January 26, 1999

Tom, Mary, Jean (Morley), and Wendy:

Here is a first draft of the Council's assessment of the NAS report "Ensuring Safe Food from Production to Consumption." The Council task force is meeting for the first time on Friday to discuss this. I would appreciate your thoughts and specific wording for changes/edits you want to see included.

Thanks, Cliff

Please get Cliff comments by Friday

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.

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

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

> "...the Council to review and respond to this report as one of its first orders of business. After providing opportunity for public comment, including public meetings, the Council shall report back to me within 180 days with its views on the NAS's recommendations. In developing its report, the council should take into account the comprehensive strategic federal food safety plan that it will be developing."

In response to the President's directive, the Council established a task force consisting of representatives from each of the following agencies: OSTP, HHS, USDA, EPA, OMB, and DOC. This task force produced the following report, which has been adopted by the Council and transmitted to the POTUS on _____. The task force benefited from valuable input obtained at four public meetings (Arlington, VA; Sacramento, CA; Chicago, IL; and Dallas, TX) and from dockets maintained by EPA, FSIS, and FDA.

Recommendation I: Base the food safety system on 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 NAS noted, can be made through a scientific, risk-based system that ensures that surveillance, regulatory, and research resources are allocated to maximize effectiveness.

Food safety agencies are aggressively using science to strengthening regulatory programs. Examples include the use of Hazard Analysis Critical Control Points (HACCP) approaches to reduce exposure to microbial pathogens and greater attention to aggregate risk of pesticides in foods as mandated by the Food Quality Protection Act (FQPA). Although more can be done, agencies extending their use of science throughout the food safety system.

USDA

The 1994 USDA reorganization fundamentally altered its structure and created the mission area of Food Safety, which is focused on public health. 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 USDA.

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 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, Emerging Pathogens and Zoonotic Diseases, Food Hazard Surveillance, and Epidemiology and Risk Assessment.

The1994 reorganization of USDA also 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.

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. In addition, 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.

HHS

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 our current 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, and ethyl carbamates).

Evaluation of the policy options to deal with risk requires the agency to balance competing risks. For example, FDA had 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 nitrite was 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 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.

FDA and NOAA embarked on a cooperative effort in 1990 to provide the seafood industry with a HACCP-based inspection program. Although the joint program did not come to fruition, each agency developed its own mechanism for the seafood industry based in part upon the studies and agreements developed during the joint program. In 1992, NOAA offered to the industry the National Marine Fisheries Service (NMFS) HACCP-based Inspection Program, which provided the industry the opportunity to implement HACCP and use it not only to control safety issues, but also wholesomeness, quality, sanitation, and labeling issues as well. In 1997, FDA's mandatory seafood HACCP rule became final and the NOAA program was modified to make certain its elements were congruent to those required by FDA.

EPA

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 or on food. The NAS report recognized this science-based approach 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."

The science-based system for regulation of pesticides was further strengthened by the 1996 Food Quality Protection Act (FQPA), which mandates that EPA look at, among other factors, 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 database on food consumption. EPA, FDA, and industry have initiated a joint effort to coordinate residue monitoring databases. These activities are designed to improve the information supporting EPA's establishment of tolerances, or maximum legal limits, for pesticide residues under the new law. However, 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.

Strengths

The Council 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. Science also yields 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. Since the

nature of food hazards change, the food safety system must be flexible enough to identify and adapt to these changes.

The food safety 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

Progress thus far in implementing a science-based strategy, and the federal government's 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 consultation 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 microbial 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.

The NAS report 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 measures. Therefore, it is important to adopt a tiered approach to food safety risk analyses. 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 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

Science must also be tempered with other considerations, such as technical feasibility, statutory mandates, policy considerations, budget constraints, and consumer preferences. As the report 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.

Barriers

There are many barriers, or challenges, to improving the scientific basis of food safety programs.

- Public health needs change, so there may not be adequate data to generate effective preventive measures in a timely manner. New food safety challenges continue 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.
- The scientific understanding of risk changes as well. In particular, microbial risk assessment is still a developing science. There remains a steep learning curve when it comes to understanding the hazards in food and how to minimize resulting risks. Another challenge is the FQPA mandate to determine aggregate or cumulative risk. EPA is using the best science available to develop multi-pathway exposure and risk assessment tools, measurement databases, and models to support this new food safety requirement.
- There are resource limits to research and fragmentation of scientific 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.

- Limited resources exist to conduct surveillance, monitoring, and risk assessments to identify the most salient public health needs.
- Inconsistent food safety standards exist at the federal, state, local, and international levels. Mechanisms are being developed to reduce this inconsistency, but it is a long-range project.
- There is a lack of alternative pesticides for some uses. When a pesticide is slated for removal from the marketplace, growers must have access to effective and safe alternatives. More research is need to develop these alternatives.

Conclusion

For the most part, the agencies' food safety programs are already science-based and the Council 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.

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.

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.

Additionally, emphasis should be placed on improving the evaluation of 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.

The Council 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, Council on Food Safety will consider in its strategic plan the following elements of a science-based food safety system:

Surveillance. As the food safety agencies approach the new millennium, they will be looking for new ways to achieve surveillance goals and to monitor the food supply. Although 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.

Risk assessment. As it has 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 as well as providing assistance in creating similar capacities internationally. This will enable limited resources to be used more effectively to conduct risk assessments and address food safety problems based on the relative risks they pose. There is an acute need to develop new methods and data for microbial risk analysis.

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 and FDA will further improve the inspection of domestically and internationally produced food and continue implementation of HACCP and HACCP-based inspection models. These agencies will also continue to promulgate science-based regulatory requirements. An example is additional performance standards for pathogen reduction that can be developed as more monitoring and surveillance data become available.

Registrations and Tolerance Setting. EPA will use risk analysis—including quantitative and qualitative risk assessment and risk management principles—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.

Consistency of Science-Based Standards. USDA, FDA, and others will work toward consistent food safety standards nationally and internationally. The Conference for Food Protection and the Codex Alimentarius Commission (CAC) 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. U.S. food safety agencies should become more active in this area of technical cooperation with developing countries.

Education. Food safety agencies will continue science-based education and training programs for producers, processors, distributors, food handlers, and consumers. It is essential to include in these programs new scientific information on foodborne hazards 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.

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

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 that is enforced by HHS via the Food and Drug Administration.

- It is FSIS's statutory responsibility to assure that no meat and poultry that 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. [need to clarify if this also applies to both inter- and intrastate shipment.]

- FDA's statute has a much different burden in that it is obligated to remove foods that it finds in the marketplace that 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 with current funding constraints cannot provide daily inspection of even high-risk food products at this time.

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 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. Specifically, it recommends revision of he current statues 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.

USDA

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. However, 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.

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 performance measures 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.

HHS

The basic food safety laws were passed in 1906, when the major food safety problem was adulteration, which often caused consumer illness and death. 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. For pesticides, FFDCA, as amended by FQPA, does mandate EPA to base programs on assessment of risk to public health.

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, North American Free Trade Agreement (NAFTA), Association of Southeast Asian Nations (ASEAN), and other international bodies to establish policies that assure a uniform, high level of food safety in imported products among trading partners.

EPA

Congress significantly revised EPA's system for regulation of pesticides 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 framework 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.

EPA also establishes program priorities for research and for its pesticide 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, since 1995, EPA has used a risk-based planning process to determine its research agenda. Some elements of this approach include focusing research and development on the greatest risks to people and the environment and on reducing uncertainty in risk assessment and improving cost-effectiveness in risk prevention and management. EPA's food safety research program follows these principles. Further, in keeping with FFDCA Section 408, EPA's reassessment of tolerances is focusing on those pesticides that are most likely to pose risks. Following this principle, EPA is currently concentrating its resources on the reevaluation of the nearly 1200 tolerances for forty organophosphate insecticides. In addition, new pesticides that 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 pesticides that are not a safer replacement.

Even though 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 improve 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 ensure that imports do not compromise U.S. standards, but this would not be feasible for pesticide tolerances. 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.

Strengths

The report's recommendation 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. Decisions based on public health risk assessments allow agencies to:

- set food safety priorities;
- allocate resources to higher risk areas; and
- instill consumer confidence that high risk situations are being addressed.

Weaknesses

In general, the report overstates the problems with the current statutory requirements. For example, the report reflects the mistaken belief that the statutes for the inspection of meat and poultry 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 NAS report. The USDA 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.

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 (MOU) under which each agency will share selected inspection results of interest with the other agency, which should minimize duplication. EPA already has similar MOUs with FDA, and FDA audits certain toxicological laboratories for compliance with good laboratory practices and shares the results with EPA so that duplication in avoided. 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. These efforts should increase the efficiency of the federal government's food safety program. More importantly, they represent only a beginning effort at coordination.

Barriers

There is enormous diversity in the commodities that comprise our nation's food supply. This diversity includes not only types of food and how it was produced, but also firms to be inspected, 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. These are all factors that need to be considered when contemplating a comprehensive food safety law.

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. 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

Council on Food Safety will need to consider the political feasibility of major statutory changes.

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. The Council recommends that a legislative review be undertaken as part of the strategic planning process. The purpose of such a legislative 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

The Council does 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 Council believes that food safety agencies have achieved and can continue to accomplish significant scientifically based improvements in their food safety programs under current authorities. However, it does recommend that the following changes be made:

- 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.
- Congress should pass the legislation that gives FDA authority to bar imports from entering the United States if they do not come from establishments that meet U.S.

Standards (excluding pesticides since they are handled internationally through harmonized test methods and good laboratory practices).

- Legislative clarification of the current system for the regulation of eggs and egg products.
- Modify FDA statutes to permit FSIS inspectors to not only report their findings to FDA but to actually perform inspections for that agency to increase interagency efficiencies.
- 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 benefit.

Background

The 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.

The planning conducted under the President's Food Safety Initiative was an initial step toward a federal food safety plan. 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.

President's Council on Food Safety Comprehensive Strategic Plan

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 Council on Food Safety will develop a national food safety plan and the budget 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. Options for a risk evaluation, prepared by the interagency Risk Assessment Consortium, are being reviewed. 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 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 national food safety system (see later discussion 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. While this is a worthwhile goal, 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, EPA 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 that addressed highly ranked risks.

Strengths

The benefits of a comprehensive strategic plan include the following:

- 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; and
- rapid sharing of information and data, particularly about outbreaks and products associated with illnesses.

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. The Council believes that the analysis of risks and benefits should be an integral part of the regulatory development process. In fact, the output from these analyses can truly serve as a guide to the process and help decision-makers choose an appropriate course of action

Weaknesses

Clearly, the benefits of having a comprehensive plan outweigh the costs of developing one. However, we must acknowledge that adequate planning will require agency resources and time to develop a smoothly functioning national food safety planning

process that meets needs at the federal and state and local levels. In order for the plan to be useful in setting priorities and allocating funds, the food safety agencies must ensure its goals and objectives are clearly stated and expected outcomes are clearly articulated.

There are also limitations to the use of comparative risk analysis, including 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. However, the science supporting risk assessments, particularly for microorganisms, needs further development before it can be use widely for risk/benefit judgements at this time.

Barriers

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.

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

The Council agrees that a comprehensive national food safety strategic plan should be developed and the agencies have made major strides in this regard. 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.

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.

In response to the NAS report, the 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 the following three options:

- 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. 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

These options could provide helpful input to a national food safety plan. However, the Council must avoid repeating mistakes of the past in 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. How economic incentives for new food safety innovations could be increased should also be investigated.

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.

Background

What the Report Recommends

The 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 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 goes on to note that 12 primary federal agencies are involved in key food safety functions. The report also references more than 50 memoranda of agreement between various agencies related to food safety.

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 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.

Current Model of Food Safety Coordination

The food safety regulatory agencies (FDA, EPA, 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.

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. Under the direction of the President's Council and given today's technology, HHS, USDA and EPA are working more closely together and are committed, as stated in the draft vision, to establishing a seamless system. How such a food safety system is accomplished should be addressed by the strategic plan under development and the other work of the agencies. There are several ways to bring such a seamless food safety system to fruition, including establishment of national priorities, better and stronger program coordination, development of coordinated budgets, and sharing of data and risk assessments.

Strengths and Weaknesses of Four Options

In this context, Council makes the following observations about the four structural/organizational options contained in recommendation IIIA.

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

Strengths:

The Council 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).

Weaknesses

The Council agrees that some parts of the federal government's food safety activities may be appropriate for consolidation within a single agency. It regrets that the NAS 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. The Council's strategic plan, which will be based on input from the agencies, will provide more attention to this topic.

If this central framework is located outside a food safety agency this, potentially, could result in a cumbersome, multi-layered 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., HHS or USDA), 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.

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

Strengths

The strengths associated with the creation of a single agency are the same as those mentioned for options 1 and 2. Specifically, there would be improved coordination and priority setting leading to the better allocation of limited resources.

Weaknesses

In addition to the weaknesses noted with Options 1 & 2, the Council points out that massive reorganizations require broad legislative support as well as additional funding and are very time-consuming. Even though in the long-term customer services may improve, if the reorganization is not managed very carefully, the near-term consequences may be reduced customer service and public health protection. Finally, the Council is particularly concerned that options 3 and 4 would be particularly detrimental to research and educational activities. While it is true that the current food safety research portfolio should to be better connected to the needs of the regulatory agencies, the Council believes that this will be accomplished under the Joint Institute for Food Safety Research.

While a single agency could solve some issues, it would create others. For example, the pesticide program at EPA considers the environmental, worker and non-dietary aspects of pesticide use as well as public health protection from pesticides in the diet. Splitting such a comprehensive program would severely complicate establishment of pesticide residue limits for food, especially our assessment of aggregate exposure from dietary and non-dietary sources and cumulative risk. The necessary interagency coordination of risk assessment and risk management efforts would present a major problem and delay food safety efforts.

Barriers

In general, the Council does 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. However, the Council is concerned about the following specific issues that relate to interagency coordination:

- *Many Food safety issues cut across jurisdictional lines.* Many food safety issues simply cannot be dealt with by a single agency. For example, bovine spongiform encephalopathy (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.
- *Not all food safety problems are amenable to regulatory solutions.* Legislation or regulation cannot resolve all food safety problems or concerns. 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.
- *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. Informed through research, education and voluntary compliance can reduce the need for regulation.
- *Need to build on old partnerships to establish new ones.* The Council 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. 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.

- *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 and genetics, which provide major contributions to the total set of information supporting the national food safety effort. Conversely, scientific expertise and endeavors should always inform regulatory activities. Each regulatory program must have a cadre of trained and involved scientists to facilitate communications and cooperation with the research/education units that are often housed in separate offices or agencies.

Conclusion

The Council agrees with the spirit of the NAS recommendation--that there should be a seamless food safety system in the U.S. The food safety agencies are committed to such an end. The Council's comprehensive 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 strategic plan can provide the framework for moving forward together, allocating resources, and creating a seamless food safety system in the U.S.

The Council recommends a thorough assessment of structural and organizational options before further legislative or administrative action proceeds on reorganization. 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. For example, the Council 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.

The Council believes that there are programs that can benefit by reorganization. For example, during the last two years, FDA and NOAA have been developing 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, thereby relocating the activities of the voluntary Seafood Inspection Program from NOAA to FDA. This action would fully consolidate federal seafood inspection activities within one agency. Funds are requested within the FY2000 budget to implement this consolidation. This consolidation of federal seafood inspection activities supports the coordination efforts being pursued by the Council.

Therefore, the Council 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. As the report recommends, the Council will 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.

In this spirit, the Council proposes an additional model that should be considered during the formulation of the food safety strategic plan.

Structural model - Joint Chiefs of Staff: An analogous situation existed some years ago in the military, where the uniformed services operated independently and at time at odds with one another, despite a shared goals. Competition, non-communication, and waste characterized inter-service relations. 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. This model could be instructive as we look for ways to make the federal government's food safety activities more effective and efficient.

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

This recommendation 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:

- 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 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.

Current Status of Federal Interactions with State and local agencies

A great deal of overlap occurs between federal and 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.

HHS (expand?)

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 required changes in many of them to achieve an integrated system. 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 national food safety system. 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.

EPA

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 ensure 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.

EPA has most of the statutory tools described in the report as necessary to integrate local and state activities. In a few cases where statutory authority is not specifically provided, appropriations language has given EPA the impetus to delegate certain pesticide responsibilities and issue supporting grants to the states and tribes.

USDA

USDA also believes that most of the statutory tools suggested by NAS already exist for its use. For example, 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.

Under Federal-State Cooperative Inspection Program Agreements (formerly Talmadge-Aiken), state employees are authorized to carry out inspection in federally inspected

plants. Approximately 250 plants now operate under such agreements. The USDA is also exploring new approaches, under current law, to extend this concept into other areas of food safety.

USDA has multiple mechanisms to support state and local programs. For example, USDA:

- is providing 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.);
- is funding (through FDA due to lack of FSIS cooperative agreement authority) animal production food safety outreach projects involving 11 states;
- has transferred an employee (CSREES) to Iowa State to develop an educational program to train veterinarians as auditors for on-farm food safety and quality assurance processes; and
- is funding animal production food safety workshops in Colorado, Nebraska and Ohio ($25,000 through the Livestock Conservation Institute); and
- is enhancing state labs and computer capabilities and supporting the state training initiative for HACCP.

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.

Strengths

The Council recognizes and agrees with the report's conclusion that the divisions among federal, state and local authority often complicate the administration of regulatory programs. We need to utilize available mechanisms to leveraged resources and expertise from government, industry, academia, and consumers to expand greatly 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 reduces the need for extensive regulation of industry and decreases the incidence of contamination at every point in the food safety system.

An integrated federal, state, and local food safety system will help build a consistent, uniform level of safety assurance across the nation by sharing resources (expertise, data, information). To accomplish this, consistent, uniform food safety messages, training, and technical assistance are needed at all levels.

Weaknesses

In addition to the fact that food safety agencies already possess the majority of the statutory tools suggested by NAS report, the Council believes the 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. 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

Barriers

The discussion under Recommendation IIA is also relevant here in that the Council will not undertake overhaul of the food safety laws without first conducting a full assessment of these statutes. Even though the time and funding required to build and maintain effective cooperative programs among the varying segments of the food safety community is substantial, the long-term benefits are great. The Council is aware, however, of the following concerns from various groups:

- 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

In order for this integration to work, it is crucial that state and local governments have access to high quality scientists and health care professionals. Unfortunately, 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.

Conclusion

The Council agrees that the roles of state, tribal and local governments in the food safety system are critical and believes that its planning process provides the opportunity to draw the states into the process as primary and equal partners in the development of the future food safety system.

The food safety regulatory agencies (FDA, FSIS, and EPA) have most of the statutory tools recommended by NAS. 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.

Any action plans developed under the auspices of the "50-state meeting" process 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.

The Council also believes that any future comment on this recommendation should fold in and be responsive to the views of the states and that the strategic plan described under recommendation IIB 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.