implementing practices and enforcement that are based in science*
- e. *Is fragmented by having 12 primary federal agencies involved in key functions of safety: monitoring, surveillance, inspection, enforcement, outbreak management, research, and education*

Except for item c., there is really nothing to "assess" here. Regarding statutory limitations to the implementation of science-based practices and enforcement, the Department of Health and Human Services (HHS) does not agree that current law, as implemented, prevents application of a science-based approach and the use of science in all food safety activities. Certain provisions of the law are archaic in light of contemporary science, but, in most instances, HHS food safety agencies have found successful solutions that allow the application of contemporary science and risk-based analysis. Otherwise, HHS agrees with the NAS panel's assessment of the current system.

Chapter 3. The Changing Nature of Food Hazards

- a. *Changes in the risk of infectious foodborne disease are due primarily to:*
 - *changes in diet*
 - *increasing use of commercial food service and in food eaten or prepared away from home*
 - *new methods of producing and distributing food*
 - *new or re-emerging infectious foodborne agents, and*
 - *the growing number of people at high risk for foodborne illnesses due to*
 - *increasing number of elderly, and*
 - *increasing number of people with depressed immunity or resistance to infection*

Background:

Surveillance is critical for detecting and responding to sporadic and outbreak-associated foodborne illnesses, including those that are new or re-emerging. When a potentially foodborne disease occurs, the role of the public health system is to identify the disease; conduct a thorough investigation to determine if the source is contaminated food and, if so, how the food became contaminated; and to pinpoint any weaknesses in the food protection system.

The Centers for Disease Control and Prevention (CDC) have strengthened national surveillance, developed new tools for outbreak detection, and improved diagnostic capacity for foodborne pathogens. CDC's foodborne disease prevention activities are building a national early warning system to rapidly identify problems in the food supply before they become widespread.

One example of the early warning system, PulseNet, is a national network of public health laboratories that perform DNA "fingerprinting" of bacteria that may be foodborne. Such a system is particularly important today; changes in food distribution are creating foodborne outbreaks that are more geographically diffuse, involving many locations but only a few people at any given place. Through this system, DNA fingerprints from organisms evaluated in participating laboratories are submitted electronically to a database maintained at CDC. Within minutes, computers can determine if there are matches among submitted patterns and can alert appropriate agencies and states through computer-generated messages when a match is found. Finding matching patterns is an early indicator of an outbreak, and that contaminated food may be in distribution. Participation of US Department of Agriculture (USDA) and Food and Drug Administration (FDA) laboratories allows rapid comparison of human isolates to those found in animal and food sources. This technology, which identified contamination with *Escherichia coli* O157:H7 of widely distributed ground beef based on isolates from only 12 patients, spared untold numbers of people a potentially life-threatening illness. In coming years, systems such as PulseNet will be expanded to include an increasing number of bacterial, parasitic, and viral foodborne pathogens.

Another key CDC program, conducted in collaboration with FDA and USDA, is FoodNet, the Foodborne Diseases Active Surveillance Network, which involves eight states and covers more than 10% of the U.S. population. Through this program, CDC is gathering more precise and systematic data on the burden of foodborne and waterborne diseases in the U.S. population than has previously been possible, while also systematically identifying risk factors for sporadic disease occurrence. The states participating in FoodNet also function as sites for model demonstration projects to evaluate the effectiveness and efficiency of foodborne disease interventions.

Strengths:

HHS agrees with this finding. It supports the need for action, such as the National Food Safety Initiative. In particular, it reinforces the need to intensify national efforts to strengthen surveillance, develop new tools for outbreak detection, and to improve diagnostic capacity for foodborne pathogens. We would, however, add that consolidation of animal production facilities into very large operations that result in easy dissemination of pathogens and increased stress on the animals that, in turn, induces shedding of pathogens is an additional factor.

Weaknesses: None_____

Barriers to Improvement:

Developing and transferring new diagnostic and other capacity to states and localities is a slow, labor-intensive, and expensive process.

Core capacity to monitor, investigate, and control foodborne hazards does not exist in all state and local health departments.

With the globalization of the food supply, the Nation also faces the introduction of foodborne pathogens more common in other countries and previously not generally found in the United States.

Competing priorities and limited resources.

b. Changes in chemical hazards associated with the food supply must be monitored and evaluated; these include:

- *increased use of dietary supplements and herbal products without requirements to meet specified safety standards*
- *new food components that mimic attributes of traditional food components*
- *introduction of new food technologies and processes*
- *changes in presence of food toxins and additives, including unintentional food additives; and*
- *presence of physical hazards associated with new technologies or sources of foods*

HHS agrees with the assessment of changes in chemical hazards.

Chapter 4. An Effective Food Safety System

a. Should be science-based with a strong emphasis on risk analysis and prevention thus allowing the greatest priority in terms of resources and activity to be placed on the risks deemed to have the greatest potential impact

Background:

FDA's food safety programs have, from the inception of the agency, been based on a scientific evaluation of risks to human health and on preventing those risks. Food safety activities ranging from research to inspection to development of policy and regulations are based on an evaluation of public health risk. For example, no agency action to initiate removal of a potentially hazardous product from the marketplace occurs without an evaluation of the hazard and the public health risk by FDA's Center for Food Safety and Applied Nutrition's (CFSAN) medical and scientific staff on the Health Hazard Evaluation Board. Based on these types of evaluations, overall agency priorities have changed over the years, for example from an emphasis on chemical hazards like environmental contaminants (e.g., polychlorinated biphenyls) in the late 1960s to a focus on microbial contaminants (e.g., *Listeria monocytogenes*). This is not to say that chemical contaminants have not periodically posed public health risks and thus, have needed to be dealt with (e.g., methyl mercury, lead, dioxin, ethyl carbamates) and, at times, to present some complex cross-over public health issues. For example, in the 1980s, questions arose about the risks of cancer from nitrites, ingredients long used as preservatives in cured meats like fermented sausages. The preservative action of nitrites is to prevent *Clostridium botulinum* spores from outgrowth and toxin production within sausage casings and other anaerobic environments.

Evaluation of the policy options to deal with this risk, required the agency to balance the risk of nitrite use against the risk of *Clostridium botulinum* spore outgrowth and the resulting illnesses and possibly deaths from botulism if the preservative were not used. Changing public health risks and evolving science and technology, in combination, have influenced the direction of the agency's long-term food safety programs, some of which have been in place since the 1920s (e.g., the milk safety, shellfish safety, and retail food safety programs). Whether FDA's food safety programs are long-term or deal with the issue of the moment, the underlying principle for initiating action is science-based risk evaluation and prioritization to prevent the risk.

Ideally, all food safety activities would always be based on evaluation and prioritization of risks. However, at times throughout the history of the agency, Congressional mandates may take precedence, causing a deviation from a risk-based prioritization of food safety activity. New statutes like the FDA Modernization Act (FDAMA), the Animal Drug Availability Act, and the Animal Medicinal Drug Use Clarification Act, while beneficial, often create a severe drain on resources and a redirection, even disruption, of the agency's risk-based priorities. Most of the mandates require regulations, public meetings, and other processes that consume staff and other resources and, in most instances, the agency is not provided additional funds to undertake these new responsibilities in an efficient manner.

Strengths:

Scientific evaluation of public health risks is an objective basis for deciding priorities in food safety activities .

Science yields the information needed to identify hazards, to design measures to prevent or reduce the incidence of their occurrence, and to measure the success of those measures.

Prioritization of public health risks and targeting work and resources to either the highest risk or the greatest public health impact (i.e., greatest risk vs. risk to the greatest number of people)

Minimal resources can have a significant impact on improving food safety when allocated based on science and risk-based analysis

Weaknesses: None.

Barriers to improvement:

Time needed to generate scientific information, where it doesn't already exist, necessary to take preventive action

Resources to conduct research and translate the results into food safety policy

Other (conflicting) statutory obligations

b. Is based on a national food law that is clear, rational, and scientifically based on risk.

Background:

The food safety agencies currently operate under several different laws with varying provisions dictating how the agencies will carry out their food safety mandates. FDA's primary law is the Federal Food, Drug, and Cosmetic Act (FFDCA), the core of which was enacted in 1938. The FFDCA authorizes promulgation of food standards and gave the agency authority for factory inspections. It provided for certification of food colors which had been only informally certified on a voluntary basis under the old act and it added the sanctions of injunction and emergency permit control to the seizure and prosecution authority in the previous act. The FFDCA was amended in the 1950's to add the requirement of premarket approval of pesticides, and tolerances were established for pesticide residues in foods to be distributed. Premarket clearance of food additives and color additives was also added at the end of the 1950's. Provisions relating to infant formula were added in 1980. Food amendments to the Act in the 1990's include the Nutritional Labeling and Education Act relating to food labeling, the Dietary Supplement Health and Education Act relating to regulation of dietary supplements, and the Food and Drug Administration Modernization Act which amended certain NLEA provisions and established a new process for marketing of food packaging materials. FDA's federal/state cooperative programs (milk safety, shellfish

sanitation, and retail food safety) are conducted under provisions of the Public Health Service Act. States and localities have their own food safety laws and regulations. Currently, under the Food Safety Initiative, the FDA is leading a federal, state, local effort to integrate the food safety activities. This effort will, ultimately, result in consistent, uniform application of food safety laws and regulations across the country, bolstering consumer confidence in the safety of all foods.

Strengths:

Consistency and uniformity in ensuring the safety of all foods and the regulation of substances added to foods to perform a function (e.g., food ingredients, pesticide residues) or inadvertently (e.g., environmental contaminants, illegal pesticide residues).

Weaknesses:

Full implementation of a science-based national law will require actions to bring the scientific expertise in all agencies — federal, state and local — to a uniform level. This could be a time-consuming and expensive process during which uniform application of the law will most likely be not possible.

Barriers to improvement:

Legislative change is required either to collapse the current multiple laws under which the agencies function into a single law or to amend all the laws to make them completely consistent. This is a time-consuming process exacerbated by the many laws affected.

A phase-in period will be needed for the agencies, particularly the regulatory agencies (FDA and USDA's Food Safety and Inspection Service (FSIS)), to make the transition from functioning under different laws to a single law. This transition period, as well as resources, will also be necessary for orderly adaptation of all agencies to a uniform working level. This phased in transition will effectively result in all agencies functioning at less than optimal level for the phase-in period, which could be a lengthy period of time.

c. Includes comprehensive surveillance and monitoring activities which serve as a basis for risk analysis

Background:

Surveillance is the first step toward building the capacity to detect and respond to sporadic instances and outbreaks of foodborne illness. Surveillance and monitoring are also essential for evaluating the system, identifying emerging issues and new trends, and assessing risk from the farm or sea to the table. Monitoring foodborne disease and investigation of outbreaks to determine their sources and causes can identify crucial weaknesses in the system. An effective

food safety system should be science-based with a strong emphasis on risk analysis and prevention, thus allowing the greatest priority in terms of resources and activity to be placed on the risks deemed to have the greatest potential impact.

Identifying the most cost-effective approaches to prevention and control of foodborne diseases requires collecting appropriate information and using that information in a structured and transparent manner for decision making.

Routine surveillance carried out by state and local health agencies and the intensive surveillance and population-based studies conducted in FoodNet sites are developing more realistic estimates of the burden of foodborne diseases in the United States. By investigating outbreaks and other efforts, we are learning about risk factors for foodborne diseases and potential places in the causal chain where intervention opportunities exist. We also are improving economic data on foodborne diseases, including cost-effectiveness and cost-benefit evaluations of intervention strategies.

FDA and CDC both conduct a variety of surveillance activities that provide information on emerging food safety hazards and public health threats. This information is used to prioritize public health risks and allocate resources.

The FDA's Adverse Event Reporting system (AERs), and specifically the Special Nutritionals AER system, alerts the agency to and tracks potential problems with dietary supplements and special nutritional products such as infant formulas and medical foods. When the agency becomes aware of a potential health threat but does not have adequate information about the extent of the problem, it may use field surveys of the industry conducted by FDA inspectors.

The Total Diet Market Basket Survey is conducted every year to estimate dietary intakes of pesticides, industrial chemicals, and toxic and nutrient elements. With the data going back to 1968, trends in pesticides levels of U.S. diets are identified and compared with diets of other countries, indicating the effectiveness of pesticide regulatory activities. Also, by periodically adding specific industrial chemicals or toxic elements or nutrients to the array of compounds and nutrients routinely analyzed for every year, such as lead and folic acid, the effects of other types of agency interventions, such as folic acid fortification and lead reduction regulations, can be determined. The data also identifies trends in dietary composition that may require intervention to reduce levels of a substance in the diet before adverse events occur.

The agencies collaboratively support the FoodNet and PulseNet systems for foodborne illness surveillance and DNA-fingerprinting of pathogens, respectively. The FoodNet surveillance system fills a critical gap in public health assurance planning: baseline data on the incidence of foodborne illness in the U.S. These surveillance data are used to identify emerging trends in microbial contamination, tailor preventive interventions to microbial public health hazards and measure the effectiveness of preventive measures (e.g., regulations, guidance). PulseNet is used in foodborne illness outbreak investigations to identify the source of the contamination. Long-term FDA support of CDC surveillance activities associated with safety issues, such as

Listeria , eventually evolved in the nationwide FoodNet system. (See discussion on Finding 3.a)

The agency also funds consumer surveys to gauge consumer perceptions and reactions to food safety issues and to interventions, such as warning labels, to inform consumers of potential hazards associated with product use.

In the animal feeds and drugs area, surveillance for emergence of antibiotic resistant pathogens is conducted through the collaborative interagency (FDA/CDC/USDA) National Antimicrobial Resistance Monitoring System (NARMS). The NARMS detects potential health hazards associated with resistant foodborne pathogens through systematic collection, analysis and interpretation of antimicrobial susceptibility surveillance data from animal and human clinical isolates, on-farm animal isolates, and isolates from healthy animals at slaughter plants. The NARMS provides the basis for regulatory decision making, food animal drug policy and identification of disease trends in human and animal medicine. In addition, the program serves as a basis for educational efforts and prudent drug use campaigns in veterinary medicine.

FDA's Center for Veterinary Medicine (CVM) Drug Experience Reporting system is a post-marketing monitoring system for approved animal drugs that collects information on drug efficacy failures, manufacturing and controls, and adverse events associated with drug use. This information is used to detect unsafe product use practices, provide an early warning system for contamination or manufacturing problems that may adversely affect the safety of products, provide a more complete picture of the desirable and undesirable attributes of each drug, and provide an accurate safety profile under actual use conditions. Use of the information can result in label changes, "dear doctor" letters, and if necessary, product recalls.

The Tissue Residue Information Management System is a post-marketing surveillance program that collects information from follow-up investigations of above-tolerance residues of animal drugs in meat and poultry. This System is linked to the FSIS National Residue Program which monitors for residues of animal drugs and other chemicals. Regulatory actions have been taken by FDA against food animal producers, veterinarians, and dealers for tissue residue violations under the adulteration clauses of the Food, Drug, and Cosmetic Act.

Strengths:

Data from surveillance and monitoring identify public hazards that need immediate preventive action (e.g., microbial hazards, illegal pesticide residues in specific foods, occurrence of chemical contaminants in the food supply). The better the surveillance and monitoring systems, the earlier public health hazards can be identified and preventive measures initiated.

Ongoing surveillance efforts such as FoodNet, NARMS, and the Total Diet Study provide information about trends and changes such as the emergence of new hazards, the reduction in hazards in response to preventive measures implemented, prevalence of hazards in the food supply, etc.

Surveillance and monitoring systems provide a significant portion of the data required for risk-based analysis and assessment and public health protection

Weaknesses: None

Barriers to improvement:

Lack of comprehensive surveillance and monitoring systems encompassing the entire food supply (domestic and imported products) from production to consumption at the federal level

Lack of uniform expertise and/or infrastructure in federal, state, and local public health agencies to participate in surveillance and monitoring and share data

The high costs of building surveillance and monitoring infrastructure and expertise and the time necessary to implement and operate the systems before credible data is consistently generated.

The epidemiologic and laboratory-based surveillance and research necessary to provide the scientific basis for our food safety system are difficult to quantify in countable inputs and outputs, making their budgets difficult to justify. Also, components of the early warning system that permit the identification of food safety problems are expensive to develop and maintain, and sometimes hard to “justify,” particularly if only a few consumer illnesses are reported. For example, whereas the prevention of a large number of illnesses and their associated economic impact would justify the cost of the early warning system, implementing and sustaining components of an early warning system is more difficult to justify when few illnesses are being reported.

d. Has one central voice at the federal level which is responsible for food safety and has the authority and resources to implement science-based policy in all federal activities related to food safety.

Background:

The food safety regulatory agencies (FDA and FSIS) function under different laws that dictate how the agencies must carry out their food safety responsibilities. These agencies currently collaborate in the formulation of policy and regulations in areas where jurisdictions overlap or are related and work together to manage public health crises. For example, FDA has jurisdiction over domestic and imported fresh fruits and vegetables and USDA has jurisdiction over grading fresh produce, providing safe produce for the school lunch program, and in working with producers through the extension service. These agencies worked together to develop the Good Agricultural Practices guidance to minimize the risk of contamination of fresh fruits and vegetables for use by producers and in providing technical assistance to put the

guidance into practice. The agencies share scientific expertise and support (for example, in carrying out the pesticide program) when needed.

Strengths:

Consistency in the development and implementation of food safety policy

Resources could more easily be directed to the greatest public health concern

Weaknesses:

If this “voice” is located outside a food safety agency this, potentially, could result in a cumbersome, multilayered process of developing food safety policy, of planning and of resource allocation. This has the potential of impeding rapid responses to emergencies, such as foodborne illness outbreaks, while decisions are made about mobilization of resources to meet the need.

If the “central voice” is located within a single department (e.g., the Secretary of HHS), there is the potential for competing or conflicting interests within the department. For example, food safety interests could conflict with commodity promotion interests or with the interests of other non-food safety, but highly significant health programs.

This finding could be interpreted as requiring the establishment of a single food agency. The time and cost, as well as disruption of normal activity, required to consolidate all food safety activities at the federal level in a single agency would be a set-back to the development and implementation of progressive food safety policy.

Barriers to Improvement:

Current federal food safety laws have different implementing provisions that will make it difficult, if not impossible, for a “central voice” to function effectively in planning and resource allocation.

Scientific expertise and infrastructure must be brought to a uniform level before a “central voice” can effectively develop policy that is applicable across the board.

Time required to consolidate all food safety activities into a single agency, obtain legislative harmonization of food safety laws, and rebuild an effective, rapid response food safety system

e. Recognizes the responsibilities and central role played by the non-federal partners (state, local, industry, consumers) in the food safety system.

Background:

Both FDA and CDC have extensive experience of working with the non-federal partners in the food safety system. HHS recognizes the importance of state and local governments, industry, and consumers in ensuring the safety of food.

FDA has a long history of working in partnership with state and local public health and regulatory agencies to improve the safety of food. The agency provides training, technical assistance, and in administering cooperative federal/state programs in milk safety, shellfish sanitation, and retail food safety. Working with the states and localities, the agency develops and publishes recommendations, such as the Pasteurized Milk Ordinance and the Food Code, for safe handling and processing of these foods. States and localities adopt the recommendations as law and conduct the actual regulatory programs. The National Shellfish Sanitation Program (NSSP) was established in 1925 to oversee sanitary control over all aspects of growing, harvesting, shucking, packing, and interstate transportation of bivalve molluscan shellfish. The Interstate Shellfish Sanitation Program (ISSC) began in 1982 to more effectively manage and operate the NSSP as a partnership of state, industry and federal government. The purpose is to improve information exchange among states, federal agencies, industry and consumers and to provide technical and policy guidance, technical training, research and materials for consumer education.

FDA initiated a 50-state conference call system to keep all state agencies up-to-date on major foodborne outbreaks. Both FDA and CDC participate in these calls to assure more effective follow up and control of outbreaks. In addition, FDA works closely with many organizations with large memberships of state public health and regulatory officials -- the Association of Food and Drug Officials, Conference for Food Protection, ISSC, Interstate Milk Shippers, Council of State and Territorial Epidemiologists, the Association of Public Health Laboratories, and the National Environmental Health Association. Many of these organizations, along with states, are represented on the Foodborne Outbreak Response Coordinating Group (FORCG). Through the 50-state conference calls, state regulatory agencies indicated the need for guidance on evaluating epidemiological data associated with foodborne illness outbreaks. FORCG took on the task and worked with the Council of State and Territorial Epidemiologists (CSTE) to develop a protocol for evaluating epidemiologic outbreak data and to develop criteria for local and state health officials to provide information on outbreaks to federal authorities for review and necessary action.

The FDA is leading a federal, state, local effort to integrate the food safety activities. This effort will, ultimately, result in consistent, uniform application of food safety laws and regulations across the country, bolstering consumer confidence in the safety of all foods. The success of this national effort hinges on the cooperation of all food safety regulatory agencies and on participation of industry and consumers in designing an effective system. In September, 1998, FDA hosted a meeting of public health and agriculture officials from all 50 states, Puerto Rico, and the District of Columbia, epidemiologists and lab personnel from states,

CDC, USDA, and EPA in Kansas City to begin work on creating a national, uniform food safety system.

FDA has initiated 2 government/academia/industry consortia focused on food safety. The National Center for Food Safety and Technology was established 11 years ago at the Illinois Institute of Technology Moffett Campus and includes FDA, IIT, the University of Illinois Department of Food Science and over 50 industry members. The focus of NCFST is the safety of food processing and packaging techniques. The Joint Institute for Food Safety and Applied Nutrition (JIFSAN), a consortium with the University of Maryland, focuses on microbiology, risk assessment, nutrition science, and chemical safety of foods. These consortia build a strong relationship with industry and academia based on concern about improving the safety of foods and fostering open discussion of food safety issues and solutions.

Working with state and local health departments and other organizations, CDC is spearheading an effort to define the core capacities necessary to ensure that the entire U.S. population is protected from foodborne diseases

CDC is bolstering state capability through such efforts as the Epidemiology and Laboratory Capacity (ELC) Cooperative Agreement program. Currently, the ELC program provides funds to 30 state and large local health departments to improve the ability of public health laboratories to conduct surveillance, investigate outbreaks, diagnose foodborne pathogens, and control foodborne disease. During the 1996 and 1997 outbreaks of foodborne cyclosporiasis in the United States, the deficiencies in parasitic disease diagnosis in state and local laboratories became very clear. By distributing NFSI resources through the ELC mechanism, CDC is implementing an Internet-based system to improve parasitic disease diagnosis nationwide. Another high priority is transferring tools for diagnosis of foodborne viral diseases to state and local health departments.

Adequate training is essential to ensuring that health agencies can address foodborne disease problems. CDC's commitment to quickly transfer new prevention technologies to state and local health departments is integrating NFSI resources into foodborne disease prevention training and education at many levels. CDC is designing and developing modules to train public health professionals on the identification, description, and elimination of foodborne agents. For example, in conjunction with the National Laboratory Training Network, CDC plans to use distance learning techniques to train microbiologists to diagnose and subtype foodborne bacterial, parasitic, and viral pathogens. CDC also is developing programs to train and educate school teachers and public health officials on prevention of foodborne diseases.

Consumers play a significant role in food safety, in general, and in agency food safety activities. They serve on advisory committees that assess safety issues and the agency's resolution of the issues. Consumers and agency specialists work together through surveys and focus groups to develop the most effective safety and health messages (e.g., the warning on juices not treated to eliminate pathogens and the warning on iron-containing dietary supplements). Consumer surveys are used as a measure of the effectiveness of preventive measures the agency implements. The agency works with consumer groups to develop and

distribute information they may use to ensure that their food practices and dietary choices improve the safety of their foods.

The Partnership for Food Safety Education — a coalition of federal agencies, industry, state groups and consumer groups — was formed under the Food Safety Initiative to promote the use of safe practices in food preparation and storage by consumers. The national “Fight BAC!™” campaign launched by the partnership slightly over a year ago includes TV and radio spots and visits around the country by the character BAC to promote the food safety messages.

Strengths:

Leveraged resources, i.e., the combined effects of resources and expertise from government, industry, academia, and consumers, greatly expand the food safety capabilities beyond what any one group could accomplish

Increased awareness and knowledge of food safety in each segment of the food safety community obviates the need for extensive regulation of industry and decreases the incidence of contamination after foods leave the distribution system and enter the home

Integrated federal, state, and local food safety systems that build a consistent, uniform level of safety assurance across the U.S. by sharing resources (expertise, data, information)

Consistent, uniform food safety messages, training, and technical assistance to meet all levels of regulatory, industry, academic, and consumer need

Weaknesses: None

Barriers to Improvement:

Time and funding, required to build and maintain effective cooperative programs among the varying segments of the food safety community - the long-term benefits outweigh the delays, however

Integration of federal, state and local food safety systems — communications from various groups, indicate that there are some concerns —

- Consumer concern that the economic interests of industry within states may be a source of conflict if states have an expanded food safety role that includes activities thought to be federal responsibility (e.g., firm inspections)
- Industry concern that food safety regulation will be inconsistent among the states if systems are integrated without adequate preparation of the state agencies to step into the expanded food safety role

Delivering training and other outputs in a timely manner remains problematic. The goal of keeping up with demand for education and training of epidemiologists, laboratory workers, public health nurses, environmental sanitarians, food workers, school children, and the general public will remain out of reach for the foreseeable future. Additional resources will be needed to adequately address foodborne disease prevention needs nationwide.

f. Receives adequate funding to carry out major functions required.

Background:

FDA has, since 1978, experienced approximately a 20% decrease in resources for food safety activities. This decrease has occurred even with increases targeted to specific food safety programs: seafood safety, imported foods, the Food Safety Initiative. The impact has been reduction in several of the agency's basic food safety programs, notably, the inspection program, particularly of imported foods. Research to support inspection, monitoring, and development of food safety policy and regulation has been reduced. Other food safety programs that have been reduced include pesticides, filth, consumer education and industry technical assistance. Programs that are not directly related to food safety but provide some support to food safety programs, such as nutrition and economic adulteration, have also experienced significant reductions. In addition, the average age of the workforce has increased and a large number will be eligible for retirement within the next few years as the result of reduced hiring of recently graduated scientists with updated expertise, as well as scientists with highly specialized expertise, creating a gap in the agency's preparedness to deal with new technologies and the potential public health and safety questions they raise. The agency has met these challenges through increased use of partnerships (with states, industry, academia, and other groups) and cooperative food safety consortia, such as the NCFST and JIFSAN, to leverage available resources, gain access to needed expertise and scientific equipment, and to bolster expertise and capabilities of existing FDA scientists. Through partnerships, the agency has increased the number of firms inspected and provided more extensive training and technical assistance to state inspectors on seafood HACCP and transportation safety. Partnerships formed under the auspices of the President's Food Safety Initiative have allowed the agency to extend consumer information programs (e.g., "Fight BAC!"™ and the conference for Food Safety Educators), assistance to states and the retail food industry, and assistance to foreign governments and producers importing foods into the U.S.

Strengths:

Scientists and investigators trained and equipped to meet the daily food safety needs of the public health and regulatory agencies and to respond rapidly in emergency situations.

Scientific research required to support public health and food safety policy can be initiated quickly and long-term research conducted at optimal productivity level.

Expansion of surveillance and monitoring programs to provide a statistically valid overview of the food supply, particularly safety factors, over the long-term

Increased inspection of food firms; all high risk firms annually and lower risk firms less frequently.

Improved safety of imported foods

Reduced incidence of antimicrobial resistant pathogens in the food supply

Weaknesses: None

Barriers to Improvement:

Difficulty in obtaining administration support for a comprehensive food safety program that encompasses domestic as well as imported products, while the agency has received support from both industry and consumer groups for funding to strengthen the science base.

Food safety priorities must be weighed against other national priorities, e.g. defense, health care

Chapter 5. Where Current US Food Safety Activities Fall Short

a. Inconsistent, uneven and at times archaic food statutes that inhibit use of science-based decision making in activities related to food safety, including imported foods

Background:

The basic food safety laws were passed in 1906, when the major food safety problem was adulteration, which often caused consumer illness and deaths. Since that time the FFDCA and other food safety laws have been amended to reflect changes in food safety and health concerns; preclearance of pesticides in the early 1950s, preclearance of food additives (with the zero tolerance of cancer risk provision) in 1958, preclearance for color additives (with zero tolerance) in 1960, and food labeling in the 1990s. The FFDCA does not provide for an assessment of risk-benefit for substances in food.

Strengths:

A stringent approach to approval of food ingredients diminishes the possibility that exposure to the ingredient may have an adverse health effect.

Consumers feel this approach ensures food safety.

Weaknesses:

Some ingredients that may be useful in improving the safety of foods may not be approved for use because they have a low possibility of causing an adverse health effect, e.g., cancer.

Barriers to Improvement:

Legislative action is required to provide maximum flexibility for use of science-based, risk assessments in food safety and public health policy decisions.

Consumer perception that flexibility may actually weaken the FFDCA.

b. A lack of adequate integration among the 12 primary federal agencies that are involved in implementing the 35 primary statutes that regulate food safety

Background:

Federal food safety agencies have a long history of cooperation that, through the Food Safety Initiative, has been strengthened and expanded as explained earlier.

Strengths:

Better, more extensive integration of an array of food safety activities among federal agencies would strengthen the U.S. food safety system and provide consumers with more confidence that all foods meet comparable safety standards.

Weaknesses: None.

Barriers to Improvement:

The time and resources required to effectively integrate the activities of the federal agencies.

c. Inadequate integration of federal programs and activities with state and local activities

Background:

FDA's federal/state cooperative programs have long joined the federal, state, and local regulatory agencies in milk safety, shellfish safety, and retail food safety programs. These programs were established in 1924, 1925, and 1934, respectively. FDA, working with states and industry, makes recommendations that states and localities adopt as law and administer the regulatory programs. In addition, the agency currently participates with states in many other areas: response to foodborne outbreaks and traceback investigations; training and technical assistance, e.g., HACCP for seafood and retail food safety; and states conduct inspections under partnership and contract arrangements. States have also conducted industry surveys, providing FDA with data on which to base food safety policy.

The FSI has provided the means of expanding and integrating federal, state, and local food safety activities. For example, state and local agencies played a major role in the development of fresh produce GAP guidance, holding public meetings around the country to bring state and local regulators and industry and consumer groups into FSI planning processes, supporting the large-scale Partnership for Food Safety Education media campaign promoting use of safe food practices by consumers, and various alliances and partnerships such as the Food Service Training and Education Alliance that provides training and education to retail food operations. Most recently, the states and local public health and regulatory agencies are collaborating with FDA and other federal agencies to develop a national federal, state, and local integrated food safety system. In December 1998, six Work Groups and an 18 member Coordinating Committee composed of federal, state and local officials met in Baltimore, Maryland to begin to develop plans for implementing recommendations and overcoming the obstacles identified at the Kansas City meeting. The Work Groups will propose short and long-term plans to make the vision of an integrated food safety system from farm-to-table a reality.

CDC has a longstanding, integrated working relationship with state and local partners (epidemiology and laboratory) in all of its surveillance and investigative activities. CDC works with these partners to determine which foodborne diseases are nationally reportable, to

develop common reporting systems. CDC has worked with the States to develop consensus standards for foodborne disease surveillance and investigation. All field investigations of outbreaks conducted by CDC are done only at the request of appropriate State and local authorities. To assure ongoing integration of CDC's programs with those of the States, resources are being made available to the States through the FoodNet, PulseNet, and Epi and Lab Capacity enhancement grants, to improve foodborne disease surveillance and investigation.

Strengths:

Integrated federal, state, and local food safety systems provide a uniform, high quality level of food safety assurance for consumers and regulatory consistency for industry.

Weaknesses: None

Barriers to Improvement: See item 4.e. above

d. Absence of focused leadership: no single federal entity is both responsible for the government's efforts and given the authority to implement policy and designate resources toward food safety activities

See item 4.d.

e. Lack of similar missions with regard to food safety of the various agencies reviewed

Background:

While the various laws the food safety agencies function under differ, the common mission is safe food for all consumers. The specific provisions of those laws define how each agency will accomplish that mission. For example, FDA will, with a force of inspectors located in offices across the country, conduct inspections of all establishments manufacturing, storing, transporting, and distributing all foods except meat and poultry on a cyclic basis. USDA inspectors will be located in meat and poultry plants and be present during all working hours. EPA will consider the risks and benefits of pesticides when setting tolerances. USDA has authority over imported products and FDA controls over imports begin at the U.S. borders. The different ways the agencies achieve their mission vary greatly

Strengths:

Harmonization of food safety laws to provide agencies with comparable authorities would assure consumers of a uniform level of food safety in all foods and would provide industry with regulatory and inspectional consistency for all products.

Weaknesses:

Current levels of scientific and inspectional competency and infrastructure vary among agencies. Harmonization of food safety laws requires movement within the agencies to achieve uniformity in capabilities.

Culture change will most likely be required as agency staffs adjust

Barriers to Improvement:

Time required to achieve legislative change to harmonize.

May require cultural shifts within agencies.

f. Inadequate emphasis on surveillance necessary to provide timely information on current and potential foodborne hazards

Background:

Comprehensive surveillance programs that provide the type and caliber of data needed by food safety agencies to estimate risks and target resources have, until recently, not existed. FoodNet is the first comprehensive surveillance system to provide data on the rates of foodborne illness and the associated pathogens. The system, initiated in 1995, is now delivering reliable data useful in risk assessments and food safety planning. These types of systems require extensive infrastructure and expertise to operate and for data sharing, but deliver data that is critical to preventing foodborne illnesses that potentially cost far more in healthcare and productivity losses. Prior to development of FoodNet, FDA and CDC collaborated on surveys to determine the extent of foodborne illness and the effect of preventive measures. In the 1980s, a survey for the incidence of *Listeria monocytogenes* over a period of several years demonstrated a decline in illnesses as the result of various preventive measures initiated. This survey provided an experience base for developing the current FoodNet system.

Strengths:

Sound data on which to base scientific investigation and risk assessment work and for use in developing and implementing food safety policy.

Reinforces the need to intensify national efforts to strengthen surveillance, develop new tools for outbreak detection, and to improve diagnostic capacity for foodborne pathogens.

Weaknesses: None

Barriers to Improvement: _____

Lack of resources, uniform expertise, and/or infrastructure in federal, state, and local public health agencies to participate in surveillance and monitoring and share data

The high costs of building surveillance and monitoring infrastructure and expertise and the time necessary to implement and operate the systems before credible data is consistently generated.

g. Resources currently identified for research and surveillance are inadequate to support a science-based system

Background:

Research and surveillance are the foundation of effective food regulatory programs. Some food safety agencies can, and have, functioned for many years with inadequate research programs and surveillance data. More comprehensive programs that provide the breadth of information required to evaluate both the microbial and chemical composition of the food supply, evaluate its effect on safety, and design mechanisms where required to prevent illness are essential. Funds from the Food Safety Initiative have significantly improved food safety research and surveillance programs and provided a strong base on which to build. Interagency research coordination, such as went into the fresh produce research plan, leverages the resources of each agency, eliminates unnecessary duplication, and meets the needs of each agency. It is anticipated that this plan will act as a model for more extensive, coordinated research planning in the future through the Joint Institute for Food Safety Research. Likewise, interagency support of FoodNet has produced a system that provides multiple agencies with information needed for their food safety programs.

Strengths: _____

Information to identify and characterize public health risks, prioritize the risks, design and implement preventive measures, and determine the effect of these measures on reducing risk.

Weaknesses: None

Barriers to Improvement: _____

Resources to conduct research and translate the results into food safety policy

Lack of uniform expertise and/or infrastructure in federal, state, and local public health agencies to participate in surveillance and monitoring and share data

The high costs of building surveillance and monitoring infrastructure and expertise and the time necessary to implement and operate the systems before credible data is consistently generated.

h. Limited consumer knowledge, which does not appear to have much impact on food handling behavior

Background:

FDA has conducted consumer education and information programs for years with little or no apparent impact on consumer behaviors that jeopardize their health and safety. This indicated the need for research-based approaches to informing consumers about the consequences of choosing to eat raw shellfish, undercooked ground beef, and other unsafe practices. Implementation of some research-based consumer education programs has shown some change in consumer behaviors to use of safe food practices. For example, survey results show that between 1993 and 1998, fewer consumption of raw eggs dropped 14%, raw oysters 3%, and undercooked hamburger 10%.

Industry, as well as FDA, is concerned that consumers use safe food practices in handling foods in the home. Studies show that home contamination of food is one of the largest contributors to foodborne illness in the U.S. As a result, the Partnership for Food Safety Education was formed by government agencies, industry, state groups and consumer groups to promote the use of safe food practices by consumers. A major consumer campaign — “Fight BAC!™” — was launched over a year ago in the national media. Consumer knowledge about and use of safe food practices is a critical element of a national food safety program. No matter how fastidious industry is in applying food safety measures all along the food distribution chain, if food is not handled correctly at the end of the chain — in the home — the potential for contamination and resultant illness is great.

Strengths:

Consumer knowledge about and practice of safe food practices completes the chain of safe food practices from the field to the table.

Weaknesses: None

Barriers to Improvement: _____

Identification of effective food safety messages that will cause changes in behavior.

1. Lack of nationwide adherence to appropriate minimum standards

Weaknesses:

There is no background or explanation of this finding in the report. Therefore, it is impossible to evaluate.

Recommendations from the NAS Report and Draft Responses

Recommendation 1: Base the food safety system on science

Background:

FDA's food safety programs have, from the inception of the agency, been based on a scientific evaluation of risks to human health and on preventing those risks. Food safety activities ranging from research to inspection to development of policy and regulations are based on an evaluation of public health risk. For example, no agency action to initiate removal of a potentially hazardous product from the marketplace occurs without an evaluation of the hazard and the public health risk by FDA's Center for Food Safety and Applied Nutrition's (CFSAN) medical and scientific staff on the Health Hazard Evaluation Board. Based on these types of evaluations, overall agency priorities have changed over the years, for example from an emphasis on chemical hazards like environmental contaminants (e.g., polychlorinated biphenyls) in the late 1960s to a focus on microbial contaminants (e.g., *Listeria monocytogenes*). This is not to say that chemical contaminants have not periodically posed public health risks and thus, have needed to be dealt with (e.g., methyl mercury, lead, dioxin, ethyl carbamates) and, at times, to present some complex cross-over public health issues. For example, in the 1980s, questions arose about the risks of cancer from nitrites, ingredients long used as preservatives in cured meats like fermented sausages. The preservative action of nitrites is to prevent *Clostridium botulinum* spores from outgrowth and toxin production within sausage casings and other anaerobic environments.

Evaluation of the policy options to deal with this risk, required the agency to balance the risk of nitrite use against the risk of *Clostridium botulinum* spore outgrowth and the resulting illnesses and possibly deaths from botulism if the preservative were not used. Changing public health risks and evolving science and technology, in combination, have influenced the direction of the agency's long-term food safety programs, some of which have been in place since the 1920s (e.g., the milk safety, shellfish safety, and retail food safety programs). Whether FDA's food safety

programs are long-term or deal with the issue of the moment, the underlying principle for initiating action is science-based risk evaluation and prioritization to prevent the risk.

Ideally, all food safety activities would always be based on evaluation and prioritization of risks. However, at times throughout the history of the agency, Congressional mandates may take precedence, causing a deviation from a risk-based prioritization of food safety activity. New statutes like the FDA Modernization Act (FDAMA), the Animal Drug Availability Act, and the Animal Medicinal Drug Use Clarification Act create a severe drain on resources and a redirection, even disruption, of the agency's risk-based priorities. Most of the mandates require regulations, public meetings, and other processes that consume staff and other resources and, in most instances, the agency is not provided additional funds to undertake these new responsibilities in an efficient manner.

Strengths:

Scientific evaluation of public health risks is an objective basis for deciding priorities in food safety activities .

Science yields the information needed to identify hazards, to design measures to prevent or reduce the incidence of their occurrence, and to measure the success of those measures.

Prioritization of public health risks and targeting work and resources to either the highest risk or the greatest public health impact (i.e., greatest risk vs. risk to the greatest number of people)

Minimal resources can have a significant impact on improving food safety when allocated based on science and risk-based analysis

Weaknesses: None.

 Barriers to improvement:

Time needed to generate scientific information, where it doesn't already exist, necessary to take preventive action

Resources to conduct research and translate the results into food safety policy

Other (conflicting) statutory obligations

Microbial risk assessment is a developing science

Recommendation IIa: Congress should change federal statutes so that inspection, enforcement, and research efforts can be based on scientifically supportable assessments of risks in public health.

Background:

The basic food safety laws were passed in 1906, when the major food safety problem was adulteration, which often caused consumer illness and deaths. Since that time the FFDCA and other food safety laws have been amended to reflect changes in food safety and health concerns; preclearance of pesticides in the early 1950s, preclearance of food additives (with the zero tolerance of cancer risk provision) in 1958, preclearance for color additives (with zero tolerance) in 1960, and food labeling in the 1990s. The FFDCA does not provide for an assessment of risk-benefit for substances in food.

USDA currently has statutory authority to bar meat and poultry from entering the U.S. if it does not come from an establishment determined to meet U.S. standards. FDA does not have comparable authority in terms of requiring pre-shipment clearance of a commodity. There is, however, Congressional interest in enhancing FDA's authority over imported foods. In addition, FDA is working with other countries through Codex, the European Union, NAFTA, ASEAN, and other international bodies to establish policies that assure a uniform, high level of food safety in imported products among trading partners.

Strengths:

Scientific evaluation of public health risks is an objective basis for deciding priorities in food safety activities.

Prioritization of public health risks and targeting work and resources to either the highest risk or the greatest public health impact (i.e. greatest risk vs. risk to the greatest number of people)

Consumers feel this approach ensures food safety.

Weaknesses:

Barriers to Improvement:

Complexity of the food supply. The diversity of commodities in the food supply, the diversity of potential firms to be inspected (e.g., land and sea farms, manufacturers, repackers, storage operations, distributors, and retail food operations (including restaurants, schools, hospitals, nursing homes, grocery stores) and their size, the state of the food or commodity (e.g., raw, minimally processed, cooked, packaged or not packaged, frozen), the susceptibility of the food to contamination and microbial growth (e.g., raw fish vs. baked goods), and the regulatory history of the firm (i.e., does it have a history of problems) are all factors which add to the complexity of the undertaking.

Consumer perception that flexibility may actually reduce the safety of the food supply

Recommendation IIb: Congress and the administration should require development of a comprehensive national food safety plan. Funds appropriated for food safety programs (including research and education programs) should be allocated in accordance with science-based assessments of risk and potential benefit.

Background:

The President's Food Safety Initiative is an initial step toward a federal food safety plan which will be further expanded in strategic planning conducted under the auspices of the President's Food Safety Council. The 1997 *Farm-to-Table* report was a means of leveraging dwindling federal food safety resources through coordinated planning and cooperative work to meet common needs such as development of surveillance data, response to outbreaks, research into preventive interventions, development of risk assessment techniques particularly for microbial risk assessments, and consumer education. This initial plan also took some steps toward extending food safety planning to the state and local level.

The Council has defined the scope of future federal level food safety strategic planning and a process for interagency planning and public participation. An interagency task force anticipates having a draft plan ready for public review and discussion in January, 2000. Options for integrating risk evaluation, prepared by the interagency Risk Assessment Consortium, into the strategic planning process are being reviewed.

A national food safety system is the objective of the current work underway by FDA, CDC, and other federal agencies with the state and local food safety agencies. State and local agencies are currently also involved in Food Safety Initiative surveillance, education, and outbreak response work, so movement into a national planning process is a natural "next step".

Strengths:

Uniform, consistent level of food safety assurance for all products and in all areas of the U.S.

Mutually agreed upon and understood food safety goals and plans developed by food safety agencies, academia, consumers, and industry

Most effective, efficient use of federal food safety resources

Clearly delineated roles for federal, state and local agencies

Rapid sharing of information and data, particularly about outbreaks and products associated with illnesses

Weaknesses:

Time to develop a smoothly functioning national food safety planning process that meets needs at the federal and state and local levels

Overcoming perceptions/misperceptions of OMB and Congress that hinder HHS's efforts to obtain federally appropriated funds based on scientific assessments of risk and benefits

Risk assessment techniques, particularly for microorganisms, are not sufficiently well developed to make risk/benefit judgements at this time

FDA does not have statutory authority to require imported foods to be produced under food safety systems that provide a comparable level of protection as U.S. systems

Barriers to improvement:

Lack of commitment of administration and Congress

Time required to give FDA statutory authority to require imported foods to be produced under food safety systems that provide a comparable level of protection as U.S. systems

IIIa: To implement a science-based system, Congress should establish, by statute a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.

Background:

The food safety regulatory agencies (FDA and FSIS) function under different laws that dictate how the agencies must carry out their food safety responsibilities. These agencies currently collaborate in the formulation of policy and regulations in areas where jurisdictions overlap or are related and work together to manage public health crises. For example, FDA has jurisdiction over domestic and imported fresh fruits and vegetables and USDA has jurisdiction over grading fresh

produce, providing safe produce for the school lunch program, and in working with producers through the extension service. These agencies worked together to develop the Good Agricultural Practices guidance to minimize the risk of contamination of fresh fruits and vegetables for use by producers and in providing technical assistance to put the guidance into practice. The agencies share scientific expertise and support (for example, in carrying out the pesticide program) when needed.

Under the Food Safety Initiative, the Clinton Administration has emphasized coordination and harmonization of current agency activities and budgets, development of uniform policies and statutory authorities, and communicating with Congress and the public health one unified message about food safety. FDA and other food safety agencies have made tremendous strides toward a unified framework for food safety through their cooperative efforts.

Strengths:

Consistency in the development and implementation of food safety policy

Resources could more easily be directed to the greatest public health concern

Weaknesses:

If this central framework is located outside a food safety agency this, potentially, could result in a cumbersome, multilayered process of developing food safety policy, of planning and of resource allocation. This has the potential of impeding rapid responses to emergencies, such as foodborne illness outbreaks, while decisions are made about mobilization of resources to meet the need.

If the central framework is located within a single department (e.g., the Secretary of HHS), there is the potential for competing or conflicting interests within the department. For example, food safety interests could conflict with commodity promotion interests or with the interests of other non-food safety, but highly significant health programs.

This recommendation could be interpreted as requiring the establishment of a single food agency. The time and cost, as well as disruption of normal activity, required to consolidate all food safety activities at the federal level in a single agency would be a set-back to the development and implementation of progressive food safety policy.

Barriers to Improvement:

Current federal food safety laws have different implementing provisions that will make it difficult, if not impossible, for a central framework to function effectively in planning and resource allocation.

Scientific expertise and infrastructure must be brought to a uniform level before a “central voice” can effectively develop policy that is applicable across the board.

Time required to consolidate all food safety activities into a single agency, obtain legislative harmonization of food safety laws, and rebuild an effective, rapid response food safety system

IIIb: Congress should provide the agency responsible for food safety at the federal level with the tools necessary to integrate and unify the efforts of authorities at the state and local levels to enhance food safety.

Background:

A great deal of overlap occurs between federal and state and local food safety efforts, particularly between FDA and state and local efforts. Neither FDA nor state and local agencies have sufficient resources to carry out a comprehensive food safety program, but all these agencies have expertise and resources that, when combined in an integrated program, would significantly enhance the impact of food safety programs.

Currently, FDA is leading an interagency federal, state, and local endeavor to develop a national, integrated food safety system. The current work is proceeding under current federal, state, and local laws although it is recognized that disparities between the laws will require changes in many of them to achieve an integrated system. The concept of a national food safety system is endorsed by the Association of Food and Drug Officials, an organization of state and local public health officials and regulators. The work began with an FDA-hosted meeting of state and local officials from public health and agriculture agencies and state laboratories, including epidemiologists, representing all 50 states, Puerto Rico, and the District of Columbia, CDC and USDA in Kansas City in September, 1998 to begin development of recommendations and implementation plans for a national, integrated food safety system. In December 1998, six Work Groups and an 18 member Coordinating Committee composed of federal, state and local officials met in Baltimore, Maryland to begin to develop plans for implementing recommendations and overcoming the obstacles identified at the Kansas City meeting. The next meeting is planned for late Winter or early Spring, 1999.

Strengths:

Provides consumers with a uniform, high level of food safety assurance anywhere in the United States

Provides industry with consistency in food safety regulation and enforcement

Weaknesses:

Barriers to Improvement:

Integration of food safety systems will take approximately 10 years

Harmonization of food safety laws, putting basic infrastructure in place where it doesn't already exist, bringing inspectional and scientific expertise to a uniform level of competency, and reaching agreement on the structure of the system is a complex and time-consuming task.

HHS believes that this cooperative federal, state, local agency effort to plan and implement a national, integrated food safety system should be allowed to play out before any efforts to Congressionally mandate an integrated system are initiated.

Strengths:

Leveraged resources, i.e., the combined effects of resources and expertise from government, industry, academia, and consumers, greatly expand the food safety capabilities beyond what any one group could accomplish

Increased awareness and knowledge of food safety in each segment of the food safety community obviates the need for extensive regulation of industry and decreases the incidence of contamination after foods leave the distribution system and enter the home

Integrated federal, state, and local food safety systems that build a consistent, uniform level of safety assurance across the U.S. by sharing resources (expertise, data, information)

Consistent, uniform food safety messages, training, and technical assistance to meet all levels of regulatory, industry, academic, and consumer need

Weaknesses: None

Barriers to Improvement:

Time and funding, required to build and maintain effective cooperative programs among the varying segments of the food safety community - the long-term benefits outweigh the delays, however

Integration of federal, state and local food safety systems — communications from various groups, indicate that there are some concerns —

- Consumer concern that the economic interests of industry within states may be a source of conflict if states have an expanded food safety role that includes activities thought to be federal responsibility (e.g., firm inspections)

- Industry concern that food safety regulation will be inconsistent among the states if systems are integrated without adequate preparation of the state agencies to step into the expanded food safety role

Delivering training and other outputs in a timely manner remains problematic. The goal of keeping up with demand for education and training of epidemiologists, laboratory workers, public health nurses, environmental sanitarians, food workers, school children, and the general public will remain out of reach for the foreseeable future.

Additional resources will be needed to adequately address foodborne disease prevention needs nationwide.

DRAFT 1/18/99

Introduction

NAS Highlights

USDA believes that the National Academy of Sciences (NAS) report, "Ensuring Safe Food from Production to Consumption," initiated in 1997 at the request of Congress, is a valuable contribution to the ongoing and necessary dialogue surrounding future directions of the national food safety system. It provides an examination of the scientific and organizational needs of an effective food safety system. Consideration of these recommendations gives us the opportunity to continue to expand that food safety and public health dialogue.

Dealing with a complex, multi-faceted food safety system - one that the report sees as evolving "piecemeal over almost a century," the authors report that they believe the present system "is not the product of planning, and it is, often not equipped to anticipate changes. But the situation is not just haphazard; changes in risks have made the system outmoded. The role and organization of government entities have remained largely unchanged, and the food safety system has fallen behind today's needs." (p. 20)

While the NAS report's analysis and recommendations offer much for USDA to consider, USDA can add its first hand perspective to bring a more complete, detailed, and accurate picture into sharper focus.

1994 Reorganization of USDA

The Administration has been actively engaged in organizational and program changes to eliminate conflicts, enhance coordination of responses to public health issues and emergencies, and coordinate research planning and prioritization.

In 1994, the Congress and Administration cooperated in enacting a major reorganization of food safety within USDA creating the new mission area and office of the Under Secretary for Food Safety, overseeing the Food Safety and Inspection Service (FSIS) and the U.S. Manager of Codex Alimentarius. Under that new legislation, a public health mission area was created within USDA, and the Under Secretary was required to have a proven track record in public health and safety.

In addition, the 1994 reorganization of USDA centralized research activities within the newly created mission area - Research, Education and Economics (REE). This centralized research focus provided the ability to better leverage existing funds. Food safety research is largely funded through three USDA agencies—the Agricultural Research Service; the Cooperative State Research, Education and Extension Service; and the Economic Research Service.

While some further changes in authority and a rationalization of resources are desirable, not all existing statutory authorities, which were reviewed and significantly amended in 1994, are necessarily major impediments to improvement. USDA's authority currently provides the flexibility needed to implement substantial change and improvement. In fact, we have already taken advantage of that flexibility in developing a revolutionary, national, science based HACCP approach to monitoring the nation's food supply. USDA plans to do more.

Much has been said about the need for organizational and structural change in the inter-governmental system as well as the need for more coordination within an improved food safety system. Here again, USDA is already engaged in continuing, daily collaboration at the Federal, state, and local levels, as well as internationally. The 1994 reorganization of the food safety functions at USDA established a solid foundation for an improved and effective food safety system for the U.S. government. USDA is the Department, cited by the NAS report as housing seven of the twelve agencies involved with food safety in the United States government. A majority of the federal dollars are already overseen by the U.S. Department of Agriculture for farm to table food safety research, risk assessment, and food surveillance; education of consumers and handlers; and the vast majority of a performance based, pathogen reduction, inspection system for a large part of the market basket, i.e., meat, poultry and egg products. In addition, USDA's authorities for oversight of imported meat and poultry and research on other foods are also a rational and appropriately cooperative system.

Some change may be desirable, but major reinvention or major restructuring of Federal food safety activities may not be needed to raise the level of food safety. We have the necessary base. Improvements are already emerging. Outlined below are a number of important points that we feel compelled to explain more completely from the USDA perspective.

NAS View of the Attributes of an Effective System and Recommendations

The National Academy of Sciences Report contains over 200 pages of information. The committee defines an operational charge or mission of an effective food safety system "...to protect and improve the public health by ensuring that foods meet science-based safety standards through the integrated activities of the public and private sectors." Further, the report outlines the following five major components or attributes of a model food safety system:

- (1) science based, with a strong emphasis on risk analysis of risks deemed to have the greatest potential impact and including comprehensive surveillance and monitoring as the basis for risk analysis,
- (2) a national food law that is clear, rational, and comprehensive as well as scientifically based on risk,
- (3) a unified mission and single food safety entity at the Federal level with authority and resources to implement a science based policy in all Federal activities related to food safety,
- (4) an responsive organization partnering with non-federal partners, and

(5) an adequately funded organization able to promote the public's health and safety.

The Committee concluded that the current system for food safety has many attributes of an effective system. USDA plays a critical role in that system from farm to table and from research to inspection.

NAS Recommendations Specifically, the Academy made three major recommendations:

- First, the report concluded that an effective and efficient food safety system must be based on science. It noted that while many rational, science-based regulatory philosophies have been adopted, progress has been uneven.
- Second, the NAS committee said that changes to the Federal statutes might well be needed to enable the U.S. food safety regulatory system to adopt and use the best science available. The committee suggested that the statutory changes would allow inspection, enforcement, and research efforts to be based on scientifically supportable risk assessments. It also recommended that Congress and the Administration require development of a comprehensive food safety plan.
- Third, the committee also urged Congress to establish a unified and central structure for managing Federal food safety programs. It offered four possible structures under which one official would be responsible for Federal efforts in food safety. Further, the NAS recommended that Congress should provide the Agency responsible for food safety at the Federal level with sufficient resources and the tools necessary to integrate and unify the efforts of authorities at the state and local levels to enhance food safety.

USDA Responses to Some of These Recommendations

A Farm-to-Table Strategy

The committee report defines safe food as “food that is wholesome, that does not exceed acceptable levels of risk associated with pathogenic organisms or chemical and physical hazards, and whose supply is the result of the combined activities of Congress, regulatory agencies, multiple industries, universities, private organizations, and consumers.” (p. 5) Clearly, this definition implies that the safety of our food supply requires that everyone, at every step of the way, make a serious commitment to food safety - we are all responsible.

Recognizing this responsibility, USDA adopted a farm-to-table approach that looks at food safety as an integrated and interdependent system. Actions and programs within the USDA are directed all along the continuum rather than focused on any individual component. This is an important point to keep in mind as we discuss other

steps USDA has taken to implement a science-based food safety system. In addition, our farm-to-table strategy recognizes that our statutory authorities limit regulatory oversight and enforcement to prescribed areas. Therefore our strategy relies on voluntary adoption of quality control programs at the production level, and partnership with states, the private sector, and research and education agencies to strengthen the base for such voluntary programs.

A Science Based USDA Reorganization: The Details

Office of the Under Secretary for Food Safety The 1994 USDA reorganization fundamentally altered our structure and created a mission area focused on public health through the mission area of Food Safety. The reorganization legislation created the Office of the Under Secretary for Food Safety and mandated that the office be occupied by an Under Secretary who has a specific and proven track record in public health and safety. In addition, this effectively eliminated the perception of a “conflict of interest” because a public health focused, food safety mission area and regulatory function was created separate from marketing functions related to agricultural products. Previously the two mission areas were housed together within the Department. Not enough has been said about the importance of this structural change

FSIS Reorganization The Food Safety and Inspection Service (FSIS), the USDA regulatory agency under the Under Secretary for Food Safety, and responsible for the safety of meat, poultry and eggs products, also underwent a major reorganization to make the best possible use of its resources to improve food safety. The reorganization accomplished a number of important objectives, a new more efficient field organization and including a strengthened focus on public health, by establishment of a new Office of Public Health and Science to provide new scientific focus, leadership, and expertise in addressing the most important public health risks related to meat, poultry, and egg products. Within this new office, the Agency established the following divisions:

- Emergency Response, which coordinates all Agency recall activities associated with outbreaks of foodborne illness;
- Emerging Pathogens and Zoonotic Diseases, which monitors emerging human pathogens in the food supply and animal populations and studies farm-to-table control and prevention strategies;
- Food Hazard Surveillance, which maintains both active and passive surveillance systems for foodborne illness; and
- Epidemiology and Risk Assessment, which leads and coordinates all agency investigation and traceback activities associated with outbreaks of foodborne illness and conducts quantitative microbial risk assessments.

With this new structure in place, and an infusion of new funds through the President’s Food Safety Initiative, significant progress is being made toward a science-based system in a number of areas.

Food Safety Research and Education Capabilities Research and education are two key components of the President's Food Safety Initiative. There are a number of actions taken by USDA and the Administration in the past few years that provide an expanded role for research as an essential ingredient in the U.S. food safety system.

Office of the Under Secretary for Research, Education and Economics In the 1994 reorganization of USDA centralized research activities in the newly created mission area - Research, Education and Economics (REE). This centralized research focus provided the ability to better leverage existing funds. The REE research activities - both intramural and extramural - are intended to meet the needs of the regulatory agencies in achieving improved food safety via HACCP implementation and other initiatives. To that end, the Agricultural Research Service (ARS), the intramural research arm of USDA, and Food Safety and Inspection Service (FSIS) have yearly food safety research budget and planning sessions. These sessions provide one mechanism to ensure that proposed research initiatives address the specific priorities of FSIS.

Food safety research is largely funded through three USDA agencies—the Agricultural Research Service (ARS); the Cooperative State Research, Education and Extension Service (CSREES); and the Economic Research Service (ERS). Together, these agencies conduct and fund approximately \$ _____ million in food safety research annually. In addition, FSIS has close consultation with the other USDA agencies to ensure that its critical research and information needs are being met. CSREES supports food safety research via several funding mechanisms—formula funds, National Research Initiative competitive grants, special research grants awarded by a competitive process, and special site-specific grants that are appropriated by Congress. The priorities for competitive grants are based on stakeholder input, including government agencies in support of their public health mission

Interagency Working Group on Food Safety Research In addition, the Administration has been actively engaged in coordinated research planning and prioritization. In 1998, an Interagency Working Group (IWG) on Food Safety Research was created. The IWG, co-chaired by USDA and Department of Health and Human Services (HHS), develops a coordinated strategy for food safety research government-wide, including the identification of gaps and priorities for future research. The IWG provides a forum for coordination, collaboration, and communication in setting and reviewing the Federal research agenda.

Joint Institute on Food Safety Research In July 1998, the President directed the Secretary of Agriculture and Secretary of Health and Human Services to develop a Joint Institute on Food Safety Research (JIFSR). JIFSR provides a mechanism for coordinated planning of food safety research among the various parts of government and the private sector as well as fostering effective translation of research results into practice. The JIFSR, operationally located in REE at USDA, expects to optimize food safety research investments, channel Federal resources to research that is needed to minimize the impact of current and emerging food safety problems, and avoid research redundancies.

Developing New Technologies Within this framework, one of USDA's goals is to encourage the application of new technologies by industry to improve food safety. Some new technologies approved for industry use include steam pasteurization, antimicrobial rinses to reduce pathogen loads on raw products, and competitive exclusion to reduce *Salmonella* levels in poultry on farms. In addition, the Food and Drug Administration (FDA) approved irradiation for meat products. Research could also clarify how to increase economic incentives for industry to develop and adopt new technologies to reduce foodborne hazards.

National Database for Food Safety Research USDA, through the direction of the ARS and its National Agricultural Library, is developing a national database on food safety research. The database will contain information on all federal food safety research and will attempt to document the private sector investments in food safety research. The database will provide one additional mechanism for communicating the range of food safety research and potential applications.

Annual Food Safety Research Conference The recently signed Agricultural Research Bill mandates that USDA sponsor an annual food safety research conference. The first national conference was held in November 1998. The conference provides a valuable method of disseminating research results and provides a forum for discussing stakeholder priorities for future food safety research.

Education

Improving surveillance, research, and inspection alone will not ensure safe food. Education and training for all those involved in producing, processing, and distributing food are essential to the goal of providing the public with safe food products. The budget for food safety education has increased from a modest \$2.8 million in Fiscal Year 1997 to \$13.5 Million in FY 1999. The Joint Institute on Food Safety Research will also provide a mechanism for joint planning and prioritization of food safety education activities.

Consumer Education The President's Food Safety Initiative has spurred new consumer education programs within USDA as well as expanded cooperative ventures with public and private partners, including other Federal agencies. One example is the Fight BAC! campaign sponsored by the Partnership for Food Safety Education, a public-private partnership, with participation of both USDA and HHS. In addition, USDA is working through organizations such as the Association of Food and Drug Officials (AFDO) to provide education to those who handle food at the retail level and is carrying out extensive HACCP education for its own employees, and for state employees involved in inspection. USDA is also working with industry to develop science-based food safety assurance programs for fresh-cut fruit and vegetable processing facilities.

Epidemiology Applications USDA is basing its safe food handling education on science. Epidemiology information from FoodNet and other sources is helping to identify types of foods associated with illness, behaviors that can contribute to disease, and populations who are more vulnerable. In addition, USDA is increasingly using risk

assessments and research data to develop accurate and high-priority consumer messages. An example is an ARS/FSIS study on the premature browning of ground beef, which has led to a nationwide education campaign to promote the use of food thermometers when cooking hamburger.

Animal and Food Handler Education CSREES administers a food safety education program (the National Food Safety and Quality Initiative) in partnership with land grant institutions across the United States. This program supports food safety education initiatives at all land grant institutions as well as specific education initiatives that reach animal and food handlers along the entire farm-to-table chain. In addition, science-based programs in HACCP training for the meat and poultry industry are funded by CSREES through Fund for Rural America grants and special research grants. The scope and focus of these educational programs are developed in consultation with stakeholders, including other Federal agencies involved in food safety education.

Risk Assessment The NAS report's focus on the use of scientific risk assessment and cost benefit analysis in order to develop rules that will have the most positive influence on public health is appropriate and is mandated by Congress in most USDA regulatory development. The analysis of risks and benefits should begin at the start of any regulatory development process. Because scientific certainty is not realistically attainable, these analyses can guide the process and help decision makers make the tough decisions a science-based food safety system will require.

USDA has a strong lead agency involved in risk assessment activities, the Office of Risk Assessment and Cost-Benefit Analysis within the Office of the Chief Economist. In addition, the Economic Research Service (ERS), and the Animal and Plant Health Inspection Service (APHIS), the FSIS, CSREES and ARS are very involved in the process. USDA is conducting quantitative microbial risk assessments to focus food safety resources on reducing those risks that have the greatest consequences for human health and draws on the technical expertise residing in these six agencies. Risk assessment also is being used to identify data gaps and target research that should have the greatest value in terms of public health impact. USDA has completed a farm-to-table, quantitative risk assessment for *Salmonella Enteritidis* in eggs and egg products, and has initiated a risk assessment for *E. coli* O157: H7 in ground beef. USDA has entered into a cooperative agreement with Harvard University's School of Public Health and Tuskegee University's School of Veterinary Medicine for a risk analysis of Bovine Spongiform Encephalopathy (BSE).

NAS Recommends Flexibility In Current Food Safety and Inspection Laws

The committee identifies a desire for a "national food law that is clear, rational, and comprehensive, as well as scientifically based on risk" as a major component of a model food safety system. Further, the committee notes its view that the continuous inspection system of meat and poultry through sight, smell and touch ("organaleptic") inspection creates inefficiencies, and should be replaced by a science-based approach that is capable of detecting hazards of concern.

“Carcass by Carcass Inspection” USDA already has the flexibility to create and is creating a more risk-based regulatory system similar to the one recommended by the report. The current statutes do not require “organoleptic” inspection of all carcasses. It is important to note that current law does require ante-mortem and post-mortem inspection of all official slaughter and processing facilities. This continuous inspection requirement for animals, serves consumers to ensure best sanitary dressing processes, prevent fecal contamination, lower the incidence of disease causing pathogens, and serves to prevent diseases such as BSE that can best be detected by direct observation. Wholesale elimination of inspection of all animals and carcasses is not the most prudent course of action.

Statutory Differences It should be noted that there is a fundamental difference between the statutes which govern the inspection and oversight of meat and poultry, implemented by the Food Safety and Inspection Service (FSIS) and the statute for other foods which is enforced by HHS via the Food and Drug Administration.

- It is FSIS’s statutory responsibility to assure that no meat and poultry which may be adulterated receives the mark of inspection and enters the marketplace. (Americans have held the opinion that meat and poultry are high risk food products.) Companies slaughtering or processing meat and poultry have a legal obligation to report that fact to FSIS and FSIS is obligated to provide appropriate inspection to the plant. The oversight granted to FSIS due to this responsibility also permits it to demand equivalent inspection and oversight of meat and poultry products intended to be exported to the United States from other countries.
- FDA’s statute appears to have a much different burden in that it is obligated to remove foods which it finds in the marketplace which are adulterated. It has authority to inspect establishments producing food, but does not have authority to mandate receipt of the sites of food production and cannot provide daily inspection of even high-risk food products at this time.

Inspections

Pathogen Reduction and HACCP In July 1996, USDA published its landmark rule on Pathogen Reduction and HACCP. The rule requires all plants that slaughter and process meat and poultry to implement HACCP systems as a means of preventing or controlling contamination from pathogens and other hazards. To make sure HACCP systems are working as intended, the rule also sets in-plant performance standards for *Salmonella*, the first-ever pathogen reduction performance standards for a broad range of products. This was a major shift from its traditional reliance on “command and control” regulations to greater use of pathogen reduction performance standards. Performance standards provide companies with the flexibility they need to innovate and efficiently meet their food safety responsibilities, and FSIS with measurable points to assure that the food plants they are

overseeing are in compliance and successfully producing meat and poultry products deserving of the USDA seal.

The largest meat and poultry plants were required to have HACCP systems in place and to meet the performance standards for *Salmonella* on January 26, 1998. Small plants must meet these requirements by January 25, 1999 and very small plants by January 25, 2000.

New Inspection Models As USDA focuses on HACCP implementation, it has been able to begin development of a project to design new inspection models that better address current public health risks in the meat and poultry supply.

State Cooperative Meat and Poultry Inspection Programs FSIS has overseen and supported (with more than \$40 million per year) twenty-five (25) state inspection programs for meat and poultry. Another state is initiating a meat inspection program. These cooperative programs permit states to inspect product for distribution within their own states.

Food Code and International Standards USDA also is working more closely with its counterparts at the Federal, State, and local level to encourage national uniformity in food safety standards through support and endorsement of the Food Code. And because world trade in agricultural commodities continues to grow, USDA is working through the Codex Alimentarius Commission to encourage international uniformity in food safety standards. Responsibility for oversight of the U.S. Manager of Codex is in the Food Safety mission area of USDA.

Coordination of the Current Food Safety System:

The NAS report notes that having 12 primary Federal agencies involved in key functions of safety fragments the current system: monitoring, surveillance, inspection, enforcement, outbreak management, research, and education. The implication is that the system suffers from a crippling lack of coordination. In fact, in recent years tremendous progress has been made in strengthening ties among food safety agencies at all levels of government, and among government, industry, academia, and the public -- sharing a common public health mission and fulfilling that mission more effectively by continuing to build partnerships in so many food safety areas.

Following are several areas in which USDA mission areas as cooperating and coordinating with other parts of federal government and with other levels of government, including other countries.

Production

- Voluntary Quality Control Programs The Animal Production Food Safety Staff in FSIS is one excellent example of developing partnerships with States to encourage the voluntary implementation of quality control programs at the animal production level. The education of small producers is a particular

concern as we move forward with HACCP implementation in small plants. We believe that changes in the marketing of animals will be expected by plants operating under HACCP, and we want to help producers be ready for these changes.

Surveillance

- The FoodNet surveillance network In July 1995, USDA began a collaborative project with HHS, through its Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), to collect more precise information on the incidence of foodborne disease in the United States. The FoodNet surveillance network has been expanded under the President's Food Safety Initiative, and it is providing valuable information on trends in foodborne illness and on the association between cases of illness and the types of foods consumed.
- Monitoring for Adulteration USDA also conducts a number of monitoring programs to ensure that FSIS regulated meat and poultry products are free of microbial, chemical, and animal species adulterants. When adulterated products are found, they are removed from commerce to protect the health of consumers.
- Farm –Level Surveillance and Education USDA also conducts farm-level surveillance through the Animal and Plant Health Inspection Service (APHIS). APHIS has a field force of veterinarians who work cooperatively at the State and local level to ensure the health of poultry and livestock populations. APHIS' National Animal Health Monitoring System has conducted nine science based studies addressing information gaps in the areas of animal health, welfare and production, product wholesomeness, and the environment in industries including cattle, swine, and layer industries.
- Antibiotic Resistance The National Antibiotic Resistance monitoring system was established in 1996 as an interagency cooperative activity to monitor emerging resistance in food borne pathogens, starting with Salmonella. The effort is coordinated and directed through HHS, by the Food and Drug Administration's Center for Veterinary Medicine and includes the CDC, and three USDA agencies – ARS, APHIS, and FSIS. Both APHIS and FSIS play an integral role in system design and the acquisition of isolates. Operation of the program is dependent on the continuing cooperation of all the agencies involved in order to solve foodborne-related problems.
- BSE Study In 1998, USDA agencies, FSIS, APHIS and ORACBA, cooperated to develop a contract for the Harvard School of Public Health to examine any unrecognized pathways of possible entry to the United States of BSE. USDA has been working successfully since 1989 to prevent this entry,

but this cooperative effort is regarded as one more safeguard for the American people.

Inspection

- Shared Information FSIS has a trained inspection force in every Federally inspected meat and poultry slaughter and processing plant in the United States. In some cases products are being processed in the same plants which fall under the jurisdiction of the Food and Drug Administration (FDA) because they are food products which do not contain meat and poultry. FSIS and FDA are in the process of establishing and implementing a Memorandum of Understanding (MOU) to facilitate appropriate sharing of information between senior agency field operatives, regarding safe food production in these plants.
- Federal-State Inspection System FSIS also cooperates with and supports twenty-five (25) states and their meat and poultry inspection systems. It matches up to 50% of the costs of the state to run an equivalent system of inspection permitting in state product to be produced and distributed within that state.
- Modernizing Information Technologies As one step in the adoption of new information technologies in inspection programs FSIS has developed an interactive computer system (FAIM) for its own use, and is encouraging states to adopt it by sharing the costs of implementation. This system permits the field inspection force to have in their possession regulations, scheduling information, and appropriate information regarding enforcement. It can also be used for training. It has conducted discussions with FDA regarding its applicability to its inspection system

Outbreak Response

- FORC G In 1998, Vice President Gore announced the formation of the Foodborne Outbreak Response Coordinating Group (FORC G), a partnership of Federal and State agencies established to better respond to foodborne illness outbreaks. The role of this interagency group, co-chaired by the Under Secretary for Food Safety and the Assistant Secretary for Health, is to coordinate and develop procedures for managing outbreaks, share information on potential sources of outbreaks and pathogens and coordinate interdepartmental action on those issues when necessary.
- FERRET Within USDA, the Secretary asked the Under Secretary for Food Safety to form and chair an internal Food Emergency Rapid Response and Evaluation Team (FERRET) which enables USDA to be prepared to respond

to such emergencies as outbreaks involving foods purchased by USDA feeding programs, and formulate plans, across mission areas, to diminish those possibilities in the future.

- Field Epidemiology USDA has stationed field epidemiology officers in a number of the FSIS district offices to provide more rapid response. USDA also is exploring changes in its recall policies and procedures in light of a number of large recalls that strained the system currently in place. And PulseNet, the national database of molecular fingerprints of pathogens, developed through partnerships involving CDC, FSIS, FDA and the states, is allowing the comparison of strains of bacteria to determine whether or not there could be a single source for outbreaks or sporadic cases.

Partnering and working together has made a big difference already and will produce even greater results as partnerships are strengthened and new ones developed, within USDA and across departments and jurisdictions.

Summary:

The NAS report and recommendations open important dialogue on the direction of food safety into the 21st century. We can never get away from the fact that at any point in the farm-to-table continuum, harmful bacteria or chemicals can contaminate food, therefore, at every point along the way, everyone must be pro-active in keeping food safe. That is exactly what we are doing at USDA - being proactive not reactive to the challenges presented by an increasingly sophisticated food production system.

In our view, we want to utilize all the effective tools available in the current food safety system as well as increasing the science-based nature of that program. We feel strongly that we must be single minded about our commitment to improving the nation's food safety system. Clearly, we in USDA and the authors of the NAS report are in agreement on this point. Where we differ – and we believe this is healthy disagreement - is in the details of how best to accomplish these improvements. We have tried to demonstrate in the preceding paragraphs that much has already been done. These accomplishments, however, came within the existing laws, structure, and system. Achieving consensus around a new comprehensive national food safety law or major organizational change will bring about worthwhile deliberations, but it will also not be easy. The American public will be best served by USDA focusing its energy on the foundation we have already established and building from there.

Response to the National Academy of Sciences report, Ensuring Safe Food from Production To Consumption

Recommendation 1: An effective and efficient food safety system must be based in science

Background

The report notes that the United States has enjoyed notable successes in improving food safety and that with increasing knowledge, many rational, science-based regulatory philosophies have been adopted. The reports adds, however, that adoption of these regulatory philosophies has been uneven and difficult to ensure given the fragmentation of food safety activities, and the differing missions of the various agencies responsible for specific components of food safety. The greatest strides in ensuring food safety from production to consumption, the Academy noted, can be made through a scientific, risk-based system that ensures that surveillance, regulatory, and research resources are allocated to maximize effectiveness.

Strengths of the Recommendation

USDA agrees that a food safety system that is based on science is important in ensuring that surveillance, regulatory, and research activities provide the greatest public health benefits. This involves identifying the foremost public health needs, discovering the most cost-effective opportunities for improvement, and setting priorities. As knowledge increases, new technologies become available. The nature of food hazards changes and the food safety system must be flexible enough to identify, adapt to, and take advantage of, these changes. The system should provide economic incentives to develop new inventions, commercial scale-up, and industry adoption.

A research effort with industry, consumer, academic, and government participation could develop options and evaluate them. The benefits and costs of each option should be considered, the impact on public and private economic incentives for food safety at each of the three stages of innovation (invention, commercial scale-up, and industry adoption) appraised, and the short run versus the long run impact on economic incentives estimated.

Weaknesses of the Recommendation

USDA's progress thus far in implementing a science-based strategy, and its commitment to further this progress, supports the underlying philosophy that food safety measures must be based in science. However, it is also true that the science underlying these measures is subject to large uncertainties. A joint Food and Agricultural

Organization/World Health Organization consultation¹ in risk management and food safety notes that, “in many cases, there is insufficient quantitative information to translate requirements for ‘safety and wholesomeness’ into a definitive quantitative assessment of the risks to human health.” By default, most food safety risk assessments are not quantitative predictions of the expected level of damaging effects but rather qualitative assessments of whether a hazard at a particular level is safe or unsafe.

In addition, the Committee failed to consider that it is neither feasible, nor good public policy, to perform detailed, quantitative risk assessments for every problem. The level of detail in a risk analysis should be commensurate with the problem’s importance; expected health, economic, or social impact; as well as the expected impact and cost of control measures². It is important to adopt a tiered approach to food safety risk analyses and to avoid paralysis by analysis. For decisions with insignificant regulatory or economic impacts, simplistic, routine analyses are often appropriate. And in emergency situations, rapid public health and scientific assessments are needed. In many cases, relative risk rankings are sufficient, and precise predictions of actual public health risk unnecessary and even counterproductive, if they result in ineffective allocation of resources. For the purposes of promulgating a major rulemaking, more elaborate analyses with independent review are warranted. So long as USDA continues to develop measures of benefits and costs of health-promoting interventions, it will be better able to choose among interventions in emergency situations and to decide whether risks and intervention costs entail significant impacts.

Science must also be tempered with other considerations, such as technical feasibility, statutory mandates, policy considerations, budget constraints, and consumer preferences. As the Committee itself acknowledged, the determination of what constitutes a safe food involves a subjective evaluation of social issues and values, as well as a scientific assessment of risk. For example, public health benefits should be balanced with associated costs. Executive Order 12866³ and USDA administrative guidance require agencies to consider economic factors in decision making. The Reorganization Act of 1994 established the USDA Office of Risk Assessment and Cost Benefit Analysis, which is charged with ensuring that major regulations proposed by USDA are based on sound scientific and economic analysis.

Barriers to Implementing the Recommendation

There are many barriers, or challenges, to improving the scientific basis of food safety programs. First, public health needs change. New food safety challenges continue

¹ FAO and WHO. 1997. Risk Management and Food Safety. Report of a Joint FAO/WHO consultation, Rome, Italy, January 27-31. FAO Food and Nutrition Paper No. 65.

² Presidential/Congressional Commission on Risk Assessment and Risk Management. 1997. Framework for Environmental Assessment and Risk Management. www.riskworld.com/Nreports/1997/risk-rpt/pdf/EPAJAN.PDF.

³ 58 FR 51735; October 4, 1993.

to emerge as a result of changing food habits, a global food supply, and a changing population. An example is the impact of *E. coli* O157:H7—a pathogen that possibly did not exist 20 years ago but has been responsible for major outbreaks of foodborne illness in recent years. Second, the scientific understanding of risk changes as well. There remains a steep learning curve when it comes to understanding the hazards in food and how to minimize resulting risks. Third, there is a fragmentation of research and regulatory efforts, although cooperation and coordination among public health agencies at the Federal, State, and local level, and with the private sector, is improving. Fourth, limited resources exist to conduct surveillance, monitoring, and risk assessments to identify the most salient public health needs. And fifth, inconsistent food safety standards exist at the Federal, State, local, and international levels. Mechanisms are in place to reduce this inconsistency, but it is a long-range project.

Conclusion

USDA's food safety programs are already science-based and the Department is striving to make them more science-based. Considerable improvements have been made over the past several years as a result of the President's Food Safety Initiative and individual agency activities. Elements important to a science-based program—surveillance, outbreak response, risk assessment, research, inspection, and education of stakeholders—exist and are continually being strengthened.

However, the scientific information produced from research and risk assessment efforts will not result in improved food safety unless there is a strong educational component in the system. This means there must be education for all those involved in producing and handling food as well as for those persons involved in government food safety activities. Strengthening also involves improving coordination among the various public-private entities involved in these activities. Under any organizational structure, coordination among agencies and between the public-private sector is critical.

In addition, science must be tempered with other considerations, such as technical feasibility, statutory mandates, policy considerations, budget constraints, practicality, and consumer preferences. A new rapid test that works in the laboratory may not work in real-life plant environments. In some circumstances, it may be more appropriate to focus resources on a lesser risk, if that risk can be addressed relatively easily and quickly.

Additionally, emphasis should be placed on better evaluating science-based programs. Initial efforts have been made in this area. For example, *Salmonella* data from the first year of HACCP implementation show a trend toward fewer contaminated products. And FoodNet data provide a picture of the incidence of foodborne illness, and whether it has changed for specific pathogens. But much more needs to be done to ensure that the programs in place are doing what they are designed to do.

USDA believes that the necessary elements of a science-based program are in place, and that improvements planned for the next 5-10 years will enhance food safety. Specifically, USDA recommends that the President's Council on Food Safety consider in its strategic planning process how to accomplish the following enhancements.

Organizational Improvements. A new organizational structure is in place in FSIS, and the Agency will be doing much more to improve its infrastructure for recruiting and retaining scientists. In particular, USDA could take more advantage of visiting scientist programs, term appointments, and senior level biomedical research scientists. More training is needed to prepare a new cadre of risk analysts. The degree to which a food safety program is science-based is directly related to staff expertise.

Surveillance. As USDA approaches the new millennium, it will be looking for new ways to achieve surveillance goals and to monitor the food supply. Although the FoodNet has provided information never before available in the United States about the prevalence of foodborne illness, it remains an incomplete picture of national prevalence.

In addition, new and improved ways are needed to monitor the food supply. For example, new detection methods for *Campylobacter* will allow USDA to better estimate the prevalence of this pathogen. In the future, it may even become possible for the consumer to judge the presence of pathogens on foods in the grocery store or refrigerator by looking at a simple colorimetric marker on the product packaging.

USDA also conducts farm-level surveillance through the Animal and Plant Health Inspection Service, which, although only indirectly involved in the area of food safety, has a field force of veterinarians who work cooperatively at the State and local level to ensure the health of poultry and livestock populations. APHIS' National Animal Health Monitoring System has conducted nine science-based studies addressing information gaps in the areas of animal health, welfare, and production, product wholesomeness, and the environment in industries including the cattle, swine, and layer industries. Further use of these resources to enhance food safety should be considered.

Outbreak response. A tremendous amount of time and expense is currently being expended on recalling products that are found to contain certain pathogens such as *E. coli* O157:H7. USDA needs to systematically evaluate the effectiveness of these recalls. In the future, USDA should be able to determine how much product was returned and make an effort to estimate, when appropriate data are available, how many illnesses may have been averted by the recall. USDA also needs emergency response funding to enable it to respond to epidemics and possible bioterrorism incidents.

Risk assessment. The Federal government needs to create and use a national microbial risk assessment capability as a means of identifying hazards and quantifying risk and assist in creating similar capacities internationally. This will enable limited resources to be used more effectively to conduct risk assessments, and will enable resources to be used more effectively to address food safety problems according to the relative risks they pose.

Finally, there is an acute need to develop new methods and data for microbial risk analysis. In the area of dose-response assessment, because clinical trials with human subjects are not feasible for the virulent pathogens of greatest concern, animal and *in vitro* models are needed to fully integrate dose-response information into the risk assessments. Investigation of outbreaks, however, could provide more information on the exposed population and the pathogen levels in foods capable of causing illness. It is equally important to develop methods and conduct monitoring that will enable an efficient assessment of the occurrence and level of microbial pathogens at different points along the farm-to-table pathway. In this area, methods and models are especially needed to predict the growth and decline of pathogens under a variety of environmental conditions and under a variety of interventions. When developing databases on pathogen occurrence and levels from farm to table, cooperative efforts among industry, academia, and government should be fostered.

Research. Through the Joint Institute for Food Safety Research, a research infrastructure has been established to ensure scientific support for a risk-based, farm-to-table food safety program. The Institute will continue a critical review of the federally-supported portfolio of food safety research that was begun through the National Science and Technology Council. Future goals in the area of research will be to establish a coordinated scientific research agenda, integrate research efforts through an increased use of partnerships and other means, increase resources to support science-based decision making, encourage the application of new technologies to improve food safety, and conduct research on the costs and benefits of interventions.

Inspection. USDA will further improve the inspection of meat, poultry and egg products through the continued implementation of HACCP and HACCP-based inspection models. It will also continue to promulgate more science-based regulatory requirements. An example is additional performance standards for pathogen reduction, which can be developed as more monitoring and surveillance data become available.

USDA also will work with FDA and others toward consistent food safety standards nationally and internationally. The Conference for Food Protection and the Codex Alimentarius Commission are the primary mechanisms through which these activities will take place. However, the CAC is only a body for the international harmonization of science-based food safety standards. It has neither the resources nor the mandate to assist its members—in particular, developing countries—to strengthen their capability to meet internationally-agreed upon standards. USDA should become more active in this area of technical cooperation with developing countries.

Education. USDA will continue science-based education and training programs for producers, processors, distributors, food handlers, and consumers as well as those involved in regulatory activities. It is essential to include in these programs new scientific information on foodborne pathogens and their control and effective food safety management strategies. An increased effort will be made to provide education to the

growers and producers of food products to reduce pathogen occurrence in the production setting, thus reducing the need for remedial action later in the food production chain. There also will be a focus on “at-risk” populations to provide the most vulnerable segments of the population with increased knowledge of how to avoid the risk of foodborne illness. This will be accomplished through enhanced cooperative programs with stakeholders from all segments of the food system. In addition, USDA will continue to encourage voluntary use of science-based food safety techniques, such as HACCP, in the food industry.

Recommendation IIa: Congress should change Federal statutes so that inspection, enforcement, and research efforts can be based on scientifically supportable assessments of risks to public health.

Background

The report contains several criticisms of the current food safety laws. It states that the laws—particularly what the report characterizes as the requirement that there be continuous inspection of meat and poultry production through sight, smell, and touch (“organaleptic”) inspection—create inefficiencies, do not allow resource use to reflect the risks involved, and inhibit the use of scientific decision-making in activities related to food safety, including the monitoring of imported food.

The report recommends revision of the current statutes on food safety to create a comprehensive national food law under which:

1. Inspection, enforcement, and research efforts can be based on a scientifically supportable assessment of risks to public health. This means eliminating the continuous inspection system for meat and poultry and replacing it with a science-based approach that is capable of detecting hazards of concern.
2. There is a single set of flexible science-based regulations for all foods that allows resources to be assigned based on risk, that permits coordination of Federal and state resources, and that makes it possible to address all risks from farm to table.
3. All imported foods come only from countries with food safety standards equivalent to U.S. standards.

Strengths of the Recommendation

The report’s recommendations that Federal statutes should provide agencies with authority to make decisions based on risks to the public health and on scientific considerations make perfect sense. USDA has no disagreement with these recommendations. In fact, the Clinton Administration’s Pathogen Reduction Act of 1994, which was not passed by Congress, would have made more explicit the mandate that the Secretary of Agriculture is to use the best available scientific and technological data in prescribing regulations. USDA supports increased coordination among Federal agencies, and between the Federal government and the states, in pursuit of food safety goals.

In fact, imported meat, poultry, and egg products now come only from countries with food safety standards that are equivalent to U.S. standards. In fact, the statutes administered by FSIS prohibit the importation of meat, poultry, and egg products from

countries not identified by the Secretary of Agriculture as having inspection systems equivalent to that of the United States. FSIS has a monitoring system in place with these exporting countries.

Weaknesses of the Recommendation

The report overstates the problems with the current statutory requirements. The statutory requirement for inspection of all poultry and meat carcasses and products is misunderstood by the authors of the report. For instance, the report reflects the mistaken belief that the statutes require the current method of organoleptic inspection of all carcasses. In fact, the statutes do not prescribe how inspection is to be carried out. USDA has the flexibility to create, and is in fact has begun to develop, the more risk-based regulatory system recommended by the Academy. The Department has adopted regulations requiring that HACCP be implemented in all slaughter and processing plants and is studying how best to effect further inspection improvements in slaughtering plants. It has also adopted pathogen reduction measures. Clearly, the Agency is pursuing a science-based approach to reducing the risks to the American public from meat and poultry.

While the current law does not “require” organoleptic inspection as it has been accomplished by FSIS historically, it does require ante-mortem and post-mortem inspection of all official slaughter and processing facilities. The report fails to note that this inspection requirement has served American consumers well. Post-mortem inspection is the key to ensuring that plants are employing the best sanitary dressing processes and that they are effectively preventing fecal contamination, which harbors the pathogens that cause disease. Inspection of all animals and carcasses also serves to protect the public from diseases and other hazards to human health. Europe’s experience with BSE should serve as a reminder that wholesale elimination of inspection of all animals and carcasses is not the most prudent course of action.

The inspection of all animals and carcasses does not necessarily lead to inefficiencies, as the report seems to suggest. FSIS has instituted a study of new inspection models for carrying out its ante-mortem and post-mortem inspection mandates. This study is designed to test whether the public will be adequately protected with plants doing the sorting and government inspectors providing oversight inspection and verification inspection of the slaughter process.

Consumers expect safe food, but they also expect food to be wholesome and not to be economically adulterated. Consumers also want assurance that animals used for food are healthy and well cared for, and are slaughtered humanely. There are several methods of assuring safety, and continuous inspection is one of many options. However, given the prominence of meat and poultry products in the American diet, a comprehensive continuous inspection program is necessary if consumer expectations are to be fulfilled.

The report also fails to recognize the efforts at resource coordination that Federal agencies are making under their current authorities. First, as part of the President's Food Safety Initiative, agencies have formed FORC-G to coordinate outbreak response and to develop appropriate procedures for emergency responses. In addition, FSIS and FDA will soon enter into a Memorandum of Understanding under which each agency will share selected inspection results of interest with the other agency, which should minimize duplication. Also, FSIS and FDA are working together on final rules and a MOU that will minimize duplication in reviews of the safety of new substances for use in food (see Page 45 of the report). These efforts should increase the efficiency of the Federal government's food safety program. More importantly, they represent only a beginning effort at coordination.

Finally, the report fails to acknowledge the difficulties in obtaining passage of the sweeping new law that it recommends. The report cites the absence of a food safety counterpart to the Clean Air Act and the Occupational Safety and Health Act (Page 85). In fact, legislative proposals to do many of the things that the report finds to be necessary (e.g., enhance FDA's authority over imports) have been introduced in Congress in recent years but have not received necessary support in the legislative process. Given this history, the President's Food Safety Council will need to consider the political feasibility of major statutory changes.

Conclusion

USDA believes that the President's Council on Food Safety should not recommend a major overhaul of the food safety laws without first conducting a full assessment of these statutes and recognizing the significant regulatory changes, both current and planned, allowed by them.

The 1994 Reorganization of USDA accomplished the creation of the Office of Under Secretary for Food Safety, separate and apart from its previous position with Marketing in the Department. In addition, the research functions were centralized in the Office of the Under Secretary for Research, Education and Economics, enabling food safety research to be coordinated and enhanced.

USDA also believes that it has achieved and can continue to accomplish, significant scientifically-based improvements in its food safety programs under current authorities. The report's failure to recognize this fact, and its reliance on an incomplete and inaccurate understanding of current laws and the inspection program has led the authors of the NAS report to recommend sweeping legislative changes which are not supported by facts in the report. This is particularly true given the report's failure to assess the significant difficulties in obtaining the type of broad legislative change that it recommends. USDA, in conjunction with the other federal food safety agencies and the states, has made substantive progress, and will continue to strive, for an ever more effective and efficient food safety system that is based on the best available science and appropriate analysis and assessment of risk. While we do not agree that major statutory

reforms are needed, we do recommend that some changes be made. For example, the following legislative changes will, we believe, enhance the Department's ongoing efforts to improve food safety:

1. USDA has sought, and would benefit from, enhancements to its enforcement authority. The Food Safety Enforcement Enhancement Act, forwarded by the Clinton Administration and introduced during the last Congress, included new tools needed to support the new science-based inspection system. Specific examples of proposed legislation that are highly desirable include authority to mandate recalls and the authority to assess civil penalties in administrative proceedings for violations of inspection laws and regulations.
2. USDA is exploring statutory changes that would allow meat and poultry products produced under state inspection to be distributed in interstate commerce while ensuring a seamless Federal-state food safety system.
3. USDA supports legislative clarification of the current system for the regulation of eggs and egg products.
4. USDA supports statutory changes to the FDA statutes that would permit FSIS inspectors to not only report their findings to FDA but to actually perform inspections for that agency to increase interagency efficiencies.
5. FSIS should be given explicit authority to enter into cooperative agreements for food safety risk assessment. Under the current statutes, FSIS has to go through other USDA agencies that have that authority.

Recommendation IIb: Congress and the Administration should require development of a comprehensive national food safety plan. Funds appropriated for food safety programs (including research and education programs) should be allocated in accordance with science-based assessments of risk and potential benefits.

Background

The NAS report's recommendation IIb contains two parts. The first part recommends that Congress and the Administration require preparation of a comprehensive, national food safety plan. The report's Executive Summary lists several essential features of such a plan, including a unified food safety mission; integrated Federal, State and local activities; adequate support for research and surveillance; and increased efforts to ensure the safety of imported foods. The second part of the recommendation suggests that resources be allocated on the basis of science-based assessments of risk and potential benefits.

Since publication of the NAS report, much has been done to initiate a comprehensive, national food safety plan. On August 25, 1998, President Clinton issued Executive Order 13100 establishing the President's Council on Food Safety. One of the Council's primary purposes is to develop a comprehensive strategic plan for Federal food safety activities that contains specific recommendations on needed changes, including goals with measurable outcomes. The plan's principal goal is to establish a seamless science-based food safety system. The plan will set priorities, improve coordination and efficiency, identify gaps in the current system and mechanisms to fill those gaps, continue to enhance and strengthen prevention strategies, and develop performance measures to show progress.

The Council will consult with all interested parties in preparing the plan and consider both long-term and short-term issues, including new and emerging threats and the special needs of vulnerable populations such as children and the elderly. The Council will advise agencies of priorities for investing in food safety and ensure that Federal agencies annually submit coordinated food safety budgets to OMB. In short, the President's Food Safety Council will develop a national food safety plan and the budget to accomplish what the Committee recommends.

Food safety agencies have already taken the first steps to develop the national plan, by holding interagency strategic planning sessions, developing a draft vision statement for the U.S. food safety system, and establishing the roles of all those involved in food safety. In addition, during 1997 and 1998, the Federal food safety agencies involved a wide range of stakeholders in public meetings and written comments to public dockets.

Both consumers and the food safety agencies have discussed the need to ensure that imported foods come only from countries that have food safety standards equivalent to those in the United States.

At its first formal meeting, on December 16, 1998, the Council approved the process to develop a national food safety plan and a unified budget to support the plan. These decisions clear the way for meeting the Committee recommendation for a comprehensive, national food safety plan.

However, the NAS report recommendation goes a step further than a national plan by urging that resources be allocated according to science-based assessments of risk and potential benefits. While this seems like a very good idea, early attempts by Federal agencies to carry out risk-based allocation of resources have not been successful.

The Federal experience with comparative risk assessment to allocate resources dates to 1986, when the U.S. Environmental Protection Agency (EPA) assessed the risks posed by various environmental problems. In 1988, the agency released its findings in a report entitled, "Unfinished Business." This project did not enjoy broad credibility because 1) it was so broad and 2) critics within the agency suggested that programs with sufficient staff to devote to the inter-office working group were able to generate the most favorable analysis.

EPA asked the Science Advisory Board (SAB) to review the validity of "Unfinished Business." The expert panel declined to provide a consensus ranking of human health risks, citing scientific uncertainties and the subjective nature of such comparisons. In 1996, EPA requested that the SAB revisit comparative risk assessment and the Board established an Integrated Risk Project (IRP). As of December 1998, the final report was still undergoing peer review and did not prioritize specific pollution problems. Ultimately, none of the national environmental risk ranking exercises has significantly impacted EPA's budget allocations.

Since 1987, more than 24 states and localities have completed risk ranking exercises. Usually, priority-setting was an initial, primary objective. However, as the projects evolved, other objectives such as "enhancing stakeholder involvement" generally eclipsed priority-setting. In state projects, contentious issues with potentially large economic repercussions were omitted from the comparative risk discussions. Commonly, the final risk rankings were used to initiate new programs or to increase the budget of existing programs which addressed highly-ranked risks.

Strengths of the Recommendation

Proponents of risk-based allocation of resources see comparative risk analysis as objective, rational, and based on sound science. They believe that it should be an integral part of food safety strategic plans because it provides an efficient method of applying limited Federal resources to public health priorities. It is argued that comparative risk

analysis would increase the predictability, transparency, and overall credibility of the process of allocating funds to food safety programs. USDA believes that the analysis of risks and benefits should be an integral part of the regulatory development process. In fact, the output from these analysis can truly serve as a guide to the process and help decision makers choose an appropriate course of action.

Weaknesses of the Recommendation

The limitations of comparative risk analysis are the time and resources required to conduct them. As more risk assessments are conducted, the techniques and databases will be developed and they will be more timely and more precise. Policy makers will have the risk assessments as valuable scientific inputs to their decision-making processes.

Barriers to Implementing the Recommendation

The President's Council on Food Safety has made significant progress in developing a process for a national food safety plan and unified budget. However, developing and successfully implementing a national plan will require strong cooperation, coordination, and communication. Each Federal, State, and local agency has unique mandates, authorities, history, culture, and operating procedures. These differences make the planning and implementation process extremely complex. While the food safety agencies may agree on goals and outcomes, it will be more difficult to ensure accountability for performance. The discipline necessary to achieve all that the NAS report has recommended will come only with a strong central authority that has the ability to direct food safety resources. Science-based risk assessments can be conducted on a variety of levels. If time is short, screening level risk assessments should be used to provide information to decision-makers. In other cases, more detailed risk assessments of a broader scope are preferred to identify and evaluate a wide range of policy options."

Conclusion

Science-based risk assessment does not seek absolute certainty. Rather, it endeavors to bring the best existing science to the problem at hand. Risk assessment and cost benefit analysis should be built into the regulatory management and decision process so that these valuable tools can inform decision makers in an appropriate way. Though risk assessment and cost-benefit analysis are an important part of the information provided to a decision maker, it must be remembered that there are legal, political, and other economic concerns that must also be considered. Only with the best analysis possible can the limited food safety and public health resources be appropriately allocated.

USDA believes that the President's Council has already set in motion activities that meet the NAS report's recommendation and supports continuation of this process. In response to the NAS report, the President's Council requested the Food Safety Risk

Assessment Consortium to consider how to develop a comparative risk analysis for food safety strategic planning. The Consortium developed three options.

Under Option 1, USDA's Economic Research Service (ERS) would lead an analysis using cost-of-illness methodology to rank foodborne pathogen risks, based on CDC surveillance data. This option does not require any additional funds, and could be accomplished during CY1999.

Option 2 would expand Option 1 by considering a broad range of food safety hazards, including pesticides and chemicals. The analysis would rank hazards on several criteria, such as cost of illness, chronic and acute illness, and environmental effects. This option would cost approximately \$823,000 and would take 24 months to complete.

Under option 3, scientists would select highly-ranked hazards and evaluate control measures and net benefits. They would determine which actions or interventions yielded the best return in terms of reducing illness. Intervention options might include education, better surveillance, more inspection, or formal, quantitative risk assessments and focused research. This option would cost approximately \$2,143,000 and would accomplish the objectives described in options 1 and 2. However, it would require 51 months to complete.

These options could provide helpful input to a national food safety plan. USDA cautions, however, that the Council avoid repeating mistakes of the past in applying risk assessment that is too strict, rigorous, or inflexible. Instead, the Department recommends that priorities be established on the known greatest risks at the current time, with the understanding that scientific risk estimates can, and will likely, change frequently over time. How economic incentives for new food safety innovations could be increased should also be investigated.

A caveat: USDA believes that the interdependence among the report's recommendations assumes critical proportions in addressing recommendations IIIA and IIIB. In order to emphasize this critical interdependence, USDA has chosen to respond to recommendation IIIB first.

Recommendation IIIB: Congress should provide the agency responsible for food safety at the federal level with the tools necessary to integrate and unify the efforts of authorities at the state and local levels to enhance food safety.

Background

The authors of the NAS report concluded that reorganization of federal food safety responsibilities is necessary to implement a science-based food safety system. Recommendation IIIB addresses the issue of integrating and unifying the efforts of authorities at the State and local levels to enhance food safety. The report identified five statutory tools required to integrate local and State food safety activities into an effective national system:

1. Authority to mandate adherence to minimal federal standards for products or processes.
2. Continued authority to deputize state and local officials to serve as enforcers of federal law.
3. Funding to support, in whole or in part, activities of state and local officials that are judged necessary or appropriate to enhance the safety of food.
4. Authority given to the Federal official responsible for food safety to direct action by other agencies with assessment and monitoring capabilities.
5. Authority to convene working groups, create partnerships, and direct other forms and means of collaboration to achieve integrated protection of the food supply.

This recommendation acknowledges the “equally critical roles” of State and local government entities with those of the federal sector in ensuring food safety, and suggests changes in federal authorizing and appropriating legislation may be necessary to achieve better integration of federal, state and local activities.

The report also notes: “The work of the states and localities in support of the federal mission deserves improved formal recognition and support.” We believe that the report is highlighting this critical point at a serendipitous time.

Strengths of the Recommendation

USDA recognizes, and agrees with the report’s conclusion, that the divisions among federal, state and local authority often complicate the administration of regulatory programs.

Weaknesses of the Recommendation

USDA believes that most of the statutory tools suggested by NAS already exist for USDA, as noted below.

- Authority to mandate adherence to minimal federal standards for products or processes.

The Federal meat and poultry inspection laws already provide USDA with the clear authority to set minimum federal standards and require adherence to those standards. Both the states and other governments must satisfy the “equal to” provisions of those key laws. USDA has preemption authority if it becomes necessary. Twenty-five states operate state inspection programs inspecting product for in-state sale, and one additional program is in development.

In practice, however USDA has rarely had to call upon this authority to achieve food safety goals. For example, it is generally for budgetary reasons rather than program inadequacies that states give up their inspection programs for products produced and sold within the state. USDA in practice often defers to State Attorneys General where state laws are equivalent in addressing particular compliance matters.

- Continued authority to deputize state and local officials to serve as enforcers of federal law.

Under Federal-State Cooperative Inspection Program Agreements (formerly Talmadge-Aiken), State employees carry out inspection in federally inspected plants. Approximately 250 plants now operate under such agreements. We are also exploring new approaches, under current law, to extend this concept into other areas of food safety.

- Funding to support, in whole or in part, activities of state and local officials that are judged necessary or appropriate to enhance the safety of food.

Under current law, USDA provides up to 50 percent of the costs of state inspection programs (for 25, and soon to be 26, states with inspection programs for meat and poultry products produced and sold within the state.) This support adds up to more than \$40.5 million dollars per year.

Under current law, USDA (through FDA due to lack of FSIS cooperative agreement authority) has funded animal production food safety outreach projects involving 11 states. These projects bring together at the state level all of those involved in food animal production, veterinary practice, animal health, public health, and related areas to assess current level of food safety awareness among food animal producers; promote increased awareness of needs for food safety at the animal production level; identify production practices which enhance food safety and articulate them to producers, transporters, and marketers; and provide a continuing forum for addressing food safety issues as they arise, and supporting education and information activity which results in food animals being presented for slaughter which will yield safe, wholesome food products. The projects vary according to regional and food animal species differences, but all seek the same result – safe food. (\$405,000.) Contract states are: Louisiana, Oregon, Michigan, South Dakota, Nebraska, Texas, New York, Wisconsin, Ohio, and Vermont.

An essentially identical contract was developed with the state of Colorado, and will be funded through APHIS (\$45,000.)

Under current law, USDA (CSREES) transferred an employee to Iowa State to develop an educational program to train veterinarians as auditors for on-farm food safety and quality assurance processes. Under current law, USDA funded animal production food safety workshops in Colorado, Nebraska and Ohio (\$25,000 through the Livestock Conservation Institute). These workshops provided extensive information to the state-based information multipliers on food safety, consumer concerns, HACCP, packers and retailers' needs, and what producers can do to best address these issues.

Under current law and the President's Food Safety Initiative, USDA is enhancing state labs and computer capabilities. Under current law, FSIS is supporting the State training initiative for HACCP.

- Authority to convene working groups, create partnerships, and direct other forms and means of collaboration to achieve integrated protection of the food supply.

USDA believes it does have the authority under current law to convene working groups and to create partnerships. The federal-state initiative to encourage adoption of the Food Code does not require statutory authority. What FSIS lacks is cooperative agreement authority, which it is pursuing already in the legislative venue.

USDA also believes that any formal comment from the Council to the President on this recommendation should fold in and be responsive to the views of the states. The Department believes the strategic plan described under Recommendation IIB above is the vehicle for obtaining that input. It is doubtful that any changes in the federal-state-local relationship on food safety will be effective if they are not mutually agreeable.

Barriers to Implementing the Recommendation

The discussion under Recommendation IIA is also relevant here in that the President's Council on Food Safety should not undertake overhaul of the food safety laws without first conducting a full assessment of these statutes.

Conclusion

USDA recommends that the President's Council on Food Safety incorporate the ongoing dialogue with the states into its strategic planning process.

At a September 1998 "50-state" meeting, participants (largely state regulatory officials) developed a vision statement for an ideal national integrated food safety system and a list of issues that would need to be addressed to reach the ideal system. Since that time, six key operational "intersections" have been identified for integrating federal, state and local government activities:

1. Roles and responsibilities; capacities and resources.
2. Coordinating outbreak responses and investigations.
3. Data collection and sharing.
4. Communication.
5. Minimum uniform standards.
6. Laboratory operations and coordination.

Action plans for these six areas need to be considered by the Council as well as the participating agencies at federal, state and local levels. It is also important to emphasize that current work on a national integrated system is built on successful federal/state/local food safety initiatives over the past several years, within existing frameworks.

In some cases, the activities were generated by the States and in other cases by the federal agencies. In some instances, specific issues have served as the trigger (promoting

adoption of the Food Code, *E. coli* O157:H7 in ground beef, HACCP implementation in small and very small plants, interstate shipment, Salmonella in eggs). In other cases, agencies such as FSIS and FDA, which have themselves established new, cooperative modus operandi (dating back, perhaps, to nutrition labeling), have drawn state and local agencies into addressing emerging issues such as food safety in transportation, and food safety in animal production.

USDA believes that some of the landmark food safety improvements from 1992 to 1998 could not have occurred without the active participation of state and local agencies. One case in point is safe handling labels for raw meat and poultry. Another is the “sentinel site project,” precursor to FoodNet and PulseNet.

USDA believes that the Council’s planning process provides the opportunity to draw the States into the process as primary and equal partners in the development of the food safety system of the future. We believe that the national integration project described above is one of the appropriate vehicles for doing so.

Recommendation IIIA: To implement a science-based system, Congress should establish, by statute, a unified central framework for managing federal food safety programs, one which is headed by a single official and which has the responsibility and control of resources for all federal food safety activities, including outbreak management, standard setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.

Background

The NAS report finds that the current regulatory structure for food safety in the United States is not well-equipped to meet current challenges. Specifically, it notes: The system is facing tremendous pressures with regard to:

- emerging pathogens and ability to detect them;
- maintaining adequate inspection and monitoring of the increasing volume of imported foods, especially fruits and vegetables;
- maintaining adequate inspection of commercial food services and the increasing number of larger food processing plants; and
- the growing number of people at high risk for foodborne illnesses.

The report cites the strengths of the current food safety system, including the advent of FoodNet and PulseNet, HACCP implementation, and the Partnership for Food Safety Education. It also identifies deficiencies, which it attributes partly to “the fragmented nature of the system.” The Committee attributes the fragmentation largely to a lack of adequate integration among the various Federal agencies involved in the implementation of the primary statutes that regulate food safety, and observes that this lack of adequate integration occurs also with state and local activities.

The report goes on to note that 12 primary federal agencies are involved in key food safety functions. The Committee also references more than 50 memoranda of agreement between various agencies related to food safety. The agencies to which the Committee refers are listed below, within their four cabinet-level agencies.

U.S. DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service
Animal and Plant Health Inspection Service
Grain Inspection, Packers and Stockyards Administration
Cooperative State Research, Education and Extension Service
Agricultural Research Service
Economic Research Service
Agricultural Marketing Service

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Centers for Disease Control and Prevention
National Institutes of Health

U.S. DEPARTMENT OF COMMERCE

National Marine Fisheries Service

U.S. ENVIRONMENTAL PROTECTION AGENCY

A Single Voice for Food Safety

USDA agrees that communication, coordination, and cooperation between federal agencies can and should be improved. The Department also points to specific examples of effective coordination between USDA agencies and other federal agencies. For example, the Joint Institute for Food Safety Research (JIFSR) is expected to provide an even more effective forum for discussion and coordination of research plans and allocation of resources.

The report attributes the lack of adequate integration among Federal, State and local food safety authorities in part to the absence of “focused leadership” that has the responsibility, the authority and the resources to address key food safety problems. The report presents several examples of possible organizational structures to create a single federal voice for food safety. These include:

- A Food Safety Council with representatives from the agencies with a central chair appointed by the President, reporting to Congress and having control of resources.
- Designating one current agency as the lead agency and having the head of that agency be the responsible individual.
- A single agency reporting to one current cabinet-level secretary.
- An independent single agency at cabinet level.

Although the report indicates many of the authoring committee’s members believe that a single, unified agency headed by a single administrator is the most viable structure for implementing the “single voice” concept, the report recognizes that there may be many other models that would be workable.

Council on Food Safety. In August 1998, the President established by Executive Order the Council on Food Safety. The Secretary of Agriculture, the Secretary of Health and Human Services and the head of the White House Office of Science and Technology Policy are the co-chairs of the Council. The Executive Order assigned three key responsibilities to the Council:

1. Develop a comprehensive strategic federal food safety plan.
2. Develop a coordinated federal food safety budget.
3. Oversee federal food safety research efforts.

Strengths and Weaknesses of Four Options

In this context, USDA agencies make the following observations about the four options presented by the Committee in recommendation IIIA.

Options 1 and 2. Council on Food Safety; designating one current agency as lead agency.

Strengths: - USDA believes Option 1, the Food Safety Council, could foster interagency cooperation, permit appropriate allocation of resources to most urgent questions, and allow synergy among research, education and regulatory functions. In addition, a Food Safety Council with specific responsibilities has already been appointed (as described above).

Some USDA agencies believe that Option 2, the Lead Agency concept with other agencies reporting to that Agency Administrator, could be workable, but do not cite any specific supporting points (and favor it second to the Council on Food Safety).

Weaknesses: USDA agencies agree that some parts of the Federal government's food safety activities may be appropriate for consolidation within a single agency. They regret that the Committee report did not focus more carefully on specific food safety issues for which interagency efforts need improvement and on specific methods for achieving that improvement, beyond what is already underway or planned. USDA agencies suggest that the Food Safety Council's strategic plan, which will be based on input from the agencies, provide more attention to this topic.

Options 3 and 4: Single agency reporting to one current cabinet-level Secretary; or Independent single agency at cabinet level.

Strengths: One strength of consolidating food safety within the USDA is that most of the Federal Government's food safety resources (7 of the 12 agencies) currently report to the Secretary of Agriculture.

Weaknesses: In addition to the weaknesses noted with Options 1 & 2, USDA agencies point out that massive reorganizations require broad legislative support as well as additional funding and are very time-consuming. They also have the potential to damage customer service and even public health protection if not managed very carefully. Finally, some USDA agencies are particularly concerned that options 3 and 4 would be particularly detrimental to research and educational activities. They do not believe that a clear need has been demonstrated for a single independent food safety agency.

The Committee has recommended that other models be examined. USDA proposes one for consideration.

Structural model - Joint Chiefs of Staff: An analogous situation existed some years ago in the military, where uniformed services operated independently if not at odds with one another, despite a shared goal: National Defense. Inter-service relations were characterized by competition, non-communication, and waste. After the Goldwater-Nichols Bill was passed into law, however, the Joint Chiefs of Staff was given command authority over the individual services, with a rotating Chair.

The result was that the services retained their core missions, but are now obliged to coordinate in many areas where their missions coincide. Logistics, research and development, information technology and communications, and emergency response are among the many functions now served by joint commands.

Service in "joint" billets, once to be avoided, has become desirable if not mandatory career steps for senior military personnel. There is near universal agreement that the changes have enabled the services to become more effective and efficient, to the benefit of the taxpayers and national defense.

This model could be instructive as we look for ways to make the federal government's food safety activities more effective and efficient.

Challenges

In general, USDA agencies do not believe that a major reorganization of responsibility, authority and budget-making is timely, necessary or desirable in order to achieve the model food safety system.

USDA agencies are concerned about a number of specific issues. These issues are surfaced because USDA believes they warrant the closer attention by the Food Safety Council in its analysis and report to the President.

- *Food safety issues jaywalk across jurisdictional lines.* Many food safety issues simply cannot be dealt with by a single agency. For example, BSE is an animal health issue and a human health issue. The foodborne disease problem is also

a waterborne disease problem. *Salmonella enteritidis* in shell eggs is not only a food safety issue but also an animal health and a marketing issue; support for the scientific investigation to unravel the secret of ovarian transmission came from both the public health and agricultural communities. And, of course, food safety is also a nutritional issue. In this country and around the world, people do not gain the nutritional benefits of the food available to them if they suffer foodborne illness, particularly when accompanied by dehydration due to prolonged diarrhea. That makes foodborne illness also an international issue of concern to susceptible populations such as children, the elderly and persons with immune-compromised conditions.

- *Not all food safety problems are amenable to regulatory solutions.* All food safety problems or concerns cannot be resolved by legislation or regulation. For example, irradiation of pork for trichina control was approved more than a decade ago; approval of irradiation of raw beef for microbial control is waiting in the wings. Despite the scientific and regulatory view that irradiation is an effective technology for minimizing food pathogens, public perceptions about irradiation—anxieties not even related to food safety—have prevented its widespread use. In our pluralistic system, the marketplace and other forces will influence, sometimes drive, our regulatory agenda.

In addition, all of the options the Committee has listed involve transfer of “command and control” functions from numerous agencies to a single Federal entity. It is noteworthy that USDA, among other federal agencies, is engaged in a politically popular regulatory reform effort to replace “command and control” regulations with science based “performance standards” whenever possible.

- *Most food safety problems have at least three “solutions.”* A regulatory solution, i.e., standard setting and enforcement, is not always the best solution to a food safety problem. Research, education and voluntary compliance can reduce the need for regulation.

- *New partnerships are silver, old ones are gold.* We should build upon, not discard, existing successful partnerships. For example, CSREES, FSIS, FDA, CDC and other private and governmental organizations now participate in the Partnership for Food Safety Education. This group serves to coordinate all food safety educational programs among private and governmental agencies, and is a key element of the Food Safety Initiative. Within that partnership, the RFP for projects on food safety education from CSREES was shared with other Federal agencies to gain input and improve coordination of these efforts.

Yet that partnership would not have been possible without relying on the many effective working relationships developed among the participants over the years, including joint projects on residue control and nutrition labeling. Moving food safety education programs into a single food safety agency would be of concern because of the potential loss of the very important partnership which CSREES has

with its partners in the Land-Grant system and the Cooperative Extension Service. This partnership is critical to the easy and rapid transfer of research results from CSREES funded programs directly into the Extension System and on to the end users.

By the same token, the Joint Institute for Food Safety Research builds on long-term research coordination among food safety agencies. ARS and CSREES continue to work closely on planning of research agendas and allocation of funds for research projects. In the writing of the two current new Requests for Proposals (RFP's) by CSREES, the general outline of the RFP was discussed in detail with other Federal agencies, including FDA, FSIS and ORACBA, to ensure that we were meeting their needs as much as possible within the confines of the authorizing language for the programs.

- *There is strength in diversity.* Public partnerships are strengthened by having diverse views and expertise among the members, to better anticipate all factors that will affect resolution of any food safety issue. For example, any attempt to placing "pure" food safety research and education in one agency could actually jeopardize our ability to deliver improved food safety to consumers. Research and education programs for food safety do not operate as separate activities within the agencies but rather draw significant strength from one another. While some projects are entirely focused only on food safety, the food safety research portfolio actually includes many other projects in such areas as animal health, animal genetics, which provide major contributions to the total set of information which supports the national food safety effort.

Conversely, scientific expertise and endeavors should always inform regulatory activities. Each regulatory agency must have a cadre of trained and involved scientists to facilitate communications and cooperation with the research/education agencies. [Applied research, especially focused on adaptation and adoption of new diagnostic methodologies and development of risk assessment models, remains a crucial element of the action agency.]

Conclusion

The President has directed the Council, as one of its first activities, to review the NAS report and, after providing opportunity for public comment, including public meetings, report back to the President within 180 days with its response. The Council was asked to consider appropriate additional actions to improve food safety, including proposals for legislative reform and reorganization of the food safety system.

However, any reorganization of food safety activities must recognize the non-food-safety-related responsibilities of the agencies and how these relate to the food safety responsibilities. Reorganization must not be done at the expense of these responsibilities and activities. Congress had valid reasons for creating a single agency, ARS, to conduct agricultural research, a single agency, EPA, to regulate pesticides, a single agency,

APHIS, to regulate animal and plant health. Those reasons still exist. USDA is concerned that separating

- food-safety-related agricultural research from non-food-safety-related agricultural research could weaken both;
- regulation of foodborne animal diseases from the regulation of other animal diseases could weaken both; and
- regulation of pesticides for food crops from the regulation of pesticides for non-food crops could weaken both.

USDA recognizes that some reorganization and consolidation of activities may be desirable but is concerned that a massive reorganization of the federal government's food safety activities may create as many problems and inefficiencies as it solves.

USDA believes that before the Council considers reorganization it should do what the Committee has suggested: Identify and analyze other existing models in government for achieving mutual and truly national food safety goals. Some of these models might address structure, and some might address facilitating mechanisms.

DRAFT -- 1/19/99

MEMORANDUM

SUBJECT: Preliminary EPA Assessment of the National Academy of Sciences' Report,
Ensuring Safe Food from Production to Consumption

FROM: Susan H. Wayland
Acting Assistant Administrator

TO: Interagency Task Force

EPA's preliminary assessment of the National Academy of Sciences' (NAS) report, *Ensuring Safe Food from Production to Consumption*, is attached. Since NAS only focused on EPA's pesticide program, we have limited our review to the policy implications of the report for pesticides. The attached paper gives our general assessment of the report's recommendations as well as background information on the pesticide program in the areas addressed by each recommendation. We have not provided all the strengths (pros) and weaknesses (cons) as well as barriers that could be envisioned; however, we are willing to do further analysis or assist with the draft unified assessment once there is general agreement on the Council's conclusion regarding each recommendation.

We recommend that the food safety agencies' responses be shared and that a meeting of senior staff from the agencies be held in the next week to try to reach an understanding of the similarities and differences in the agencies' responses to the recommendations. This would foster communication and coordination as well as provide information to articulate any differences to the Task Force members prior to the high-level meeting on January 29, 1999.

I'd also like to mention our concern about the coverage of EPA in the report. The NAS committee was very highly qualified, but, given the limited time available, they focused primarily on USDA and HHS responsibilities and programs. It appears that the Committee did not have the time to reach a full understanding of the complexities of EPA's pesticides program and its relationship to not only food safety but to its other areas of responsibility such as worker protection, environmental protection, and public health protection from non-food uses of pesticides. This could lead to unintended consequences during consideration of a single food safety agency. We need to be diligent to insure that a thorough analysis is done which takes into account the breadth of our pesticides work as well as its relationship to EPA's other public health and environmental protection mandates.

DRAFT -- 1/15/99

I hope you find EPA's assessment useful, and I look forward to working with you on the Council's report to the President. Please feel free to call me (260-2902) or Judy Nelson (260-4177) if you have any questions.

cc: J. Charles Fox
Noreen Noonan
Steven Herman
Sallyanne Harper
Marcia Mulkey
Jane Henriques

EPA'S PRELIMINARY ASSESSMENT OF NAS REPORT

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 on scientific and organizational changes needed to ensure an effective food safety system. The NAS released its findings, conclusions, and recommendations in an August 20, 1998 report, *Ensuring Safe Food from Production to Consumption*. On August 25, 1998, the President issued a directive tasking his Council on Food Safety to provide him with an assessment of the NAS report. The Council has established a task force to address the NAS's findings and recommendations, and, as an initial task, has requested that each agency provide its assessment of the NAS report. The NAS conclusions and recommendations are shown in Attachment A. This paper provides our preliminary assessment of those recommendations.

DISCUSSION OF NAS CONCLUSIONS AND RECOMMENDATIONS

I. Base the food safety system on science.

Background: EPA's regulation of pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food Drug and Cosmetic Act (FFDCA) has historically been science-based, using risk assessment principles to determine whether a pesticide should be licensed for use on designated crops and to establish maximum allowable residue levels in/on food. The NAS report recognized this science-based approach when it stated that "risk assessment is fairly well-developed for chemical hazards, such as pesticides" (p. 68) and cited EPA's estimation of maximum allowable exposure levels to pesticides as an example of a "science-based" action that has been implemented in the U. S. food safety system that is a positive element of the system. (p. 6).

The science-based system for regulation of pesticides was further strengthened by the 1996 Food Quality Protection Act (FQPA) which mandates that EPA look, among other factors, at aggregate exposure, cumulative risk, and the potential need for additional safety factors to protect children and other vulnerable subpopulations. FDA, USDA and EPA together have undertaken efforts to improve the data base on food consumption, and EPA, FDA and industry have initiated a joint effort to coordinate residue monitoring data bases; both activities are designed to improve the information supporting EPA's establishment of tolerances, or maximum legal limits, for pesticide residues under the new law.

Implementation of the new FQPA standards for pesticide residues has not been without difficulty. EPA is breaking new ground in determining how to assess aggregate risk from food, water, and residential exposure as well as cumulative risk from pesticides with common mechanisms of toxicity, and incorporating those assessments into the tolerance setting process. Further, as residue standards are changed, some pesticide uses may be eliminated and impacts on growers and the food supply can occur unless alternative products are available. For this reason, EPA,

working with USDA, will endeavor to provide reasonable transition periods when the Agency acts to remove a pesticide use.

Conclusion: EPA agrees that the food safety system should be based on science; we use risk analysis -- including quantitative and qualitative risk assessment and risk management principles -- to determine acceptable levels of pesticide residues in/on food. Under FQPA, this science-based approach has been strengthened to further protect all consumers, and especially children, from the risks of pesticides in their diet.

IIa. Change Federal statutes so that inspection, enforcement and research can be based on assessments of public health risks.

Background: EPA's Office of Pesticide Programs registers (i.e., licenses) pesticides for use on crops and establishes maximum allowable residue levels in/on food. EPA's Office of Research and Development supports this program with advice and research on critical risk assessment issues and development of testing and monitoring methods. EPA's Office of Enforcement and Compliance Assurance, along with the States, ensures that pesticides used on food are registered and used correctly, as well as ensures that data used to support registration is not fraudulent. FDA inspects domestically-grown and imported food, except meat and poultry which is handled by USDA, to insure that the food is not adulterated (i.e., it does not contain pesticide residues for which there is no approval or in amounts which exceed approved levels. FDA has the authority to prevent marketing of food which is adulterated with pesticides.

This system for regulation of pesticides was significantly revised by Congress with the passage of FQPA in 1996, primarily to strengthen its science basis and provide better public health protection. The new Act continues to mandate that tolerances, or maximum allowable pesticide residue limits, be based on scientifically supportable assessments of public health risks, and prescribes consideration of aggregate risk from exposure through the diet and other non-occupational sources as well as cumulative risk from pesticides with common mechanisms of toxicity. FQPA also eliminated long standing problems posed by differing standards for pesticides in raw and processed foods; specifically FQPA removed the application of the Delaney clause in FFDCA Section 409 to certain processed foods and established a single, risk-based standard under which EPA must determine that residue levels are "safe," -- i.e., that there is a "reasonable certainty that no harm will result from aggregate exposure" to the pesticide.

Thus, under the current statutory structure of FIFRA and FFDCA, as amended by FQPA, pesticide registration and tolerances as well as the supporting research, inspection and enforcement are based on a standard-setting process that uses risk assessment and risk management principles. Further, EPA has established program priorities for the registration and tolerance reassessment programs based on our assessment of either the greatest risks or where substantial benefits can be achieved quickly at reasonable cost. For example, new pesticides which are safer than currently used alternatives are given priority in registration, and thus typically

reach the market in half the time that it takes for new pesticides which are not a safer replacement.

In addition, in keeping with FFDCA Section 408, EPA's reassessment of tolerances is focusing on those pesticides which are most likely to pose risks -- the "worst first". Following this guidance, EPA is concentrating its resources on the reevaluation of the nearly 1200 tolerances for forty organophosphate insecticides.

Conclusion: Given the recent overhaul of pesticide legislation, further statutory changes are not needed for pesticides at this time. Updating other food safety statutes should be evaluated, but it is too soon to know whether substantial changes are necessary. Development of the strategic plan will provide the opportunity to identify statutory as well as other barriers, and to assess the need for legislative change. We recommend that a legislative review be undertaken as part of the strategic planning process. The purpose of such a legislative review would be to: examine the similarities and differences in Federal food safety statutes; identify the "best" approaches for reducing foodborne illness; and assess both gaps and statutory barriers to implementation of the plan. The need for statutory changes could then be determined, and, if necessary, legislative principles developed which would form the basis for discussions with stakeholders and Congress.

Such a legislative review by the food safety agencies would also help to avoid adopting proposals which on their face seem reasonable, but that might have significant unintended consequences on existing Federal, State or international food safety efforts. For example, although on its face it may seem reasonable to "mandate that all imported food come from only countries with food safety standards deemed equivalent to U.S. standards", this approach would be extraordinarily difficult and unwise for some food safety programs such as pesticides. EPA, in cooperation with OECD, Codex, and our NAFTA partners, has devoted substantial effort to developing harmonized test methods and good laboratory practices as a means to international coordination of pesticide regulation, while maintaining the levels of protection deemed appropriate for U.S. consumers. Other U.S. food safety agencies may be able to review legal, regulatory and procedural requirements in other countries and insure that imports do not compromise U.S. standards, but this would not be feasible for pesticide tolerances. In sum, any legislative revisions adopted for imported food need to be developed and implemented in such a way that they do not do collateral damage to other food safety programs.

IIb. Develop a Comprehensive National Food Safety Plan.

Background: HHS, USDA and EPA's May 1997 report to the President, *Food Safety from Farm to Table: A National Food Safety Initiative*, 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, established in August 1998 under Executive Order 13100, is now responsible for the development of this Federal food safety strategic plan. The food safety agencies (USDA, HHS and EPA) have already taken the first steps to develop 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:

Draft Vision Statement

"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 subpopulations. We use science- and risk-based approaches along with public/private partnerships. Food is safe because everyone understands and accepts their responsibilities."

The President's Council on Food Safety held four public meetings in the Fall of 1998 in Washington, D.C., Sacramento, CA, Chicago, IL, and Dallas, TX to solicit comments on this draft vision for food safety and to identify a strategic planning process, goals and critical steps as well as potential barriers to achieving that vision.

The Council now plans to convene a task force to develop a comprehensive food safety strategic plan; 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 analyze the transcripts of the 1998 public meetings and the input received through the notice and comment process to determine the major themes, issues, and subject areas. The task force will also consider the conclusions and recommendations of the NAS report, input from the "50-state meetings" on state/local issues, and input from the agencies involved. The task force will then develop a proposed set of strategic goals and objectives and present a draft plan to the President's Council on Food Safety. Following Council review, the draft plan will be provided to the public for review and comment. After public comment, the task force will prepare a final draft 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 this final plan to the Council for approval.

A coordinated food safety strategic planning effort will build upon common ground and provide the forum to tackle some of the difficult public health, resource, and management questions facing the Federal food safety agencies and our State, Tribal and local government partners. The plan will be used to 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. It should also identify areas for enhanced coordination and efficiencies, determine whether legislative changes would be beneficial (see above), and identify state and local government roles and responsibilities in the U.S. food safety system (see later discussion).

Conclusion: We agree that a comprehensive national food safety strategic plan should be developed and the food safety agencies, under the auspices of the President's Council, have already initiated the process to develop this plan. A comprehensive food safety strategic plan will set goals, identify the roles and responsibilities of each Federal agency and our partners, and give

us the basis upon which to allocate Federal resources. We look forward to incorporating EPA's strategic plan goals under the Government Performance and Results Act for "safe food" and "clean and safe water" into the interagency strategic plan.

IIIa. Establish a Unified Framework for Managing Federal Food Safety Programs.

Background: On August 25, 1998, the President issued Executive Order 13100 establishing his Council on Food Safety to develop a comprehensive strategic plan for food safety activities, ensure the most effective use of Federal resources through the development and submission of coordinated food safety budgets, and oversee the Joint Institute for Food Safety Research. A Food Safety Council was one of the possible organizational structures mentioned by NAS as a way to create a central and unified framework. Establishing the President's Council is directly responsive to this NAS' recommendation by providing a Federal voice for food safety and the ability to influence resources through both planning and budgeting. Under the direction of the President's Council and given today's technology, the food safety agencies are working more closely together to begin the strategic plan, submit joint budgets to OMB, address key risk assessment issues, and jointly handle day-to-day issues affecting food safety.

[to be filled in]

Conclusion: The comprehensive food safety strategic plan should bring agreement on the vision, goals and actions needed to enhance the safety of the nation's food supply and protect public health by reducing the annual incidence of acute and chronic foodborne illness. It will also identify the roles and responsibilities of each food safety agency as well as those of our state, tribal, and local government partners. This action plan can provide the framework for moving forward together and allocating resources. The Council and the agencies should be given the opportunity to develop and implement this comprehensive strategic plan before organizational changes to create a single food safety agency are considered.

[to be filled in]

IIIb. Integrate and Unify Efforts at State and Local Levels To Enhance Food Safety.

Background: EPA works closely with the States and Tribes on pesticide program implementation and enforcement. States/Tribes have primacy for compliance and enforcement of Federal use provisions for pesticides. Additionally, EPA has delegated responsibilities to the States and Tribes for:

- program implementation of certification and training;
- program implementation of worker protection (including training);
- program development and implementation of endangered species protection; and
- program development and implementation of groundwater protection from pesticides.

Since the 1970s, EPA has provided eighty-five percent (85%) of the funding for State compliance and enforcement programs and fifty percent (50%) of the funds for State pesticide applicator certification and training activities under FIFRA 23(a)(2). In FY90, EPA began providing funds under a cost-sharing arrangement with States to develop and implement programs to protect groundwater, endangered species and workers. Cooperative agreements for all of the above activities are issued yearly based on negotiated commitments for program activities. States/Tribes report to EPA at the end of the year on their accomplishments under these cooperative agreements.

To insure good communication and coordination as we jointly implement pesticide regulation, EPA and state officials established the States FIFRA Issues Research and Evaluation Group (SFIREG) in 1978. SFIREG consists of ten state pesticide regulatory officials (one from each EPA region and elected by the states in the region) who meet periodically with EPA pesticide officials. SFIREG identifies, analyzes and provides the States' comments to EPA on matters related to pesticide registration, enforcement, training and certification, water quality, disposal and other areas of concern related to pesticide manufacture, use and disposal. In addition, SFIREG provides a mechanism for EPA to keep the states informed and up-to-date on its pesticide regulatory program.

In sum, EPA works closely with and provides substantial financial support to its state and tribal partners to assist with pesticide program and enforcement activities. EPA has most of the statutory tools described by NAS as necessary to integrate local and state activities:

- "authority to mandate adherence to minimal federal standards for products...;
- continued authority to deputize state and local officials to serve as enforcers of federal law;
- funding to support, in whole or in part, activities of state and local officials that are judged necessary or appropriate to enhance the safety of food; and
- authority to convene working groups, create partnerships, and direct other forms and means of collaboration to achieve integrated protection of the food supply."

In a few cases where statutory authority is not specifically provided, appropriations language has provided EPA with the impetus to delegate certain pesticide responsibilities and issue supporting grants to the States and Tribes.

EPA is also working with USDA, FDA, and CDC as well as state and local officials on recommendations and plans for improving the coordination of foodborne disease outbreak investigations and responses and for an integrated food safety system encompassing all levels of government. Local, state, and federal officials first met in September, 1998, in what has become known as the "50-State meeting," to begin work on a vision and plan for an integrated food safety system; a second meeting was held in December, 1998 at which the group adopted the Council's draft vision as the foundation for its plan.

At this point, six work groups have been charged with identifying their vision, goals and actions

for a specific area, what obstacles exist to getting to the vision/goals, and how to overcome the obstacles. The areas are:

- Roles and responsibilities,
- Coordinating outbreak responses and investigations,
- Information sharing and data collection,
- Communications,
- Minimum uniform standards, and
- Laboratory operations and coordination.

The work of these groups will be combined by a Coordinating Committee into a proposed plan for an integrated food safety system and will be used as state/local input into the comprehensive strategic plan and the budget process.

Interestingly, at the first two "50-State meetings", the States commended EPA on its approach to delegation and funding of program implementation; this approach will be looked at by USDA and FDA as a potential model for improved coordination and integration.

Conclusion: We agree that the roles of state, tribal and local governments in the food safety system are critical. EPA has most of the statutory tools recommended by NAS and has delegated responsibility to its state and tribal partners. EPA, USDA and HHS are working together through the "50-State meetings" to develop a mission and common goals, and to identify the appropriate roles of all levels of government in the U.S. food safety system. This work will be considered in developing the comprehensive strategic plan and coordinated budgets and should form the basis for improved integration with state, tribal and local governments.

ATTACHMENT A

Conclusions and Recommendations of NAS Report, *Ensuring Safe Food From Production To Consumption*

Conclusions:

- I. An effective and efficient food safety system must be based in science.
- II. To achieve a food safety system based on science, current statutes governing food safety regulation and management must be revised.
- III. To implement a science-based system, reorganization of federal food safety efforts is required.

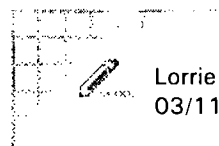
Recommendations:

- I. Base the food safety system on science.
- IIa. Congress should change federal statutes so that inspection, enforcement, and research efforts can be based on scientifically supportable assessments and risks to public health.
- IIb. Congress and the administration should require development of a comprehensive national food safety plan. Funds appropriated for food safety programs (including research and education programs) should be allocated in accordance with science-based assessments of risk and potential benefit.
- IIIa. To implement a science-based system, Congress should establish, by statute, a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.
- IIIb. Congress should provide the agency responsible for food safety at the federal level with the tools necessary to integrate and unify the efforts of authorities at the state and local levels to enhance food safety.

1. Executive
2. facts
3. $\uparrow$ study
4. $\uparrow$ resources
5. Unby Ed's system

NAS report.

1. FDA has trouble getting money
2. USDA does not.
3. USDA does a lot of inspections, FDA does not.
4. USDA is going to have pressure to get rid of inspectors.
5. The agencies don't work together particularly well. Joint budget problem.
6. Consumers support.
7. Congress support.
8. Industry split , known vs unknown.



Lorrie McHugh
03/11/99 09:44:36 AM

Record Type: Record

To: Thomas L. Freedman/OPD/EOP

cc:

Subject: Re: NAS Response

I'm trying to get the draft release to see how it reads. The keeper of it at FDA is out because his wife is having surgery.

Having not seen the release, I would be hesitant to say that it rose to the level of a Presidential statement or release. In the absence of any real news on Friday or Monday at this time, it could create attention if released out of here. That's fine if we are ready for the attention, but I guess I am not sure that we are. Do you think we are?



Eric Olsen <Eric.Olsen @ usda.gov >
03/11/99 09:47:00 AM

Record Type: Record

To: Thomas L. Freedman/OPD/EOP

cc:

Subject: Re: food safety

well i talked briefly with caroline yesterday and played phone tag with carol. my guess is they will just continue pushing for single agency and see this as "balking" .there isn't really any "news" in the report, so i don't think we should overhype it at all. I also think it's a bit disconcerting that there aren't proposals to deal with issues like eggs, but tthe lack of those probably stems from the absence of clear direction from principals...i'm going to try and talk with them today. Did you hear that FDA's concerns with the report stemmed from their perception of an agenda i.e. Joe Levitt specifically said he was told by industry that USDA has a plan to take over their functions...i told him that our position was we needed to have a policy level discussion of options for restructuring...

> > > Thomas_L._Freedman@opd.eop.gov@i 03/11 9:04 AM > > >
Did you have any thoughts on the response to the NAS report -- I'm supposed to talk to bruce about it this a.m. How will Carol/Caroline respond?

DRAFT FOR DISCUSSION PURPOSES ONLY
The Context for Possible Changes in Federal Food Safety Structure

The consideration of structural changes in the current federal food safety organizational responsibilities and departmental locations requires evaluation of a number of issues in various contexts. The attached outline of one possible structural shift is premised on the following analysis.

(1) HHS and FDA will continue to be unable to obtain from Congress the resources necessary to strengthen its food safety program. There are a number of reasons for this failure, including organizational weaknesses. First, while food is the first word in FDA, its importance is overwhelmed by other products under FDA's jurisdiction, including pharmaceuticals, veterinary medicines, medical devices, functional foods, and biotechnology. Second, unlike USDA, FDA has no food inspection force that is dedicated to food safety; rather, its inspectors oversee all of the products regulated by FDA. FDA also unfortunately frequently fails to develop persuasive budget justifications for funding increases. While certain parts of its regulated industry are pleased by the fact that it cannot inspect ordinary manufacturing plants more than an average of every 4-8 years, other parts of industry are concerned at its inability to work cooperatively with industry when it embarks on new initiatives.

FDA
no
dedicated
inspection
force

(2) As HACCP implementation in meat and poultry continues to be successful, there will be increased pressure to reduce USDA's inspection resources from budget sources and from those elements in industry who seek to weaken federal oversight over food safety. These efforts are already underway by a number of entities.

USDA
has
a
great
inspection
force

(3) Without a strategic plan that the Administration and the Congress support over the long term, the efforts to cut USDA's food safety resources are likely to succeed while FDA's resources for food safety will not increase. This would result in substantially weakened Federal food safety presence.

USDA
food
safety
resources
will
not
increase

(4) The President's Council on Food Safety is unlikely to be able to develop such a strategic plan under the current organization structure. The principal food safety agencies, FDA and FSIS, currently have great difficulty developing simple documents such as a joint budget summary. It may be impossible for the agencies to develop such a complex and sensitive undertaking such as a strategic plan. For example, as long as FDA believes it may be able to obtain funding for its food safety program, FDA has little interest in developing ways to leverage USDA's resources, since doing so would undercut its efforts to gain increased funding or act as a conduit for Federal funds to states. USDA is concerned that the redeployment of its resources must be carefully managed to maintain the base of industry, producer, and consumer group support, and that outside interests may seek to change the pace of USDA's redeployment of its inspectors.

FDA
has
little
interest
in
leveraging
USDA's
resources

(5) In short, while some may say that structural changes should not be proposed before a strategic plan is developed, it very well may be that structural changes need to be made in order to develop a strategic plan that maintains a strong Federal food safety presence.

(6) Good regulatory programs need a strong scientific base. USDA's research agencies (ARS, CSREES, and ERS) sponsor approximately \$60 million annually in food safety research. These agencies also can rapidly disseminate research results to the private sector through the Cooperative Extension Service in all 50 states.

Consumer (7) USDA's reorganization in 1994 laid to rest the criticism from consumer groups that it had a conflict of interest in managing food safety and agriculture promotion programs. The creation of the Office of the Under Secretary for Food Safety and the legislated requirement that the incumbent be experienced in public health and food safety effectively separate the regulatory and marketing functions.

*USDA
1-2 stages* (8) Neither a Democratic nor a Republican Congress will accept moving FSIS from USDA. The agricultural community and food industry would strenuously oppose such a move. It is extremely unlikely any such shift would occur unless there were a terrible food safety catastrophe for which USDA was responsible. Given general industry support for USDA, a Republican Congress may be willing to move FDA functions to USDA.

(9) A Democratic Administration with a strong food safety record would have the credibility to move certain FDA food safety functions to USDA. A Republican Administration would likely be criticized for such a proposal.

13-20 (10) Agricultural producer community would likely support such a move.

Consumer (11) Consumer community would likely not oppose and may even support such a move. USDA has developed a strong record with consumer groups, many of whom have also been frustrated with recent FDA efforts and also fear that efforts to cut USDA's food safety budget will be successful without a strong strategic plan in place for redeployment.

(12) Parts of the food industry may be supportive, but trade organizations may split as member companies may prefer dealing with a known agency i.e. if an industry sector or company deals predominantly with FDA, it may not want to deal with a new agency. However, company's and trade organizations have expressed interest in replicating USDA's strong federal-state structure in which states that enforce meat and poultry laws may not stray into contrary forms of regulation, so inclusion of preemption in this transfer may generate industry support. In addition, industry would like FDA to have additional resources and staff to address functional foods i.e. foods with new nutritional claims, food additives, and biotechnology. Certainly, some industry groups prefer playing the agencies against one another, while others believe USDA is too consumer or producer focused.

(13) Legislation would be required to accomplish such a transfer, and some additional funds and personnel may be necessary to effectively execute the transfer. However, the proposal contained in the outline would be simple to draft and would not likely require a large amount of additional resources.

Received Mar 11 04:41PM (00:58) on C.S.P.I. line [0] for 'ADMINISTRA'
MAR-11-1999 16:45 REUTERS HOUSE GALLERY

WORKSRV3 printed ADM36E7F29F3A4C on Mar 11 04:43PM * Pg 1/1
P.01

Printed By Reuters :

Thursday, 11 March 1999 16:31:56

22:31 09 Mar USDA: Clinton report on food safety agency due soon

WASHINGTON, March 9 (Reuters) - The Clinton Administration has nearly completed its response to a call by the National Academy of Sciences to end the patchwork quilt of regulations and agencies that safeguard the nation's food supply, a senior U.S. Agriculture Department official said on Tuesday.

The report is unlikely to endorse a proposal by some Democratic lawmakers, consumer groups and scientists to create a new agency with responsibility for everything from hamburgers to imported strawberries, sources said.

Instead, the administration is expected to outline ways it will encourage the dozen federal agencies involved in food safety to work together more closely, they said. That approach is supported by food industry groups.

An estimated 9,000 Americans die and millions get sick annually from eating contaminated food. A recent outbreak of listeria in hot dogs and deli meats made by a Michigan plant claimed 20 lives.

Catherine Woteki, USDA undersecretary for food safety, said the administration's report was nearly ready.

"We're down to weeks or even days," she told reporters after appearing before a House Agriculture Appropriations hearing on food safety spending for fiscal 2000.

"The president's Food Safety Council has done a thorough review of the academy's report," added Woteki, declining to elaborate.

The Food Safety Council was created by Clinton last August, days after the National Academy of Sciences completed a lengthy analysis of food safety laws requested by Congress.

The academy concluded that the U.S. government needs a single powerful food safety chief with a budget and staff to streamline the hodgepodge of food regulations that now exist.

That could mean creating a single food safety agency - an approach likely to set off political and turf battles -- or it could come about by appointing a food safety czar with broad powers, the Independent group of scientists said.

The USDA has authority over meat and poultry products, while the U.S. Food and Drug Administration is responsible for fruit, vegetables and imported food. Because of varying laws and budgets over the years, the USDA has many more inspectors than the FDA.

An example often used by critics of the current system is that a U.S. plant producing pepperoni pizzas will be checked daily by a USDA meat inspector. But a plant making only cheese pizzas may not be visited by an FDA inspector for a decade or more.

Some of the other agencies that get involved in food safety include the Environmental Protection Agency, the Bureau of Alcohol, Tobacco and Firearms, and the Commerce Department.

"Why do we have so many agencies involved in food safety? It's got to be the most inefficient thing in the world," Rep. Allen Boyd, a Florida Democrat, said during the hearing.

Both Democratic and Republican members of the budget subcommittee pressed Woteki for her views on a single food agency. "We've been able to build a much more cooperative infrastructure," she said, referring to USDA's work with the FDA, the Centers for Disease Control, and other agencies.

Rep. George Nethercutt, a Republican from Washington state, asked the USDA if it could share some of its inspectors with the under-staffed FDA.

The USDA has held some "initial discussions" with FDA leaders about sharing inspectors, said Tom Billy, administrator of USDA's Food Safety and Inspection Service, told the panel.

But many USDA meat inspectors are not highly trained and would offer little to help the FDA, said Billy, a former FDA food safety manager.

"It doesn't match up very well," he said. "We think there's a potential down the road but we need to continue our discussions with the FDA."

The leaders of the Food Safety Council include Agriculture Secretary Dan Glickman, Health and Human Services Donna Shalala, and White House science advisor Neal Lane.

((Julie Vorman, 202 898 8467

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

Tuesday, 9 March 1999 22:31:58

ENDS [nN09127221]

**AGENDA FOR
FOOD SAFETY MEETING**

MARCH 11, 1999

I. NAS RESPONSE

- A. Final sign-off (Cliff)
- B. Release discussion (timing, Presidential statement)

II. AGENCY STRUCTURE (discussion)

Rationale, Concept, Politics

**AGENDA FOR
FOOD SAFETY MEETING**

MARCH 11, 1999

I. NAS RESPONSE

- A. Final sign-off (Cliff)
- B. Release discussion (timing, Presidential statement)

II. AGENCY STRUCTURE (discussion)

Rationale, Concept, Politics

**AGENDA FOR
FOOD SAFETY MEETING**

MARCH 11, 1999

I. NAS RESPONSE

- A. Final sign-off (Cliff)
- B. Release discussion (timing, Presidential statement)

II. AGENCY STRUCTURE (discussion)

Rationale, Concept, Politics

DRAFT FOR DISCUSSION PURPOSES ONLY
Outline of Possible Changes in Federal Food Safety Structure

Note: Movement of functions from one agency to another would not require opening and negotiating the terms of the underlying statutes. The Secretary that is authorized to implement portions of these acts would be changed, including the delegations for implementation, and USDA's food safety mission area and agency would be modified to ensure protection of public health.

(1) The following functions would be moved from FDA's Center for Food Safety and Applied Nutrition (CFSAN) to USDA: Food inspection, enforcement, and standard-setting/regulation for microbial, viral, and parasitic pathogens, including seafood, eggs, milk, fruits and vegetables. In addition, FDA/state boards on milk and seafood would be moved to USDA, as well as the food code, which is a model food safety code developed by FDA, other Federal agencies, and the states.

The following functions would remain at CFSAN — food additives, dietary supplements, biotechnology, chemical/pesticide/drug residues/standards. In addition, it is possible that food labeling under the Nutrition Labeling Act would remain at CFSAN, including meat and poultry products which are currently under USDA's jurisdiction.

(2) FDA would be provided with funding and staffing increases to address functional foods (i.e. new food products making special nutritional claims), food additives, dietary supplements, and biotechnology. Industry believes FDA lacks resources for these items.

(3) Personnel Resources-- a relatively small number of FDA field personnel with special expertise such as imports would be moved from FDA to USDA. All other inspection personnel would remain for FDA inspections of drugs, medical devices etc. USDA would also need a number of senior level managers and regulatory personnel from CFSAN or FDA to be transferred to USDA in order to ensure a successful transition.

(4) USDA/FSIS would be provided with base increase of XX million to ensure a successful transition of these new responsibilities. Pending full redeployment of USDA's inspection resources, USDA would need increased funding in order to maintain at least the level of inspection currently provided by FDA. As redeployment proceeds over the long term, the need for these additional funds would likely decrease.

(5) To emphasize the commitment to food safety, the name of USDA would be changed to the U.S. Department of Food and Agriculture, with the current Under Secretary for Food Safety becoming the Under Secretary for Public Health and Food Safety. Given the increased responsibilities, an additional Deputy Under Secretary would be desirable (there is currently one Deputy). All subcabinet positions would require commensurate public health backgrounds.

(6) The underlying statutes governing FDA and USDA (FFDCA, FMIA etc) would remain intact, although one could include a directive that the Administration should develop a proposal to unify

the statutes. This would (1) simplify the legislation, (2) provide general consistency for regulated industries, and (3) avoid possible legislative attempts to weaken any of the relevant statutes. One possible exception should be considered. Under current law, states that implement meat and poultry laws may not stray into contrary forms of regulation, so inclusion of preemption in this transfer may generate industry support. This may be opposed by the states and it is unclear where the consumer community would be on this issue.

(7) While it may perhaps be unnecessary to address consumer concerns, one should consider whether to include additional measures to ensure the independence of food safety from USDA's role of promoting agricultural commodities. Examples include the creation of a statutory advisory board or statutory reaffirmations of this independence.

(8) While this would not likely be included in legislation since it is a Congressional matter, the Administration would support having the Public Health and Agriculture Committees share full jurisdiction over food safety.

(9) Given the increased responsibilities for USDA, there would also likely be a need for increased resources for USDA's Office of General Counsel (perhaps by transfer from FDA) and for USDA's Office of Risk Assessment and Cost Benefit Analysis.

DRAFT FOR DISCUSSION PURPOSES ONLY
Outline of Possible Changes in Federal Food Safety Structure

Note: Movement of functions from one agency to another would not require opening and negotiating the terms of the underlying statutes. The Secretary that is authorized to implement portions of these acts would be changed, including the delegations for implementation, and USDA's food safety mission area and agency would be modified to ensure protection of public health.

(1) The following functions would be moved from FDA's Center for Food Safety and Applied Nutrition (CFSAN) to USDA: Food inspection, enforcement, and standard-setting/regulation for microbial, viral, and parasitic pathogens, including seafood, eggs, milk, fruits and vegetables. In addition, FDA/state boards on milk and seafood would be moved to USDA, as well as the food code, which is a model food safety code developed by FDA, other Federal agencies, and the states.

The following functions would remain at CFSAN — food additives, dietary supplements, biotechnology, chemical/pesticide/drug residues/standards. In addition, it is possible that food labeling under the Nutrition Labeling Act would remain at CFSAN, including meat and poultry products which are currently under USDA's jurisdiction.

(2) FDA would be provided with funding and staffing increases to address functional foods (i.e. new food products making special nutritional claims), food additives, dietary supplements, and biotechnology. Industry believes FDA lacks resources for these items.

(3) Personnel Resources-- a relatively small number of FDA field personnel with special expertise such as imports would be moved from FDA to USDA. All other inspection personnel would remain for FDA inspections of drugs, medical devices etc. USDA would also need a number of senior level managers and regulatory personnel from CFSAN or FDA to be transferred to USDA in order to ensure a successful transition.

(4) USDA/FSIS would be provided with base increase of XX million to ensure a successful transition of these new responsibilities. Pending full redeployment of USDA's inspection resources, USDA would need increased funding in order to maintain at least the level of inspection currently provided by FDA. As redeployment proceeds over the long term, the need for these additional funds would likely decrease.

(5) To emphasize the commitment to food safety, the name of USDA would be changed to the U.S. Department of Food and Agriculture, with the current Under Secretary for Food Safety becoming the Under Secretary for Public Health and Food Safety. Given the increased responsibilities, an additional Deputy Under Secretary would be desirable (there is currently one Deputy). All subcabinet positions would require commensurate public health backgrounds.

(6) The underlying statutes governing FDA and USDA (FFDCA, FMIA etc) would remain intact, although one could include a directive that the Administration should develop a proposal to unify

the statutes. This would (1) simplify the legislation, (2) provide general consistency for regulated industries, and (3) avoid possible legislative attempts to weaken any of the relevant statutes. One possible exception should be considered. Under current law, states that implement meat and poultry laws may not stray into contrary forms of regulation, so inclusion of preemption in this transfer may generate industry support. This may be opposed by the states and it is unclear where the consumer community would be on this issue.

(7) While it may perhaps be unnecessary to address consumer concerns, one should consider whether to include additional measures to ensure the independence of food safety from USDA's role of promoting agricultural commodities. Examples include the creation of a statutory advisory board or statutory reaffirmations of this independence.

(8) While this would not likely be included in legislation since it is a Congressional matter, the Administration would support having the Public Health and Agriculture Committees share full jurisdiction over food safety.

(9) Given the increased responsibilities for USDA, there would also likely be a need for increased resources for USDA's Office of General Counsel (perhaps by transfer from FDA) and for USDA's Office of Risk Assessment and Cost Benefit Analysis.

DRAFT FOR DISCUSSION PURPOSES ONLY
Outline of Possible Changes in Federal Food Safety Structure

Note: Movement of functions from one agency to another would not require opening and negotiating the terms of the underlying statutes. The Secretary that is authorized to implement portions of these acts would be changed, including the delegations for implementation, and USDA's food safety mission area and agency would be modified to ensure protection of public health.

(1) The following functions would be moved from FDA's Center for Food Safety and Applied Nutrition (CFSAN) to USDA: Food inspection, enforcement, and standard-setting/regulation for microbial, viral, and parasitic pathogens, including seafood, eggs, milk, fruits and vegetables. In addition, FDA/state boards on milk and seafood would be moved to USDA, as well as the food code, which is a model food safety code developed by FDA, other Federal agencies, and the states.

The following functions would remain at CFSAN — food additives, dietary supplements, biotechnology, chemical/pesticide/drug residues/standards. In addition, it is possible that food labeling under the Nutrition Labeling Act would remain at CFSAN, including meat and poultry products which are currently under USDA's jurisdiction.

(2) FDA would be provided with funding and staffing increases to address functional foods (i.e. new food products making special nutritional claims), food additives, dietary supplements, and biotechnology. Industry believes FDA lacks resources for these items.

(3) Personnel Resources-- a relatively small number of FDA field personnel with special expertise such as imports would be moved from FDA to USDA. All other inspection personnel would remain for FDA inspections of drugs, medical devices etc. USDA would also need a number of senior level managers and regulatory personnel from CFSAN or FDA to be transferred to USDA in order to ensure a successful transition.

(4) USDA/FSIS would be provided with base increase of XX million to ensure a successful transition of these new responsibilities. Pending full redeployment of USDA's inspection resources, USDA would need increased funding in order to maintain at least the level of inspection currently provided by FDA. As redeployment proceeds over the long term, the need for these additional funds would likely decrease.

(5) To emphasize the commitment to food safety, the name of USDA would be changed to the U.S. Department of Food and Agriculture, with the current Under Secretary for Food Safety becoming the Under Secretary for Public Health and Food Safety. Given the increased responsibilities, an additional Deputy Under Secretary would be desirable (there is currently one Deputy). All subcabinet positions would require commensurate public health backgrounds.

(6) The underlying statutes governing FDA and USDA (FFDCA, FMIA etc) would remain intact, although one could include a directive that the Administration should develop a proposal to unify

the statutes. This would (1) simplify the legislation, (2) provide general consistency for regulated industries, and (3) avoid possible legislative attempts to weaken any of the relevant statutes. One possible exception should be considered. Under current law, states that implement meat and poultry laws may not stray into contrary forms of regulation, so inclusion of preemption in this transfer may generate industry support. This may be opposed by the states and it is unclear where the consumer community would be on this issue.

(7) While it may perhaps be unnecessary to address consumer concerns, one should consider whether to include additional measures to ensure the independence of food safety from USDA's role of promoting agricultural commodities. Examples include the creation of a statutory advisory board or statutory reaffirmations of this independence.

(8) While this would not likely be included in legislation since it is a Congressional matter, the Administration would support having the Public Health and Agriculture Committees share full jurisdiction over food safety.

(9) Given the increased responsibilities for USDA, there would also likely be a need for increased resources for USDA's Office of General Counsel (perhaps by transfer from FDA) and for USDA's Office of Risk Assessment and Cost Benefit Analysis.