

DRAFT

Food Safety
- planning

National Academy of Sciences study of the effectiveness of the current food-safety system

In October 1997, Congress mandated a study by the National Academy of Sciences (NAS) on the effectiveness of the current food-safety system. This study has, in effect, become part of the strategic planning component of the federal food safety initiative.

According to the NAS's study plan, the study will focus on 1) determining the scientific basis of an effective food safety system; 2) assessing the effectiveness of the current food safety system; 3) identifying scientific needs and gaps within the current system; and 4) providing recommendations on scientific and organizational changes needed to ensure an effective science-based food safety system.

The committee that will carry out this study had its first meeting March 23-25, with subsequent meetings planned for April and May. The study report is scheduled to be delivered to Congress by August 15, 1998. The NAS's public statement about this committee and the committee list is attached.

The federal food safety agencies that are part of the NAS committee's analysis should consider planning a public meeting or other mechanisms to discuss the study's conclusions and recommendations after the study is submitted to Congress. A meeting could be constructed as a panel discussion among federal agency representatives, state and local government representatives, industry and consumer representatives, and representatives from the Congressional committees that mandated the study with opportunity for public comment. Alternatively, the committee's recommendation could be published in the Federal Register for comment.

Office of Science and Technology Policy's interagency food-safety research budget review for FY 1999 Budget

Following the recommendation of the May 1997 food-safety report to the President, an interagency committee was established to coordinate federal food safety research and planning. The Office of Science and Technology Policy's (OSTP) National Science and Technology Council (NSTC) has established the NSTC Interagency Working Group (IWG) on Food Safety Research.

The IWG will conduct an in-depth review of all federal research related to microbiological aspects of food safety, as well as research related to natural toxins, and tissue residues of veterinary drugs. The review, which began in February 1998, will have several steps: 1) describing all existing research efforts; 2) identification of data needs and priorities; and 3) comparison of current research portfolio with identified needs. The third step will include identification of unnecessary duplication, jurisdictional issues, research gaps, and other information pertinent to designing a more coordinated research and education plan. Based on this review, the IWG will make recommendations for future coordinated research.

As part of the review of the research portfolio, the IWG should consider convening a national meeting of stakeholders to solicit their views and recommendation on the adequacy of the federal investment and the appropriateness of priorities and funding mechanisms.

The goal of this exercise is to produce a report that can inform budget planning for FY 2000. Therefore, the IWG plans to complete its work by May 29, 1998 (and proposes annual updates for five years). In addition to using the report to inform FY 2000 budget planning, the food safety agencies could highlight the report, its findings and recommendations, and their responses to it through a White House Conference on Food Safety Research and Technology.

Planning for the FY 2000 Food Safety Initiative Budget Proposal

The FY 2000 budget proposal needs to identify significant new programs for attention and resource commitment to improving the safety of the food supply. The process of developing these new themes should engage the public in identifying priorities for FY 2000's focus.

Data from Food Net will be invaluable in identifying new pathogens problems/new emphases as will engaging public health, medical, and scientific experts, and industry and consumer groups to assist in framing the major food safety issues.

Issue analysis for strategic plan development

In the May 1997 Report to the President, the food safety agencies committed to undertake a longer-term strategic planning effort to consider "how best to address important challenges and make the best use of the agencies' limited resources. The report suggested development of a 3-to 5-year strategic long-range agenda to help "set priorities, improve coordination and efficiency, identify gaps in the current system, enhance and strengthen prevention and intervention strategies, and identify measures to show progress." Although the NAS will be considering some of these matters, given the broad scope of that committee's charge (and the August deadline), many important issues will remain in need of focused analysis by federal agencies.

We suggest that the federal food safety agencies consider two options for analysis to support the development of a food-safety strategic plan: 1) an analysis focused on present-day strategic questions, and 2) an analysis focused on anticipating issues that are 5-10 years in the future.

An analysis focused on present-day issues could be constructed to develop approaches to further optimize food-safety assurance for one or more sectors of the food supply. Such an activity could consist of a series of public meetings with stakeholders (consumer organizations, state and local governments, food industry) to develop, for example, agreement about optimal approaches for the introduction of HACCP concepts into additional sectors of the food production system, or agreement about optimal approaches for health-protective management of animal manures. More than one such issue could be tackled in a series of stakeholder dialogues.

A predictive analysis focused on anticipating future food-safety challenges could be constructed, for example, to develop scenarios to describe the likely characteristics of the food system 5-10 years in the future and the actions that would be required of federal, state and local food-safety agencies to respond to changes in the system. Factors that could be considered in such an analysis include likely new production and processing technologies, new products and packaging, consumer interests, population demographics, and trends towards increasing concentration in domestic food industries and globalization of the food supply. An analysis of this sort could be undertaken by an independent contractor or by the USDA's Economic Research Service.

Because the May 1997 report committed to giving interested parties opportunities to comment on possible approaches for structuring the strategic planning process before its implementation, it would be advisable to vet ideas with major stakeholders and develop initial support for the general approach.

*Food Safety
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Single Food Agency Outline
June 3, 1998

I. Potential issues in the NAS report and/or gaps in the food safety system.

Research

- CNA*
- ▶ *redundancy, inefficiency, and adequacy of food safety research among agencies (EPA, FDA)*
 - ▶ *sufficiency of scientific basis for and difficulty of determining aggregate and cumulative risk in setting pesticide tolerances under FQPA (EPA)*
 - ▶ The various research programs need to be more effectively coordinated to eliminate duplication and focus on the highest priorities.
 - Issues revolve around lack of coordination on a federal food safety research agenda by food safety agencies.
 - Lack of identification of highest priorities.
 - Poor interaction between the research agencies and the federal food safety agencies due to conflicting priorities and scarce resources. Development of new technology is hampered by competing priorities.

Education and Outreach Program

- ▶ Concerns raised in this area are the need for a consistent federal food safety message to the consumer, public health professionals and physicians; retail, food-service, and institutional food preparers, veterinarians, animal and other producers, and food transportation workers.

Consolidation and Coordination

- CNA*
- ▶ *whether science/research should be consolidated in a single agency (EPA)*
 - ▶ *how to best link food safety research and surveillance by CDC (EPA)*
 - ▶ *whether and how to best link research and regulation (EPA)*
 - ▶ *whether to combine in a single agency or separate in different agencies the standard-setting and enforcement of food safety regulation (EPA)*
 - ▶ *need to provide a coordinated, consistent Federal response to food contamination and food-borne illnesses (EPA)*
 - ▶ *need for coordinated communication with State and local authorities on food safety issues, especially in cases of food contamination and illness (EPA)*

Statutory Authority Issues

- ▶ Differences in the principles on which FDA, FSIS, and EPA statutory authorities are based (i.e., FDA food regulation is based on considerations of risk only; EPA pesticide

regulation must balance risks and benefits; and USDA's statute requires continuous inspection)(EPA, FDA)

- ▶ Inspection manpower and statutory authority disparity between USDA and FDA for imported foods (EPA, FDA)
- ▶ Confusing and inefficient division of regulatory authorities between USDA and FDA for several issues such as egg safety, safety of foods during transportation (an issue shared with Department of Transportation), additives to meat and meat products, game meats (FDA)
- ▶ Confusing and inefficient division of regulatory authorities between EPA and FDA for drugs that also have pesticidal activity under FFDCA and FIFRA and the regulation of antimicrobial chemicals under FFDCA and FQPA

Funding

- ▶ Funding disparity between USDA and FDA (especially for inspection and research activities)

Surveillance: Improve Safety and Decrease Contamination of Food

- ▶ The surveillance of the food supply is not adequate to identify the source of infectious agents.
 - Our understanding of many pathogens and how they contaminate food is limited; for some contaminants, we do not know how much must be present in food before there is a risk of illness and for others, we do not have the ability to detect their presence in foods. For example, there has been an increase in new disease-causing microbes. Just in the last year, new forms of Salmonella and E.coli have appeared. *E.coli* O157:H7 was not discovered until 1982. Originally thought to be only in animal products, it has been found in apple juice and lettuce.
 - A national and global increase in antimicrobial resistance, making infections very difficult to treat and a lack of resources to effectively address this critical public health concern.
- ▶ Agencies have different priorities for the types of pathogens that should be included in a surveillance program, leading to different agendas.
- ▶ number of illnesses due to bacterial contamination of food (EPA)
- ▶ illnesses caused by adulterated food from use (or misuse) of pesticides (EPA)
- ▶ need for improved control of microbial contamination by pesticides (EPA)

Responses to Food-Borne Outbreaks

- ▶ There is a piecemeal approach to food safety problems at the federal level. In addition, split jurisdictions, a misunderstanding of each agency role in an outbreak and lack of communication hampers an effective and rapid response.
 - An example frequently cited is the outbreak of Hepatitis A from frozen strawberries, served in the federal school lunch program over a year ago. Agencies involved in this outbreak included AMS that purchased the frozen strawberries for the school lunch program, FNS that has jurisdiction over school

lunch, FDA that has jurisdiction over strawberries, the state of California where they were packed and the state of Michigan that received the strawberries. Cited was the lack of coordination and communication between these agencies to clearly articulate the problem and identify the solution as well as confusion over who had jurisdiction.

- States and local regulatory agencies play a critical role in food-borne outbreaks. Yet, many state and local authorities complain that there is a lack of communication and exchange of information, jurisdictional squabbling and heavy-handed approach by the federal government rather than a national integrated system.

Risk Assessment System

- ▶ Government agencies are reacting to food safety problems rather than acting to prevent them. Food safety risks are not addressed in a consistent manner across the current government-wide food safety system.

Regulatory Reform

- ▶ Despite the fact that HACCP has been implemented in more than 300 large plants, critics state that the current regulatory agenda has not changed to reflect this new science-based system of food safety controls. Rather than streamlining burdensome regulations, critics contend that FSIS is still operating under a prescriptive “command and control” setting.

Overall Mission

- ▶ Additional areas raised might focus on whether the overall mission of the food safety agency is public health and if that mission is compromised by competing interests within the Agency or Department -- such as promoting American agricultural products or approving drugs.
 - Incompatibility of USDA’s dual missions of promotion of agriculture and protection of the public’s health (FDA)

Traceback

- ▶ Issues involve the lack of authority to take regulatory action at the farm level including traceback to identify the source of contamination.

Miscellaneous

- ▶ Divided Congressional committee jurisdictions for USDA, HHS (with different committees having jurisdictions for CDC and for FDA), and EPA (FDA)

Inspections

- ▶ Inspection manpower disparity between USDA and FDA for domestic foods (EPA, FDA)
 - Firms that process food products that pose similar health risks to the public are inspected at widely different frequencies, depending on which agency and regulatory approach govern them
 - USDA has daily inspection of meat and poultry in slaughter plants and egg-product processing plants while FDA conducts periodic inspections for all other food processing plants; that entails fewer than 700 inspectors
 - Food establishments are sometimes inspected by more than one federal agency because they come under multiple jurisdictions. For example, FDA has jurisdiction over frozen cheese pizza and inspects cheese pizza processors once every 10 years on average while USDA, with responsibility over frozen pepperoni pizzas, inspects such processors daily. Critics point to an inefficient use of inspection resources.
- ▶ Inspection manpower and statutory authority disparity between USDA and FDA for imported foods (EPA, FDA)
 - Increase in imported food, particularly fruits and vegetables from countries that have less stringent standards than that of the United States and a lack of FDA resources to provide appropriate coverage.
- ▶ FDA's inability to adequately cover imported food entries into the United States (FDA)
- ▶ more efficient and cost-effective use of Federal resources by combining Federal and/or State inspections for food safety (EPA)
 - Multiple systems between federal, state and local regulatory agencies that are not fully integrated and coordinated in their approach. State and local authorities have responsibility for the regulation of retail stores and restaurants and there can be large disparities in regulatory standards and resources between the various state and local jurisdictions.
- ▶ Enforcement authorities granted to the agencies also differ. USDA has the authority to (1) require food processors to register so that they can be inspected (2) presume that the food firms are involved in interstate commerce and are thus subject to regulation, (3) prohibit the use of processing equipment that may potentially contaminate food products, (4) temporarily detain any suspect foods from entering commerce. Conversely, FDA, without such authority, is often hindered in its ability to oversee food processors.
- ▶ Agency coordination agreements designed at overcoming the fragmented food safety system by avoiding duplication and/or gaps in inspection coverage are cited as ineffective. For example, unsanitary and other unsafe conditions are said to have persisted in food processing plants because notification required by the coordination agreements does not always take place and are not referred to the responsible agency in a timely manner.
- ▶ The lack of mandatory recall and civil penalty authority impede an agency's ability to deter abuse of food safety inspection regulations.
- ▶ GAO recently criticized the FSIS inspection force for focusing too much on violations like missing labels for imported meat and poultry products that bear little relationship to food safety. Again, the issue is that inspection needs to zero in on foods likely to pose the

- greatest risks.
- ▶ More efficient use of inspection resources by basing inspection frequencies on risk-- the potential hazards associated with a product, process, and processor's compliance with federal regulations--and by eliminating duplicative inspections. Instead of continuous inspections --critics state that the agencies should test the feasibility of reducing the frequency of inspections at plants where safety risks are low and reallocating inspectors to high risk foods.

II. What Agencies are currently doing to address issues.

Inspection

- ▶ Following through on the recommendations of the first NPR report, the Administration implemented the new science-based food safety system known as HACCP. This new system focuses on preventing problems rather than catching problems after they occur. Instead of relying only on sight, touch, and smell, USDA inspectors now have additional tools targeted directly at reducing harmful bacteria like *E. coli* O157:H7 and salmonella. In 1995, the FDA issued new rules to ensure the safety of seafood using the HACCP regulatory approach.
- ▶ Leveraging inspection resources and increasing inspections for higher risk foods was addressed in the 1998 and 1999 National Food Safety Initiative.
- ▶ Working groups between USDA and FDA have been formed to:
 - Evaluate the expansion of cooperative agreements so that FSIS inspectors can provide information to FDA plants producing meat and nonmeat foods. FSIS inspectors are already in the plants, and their presence could be better used to maximize use of federal resources.
 - Review possible procedures for FSIS inspectors to exchange information with FDA on the basic sanitation conditions in warehouses.
 - Work closely with state and local regulators to establish uniform retail program standards through adoption of the Food Code. Currently as mentioned above, there are large disparities in regulatory standards between state, local and federal regulators.
 - Identify and address food safety issues related to the school lunch program and other feeding programs in USDA.
 - Consider the tasks of USDA inspectors in an HACCP environment.
 - Develop Good Agricultural Practices and Good Manufacturing Practices guidance for the domestic produce industry. FDA is also seeking legislation that would decrease the risk of importing unsafe food products from countries with food safety systems for exported products that are not on par with the U.S. system.
 - In addition, the FSIS Advisory Committee on meat and Poultry Inspection, which serves as a forum for sharing ideas and policy development on regulatory issues,

includes consumer and industry representatives, as well as state and federal officials.

Surveillance

- ▶ The Administration increased funding through the national food safety initiative to target a broad range of food-borne pathogens. The strengthened capacity of FoodNet (the food-borne diseases active surveillance network) will provide rapid identification of the causes of the outbreaks.
- ▶ FSIS, FDA and CDC collaborate with local state and health departments to analyze data, recognize trends and target prevention strategies to evaluate their effectiveness.
- ▶ FSIS, FDA and CDC have developed an MOU that will allow the agencies to jointly collect more precise information on the incidence of food-borne illness in the U.S.

Responses to Food-borne Outbreaks

- ▶ To strengthen the outbreak response and coordination, USDA, HHS and EPA have formed the Food-borne Outbreak Response Coordination Group (FORCG), an inter-departmental task force that will review food-borne illness outbreak response by federal and state governments and, based on these findings will develop and implement accelerated response procedures.
 - The Foodborne Outbreak Response Coordinating Group (FORCG) is designed to improve the approach to interstate outbreaks of foodborne illness through the development of a national comprehensive and coordinated foodborne illness outbreak response system involving federal, state and local agencies charged with responding to such outbreaks.
- ▶ Each Department will have an outbreak coordinator. For HHS, the Assistant Secretary for Health will be the primary person in charge of coordination for HHS. Outbreaks that fall under the jurisdiction of USDA will be coordinated by the Under Secretary for Food Safety. EPA will designate the Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances.

Risk Assessment

- ▶ The Risk Assessment Consortium, JIFSAN, is an interagency group that will coordinate risk assessment activity. Created as a part of the National Food Safety Initiative, USDA, FDA, CDC, EPA and NIH will collaborate on identifying risk-assessment research priorities.
- ▶ The FSIS-FDA National Advisory Committee on Microbiological Criteria for foods also

serves as an interagency resource to provide risk assessment models for the future regulations. USDA is required to include a risk assessment in order to promulgate regulations.

- ▶ USDA and FDA sponsor an Interagency Committee on Animal Production and Food Safety. This Committee focuses on risk assessment needs at the farm level and issues such as animal identification and Salmonella.

Research

- ▶ Under the FQPA, EPA is working hard to strengthen the scientific basis of its actions, including obtaining expert scientific advice, peer review, and the input of stakeholders.
- ▶ USDA has formed the Food Safety Working Group to establish a research agenda that supports the fundamental changes that FSIS is making to food safety regulations based on the HACCP system. The goal of research agenda is to reduce the incidence of food-borne associated with the consumption of meat, poultry and egg products. The Food Safety Research Group includes the Following USDA agencies: ARS; APHIS; CSREES; ERS; FSIS; ORACBA; and the Office of the Secretary.
- ▶ USDA, HHS and EPA have also formed an interagency research planning group to identify research priorities aimed at reducing microbial risk in produce.
- ▶ The Office of Science and Technology (OSTP) has convened an interagency group which includes, USDA, HHS, EPA and NIH, to coordinate federal food safety research priorities and will recommend direction of research funds for the FY 2000 budget for the federal food safety agencies.

Education

- ▶ The Partnership for Food Safety Education is a joint effort among USDA, HHS, EPA, the Department of Education and the private sector to respond to needs identified in the Food Safety Initiative. The partnership identifies key food safety messages to improve consumers, retail and food service workers' unsafe practices and handling of food.

Pesticides

- ▶ Under the Food Quality Protection Act (FQPA), the EPA is required to reassess all "tolerances" of pesticides, or maximum residue limits, by the year 2006. This will "update" pesticide residue limits in/on food in the U.S. based on the latest scientific studies and consideration of aggregate exposure to pesticides from food, drinking water and residential and lawn uses, with special emphasis on protection of children.

Microbial Contamination

- ▶ Under FQPA, EPA must revise the antimicrobial (substances used to control harmful microorganisms) registration process with the goal of achieving significantly shorter review times for all types of antimicrobial registration actions.. EPA's plan for improving the efficiency of its regulation of antimicrobial pesticides has four stages:
 1. Establish a New Antimicrobial Division (accomplished 2/97).
 2. Develop New Policies.
 3. Address the Backlog of Pending Applications
 4. Establish a Streamlined Antimicrobial Regulatory Process.

III. Current food safety coordination efforts.

Working Groups and Meetings

- ▶ FDA, EPA and USDA Principles meetings on Food Safety
- ▶ Interagency Food Safety Risk Assessment Group (I-FRAG)
- ▶ EPA/FDA workgroup to consolidate current FIFRA, TSCA and FDA Good Laboratory Practice (GLP) regulations, harmonize internationally, and verify compliance with GLP's
- ▶ Interagency Working Group on Food Safety Research (NSTC Committee on Science)
- ▶ FDA/FSIS WGs on methods development for animal-drug residues in milk and in animal tissues
- ▶ Surveillance Advisory Committee WG
- ▶ National Antimicrobial Susceptibility Monitoring Program WG (FDA, CDC, USDA)
- ▶ Interagency Residue Control WG (FDA, USDA)
- ▶ Interagency produce research WG
- ▶ National Food Safety Initiative interagency WG
- ▶ Food safety education interagency WG
- ▶ Food Safety Education IAG (FDA/USDA)
- ▶ BSE/TSE interagency coordinating group
- ▶ Interagency WG on GPRA goals
- ▶ FoodNet WG
- ▶ CDC/FDA *Clostridium botulinum* WG
- ▶ Water WG (EPA/FDA/USDA)
- ▶ Emerging Infectious Diseases WG
- ▶ Interagency WG on GAPs/GMPs (FDA/USDA/USDA)

Committees

- ▶ The EPA & USDA co-chaired Tolerance Reassessment Advisory Committee (TRAC)

- ▶ Interagency Committee on Animal Production and Food Safety
- ▶ Food Safety Initiative Steering Committee (USDA, DHHS, EPA)
- ▶ HHS Environmental Health Policy Committee
- ▶ A variety of U.S. Codex committees

Other

- ▶ The Food Safety Initiative
- ▶ Partnership for Food Safety Education
- ▶ The Risk Assessment Consortium
- ▶ National Agricultural Pesticide Impact Assessment Program (NAPIAP)
- ▶ Conference of Food Protection
- ▶ Ad hoc Executive Board Members of: AFDO, CSTE, ASTHO, ASTPHLD
- ▶ Food Service Training and Education Alliance
- ▶ Healthy People 2000 and 2010

MOUs

- ▶ Foodborne Outbreak Response Coordinating Group (FORCG)(MOU/USDA, DHHS, EPA)
- ▶ MOU with USDA and FDA on oversight and direction for the Pesticide Data Program (PDP) through an Executive Steering Committee
- ▶ MOU and quarterly meetings with FDA (to coordinate and perform certain FIFRA/GLP inspections)
- ▶ Interagency Coordinating Committee on Animal Production and Food Safety (MOU/USDA, DHHS, DOD, and EPA)
- ▶ CVM, USDA, FSIS, AMS and EPA MOU on Regulatory Activities Concerning Residues of Drugs, Pesticides and Environmental Contaminants in Foods.
- ▶ CVM/EPA MOU on pesticides/animal drug overlaps
- ▶ CVM/APHIS MOU on biologics/immune mediators/animal drug overlaps
- ▶ FDA/FSIS MOU on cooperative notification of in-plant violations
- ▶ FDA/USDA MOU on National Advisory Committee on Microbiological Criteria for Foods
- ▶ Interstate Shellfish Sanitation Conference MOU

Coordination

- ▶ EPA/FDA/USDA coordination on possible pesticide misuse cases (illegal residues on crops or food)
- ▶ OECA/OPPTS/FDA coordination on food contamination cases

IV. Organizational issues/options for a single food agency that must be addressed.

- Combine all regulation/risk assessment and enforcement/risk management functions for all foods (for man or other animals) in one agency (including chemical contaminants, pesticide, food additives pre-market approval, nutrition, education, etc.), and separate mercantile functions in a different agency
- Combine all food-related functions (public health, and mercantile) in one agency
- Separate regulation/risk assessment from enforcement/risk management
- Separate science/research from regulation and enforcement
- Separate surveillance from other public-health functions
- Maintain current division of responsibility, but eliminate divided responsibilities (i.e., put responsibility for all meat and poultry products, all eggs and egg products, etc. in one agency)
 - ▶ Pesticide regulation in a single food agency or with EPA (EPA)
 - ▶ Drinking water in a food agency or with EPA