



Food Safety and Inspection Service
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Backgrounders

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The Final Rule on Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) Systems

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SUMMARY

The Food Safety and Inspection Service (FSIS) is establishing new requirements for all meat and poultry plants to improve food safety and begin the long-awaited modernization of USDA's meat and poultry inspection system.

All slaughter and processing plants will be required to adopt the system of process controls to *prevent* food safety hazards known as Hazard Analysis and Critical Control Points (HACCP). To verify that HACCP systems are effective in reducing contamination with harmful bacteria, FSIS is setting pathogen reduction performance standards for *Salmonella* that slaughter plants and plants that produce raw, ground meat and poultry will have to meet. In addition, slaughter plants will be required to conduct microbial testing for generic *E. coli* to verify that their process control systems are working as intended to prevent fecal contamination, the primary avenue of contamination for harmful bacteria. FSIS is also requiring plants to adopt and follow written Standard Operating Procedures for sanitation to reduce the likelihood that harmful bacteria will contaminate the finished product.

FSIS expects this combination of HACCP-based process control, microbial testing, pathogen reduction performance standards, and sanitation standard operating procedures to significantly reduce contamination of meat and poultry with harmful bacteria and reduce the risk of foodborne illness.

This new food safety system will also enable USDA to modernize its inspection program by focusing its attention on the most significant food safety hazards and on ensuring that all plants have systems in

place that are effectively preventing food safety problems.

The new requirements are summarized as follows.

Hazard Analysis and Critical Control Points (HACCP)

All plants must develop, adopt and implement a HACCP plan for each of their processes. Under HACCP, plants identify critical control points during their processes where hazards such as microbial contamination can occur, establish controls to prevent or reduce those hazards, and maintain records documenting that the controls are working as intended. FSIS believes that HACCP-based process control, combined with appropriate food safety performance standards, is the most effective means available for ensuring the safety of food, including controlling and reducing harmful bacteria on raw meat and poultry products.

Implementation dates for HACCP are based on plant size; the largest plants are being required to have their HACCP systems in place first. Implementation dates range from 18 months to 42 months after publication of the final rule.

Pathogen Reduction and Microbial Testing

To be effective, HACCP-based process control must be combined with objective means of verifying that meat and poultry plants are achieving acceptable levels of food safety performance. FSIS will require all slaughter plants to conduct microbial testing for generic *E. coli*, a species of *E. coli* that is commonly found in the intestinal tract of food animals. Generic *E. coli* is an excellent indicator of fecal contamination, which is the primary pathway for contamination of meat and poultry with bacteria such as *E. coli* O157:H7, *Salmonella*, and *Campylobacter* that can cause illness. The testing requirement, which will be effective 6 months after publication of the final rule, will assist plants in maintaining adequate process control for fecal contamination. FSIS is establishing verification performance criteria that reflect the prevalence and levels of contamination of carcasses with *E. coli* as determined by FSIS baseline surveys.

In addition, FSIS is establishing pathogen reduction performance standards for *Salmonella* that slaughter plants and plants that produce raw ground products will be required to meet to verify that their HACCP systems are effective in reducing contamination with that pathogenic microorganism. The standards will provide incentives for innovation to improve food safety, and FSIS will conduct testing to verify compliance with the standards. Implementation dates for the standards are based on plant size and will coincide with those for HACCP. Prior to the implementation dates, FSIS will begin *Salmonella* testing to provide plants with information regarding their current level of performance relative to the pathogen reduction performance standard.

Standard Operating Procedures for Sanitation

All plants must prepare and implement plant-specific standard operating procedures (SOPs) for sanitation to ensure they are meeting their responsibility to keep their facilities and equipment clean. This requirement will become effective 6 months after publication of the final rule.

Safe Handling Beyond the Plant

These new requirements--mandatory HACCP, pathogen reduction performance standards and testing procedures, and SOPs for sanitation--are designed to reduce contamination of meat and poultry products

with harmful bacteria when they leave the meat or poultry slaughter or processing plant. However, distributors, employees in retail stores and restaurants, and consumers must continue to store, handle, and prepare meat and poultry products carefully to keep food safe.

FSIS is working with the Food and Drug Administration (FDA) to adopt standards to control growth of harmful bacteria during transportation and storage and is working with FDA and state and local authorities to improve food safety practices at the retail level. FSIS works with other government agencies, the food industry, and others to educate consumers on safe food handling practices.

Implementation Costs

FSIS estimates the four-year implementation cost of the final rule to the meat and poultry industry at \$305 to \$357 million, or an average of \$76 to \$89 million per year. Annual recurring costs following the implementation period are estimated at \$99.6 to \$119.8 million. Estimates of yearly public health benefits from reduced foodborne illness costs, including medical care and lost work time, range from \$990 million to \$3.7 billion. The total implementation costs amount to between one- and two-tenths of a cent per pound of product.

Request for Comments

FSIS is seeking comments, due by 60 days after the date of publication of the final rule, on certain technical issues that are associated with *E. coli* testing and the verification performance criteria. In addition, FSIS is requesting comments, due 120 days after the date of publication of the final rule, on the revised HACCP implementation schedule and guidance materials that have been prepared as appendices to the final rule.

BACKGROUND

Current FSIS regulatory requirements and inspection procedures contribute to the FSIS mission of ensuring that meat and poultry products are safe, wholesome, and accurately labeled. More than 7,400 FSIS inspectors are present in 6,200 slaughter and processing plants to ensure that diseased animals and birds do not enter the food supply and that sanitation and other requirements are met. Inspectors also monitor the meat and poultry supply for violative levels of chemical residues.

Despite the successes of the current program in removing diseased animals from the food supply and enforcing sanitation and other standards, there is a critical gap in its ability to protect public health. The current system of slaughter inspection relies largely on organoleptic (sensory) methods, which were appropriate when the first major meat inspection law was passed in 1906. At that time, animal diseases were the major concern, and invisible hazards such as pathogenic microorganisms and drug residues had not yet attracted the attention of public health authorities and regulators. Since that time, changes have been made in the inspection program to reflect changes in the production of meat and poultry, address chemical residues in slaughter plants, address bacteria in processed products, and increase the efficiency of inspection. However, the current program does not adequately target and reduce pathogenic microorganisms on raw meat and poultry. And it does not integrate systematic, preventive process control into the production process to make all meat and poultry products as safe as possible. Implementation of the final rule will help to correct these gaps.

While precise data on the incidence of illness associated with microbiological contamination of meat and poultry products is limited, foodborne illness is an important public health problem in the United States. Data from the Centers for Disease Control and Prevention suggest that foodborne microbial

pathogens account for up to 7 million cases of foodborne illness each year, and up to 7,000 deaths. Of these, nearly 5 million cases of illness and more than 4,000 deaths may be associated with meat and poultry products.

The seriousness of the problem was illustrated by the outbreak of foodborne illness that occurred in several western states in early 1993. The outbreak was attributed to undercooked hamburgers contaminated with *E. coli* O157:H7 that were served at a chain of fast-food restaurants. This particular outbreak led to hundreds of cases of illness and four deaths.

This conclusion is consistent with many external studies conducted during the past decade. The National Academy of Sciences; the General Accounting Office, the National Advisory Committee on Microbiological Criteria for Foods, and many others have called for change in the current inspection system to better address microbial pathogens and make the system more prevention-oriented.

THE RULEMAKING PROCESS

To address these concerns, FSIS, on February 3, 1995, published a proposal on Pathogen Reduction and HACCP that would mandate HACCP, set targets for pathogen reduction, require daily microbial testing to determine compliance with the targets, and require three near-term initiatives--standard operating procedures for sanitation, antimicrobial treatments, and carcass cooling standards. FSIS conducted a thorough and interactive rulemaking process on the proposal by soliciting extensive public comment and encouraging dialogue between FSIS and interested parties on the many policy and technical issues involved in the proposal.

During the comment period, which was extended twice, FSIS held seven information briefings, three scientific and technical conferences, a two-day public hearing, six issue-focused public meetings, a Federal-State conference, and a Food Safety Forum chaired by Secretary of Agriculture Dan Glickman. In addition, FSIS received approximately 7,500 written comments on the proposal.

FSIS carefully evaluated the written comments and input received through the various public events and addressed the many issues raised in formulating a final rule.

THE FINAL RULE

Hazard Analysis and Critical Control Points (HACCP)

FSIS is requiring that all federally inspected meat and poultry plants adopt HACCP systems to ensure that they have in place science-based process controls to prevent and reduce the significant food safety hazards that may arise in their particular processes and products. The HACCP approach is a system of process control that is widely recognized by scientific authorities and international organizations and is used extensively in the food industry to produce products in compliance with health and safety requirements. HACCP also provides a framework for better targeting FSIS inspection on the most significant food safety hazards and controls and more efficiently using inspection resources.

Implementation of HACCP will clarify the responsibility of industry and FSIS to produce safe meat and poultry products. FSIS's role is to set appropriate food safety standards and maintain vigorous inspection

oversight to ensure that those standards are met.

Plants will be required to develop HACCP plans based on the seven principles articulated by the National Advisory Committee on Microbiological Criteria for Foods:

1. hazard analysis,
2. critical control point identification,
3. establishment of critical limits,
4. monitoring procedures,
5. corrective actions,
6. recordkeeping, and
7. verification procedures.

Plants will identify and evaluate the food safety hazards that could affect the safety of their products and institute controls necessary to prevent those hazards from occurring or to keep them within acceptable limits. HACCP systems will be required to cover those critical control points that affect product safety, as opposed to those related to economic adulteration and quality. Each meat or poultry product produced must be covered by a HACCP plan. Plants will be required to validate their own HACCP plans--that is, ensure that they do what they were designed to do. FSIS will not approve HACCP plans in advance but will review them for conformance with the final HACCP regulations.

Verification--making sure the plan is adequate and working on a day-to-day basis--will be the responsibility of both industry and FSIS. Industry will monitor and verify the performance of the controls in their HACCP plans and maintain records of this monitoring and verification. FSIS will evaluate the HACCP plan's adequacy and successful operation as part of the inspection process. HACCP plans found by FSIS to be inadequate will have to be corrected, or the plant will face appropriate regulatory action.

FSIS currently carries out carcass-by-carcass inspection in slaughter plants to remove diseased animals from the food supply. Carcass-by-carcass inspection will continue in these plants. However, in light of improvements in process control that are expected under HACCP, FSIS of illness and four deaths. USDA's review of the outbreak concluded that the current food safety system does not adequately address the risk of microbial contamination.

This conclusion is consistent with many external studies conducted during the past decade. The National Academy of Sciences, the General Accounting Office, the National Advisory Committee on Microbiological Criteria for Foods, and many others have called for change in the current inspection system to better address microbial pathogens and make the system more to examine current tasks related to carcass-by-carcass inspection and determine what changes should be made to improve inspection effectiveness and make the use of inspection resources more productive.

FSIS is committed to implementing HACCP as rapidly as possible, taking into account the logistical effort required for such a fundamental change in industry practices and FSIS inspection strategy. FSIS has revised its proposed implementation schedule so that it is based on plant size rather than product category. Large plants with 500 or more employees will be required to have a HACCP system in place 18 months after publication of the final rule. The revised implementation schedule will ensure that 75 percent of slaughter production and 45 percent of processed products will be produced under a HACCP system within 18 months. As a result, most of the Nation's meat and poultry supply will come under HACCP-based process control one year earlier than originally proposed. Smaller plants, with 500 or fewer but 10 or more employees, must have a HACCP system in place 30 months after publication of

the final rule. Very small establishments--those having fewer than 10 employees or annual sales of less than \$2.5 million--have until 42 months after publication of the final rule to have their HACCP systems in place.

ASSISTANCE FOR SMALL PLANTS

HACCP is a useful tool for improving food safety in plants of all sizes. FSIS recognizes, however, that many small plants may lack familiarity with HACCP. Thus, FSIS plans an array of assistance activities that will facilitate implementation of HACCP in small plants.

FSIS is developing 13 generic HACCP models for the major process categories, which will be available in final form before plants must begin work on their HACCP plans. The generic models will serve only as illustrations rather than as prescriptive blueprints for a specific HACCP plan.

FSIS will also conduct small-plant demonstration projects during the two-year period following issuance of the final rule at a number of sites around the country to show how HACCP systems can work in even the smallest plants under actual operating conditions.

FSIS is also making available guidance materials, as appendices to the final regulations, that will assist small, as well as large, plants in conducting their hazard analyses and developing HACCP plans. They include a *Guidebook for the Preparation of HACCP Plans* and a *Hazards and Preventive Measures Guide*. Additional guidance materials addressing other parts of the final regulations also are available.

HACCP IMPLEMENTATION CONFERENCE

FSIS plans to convene a three-day HACCP implementation conference to be held in Washington, D.C., about 60 days after publication of the final rule and intends to hold regional HACCP implementation conferences at several sites around the country. The purpose of the conference is to continue the dialogue among a diverse array of interested parties on a variety of issues related to HACCP implementation such as training and enforcement issues.

PATHOGEN REDUCTION AND MICROBIAL TESTING

The HACCP requirement will ensure that all meat and poultry plants implement science-based process controls to prevent and reduce the significant food safety hazards that are reasonably likely to occur in their particular processes and products. But HACCP-based process control must be combined with objective means of verifying that meat and poultry plants are achieving acceptable levels of food safety performance. While FSIS has in place microbiological performance standards for ready-to-eat and other processed products, microbiological performance criteria or standards for raw products, with the exception of *E. coli* O157:H7 in ground beef, do not exist.

FSIS believes it is essential to the reduction of nationwide exposure to foodborne pathogens that slaughter establishments control their operations to prevent fecal contamination and that all plants producing raw meat and poultry products institute process controls to reduce the prevalence of

Salmonella. These regulations provide both an objective means to verify process control in slaughter plants with respect to fecal contamination and pathogen reduction performance standards for raw products that will reduce the nationwide exposure to *Salmonella*, the most common cause of foodborne illness among enteric pathogens.

GENERIC *E. COLI* TESTING FOR PROCESS CONTROL

FSIS is requiring meat and poultry slaughter plants to test carcasses for generic *E. coli* as an indicator of the adequacy of the plant's process control for fecal contamination. Plants will be required to conduct *E. coli* testing 6 months after publication of the final rule. FSIS is seeking further comment on certain technical issues such as testing frequency and sampling procedures and will be holding a conference on these issues approximately 45 days after publication of the final rule. FSIS will make any appropriate technical amendments to the *E. coli* testing protocols at least 30 days before the effective date of the rule. FSIS inspectors will not use *E. coli* testing results as an indication of process control until 6 months after the effective date for the testing requirement. A second conference is tentatively planned for approximately 9 months following publication of this rule to provide an opportunity for members of industry and others to discuss with FSIS new information based on the three months of testing that will have occurred that might justify further adjustments to the protocol.

FSIS is adopting *E. coli* verification performance criteria for each species that reflect the frequency and levels of contamination of the microorganism on such carcasses produced nationwide as determined by FSIS baseline surveys. FSIS is using the term criteria because they are guidelines, not regulatory standards. FSIS will not use the test results by themselves to take any regulatory action but will consider them in conjunction with other information to evaluate whether a problem exists that requires regulatory action.

The required frequency of *E. coli* testing is based on production volume. Slaughter plants will be able to adopt alternative testing frequencies when they implement HACCP if the alternative is equally or more effective in verifying process control for fecal contamination. FSIS intends to update the *E. coli* criteria periodically, based on future surveys and data generated by the testing, to ensure that the criteria adequately reflect an appropriate and adequate level of performance with respect to prevention and removal of fecal contamination.

The requirement for *E. coli* testing in slaughter plants will become effective 6 months after publication of the final rule. *E. coli* test results will provide process control data that will help plants find and correct process control problems at this most fundamental phase of production. The results will also support more objective assessments by inspectors of whether plants are meeting current statutory requirements for sanitation and the prevention of adulteration. They will also play an integral role in the successful implementation of HACCP in slaughter plants.

PERFORMANCE STANDARDS FOR *SALMONELLA* AND FSIS TESTING

FSIS is adopting pathogen reduction performance standards for *Salmonella* to verify that plant HACCP systems are effective in reducing contamination with this pathogenic microorganism. FSIS believes that the production of raw meat and poultry with *Salmonella* prevalence below the current national level is readily achievable with available technology and production methods. *Salmonella* was selected as the

target pathogen because it is the leading cause of foodborne illness among enteric pathogens, it is present at varying frequencies on all types of raw meat and poultry products, and it can easily be tested for in a variety of products. Furthermore, improvements in process control that result in reductions in *Salmonella* are expected to result in reductions of other pathogens found in the intestines of animals.

The microbiological performance standards FSIS is adopting are part of a fundamental shift in FSIS regulatory philosophy and strategy. FSIS is shifting from an extensive reliance on command and control regulations, which generally prescribe *how* desired objectives are to be achieved, to much greater reliance on performance standards, which generally express the objective but do not specify the means for achieving it. FSIS believes that its food safety and consumer protection goals can, in most cases, be achieved most effectively by establishing clear objectives in terms of performance standards, providing industry flexibility to devise the optimal means of achieving the objective, and then verifying through inspection and other forms of oversight that firms are meeting the established standard.

The pathogen reduction performance standards for *Salmonella* and the *E. coli* verification performance criteria complement one another. While *E. coli* testing is a good indicator of fecal contamination, it is not directly correlated with *Salmonella* contamination, which is affected by other factors as well, including the condition of incoming animals. The *Salmonella* standards will force plants not currently meeting the standards to take steps to reduce pathogens that can cause foodborne illness.

Plants will be required to achieve a prevalence of *Salmonella* contamination that is below the baseline prevalence for each raw product as reflected in the FSIS baseline surveys. These are regulatory standards that FSIS will require the plant to meet consistently over time as a condition to maintaining inspection.

FSIS, rather than the plant, will test for *Salmonella* to ensure compliance with the standards. FSIS will conduct initial testing prior to actual enforcement of the performance standards to determine whether each plant is meeting the standard. These results will assist plants in preparing for implementation of HACCP and the pathogen reduction performance standards. FSIS will continue its testing program once the standards become effective to ensure compliance. The frequency and intensity of testing will be based on past plant performance and other factors.

The *Salmonella* enforcement strategy embodies an objective, uniform systems approach that will be administered and applied in a fair, equitable, and common-sense manner. The Agency will continually monitor and adjust its enforcement program and activities to reflect these principles while ensuring food safety.

Implementation will coincide with the implementation schedule for HACCP. Slaughter plants and plants producing raw ground product or fresh pork sausage will be required to meet the standards at the same time the plant is required to implement HACCP.

Approximately 15 months after the publication of this final rule, FSIS will convene a public conference to review available data and discuss whether they warrant refining the *Salmonella* performance standards.

The *Salmonella* standards being established are a first step in what FSIS expects to be a broader reliance in the future on pathogen-specific performance standards for raw products. FSIS plans to repeat its baseline surveys and collect substantial data through other means and, on that basis, adjust the *Salmonella* targets and possibly set targets for additional pathogens, as appropriate.

Sanitation Standard Operating Procedures

Insanitary conditions during the production of meat and poultry products increase the likelihood that pathogenic bacteria will contaminate the finished product. Poor sanitation is the most frequently observed problem in meat and poultry plants. FSIS is requiring that all meat and poultry plants adopt, maintain, and follow written Standard Operating Procedures (SOPs) for sanitation. The written sanitation SOPs must describe the specific activities plant management has determined are necessary to maintain good sanitation and prevent direct product contamination. The SOP must specify the persons responsible for carrying out these activities. Daily records must be kept showing when procedures are accomplished and when corrective actions are taken.

Sanitation SOPs will clarify that sanitation is industry's responsibility. They will make it easier for FSIS inspectors to perform their proper role of verifying that plant management is carrying out its sanitation responsibilities and will allow FSIS to focus on the prevention and correction of direct product contamination risks.

Requirements for Foreign Establishments and State Programs

Foreign countries exporting to the United States must establish inspection system requirements that are "*equivalent*" to U.S. requirements. Thus, all foreign meat and poultry plants that export to the United States must operate HACCP-type process control systems that are "*equivalent to*" HACCP and adopt equivalent performance standards.

State inspection programs must operate programs "*equal to*" the Federal program and will also be required to comply with the new requirements.

FOOD SAFETY FROM FARM TO TABLE

The new regulatory measures address hazards within slaughter and processing plants. FSIS recognizes, however, that these measures must be part of a comprehensive food safety strategy that addresses hazards at other points in the farm-to-table chain. To that end, FSIS is broadening the scope of its food safety activities beyond slaughter and processing plants, with particular new emphasis on hazards that arise during transportation, distribution, and retail sale.

To improve food safety at the animal production and intermediate stages before the slaughter plant, FSIS is working with industry, academia, and other government agencies to develop and foster measures that can be taken on the farm and through distribution and marketing of animals to reduce food safety hazards associated with animals presented for slaughter. FSIS does not intend to mandate production practices at this stage but instead believes that the voluntary application of food safety assurance programs based on HACCP principles can be useful in establishing risk reduction practices on the farm and during intermediate marketing stages. The Agency believes that continued public concern about foodborne pathogens and the adoption of HACCP and performance standards will increase incentives for producers to adopt food safety practices at the animal production level.

Food safety during transportation, storage and retail sale are also important links in the food safety chain. In these areas, FSIS, the Food and Drug Administration (FDA), and State and local governments share authority for oversight of food products. FSIS and FDA are working together to develop standards governing the safety of foods during transportation and storage, with particular emphasis on the

importance of temperature control in minimizing the growth of pathogenic microorganisms. In the retail area, FSIS and FDA are working with state officials to ensure the adoption of uniform, science-based standards and to foster the adoption of HACCP-type preventive approaches. State and local authorities have primary responsibility for food safety oversight of retail stores and restaurants, but FSIS and FDA, working through the Conference for Food Protection, can provide expertise and leadership to support local authorities and foster the development of sound food safety standards and practices nationwide.

Even as progress is made in reducing contamination during these stages, it will remain critical that retail food handlers and consumers follow safe food handling practices. Proper storage, preparation, and cooking of meat and poultry products are essential to achieving the goal of reducing the risk of foodborne illness to the maximum extent possible. FSIS intends to augment its food handler education efforts by expanding its collaboration with industry, other government agencies, consumer and public interest groups, educators and the media to foster the effective delivery of food safety education and information.

CHANGE WITHIN FSIS

To achieve its food safety goals and carry out the new food safety strategy, FSIS must also change itself. FSIS has conducted a top-to-bottom review of its regulatory roles, resource allocation and organizational structure and is making fundamental internal changes required to successfully carry out its HACCP-based, farm-to-table food safety strategy.

First, the Agency is reforming its existing regulations to be consistent with HACCP principles and greater reliance on performance standards and to remove unnecessary regulatory obstacles to innovation. On December 29, 1995, FSIS published an advance notice of proposed rulemaking and additional rulemaking proposals describing the Agency's strategy for regulatory and inspectional reform and initiating the rulemaking process required to achieve necessary changes. It also published, on May 2, 1996, two additional regulatory reform documents--a proposal to eliminate the prior approval system for facility blueprints, equipment, and most partial quality control plans and a proposal to add a performance standard alternative to the current command-and-control requirements governing cooked meat and poultry products. FSIS will ensure that current regulations are revised as necessary before the implementation dates to ensure consistency with the new rules.

Second, FSIS is planning a reorganization to prepare the Agency to implement a modernized system of inspection. FSIS must realign its structure with a HACCP-based, farm-to-table strategy.

Third, FSIS will soon begin a public process to develop and evaluate new approaches to inspection that would ensure that FSIS is making the best possible use of its resources to improve food safety while still meeting all the consumer protection objectives of the current system. FSIS anticipates a major redeployment of its inspection resources to successfully implement HACCP and better target food safety hazards during transportation, storage, and retail sale.

To address these concerns, FSIS, on February 3, 1995, published a proposal on Pathogen Reduction and HACCP that would mandate HACCP, set targets for pathogen reduction, require daily microbial testing to determine compliance with the targets, and require three near-term initiatives--standard operating procedures for sanitation, antimicrobial treatments, and carcass cooling standards. FSIS conducted a thorough and interactive rulemaking process on the proposal by soliciting extensive public comment and encouraging dialogue between FSIS and interested parties on the many policy and technical issues

involved in the proposal.

During the comment period, which was extended twice, FSIS held seven information briefings, three scientific and technical conferences, a two-day public hearing, six issue-focused public meetings, a Federal-State conference, and a Food Safety Forum chaired by Secretary of Agriculture Dan Glickman. In addition, FSIS received approximately 7,500 written comments on the proposal.

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E. coli was chosen as a more appropriate microorganism to use as a verification of process control than the originally proposed *Salmonella* based on numerous comments and the results of the scientific and technical conference on the Role of Microbiological Testing in Verifying Food Safety conducted by FSIS during the comment period. Generic *E. coli* is present in all animal feces and thus is more effective than *Salmonella* as an indicator of fecal contamination, the primary avenue of contamination for pathogenic microorganisms.

To obtain paper or diskette copies of the final rule contact:

National Technical Information Service (NTIS)
U.S. Department of Commerce
5285 Port Royal Road
Springfield, VA 22161

Orders must reference NTIS accession number PB96-177613 for a paper copy and PB96-502166 for the diskette version. For telephone orders or further information on placing an order, call NTIS at (703) 487-4650 for regular service or (800) 553-NTIS for rush service.

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Additional information materials on the new rules are available on the FSIS Home Page at:
<http://www.fsis.usda.gov/>

For internet access to the Federal Register, contact GPO Access at:
www.access.gpo.gov/su_docs/

For Further Information Contact:

- *Technical Inquiries:* Technical Service Center HACCP Hotline at 1-800-233-3935
- *Media, Congressional, and Constituent Inquiries:* (202) 720-3897
- *Consumer Inquiries:* Call the USDA's Meat and Poultry Hotline at 1-800-535-4555; in the Washington, D.C. area, call (202) 720-3333.

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FOOD SAFETY RESEARCH AGENDA

DIRECTIONS FOR THE FUTURE

May 1997

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Introduction

The U.S. Department of Agriculture has embarked on a series of dramatic changes to improve food safety and reduce the incidence of foodborne illness associated with the consumption of meat, poultry, and egg products:

First, the Food Safety and Inspection Service (FSIS), the USDA Agency charged with ensuring the safety of meat, poultry, and egg products, has made significant changes in the regulatory structure of its food safety programs by placing a new emphasis on controlling microbial pathogens. On July 25, 1996, FSIS issued final regulations on Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) systems (1). The new regulations require all slaughter and processing establishments to adopt a system of process control--known as HACCP--to prevent food safety hazards. To verify that HACCP systems are effective in reducing contamination with harmful bacteria, FSIS has set pathogen reduction performance standards for Salmonella that slaughter plants and plants that produce raw, ground meat and poultry have to meet. In addition, slaughter plants are required to conduct microbial testing for generic E. coli to verify that their process control systems are working as intended to prevent fecal contamination, the primary avenue of contamination for harmful bacteria.

Second, FSIS is implementing a reorganization to better prepare the Agency to operate in a HACCP environment that will emphasize the prevention of foodborne illness. One objective of the reorganization is to strengthen the Agency's focus on public health by creating an Office of Public Health and Science (OPHS). Within that office, FSIS has established a Division of Epidemiology and Risk Assessment and a Scientific Research Oversight staff. OPHS will generate and use the best available science to estimate risks associated with meat, poultry and egg products and to identify potential interventions consistent with the public health risks. These risk evaluations will guide FSIS's policy and regulatory decision making.

Research is extremely important to the success of the Agency's new food safety initiatives. To effectively address the safety of meat, poultry and egg products, FSIS needs to know more about the hazards in these products and their relation to adverse human health outcomes. Because the Agency's food safety strategy has broadened to cover the entire farm-to-table continuum, its research agenda also must broaden to address information needs at all points along the farm-to-table chain. To a large extent, the FSIS research agenda is guided by public health concerns, the new HACCP Pathogen Reduction regulations and the need to conduct risk assessments to achieve food safety objectives. It is critical that FSIS identify and establish the linkages between pathogens present on or in food animals and consequent human disease and to use this information to identify effective interventions consistent with the public health risk and to reduce foodborne illness.

Research and the Food Safety Research Group

The Food Safety Research Working Group was formed at the request of Michael Taylor, then Acting Under Secretary for Food Safety, to establish a research agenda that supports the fundamental changes FSIS is making to food safety regulation. The ultimate goal of the research agenda is to reduce the incidence of adverse human health effects associated with the consumption of meat, poultry and egg products.

Using human health effects as the basis for determining FSIS research needs is consistent with the formal risk assessment process, which provides a framework to identify data gaps and research needs along the farm-to-table continuum. The Food Safety Research Working Group was asked to use this concept in their deliberations, with the following objectives:

(1) to determine research needs for public health goals, (2) to determine what research is needed to support the Pathogen Reduction and HACCP regulation in preventing foodborne illness from meat and poultry, and (3) to shift the research orientation from a technology-based approach to a risk-based approach.

The working group is composed of scientists representing a broad base of expertise, including individuals with experience in research and knowledge of food safety and public health issues. The following Federal agencies are represented: Agricultural Research Service (ARS); Animal and Plant Health Inspection Service (APHIS); Cooperative State Research, Education & Extension Service (CSREES); Economic Research Service (ERS); FSIS; Office of the Secretary; Office of Risk Assessment and Cost Benefit Analysis (ORACBA); Centers for Disease Control and Prevention (CDC); Food and Drug Administration (FDA); National Institutes of Health (NIH); and the Department of Defense (DOD). Appendix 1 lists the participants.

Prior to its first meeting in June 1996, the Food Safety Research Working Group was given the following background material: 1) FSIS Strategic Plan ⁽²⁾; 2) proposed HACCP/Pathogen Reduction regulation ⁽³⁾; 3) Pathogen Reduction Task Force Subcommittee Report ⁽⁴⁾; and 4) FSIS Food Safety Research: Current Activities and Future Needs ⁽⁵⁾. The group met again in the fall of 1996 and communicated extensively by e-mail, fax and regular mailings during that time.

Background

Because FSIS is not a research Agency, it must rely on others, particularly the research agencies within USDA, to realize its research objectives and provide the scientific data needed to make regulatory decisions. For this reason, the longstanding collaboration between FSIS and ARS has increased in importance since 1995, when Congress asked that FSIS discontinue its research in diagnostic methods development. ARS has been, and is, developing the necessary tools for FSIS to use in its field laboratories and studies bacterial physiology, ecology, pathogenesis, growth dynamics of pathogens and methods of predictive microbiology in various food matrices. The 1996 Progress Report on Food Safety Research conducted by ARS lists 35 research projects currently being conducted by ARS at the request of FSIS ⁽⁶⁾.

FSIS in its own right, and through collaborative projects, has been and is conducting food pathogen surveys and studies to generate information needed to form food safety policies:

- For instance, FSIS's Animal Production Food Safety staff is working with academia and the industry to collect pre-harvest (on the farm and pre-slaughter) pathogen data to encourage the development of preventive controls at the animal production level to reduce pathogens and other hazards before animals reach federally-inspected facilities. The staff is also evaluating the impact of pathogens in and on live animals on the types and levels of pathogens present after slaughter and processing.
- FSIS is conducting microbiological baseline studies for various animal species. These studies have provided a national picture of the presence of pathogens in or on animals after slaughter and processing. The Agency used those data to set pathogen reduction performance standards for *Salmonella* and criteria for generic *E. coli* in its rule on Pathogen Reduction and HACCP.
- In addition, CDC, FSIS, and FDA, working with local health departments in five states, have established an active surveillance system, called FoodNet, at sentinel sites. These sites with established population bases should provide the most accurate information available on the incidence of sporadic and epidemic disease due to the major foodborne pathogens

(*Salmonella*, *Campylobacter*, *E. coli* O157:H7, *Shigella*, *Yersinia*, and *Vibrio*). Case-control studies within this project will determine the association of specific pathogens with specific food vehicles.

Risk Assessment and the Research Agenda

Risk assessment is an integral feature in determining the public health hazards associated with pathogens and will be prominent in the development and design of the FSIS research agenda. The Food Safety Research Working Group discussed the multiple reasons for this approach. In 1994, the U.S. Council for Agricultural Science and Technology (CAST) created a task force to determine what was currently known in the scientific community about the risks and consequences of foodborne pathogens and disease. A major recommendation that came from the CAST task force was that future food safety policy be based on quantitative microbial risk assessment ⁽⁷⁾. This confirmed and extended earlier recommendations from the National Academy of Sciences in two studies conducted for FSIS ^{(8),(9)}.

While the value of risk assessment is without question, the science of risk assessment, particularly for microbial pathogens, is in a developmental stage. The fact that the numbers of bacteria in food are not constant is a key challenge to the application of risk assessment techniques to microbial food safety issues. Recent advances in predictive microbiology and computer modelling, however, have begun to allow the first quantitative microbial risk assessments.

The Division of Epidemiology and Risk Assessment, within OPHS, will ensure that the risk assessment paradigm is incorporated into the spectrum of work throughout the office. In addition to the actual estimates of risk, the assessment process provides a systematic approach to organizing the available data and identifying the need for additional data. Appendix 2 describes the first FSIS risk assessment project and shows how the Fault Tree Analysis for *E. coli* O157:H7 in ground beef served to organize data from outbreak investigations and studies and to highlight missing data points needed to make decisions at each "node" or branching of the tree. This illustrates how the risk assessment perspective can be used to estimate risk to human health potentially encountered along the farm-to-table continuum and to target research that should have the greatest value in terms of public health impact.

FSIS will also use risk assessment to evaluate cost-effective risk mitigation strategies. In this area, risk assessment will help rank alternative strategies to make economically sound policy decisions and allocate resources optimally. These processes will become an integral part of FSIS rule making activities, as required by Congress and the Department. Further, FSIS has stated in the final rule on Pathogen Reduction and HACCP ⁽¹⁰⁾ that the Agency will work closely with other Federal agencies to improve the scientific basis for establishing food safety standards for microbial pathogens. An interagency task force will determine the research needed for developing a workable approach to quantitative microbial risk assessment. It is conceivable that members of the Food Safety Research Working Group will be part of this task force.

Internationally, risk assessment has become the means of ensuring that countries establish food safety requirements that are scientifically sound and a means for determining equivalent levels of food safety between countries in international trade. These requirements are spelled out in the Sanitary and Phytosanitary provisions of the GATT Agreement ⁽¹¹⁾.

Scientists within FSIS, ARS, and ERS are working to develop risk assessment models based on predictive microbiology and data available through the various surveillance and monitoring activities described above. In addition to the fault tree analysis for *E. coli* O157:H7 in hamburger, they have developed a "Flow" Tree Analysis for this same pathogen and food using innovative programming,

incorporating the dynamics of microbial growth and death with the known levels of pathogen in epidemiologically implicated hamburgers. The Dynamic Flow Tree Process is described in an article authored by FSIS and published by the Office of Risk Assessment and Cost Benefit Analysis (ORACBA) ⁽¹²⁾.

FSIS has also initiated a quantitative risk assessment for shell eggs and egg products. This project was started in September 1996 and includes scientists from FSIS, ERS, ARS, APHIS, FDA, CDC, and academia. The project objectives are: (1) to establish the unmitigated risk of salmonellosis associated with the consumption of contaminated shell eggs and egg products, (2) to address risk along the farm-to-table continuum, (3) to evaluate various risk mitigation strategies in terms of effective risk reduction, and (4) to identify data needs and prioritize data collection efforts. A public process will include opportunity for industry and consumer input. A project report, including risk-cost-effectiveness/ cost-benefit studies on alternative mitigation strategies, is expected by the end of 1997.

Criteria Used to Develop the Research Agenda

After reviewing, evaluating and generally discussing the background documents (see introduction), the Food Safety Research Working Group members used their considerable expertise to reach a consensus on the major research questions that needed to be answered. To encourage consideration of all possible issues, the working group was asked not to be limited by resource constraints in identifying the research needs. The working group developed criteria for identifying information needs on adverse health events.

Criteria For Identifying Information Needs

1. Incidence of Adverse Health Outcome
2. Causes of Adverse Health Outcome
 - a. Chemical
 - b. Physical
 - c. Biological
3. Linkage (etiological/vehicle linked to food)
4. Outcomes
 - a. Sequela
 - b. Deaths
 - c. Distribution (demographics/populations)
 - d. Costs
 - * Medical
 - * Productivity Losses
 - e. Public Sensitivity/Perceptions

The Food Safety Research Agenda

The Working Group began the process of creating a research agenda by identifying, in priority, general research questions and the major foodborne pathogens of concern. They then identified research needs that are unique to the following specific pathogens: *Salmonella*, *Campylobacter*, *Listeria*, and EHEC. The general questions are considered applicable to the specific pathogens and are, in general, prioritized; however, all of these questions are considered of high priority.

Research Agenda

I. General Research Questions

1. What is the actual incidence of foodborne illness in the United States? What is the incidence by specific pathogen and by specific food product?
2. What is the relationship between the numbers of bacteria on raw product and foodborne illness, and is the number different for different subpopulations, e.g., by age, socioeconomic status, immune status, race, etc.? What is the relationship of changes in performance standards for pathogen reduction (*Salmonella* or future performance standards) to human health downstream?
3. What are the risks, i.e., probability of foodborne illness, along the food chain? How does the determination of risk translate into the identification of critical control points along the farm-to-table continuum?
4. Is there adequate information on the sensitivity of subpopulations exposed to chemical, physical, and microbiological hazards in foods? Are different intervention strategies more effective for reducing risk of foodborne illness for different subpopulations?
5. Can critical limits around a control point within a hazard analysis critical control point (HACCP) system be directly linked to a public health impact?
6. How are pathogens introduced into the food chain? Studies show that transportation and/or stress cause an increased shedding of pathogens in animals; does this increase the number of pathogens on raw product or the risk of foodborne illness? Are CCPs known in animal production and, if so, is existing technology available to monitor the limits around each point?
7. Is it possible to predict emerging foodborne pathogens? For example, can conditions be identified which increase the likelihood of a pathogen, or a category of pathogens emerging or re-emerging at any point along the farm-to-table continuum?
8. Are there effective models for risk communication in relation to foodborne illness?
9. What are the costs and benefits for risk reduction, and what will consumers pay for food safety?
10. Are there vaccines or other production level interventions which would eliminate or reduce pathogens in raw products and/or prevent foodborne illness?

Research Agenda

II. Salmonella

Salmonella species cause diarrhea and systemic infections, which can be fatal in particularly susceptible persons, such as the immuno-compromised, the very young, and the elderly. An estimated 800,000-4,000,000 infections occur each year in the United States, most of them as individual cases apparently unrelated to outbreaks. Animals used for food production are common carriers of salmonellae, which may subsequently contaminate foods such as meat, dairy products, and eggs. Foods often implicated in outbreaks include poultry and poultry products, meat and meat products, dairy products, egg products, seafood and fresh produce. Between 128,000-640,000 of these infections

are associated with *Salmonella enteritidis* (SE) in eggs. Over the past decade, more than 500 outbreaks have been attributed to SE with more than 70 deaths. In 1994, an upper limit estimate of 224,000 people became ill from consuming contaminated ice cream in one outbreak alone.

***Salmonella* Research Questions**

- S1. What is the incidence of salmonellosis that can be attributed to cross-contamination, particularly during food preparation in the kitchen?
- S2. What are the sequelae of acute salmonellosis in humans? How common are they, and which subpopulations are most affected?
- S3. How does *Salmonella* colonize both animals and humans? What are the specific colonization factors and their role in pathogenesis?
- S4. What is the value of *Salmonella* serotyping? Can we determine seasonality of occurrence and geographic distribution in animals and/or humans? Is it needed, or is it enough to evaluate interventions and to identify emerging pathogens and/or antibiotic resistance? Are alternative methods available to subtype more cost effective, and can they be correlated with serotype?
- S5. Do interventions that control the occurrence of *Salmonella* in the food chain also control the occurrence of other foodborne pathogens and non-pathogenic microorganisms? Do interventions that have an impact on human salmonellosis also control illness caused by other microorganisms?
- S6. What is known about the microbial ecology of *Salmonella*? What are the environmental reservoirs for *Salmonella* along the farm-to-table continuum? What are the survival and growth characteristics before and after cooking?

Research Agenda

III. *Campylobacter*

Campylobacter is the most frequently identified cause of acute infectious diarrhea internationally and is the most commonly isolated bacterial intestinal pathogen in the United States. It has been estimated that between 170,000-2,100,000 cases of campylobacteriosis occur annually with an associated 120-360 deaths. *Campylobacter jejuni* and *Campylobacter coli* (two closely related species) are commonly foodborne, and are the infectious agents most frequently described in association with Guillain-Barré Syndrome, perhaps as frequently as 1 in a 1000 cases. Several prospective studies have implicated raw or undercooked chicken as major sources of *C. jejuni/coli* infections. Unpasteurized milk and untreated water have also caused outbreaks of disease.

***Campylobacter* Research Questions**

- C1. What is the incidence of campylobacteriosis that can be attributed to cross-contamination, particularly during food preparation in the kitchen?
- C2. What are the sequelae of acute campylobacteriosis in humans? How common are they, and which subpopulations are most affected? Which strains (serotypes) of *Campylobacter* are associated with Guillain-Barré Syndrome?
- C3. How does *Campylobacter* colonize both animals and humans? What are the specific virulence factors, including colonization?
- C4. What interventions in the food chain (particularly farm practices) will decrease human illness or infections by *Campylobacter*? How can we measure the impact of interventions?

- C5. What is the best method of subtyping *Campylobacter* for epidemiologic purposes?
- C6. How can *Campylobacter* be detected in foods and in humans economically?

Research Agenda

IV. *Listeria*

Listeria monocytogenes is ubiquitous and is recognized as an important foodborne pathogen that can replicate at refrigeration temperatures. Listeriosis is a severe disease (e.g., causing conditions such as meningitis, spontaneous abortion, and septicemia) with a high fatality rate (20-30% of cases). Host susceptibility plays a major role particularly with infants, the elderly, pregnant women, and immunocompromised individuals. Epidemiological data implicate meat, poultry, and dairy products among the food vehicles of listeriosis. Reports covering 1971-1994 indicate the prevalence of *L. monocytogenes* in meats to be highly variable with about 16 percent of products being positive. Data accumulated during the past ten years indicate that the highest risk foods are often ready-to-eat and stored at refrigeration temperatures for days to weeks. Public health agencies and regulatory agencies have established a zero tolerance for *L. monocytogenes* in cooked, ready-to-eat food.

Listeria Research Questions

- L1. How common are gastroenteritis, flu-like, or other "mild" symptoms due to *Listeria monocytogenes* infection? What are the sequelae of acute listeriosis in humans? How common are they and which subpopulations are most affected?
- L2. What is the infectious dose and the dose-response relationship of *L. monocytogenes* for humans and animals? Does a threshold exist below which illness does not occur? Is a zero tolerance standard supportable by scientific evidence?
- L3. Is the presence of *L. monocytogenes* a concern in raw food products?
- L4. Where is *L. monocytogenes* in the production/processing plant, and can it be eliminated?
- L5. Are methods available to isolate and identify *L. monocytogenes* from foods and human fecal specimens?

Research Agenda

V. Enterohemorrhagic *Escherichia coli* in General and *E. coli* O157:H7 Specifically

Several strains of the bacterium *E. coli* cause a variety of diseases in humans and animals. Some strains produce Shiga toxins and are associated with a particularly severe form of human disease in many countries around the world; they are called enterohemorrhagic *E. coli* (EHEC). *E. coli* O157:H7 and a few other serotypes of EHEC (e.g. O111:NM and O26:H11) cause hemorrhagic colitis, which begins with watery diarrhea and severe abdominal pain and rapidly progresses to passage of bloody stools, and has been associated with Hemolytic Uremic Syndrome (HUS). HUS is a life-threatening complication characterized by acute kidney failure, and is particularly serious in young children. *E. coli* O157:H7 has its primary reservoir in cattle (also in deer and sheep), but the dynamics of *E. coli* O157:H7 and other EHEC in food-producing animals are not well understood. An estimated 25,000 cases of foodborne illness can be attributed to *E. coli* O157:H7 each year with

as many as 100 deaths resulting. Recent *E. coli* O157:H7 outbreaks have been associated with ground beef, venison, raw milk, lettuce and minimally-processed and fresh fruit juices. The most recent outbreak in the fall of 1996 in three western states and British Columbia which was associated with unpasteurized apple juice, sickened 66 people and caused the death of one child. Much less is known about other EHEC, some of which have caused major outbreaks in Australia and Europe.

E. coli Research Questions

- E1. What is the incidence of EHEC and *E. coli* O157:H7 disease/infection in humans and animals in the United States? What is the relative incidence among different subpopulations?
- E2. What are the virulence factors associated with EHEC? Are all Shiga toxin-producing *E. coli* (STEC) pathogenic for humans, i.e., are all STEC also considered EHEC? Which virulence factors are associated with bloody diarrhea, hemolytic uremic syndrome, or other sequelae?
- E3. How do EHEC colonize both animals and humans?
- E4. What is the infectious dose and the dose-response relationship of EHEC and *E. coli* O157:H7 for humans and animals? Does a threshold exist below which illness does not occur? Is a zero tolerance standard supportable by scientific evidence? Can dose response data calculated for *Shigella sp.* or *S. dysenteriae* type 1, be used for EHEC and *E. coli* O157:H7?
- E5. What is known about the microbial ecology of EHEC and *E. coli* O157:H7? What are the environmental reservoirs for EHEC and *E. coli* O157:H7 along the farm-to-table continuum? What are survival and growth characteristics before and after cooking?
- E6. Should we be screening *E. coli* from human disease, and/or from food, for toxin production, or for the presence of stx, eae, hyl, EHEC plasmid, adhesins, etc.? Should we be screening human fecal specimens and/or foods for the presence of Shiga toxins?

The Risk Assessment Framework

The Food Safety Research Working Group also evaluated the research agenda as it should or could fit with the traditional risk assessment framework. Subheadings within each classification category describe specific research issues in terms of both risk assessment and HACCP.

Classification System for Research Questions

Classification	General	<i>Salmonella</i>	<i>Campylobacter</i>	<i>Listeria</i>	EH
Hazard ID:					
Incidence (human, animal, food)	1, 6, 10	S1, S6	C1		E1,
Pathogenesis	2, 7	S2, S3, S6	C2, C3	L1	E2,E3
Diagnostics	2	S4	C5	L5	E6
Food Vehicles		S4	C5	L3, L5	E6
Dose-Response Assessment					

General Population	2, 4	S2	C2	L1, L2	E4
Sub-Populations	2, 4	S2	C2	L1, L2	E4
Exposure Assessment					
Points of Introduction	6, 7			L4	E5
Growth and Decline	2, 6	S6		L2	
Cross-Contamination		S1	C1	L4	
Risk Characterization	2, 3, 5	--	C4	--	--
Risk Management			--		--
Interventions	4, 10	S5		L4	
CCP Identification	2, 3			L4	
Sub-Populations	2, 4				
Cost-Benefit Analysis	9	--	--	--	--
Risk Communication/Education/Consumer Behavior	8	--	--	--	--

FoodNet Update

First year (1996) data from the joint USDA, FDA, CDC FoodNet project, which was summarized and reported to Congress in February 1997, indicate that *Campylobacter* is the most frequent cause of foodborne disease in the United States ⁽¹³⁾. This is something that public health officials had suspected for some time but could not demonstrate, because current surveillance (other than FoodNet) data are based mainly on the reports of outbreaks of disease, while *Campylobacter* primarily causes sporadic disease. FSIS is particularly concerned because several small prospective studies have linked the preparation or consumption of raw or undercooked poultry with *Campylobacter* infections. That concern was heightened by a 1996 conference sponsored by NIH, which linked acute *Campylobacter* infections to severe outcomes such as Guillain-Barré Syndrome. Consequently, FSIS convened a meeting with CDC, FDA, and ARS scientists to discuss research needs, particularly methodology to improve the costly and time-consuming methods now required to sample, isolate, and identify this pathogen. This will be the first step to develop methods and procedures that FSIS can then apply in field studies necessary to generate information for risk estimates and intervention strategies.

Future Directions

The Research Agenda outlined above will be used to develop an operational plan for meeting research needs. However, the Food Safety Research Working Group also has a broader impact on food safety activities:

- Individuals on the working group are also participants in the Presidential Food Safety Initiative, which will expand the FoodNet early warning system for foodborne illness, enhance seafood safety inspections and expand food safety research, risk assessment, training, and education.
- In its final rule on Pathogen Reduction and HACCP, FSIS stated that the White House Office of Science and Technology Policy will oversee a task force to determine what research and data collection are needed to develop a workable approach to quantitative risk assessment for foodborne pathogens and determine the most cost-effective way of conducting the necessary research. The Food Safety Research Working Group may be reconvened at a later date to carry out this task.
- While ARS is charged with conducting research for USDA agencies, its efforts alone cannot be expected to address or answer all of the questions posed in the Research Agenda. For research requiring human health based needs, FSIS will work with CDC, NIH and FDA. This inter-agency approach to food safety research planning and implementation characterizes the complementary nature of the research agenda and its cross-cutting needs and prevents unnecessary duplication of effort. The Agency will also invite participation of academic institutions and the industry as appropriate to meet its food safety objectives in a timely way.

APPENDIX 1

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APPENDIX 2

Fault-Tree Analysis

Development and Documentation of *E. coli* O157:H7 Ground Beef Model

Following is a proposed structure for a fault tree model developed by Peg Coleman, of the Food Safety and Inspection Service, and Tanya Roberts, of the Economic Research Service. Data from the various stages of the farm-to-table chain can be incorporated into the model to determine the risk associated with the ground beef.

QUANTITATIVE EVIDENCE

NODE 3 - What beef products are characterized for O157:H7?
Prevalence data from nationwide random and targeted surveys:
4/2081 (FSIS steer/heifer baseline, 1994)
0/563 (FSIS ground beef baseline, 1995)
3/5291 (FSIS testing program, 1995)
2/2485 federal plants

NODE 7 - How is ground beef cooked?
23% serve undercooked
(Klontz et al., 1995)
3% rare, 16% medium-rare, 17% m
23% M-W, 39% well, 3% don't eat
(TX consumers, McIntosh et al.,

1/2740 retailers
 0/37 state plants
 0/29 imports

NODE 4 - Where is ground beef consumed?

52% fast food
 33% at home
 10% restaurant or institution
 5% other locations
 (ERS data)

NODE 5 - Is ground beef eaten cooked?

95% eaten cooked, 5% raw, steak tartare
 (Klontz et al., 1995).

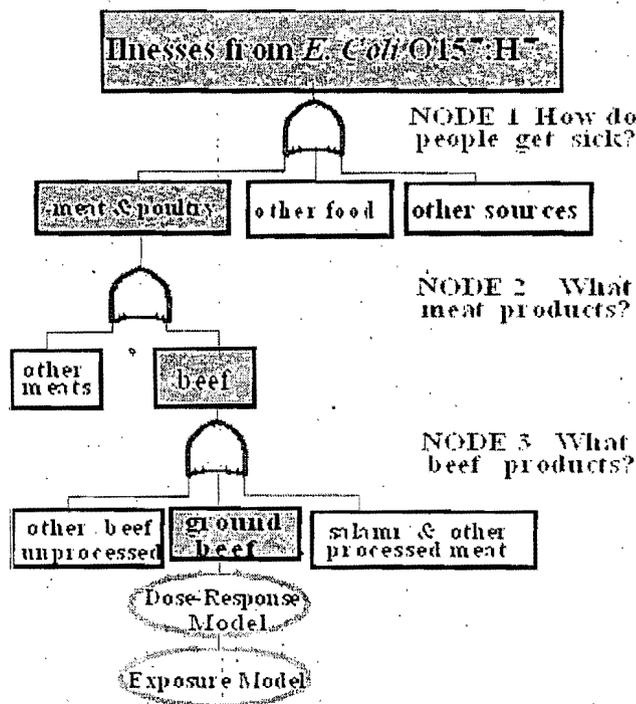
NODE 10 - Does supermarket grind?
 94% grind own ground beef
 6% purchase fine grind or packa
 (ERS data, 1990 industry survey)

NODE 14 - What are supermarket so
 for ground beef?

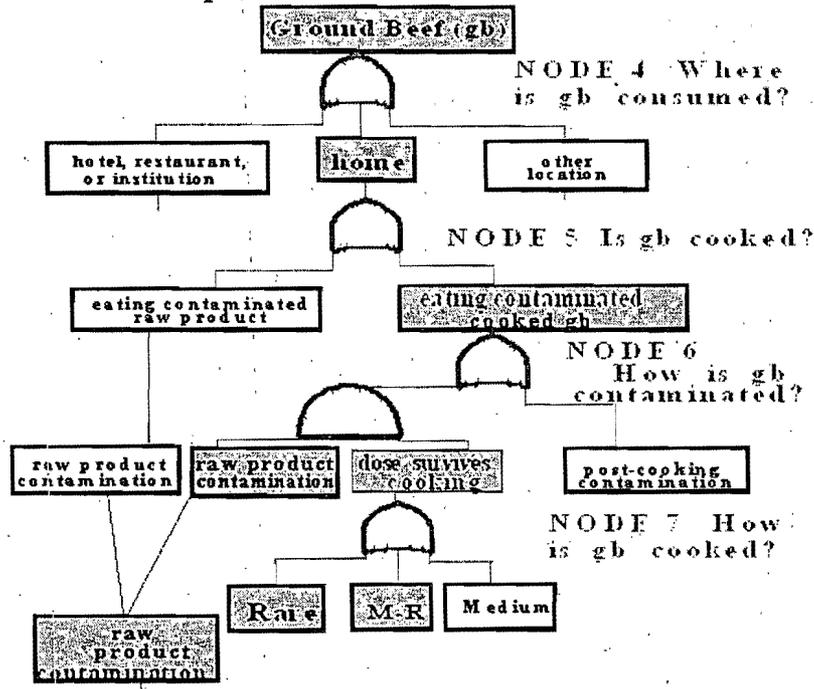
16% coarse ground
 9% beef for grinding
 5% fine ground
 70% boxed beef (trim)
 (ERS data, 1990 industry survey)

Contamination probability for eac

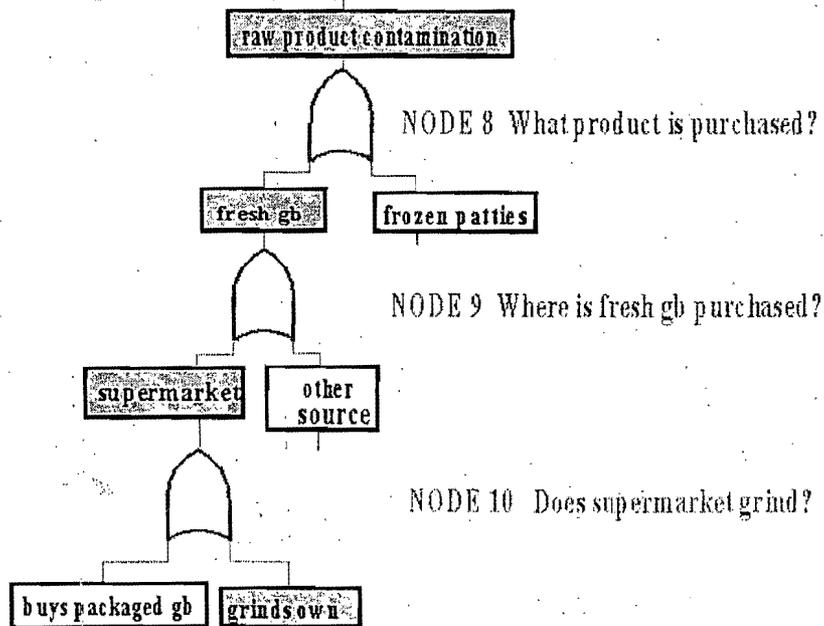
Risk Characterization



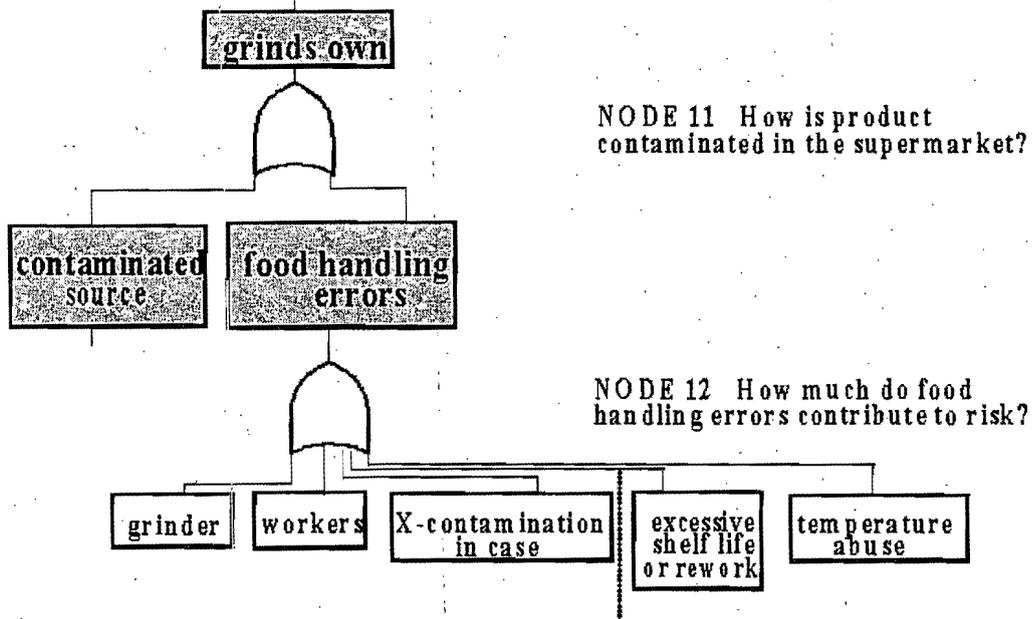
FTA Exposure Model



FTA Exposure Model (con't)

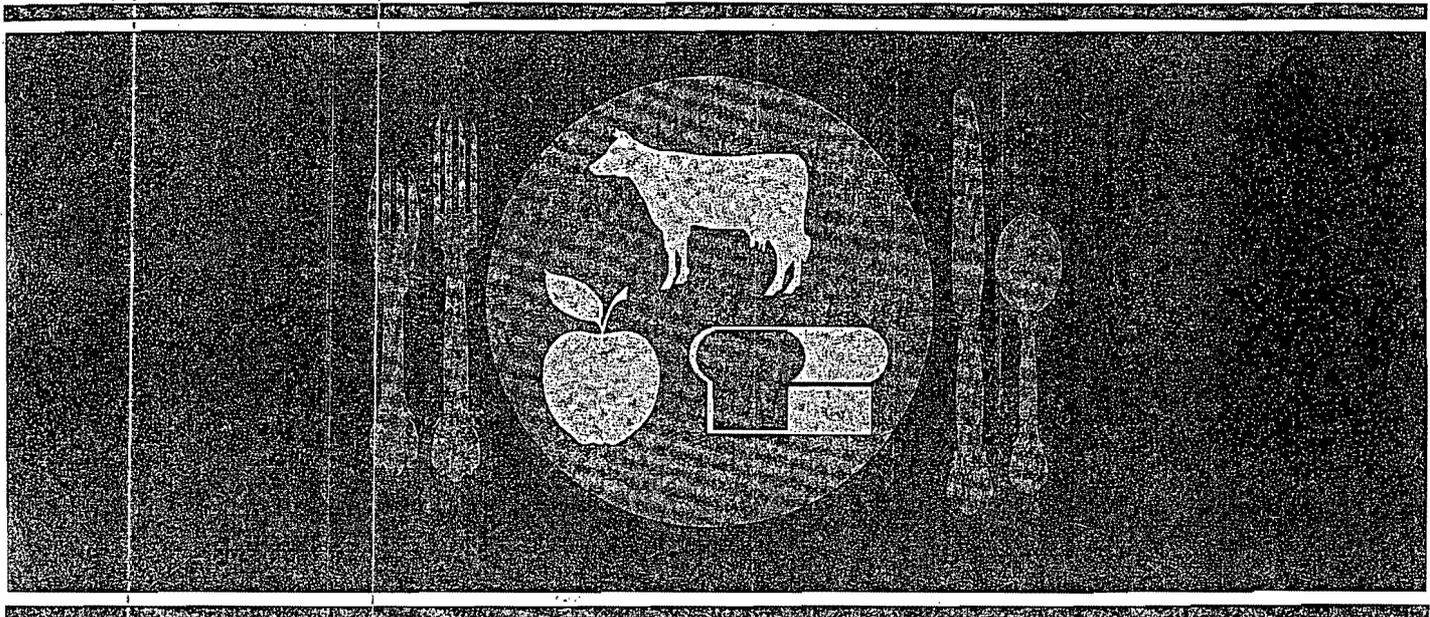


FTA Exposure Model (con't)



FOOD SAFETY FROM FARM TO TABLE

A National Food-Safety Initiative



A Report to the President
May 1997



**FOOD SAFETY FROM FARM TO TABLE:
A NATIONAL FOOD-SAFETY INITIATIVE**

**REPORT TO THE PRESIDENT
MAY 1997**

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EXECUTIVE SUMMARY

While the American food supply is among the safest in the world, there are still millions of Americans stricken by illness every year caused by the food they consume, and some 9,000 a year--mostly the very young and elderly--die as a result. The threats are numerous and varied, ranging from *Escherichia coli* (*E. coli*) O157:H7 in meat and apple juice, to *Salmonella* in eggs and on vegetables, to *Cyclospora* on fruit, to *Cryptosporidium* in drinking water--and most recently, to hepatitis A virus in frozen strawberries.

In his January 25, 1997 radio address, President Clinton announced he would request \$43.2 million in his 1998 budget to fund a nationwide early-warning system for foodborne illness, increase seafood safety inspections, and expand food-safety research, training, and education. The President also directed three Cabinet members--the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency--to identify specific steps to improve the safety of the food supply. He directed them to consult with consumers, producers, industry, states, universities, and the public, and to report back to him in 90 days. This report responds to the President's request and outlines a comprehensive new initiative to improve the safety of the nation's food supply.

The goal of this initiative is to further reduce the incidence of foodborne illness to the greatest extent feasible. The recommendations presented in this report are based on the public-health principles that the public and private sectors should identify and take preventive measures to reduce risk of illness, should focus our efforts on hazards that present the greatest risk, and should make the best use of public and private resources. The initiative also seeks to further collaboration between public and private organizations and to improve coordination within the government as we work toward our common goal of improving the safety of the nation's food supply.

Six agencies in the federal government have primary responsibility for food safety: two agencies under the Department of Health and Human Services (HHS)--the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC); three agencies under the Department of Agriculture (USDA)--the Food Safety and Inspection Service (FSIS), the Agricultural Research Service (ARS), and the Cooperative State Research, Education, and Extension Service (CSREES); and the Environmental Protection Agency (EPA). Over the last 90 days, these agencies have worked with the many constituencies interested in food safety to identify the greatest public-health risks and design strategies to reduce these risks. USDA, FDA, CDC, and EPA have worked to build consensus and to identify opportunities to better use their collective resources and expertise, and to strengthen partnerships with private organizations. As directed by the President, the agencies have explored ways to strengthen systems of coordination, surveillance, inspections, research, risk assessment, and education.

This report presents the results of that consultative process. It outlines steps USDA, HHS, and EPA will take this year to reduce foodborne illness, and spells out in greater detail how agencies

It will use the \$43.2 million in new funds requested for fiscal year 1998. It also identifies issues the agencies plan to consider further through a public planning process.

The actions in this report build on previous Administration steps to modernize our food-safety programs and respond to emerging challenges. As part of the Vice President's National Performance Review (NPR), the agencies have encouraged the widespread adoption of preventive controls. Specifically, the NPR report urged implementation of Hazard Analysis and Critical Control Point (HACCP) systems to ensure food manufacturers identify points where contamination is likely to occur and implement process controls to prevent it. Under HACCP-based regulatory programs there is a clear delineation of responsibilities between industry and regulatory agencies: Industry has the primary responsibility for the safety of the food it produces and distributes; the government's principle role is to verify that industry is carrying out its responsibility, and to initiate appropriate regulatory action if necessary.

The Administration has put in place science-based HACCP regulatory programs for seafood, meat, and poultry. In late 1995, the Administration issued new rules to ensure seafood safety. In July 1996, President Clinton announced new regulations to modernize the nation's meat and poultry inspection system. The Early-Warning System the President announced in January will gather critical scientific data to further improve these prevention systems. Additional actions outlined in this report will encourage the use of HACCP principles throughout the food industry.

The need for further action is clear. 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 for there to be a risk of illness; for others, we do not have the ability to detect their presence in foods. The public-health system in this country has had a limited ability to identify and track the causes of foodborne illness; and federal, state, and local food-safety agencies need to improve coordination for more efficient and effective response to outbreaks of illness. Resource constraints increasingly limit the ability of federal and state agencies to inspect food processing facilities (e.g., years can go by before some plants receive a federal inspection.) Increasing quantities of imported foods flow into this country daily with limited scrutiny. Some food processors, restaurateurs, food-service workers, supermarket managers, and consumers are unaware of how to protect food from the threat of foodborne contaminants. These and other deficiencies will be addressed by key Administration actions outlined in this report and described below.

Enhance Surveillance and Build an Early-Warning System

As the President announced in January, the Administration will build a new national early-warning system to help detect and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks. For example, with FY98 funds, the Administration will:

Enhance Surveillance. The Administration will expand from five to eight the number of FoodNet active surveillance sentinel sites. Personnel at these sentinel sites actively look for foodborne diseases. Existing sites are in Oregon, Northern California, Minnesota,

Connecticut, and metropolitan Atlanta. New sites will be in New York and in Maryland, with an eighth site to be identified. CDC will also increase surveillance activities for certain specific diseases. For example, CDC will begin a case-control study of hepatitis A to determine the proportion of cases due to food contamination, FDA will strengthen surveillance for *Vibrio* in Gulf Coast oysters, and CDC will strengthen surveillance for *Vibrio* in people.

Equip FoodNet sites and other state health departments with state-of-the-art technology, including DNA fingerprinting, to identify the source of infectious agents and with additional epidemiologists and food-safety scientists to trace outbreaks to their source.

Create a national electronic network for rapid fingerprint comparison. CDC will equip the sentinel sites and other state health departments with DNA fingerprinting technology, and will link states together to allow the rapid sharing of information and to quickly determine whether outbreaks in different states have a common source.

Improve Responses to Foodborne Outbreaks

At the federal level, four agencies are charged with responding to outbreaks of foodborne and waterborne illness: CDC, FDA, FSIS, and EPA. States and many local governments with widely varying expertise and resources also share responsibility for outbreak response. The current system does not assure a well-coordinated, rapid response to interstate outbreaks. To ensure a rapid and appropriate response, with FY98 funds, agencies will:

Establish an intergovernmental Foodborne Outbreak Response Coordinating Group Federal agencies will form an intergovernmental group, the Foodborne Outbreak Response Coordinating Group, to improve the approach to interstate outbreaks of foodborne illness. This group will provide for appropriate participation by representatives of state and local agencies charged with responding to outbreaks of foodborne illness. It will also review ways to more effectively involve the appropriate state agencies when there is a foodborne outbreak.

Strengthen the infrastructure for surveillance and coordination at state health departments. CDC, EPA, FDA, and FSIS will assess and catalogue available state resources, provide financial and technical support for foodborne-disease-surveillance programs, and other assistance to better investigate foodborne-disease outbreaks.

Improve Risk Assessment

Risk assessment is the process of determining the likelihood that exposure to a hazard, such as a foodborne pathogen, will result in harm or disease. Risk-assessment methods help characterize the nature and size of risks to human health associated with foodborne hazards and assist regulators in making decisions about where in the food chain to allocate resources to control those hazards. To improve risk-assessment capabilities, with FY98 funds, the agencies will:

Establish an interagency risk assessment consortium to coordinate and guide overarching federal risk-assessment research related to food safety.

Develop better data and modeling techniques to assess exposure to microbial contaminants, and simulate microbial variability from farm to table. Such techniques will help scientists estimate, for example, how many bacteria are likely to be present on a food at the point that it is eaten (the end of the food chain), given an initial level of bacteria on that food as it entered the food chain.

Develop New Research Methods

Today, many pathogens in food or animal feed cannot be identified. Other pathogens have developed resistance to time-tested controls such as heat and refrigeration. With FY98 funds, the agencies will focus research immediately to:

Develop rapid, cost-effective tests for the presence in foods of pathogens such as *Salmonella*, *Cryptosporidium*, *E. coli* O157:H7, and hepatitis A virus in a variety of foods, especially foods already associated with foodborne illness.

Enhance understanding of how pathogens become resistant to food-preservation techniques and antibiotics.

Develop technologies for prevention and control of pathogens, such as by developing new methods of decontamination of meat, poultry, seafood, fresh produce, and eggs.

Improve Inspections and Compliance

With FY98 funds, the agencies will pursue several strategies to increase inspections for higher-risk foods; the agencies will, among other things:

Implement seafood HACCP. FDA will add seafood inspectors to implement new seafood HACCP regulations, and will work with the Commerce Department to integrate Commerce's voluntary seafood-inspection program with FDA's program.

Propose preventive measures for fresh fruit and vegetable juices. Based on the best science available, FDA will propose appropriate regulatory and non-regulatory options, including HACCP, for the manufacture of fruit and vegetable juice products.

Propose preventive measures for egg products. Based on the best science available, FSIS will propose appropriate regulatory and non-regulatory options, including HACCP, for egg products.

Identify preventive measures to address public-health problems associated with produce such as those recently associated with hepatitis A virus in frozen strawberries and *E. coli* O157:H7 on lettuce. These measures will be identified through a

comprehensive review of current production and food-safety programs including inspection, sampling, and analytical methods.

Improve coverage of imported foods. FDA will develop additional mutual recognition agreements (MRAs) with trading partners, initiate a federal-state communication system covering imported foods, and FDA and FSIS will provide technical assistance to countries whose products are implicated in a foodborne illness.

Further Food-Safety Education

Foodborne illness remains prevalent throughout the United States, in part because food preparers and handlers at each point of the food chain are not fully informed of risks and related safe-handling practices. Understanding and practicing proper food-safety techniques, such as thoroughly washing hands and cooking foods to proper temperatures, could significantly reduce foodborne illness. The Administration--working in partnership with the private sector--will use FY98 funds to, among other things:

Establish a Public-Private Partnership for Food-Safety Education. FDA, USDA, CDC, and the Department of Education will work with the food industry, consumer groups and the states to launch a food-safety public awareness and education campaign. The Partnership will develop, disseminate, and evaluate a single food-safety slogan and several standard messages. Industry has pledged \$500,000 to date to support the partnership's activities and plans to raise additional funds.

Educate professionals and high-risk groups. Agencies will better educate physicians to diagnose and treat foodborne illness; strengthen efforts to educate producers, veterinarians, and state and local regulators about proper animal drug use and HACCP principles; and work with the Partnership to better train retail- and food-service workers in safe handling practices and to inform high-risk groups about how to avoid foodborne illness, e.g., in people with liver disease, illness that may be caused by consuming raw oysters containing *Vibrio vulnificus*.

Enhance federal-state inspection partnerships. New federal-state partnerships focused on coordinating inspection coverage (particularly between FDA and the states) will be undertaken, in an important step towards ensuring the effectiveness of HACCP and ensuring that the highest-risk food plants are inspected at least once per year.

Continue the Long-Range Planning Process

Through this initiative, and through previous activities, HHS, USDA, and EPA have laid the groundwork for a strategic planning effort. There is a broad recognition of the need to carefully implement the initiative's programs, and to consider how to apply preventive measures in other areas of concern. A strategic-planning effort is needed to build on this common ground, and to tackle some of the difficult public-health, resource, and management questions facing federal

food-safety agencies. The federal food-safety agencies are committed to continuing to meet with stakeholders, ultimately to produce a strategic plan for improving the food-safety system.

A NEW INTERAGENCY STRATEGY TO PREVENT FOODBORNE DISEASE

In his radio message on January 25, 1997, President Clinton announced a new initiative to improve the safety of the nation's food supply. The President announced he would request \$43.2 million in his 1998 budget to fund a nationwide early-warning system for foodborne illness, enhance seafood safety inspections, and expand food-safety research, risk assessment, training, and education (see Appendix A). President Clinton also directed the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency to work with consumers, producers, industry, states, universities, and the public to identify additional ways to reduce the incidence of foodborne illness and to ensure our food supply is the safest in the world. The President directed Secretaries Glickman and Shalala and Administrator Browner to report to him with recommendations in 90 days. He instructed them to consult with a broad range of stakeholders in the food-safety system and to explore opportunities for public-private partnerships to improve food safety. And he asked that their recommendations include ways to improve surveillance, inspections, research, risk assessment, education, and coordination among local, state, and federal health authorities.

To start the discussion, the agencies issued a draft document summarizing their initial ideas. Subsequently, the agencies held two public meetings on March 5 and March 31-April 2, and established public dockets for written comments.

This report is the result of that 90-day process of deliberation and discussion among all stakeholders in the nation's food-safety system, including federal, state, and local agencies, consumers, academia, food producers, processors, manufacturers, distributors, representatives of the retail and restaurant sectors, veterinarians and health professionals, and many others.

The goal of this initiative is to reduce the incidence of foodborne illness to the extent possible. The recommendations presented in this report are based on the public-health principles that society should identify and take preventive measures to reduce the risk of illness and that it should focus its efforts on hazards that present the greatest risks.

FOODBORNE ILLNESS: A SIGNIFICANT PUBLIC-HEALTH PROBLEM

The Council for Agricultural Science and Technology, a private nonprofit organization, estimated in its 1994 report, *Foodborne Pathogens: Risks and Consequences*, that as many as 9,000 deaths and 6.5 to 33 million illnesses in the United States each year are food-related. The Department of Agriculture (USDA) estimates that medical costs and productivity losses for 7 specific pathogens in food have been estimated to range between \$6.5 billion and \$34.9 billion annually. Total costs

for all foodborne illnesses are likely to be much higher. Those estimates do not include the total burden placed on society by the chronic illness caused by some foodborne pathogens.

Several population groups have increased susceptibility to foodborne infections, such as persons with lowered immunity due to HIV/AIDS and those on medications for cancer treatment or for organ transplantation, as well as pregnant women and their fetuses, young children, and the elderly. Patients taking antibiotics or antacids are also at greater risk of infection from some pathogens. The consequences of foodborne disease are particularly serious for those with inadequate access to health care, such as homeless people, migrant farm workers, and others of low socioeconomic status.

Sources of Foodborne Contamination

Bacteria and other infectious organisms are pervasive in the environment.

- *Salmonella* serotype Enteritidis enters eggs directly from the hen.
- Bacteria (occasionally pathogenic) inhabit the surfaces of fruits and vegetables.
- Molds and their toxic byproducts can develop in grains during unusually wet or dry growing seasons, damage and stress during harvesting, or during improper storage.
- Seafood can become contaminated from agricultural animal manures and wastes and other runoff, as well as by sewage, microorganisms, and toxins present in marine environments.
- Many organisms that cause foodborne illness in humans can be part of the normal flora of the gastrointestinal tract of food-producing animals without any adverse effects to the animals.
- Milk, eggs, seafood, poultry, and meat can become contaminated from contaminated feed, misuse of veterinary drugs, or poor farming practices, in particular, mismanagement of animal manures, including production and harvesting activities.
- Foods can become contaminated during processing due to malfunctioning or improperly sanitized equipment, misuse of cleaning materials, rodent and insect infestations, and improper storage.
- Foods can become contaminated in retail facilities and in homes through poor food-handling practices.

Some microbial pathogens give rise to diseases that are far more serious than the uncomfortable but relatively temporary inconvenience of diarrhea and vomiting, which are the most common symptoms of so-called "food poisoning." Foodborne infections can result in very serious immediate consequences, such as spontaneous abortion, as well as long-lasting conditions, such as reactive arthritis, Guillain-Barré syndrome (the most common cause of acute paralysis in adults and children), and hemolytic uremic syndrome (HUS), which can lead to kidney failure and death, particularly in young children. Some of the microbial pathogens that have been the source of foodborne illness cases and outbreaks recently include, *Salmonella*, *Campylobacter*, Shiga-like toxin-producing *Escherichia coli*, *Vibrio*, *Toxoplasma gondii*, *Cryptosporidium parvum*, Norwalk virus, and hepatitis A. A full description of these pathogens, the foodborne illnesses they cause, and frequently implicated foods may be found in Appendix B. In addition to microbial pathogens, other substances may contaminate foods and cause foodborne illness. Among these are naturally occurring mycotoxins and marine toxins.

THE CURRENT SYSTEM FOR PROTECTING FOOD

Our food-safety system, although generally successful in protecting the public, is characterized by complexity and diversity. Regulatory authority is divided among federal, state, and local governments. The private sector has the primary responsibility for ensuring the safety of the food that it produces. From the farm to the consumer's dinner table, the responsibilities can be summarized as follows:

- Consumer education on food handling and storage in the home is the primary responsibility of USDA's Cooperative State Research, Education, and Extension Service (CSREES), FSIS, FDA, and CDC. FSIS, with responsibility for meat, poultry and most egg products, FDA, with jurisdiction over all other foods, and CDC, with epidemiological capabilities, all produce educational materials. FDA and FSIS staff consumer hotlines, and all agencies have web sites. CSREES has an enormous network of extension agents across the country, and FDA has Public Affairs Specialists in offices around the country to respond to inquiries and conduct safe handling programs for consumers, health professionals, and the media.
- In the home, consumers have a responsibility for proper handling and storage of food. Because consumer use of proper food-handling practices can prevent many cases of foodborne illness, FSIS issued rules requiring the use of a safe-handling label on raw meat and poultry products.
- On the farm, food is regulated by state agencies supported principally by the Environmental Protection Agency (EPA), which acts to ensure that pesticides are approved for safe use; by the FDA, which oversees use of drugs and feed in milk- and food-producing animals; and by USDA's Animal and Plant Health Inspection Service (APHIS), which is concerned with food-animal-disease control. Federal responsibility also covers production and harvesting activities that discharge wastewater to surface and to

ground waters and solid waste to land, all of which could contaminate growing and processing waters or grazing land. Animal manures are currently excluded from the definition of solid waste under EPA's solid-waste-disposal regulation, and therefore, an EPA regulatory mechanism does not exist for these materials. The ecology of human pathogens in food animals and in their manures produced on farms and ranches, in slaughter operations, and in processing facilities has received little attention in the past. Regulations under the Clean Water Act require large animal-feeding operations to obtain a discharge permit.

- Food processing for foods other than meat, poultry, and egg products (except shell eggs) is regulated by FDA, whose inspectors are responsible for visiting about 53,000 plants periodically, with emphasis on the highest risk foods or processing techniques. FDA devotes about 700 inspectors and laboratory personnel to this activity. Meat, poultry, and all other egg products are regulated by FSIS, whose inspectors are present in slaughter and processing establishments to ensure that these products are safe, wholesome, and properly labeled. State and local governments also inspect food processors, with varying frequencies and under varying standards.

- Food being transported in interstate commerce is subject to federal and state regulation. In 1996, FSIS and FDA jointly published an Advanced Notice of Proposed Rulemaking (ANPR) on whether regulations are needed to govern the handling of meat, poultry, seafood, eggs, and other foods susceptible to microbial contamination during transportation. FDA and FSIS will evaluate the comments and information received in response to the ANPR as a basis for determining what, if any, regulatory approach to take, including development of guidelines. These guidelines may include such elements as suggested performance standards for temperature control, providing information on prior cargo, and cleaning information for the food-shipper's use, to ensure the safety of the food at its destination.

- Importation of food from foreign countries is overseen by FSIS for meat, poultry, and most egg products and by FDA for all other foods. If an imported food is suspect, it can be tested for contamination and its entry into the United States denied.

- Restaurants, supermarkets, and institutional food services (such as schools and hospitals) fall under the FDA's retail food-protection program, a cooperative federal-state food-safety effort operated under the Public Health Service Act. FDA has regulatory authority under the Federal Food, Drug, and Cosmetic Act over retail establishments because the food used in these establishments traveled in interstate commerce, however, the PHS Act provides the means for more efficient regulation and use of available resources, as well as broader inspection coverage. FDA publishes the Food Code, which consists of model recommendations that states and local authorities adopt and use to regulate retail food establishments. FDA, along with FSIS and CDC, work with states biennially to update the Food Code.

- National standards for drinking water and criteria for surface waters are set by EPA and enforced generally by local public-water authorities; FDA establishes complementary standards for bottled water.
- Surveillance of foodborne illness is primarily the responsibility of state and local health departments and the CDC, which seek to identify cases of illness, determine their sources, and control outbreaks. CDC conducts field investigations of foodborne diseases only at the request of state health departments, which have the authority to implement outbreak control measures. FDA, FSIS, or both are called in when food within their jurisdiction is suspected. FDA and FSIS are charged with ensuring that foods implicated in a foodborne illness outbreak and traveling in interstate commerce are removed from the market.
- Research serves many purposes in reducing the incidence of foodborne illness and is integral to the programs of all public-health agencies. Research is essential to evaluate effectiveness of surveillance initiatives, control and prevention strategies, conduct risk assessments, and verify effectiveness of preventive techniques such as HACCP. Research into the cause and transmission of foodborne illness is the primary responsibility of CDC, FDA, ARS, CSREES, and EPA. The development of screening and analytic methods to rapidly and accurately identify and characterize foodborne hazards, identifying and tracking to the source the causes of foodborne illness, is the responsibility of FDA, ARS, CSREES, EPA, and CDC. Research to develop preventive technologies, ranging from new production techniques, to disinfection and food-processing techniques to reduce levels of pathogens, is the primary responsibility of ARS, CSREES, FDA, and industry. Basic research is conducted largely in university laboratories on the biology, genetics, pathogenesis, natural history, and epidemiology of microorganisms implicated in foodborne disease and is actively supported by the NIH, and in particular, by the National Institute of Allergy and Infectious Diseases. These efforts are focused on understanding the disease process and designing prevention and treatment strategies. Other agencies of the federal government also support related research in universities. The private sector supports research within its own laboratories and in universities.

**THE FOOD-SAFETY SYSTEM MUST BE PREPARED
FOR THE 21st CENTURY**

The system for identifying and preventing foodborne illnesses described above was largely created in the early 1900s. It must be modernized. The system cannot properly identify, track, and control food-related illness, or prevent, to the extent possible, future cases from occurring. In 1981, FDA inspected food firms every 2-3 years, but can now visit those firms, on average, only once every 10 years (although some plants that produce higher-risk foods may be inspected more frequently). State and federal resources are not closely coordinated. Our understanding of some disease-causing organisms is so limited that our ability to protect the public health is seriously constrained.

The Clinton Administration has already taken a number of steps to improve the safety of the food supply.

- In 1993, the Vice President's National Performance Review issued a report recommending that the government and industry should move toward a system of preventive controls.
- FSIS and FDA issued regulations that will require the meat, poultry, and seafood industries to follow HACCP procedures. These HACCP rules require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety-assurance actions. FSIS and FDA will streamline their current regulations as part of their conversion to HACCP.
- In 1994, CDC embarked upon a strategic program to detect, prevent, and control emerging infectious disease threats, some of which are foodborne, and has made significant progress toward this goal in each successive year.
- The Food Quality Protection Act of 1996, including many provisions of the Administration's bill, streamlined regulation of pesticides by FDA and EPA and put important new public-health protections in place, especially for children.
- Last year, the President signed the Safe Drinking Water Act of 1996, which includes regulatory improvements to help states and water-utility managers prevent drinking-water contamination problems. Resources are provided for the first time for drinking-water infrastructure that will help hundreds of communities protect their residents from harmful contaminants.

These advances are significant, but they are not enough. New pathogens, new food products, huge increases in imported foods, the growing importance of food exports, and increasing antimicrobial resistance among foodborne pathogens present new challenges to the nation's food-safety programs. The food-safety system is in need of change, especially change that builds on the preventive principles embodied in HACCP.

IMMEDIATE ACTIONS TO IMPROVE FOOD SAFETY

Because there are many causes of foodborne illness, many points at which foods can become contaminated, and many factors that make some groups of people more susceptible than others, no single preventive measure will ensure the safety of all foods. However, practical preventive steps can be taken immediately to reduce the incidence of foodborne infections.

The Administration's food-safety efforts focus on the hazards and foods that present the greatest risks to public health and impose the greatest economic burden on the nation, emphasize development and implementation of preventive controls of those risks, and seek to ensure that preventive controls are cost-effective. The Administration is emphasizing the use of HACCP

principles, and seeks opportunities for such controls through a collaborative process with the responsible sectors of the food industry and all other stakeholders.

Under this initiative, the federal government, in concert with state and local governments, industry and academia, would conduct research and risk assessments and cost-benefit analyses to determine how foodborne illnesses occur and can be prevented or controlled in the most efficient and cost-effective manner; improve surveillance and investigative efforts to locate and monitor illnesses caused by food; achieve more effective and efficient monitoring of the safety of the food supply through inspections of food processors; and reinvigorate education of all those involved in food preparation focusing on the use of safe practices. These issues, and actions and recommendations for addressing them are described below. Because the components of the food-safety initiative are interrelated, overlapping activities will be noted throughout this report (for example, among research and risk assessment, and education and inspection).

A NEW EARLY-WARNING SYSTEM FOR FOODBORNE DISEASE SURVEILLANCE

Background

The primary objective of the American system of public health is to prevent disease before it occurs. Although prevention of all disease might not be possible, stopping outbreaks of foodborne illness before they affect large numbers of people is a major goal. America needs an effective early-warning system that can detect and stop outbreaks before they spread. Such a system will also advance understanding of foodborne illness and further prevention efforts. In his January 25 radio address, the President announced a new national early-warning system for foodborne illness for which he is requesting funds in his FY98 budget.

Problem

The current public-health system in the United States has limited means to identify and track the causes of foodborne illness. A more effective early-warning system is needed to detect and stop outbreaks early before they spread. Also, the national and global increase in antimicrobial resistance is a compelling public-health problem. Human infections caused by resistant pathogens increase morbidity and mortality and increase health care costs as newer, more expensive antibiotics are needed to treat common infections.

Recommendations

Surveillance and investigation are powerful tools to detect new foodborne disease challenges, to determine what specific food sources are implicated in foodborne illness, and to learn how best to keep foods from becoming contaminated in the first place. Surveillance for antimicrobial resistance will allow early detection of resistance and containment of its spread. Rapid detection of outbreaks is critical to stopping them before they affect many people. A key element in an early-warning system is the ability to detect, compare, and communicate unusual patterns of illness and laboratory findings within and among states and federal partners.

Enhancing the capacity of states to monitor foodborne disease and to investigate and control outbreaks will lead to better general control measures and fewer illnesses. One way to achieve this is to enhance and expand the existing Foodborne Disease Active Surveillance Network (FoodNet) to identify, investigate, and control a broad spectrum of foodborne diseases. A second important way to enhance early warning is to increase the capacity of many states to deal with new foodborne challenges. These enhancements will help us identify outbreaks and other foodborne disease challenges early, and prevent illness and premature deaths related to foodborne diseases.

In cooperation with state and local health departments, the federal government is proposing to take the following steps to establish a national early-warning system for foodborne diseases, and to enhance surveillance of such disease. These changes will result in an improved system for promptly and accurately detecting and reporting foodborne illnesses and outbreaks so public-health agencies can rapidly institute appropriately and correctly focused measures to control the spread of foodborne disease. This system will also collect critical data to recognize trends and target prevention strategies, including systems based on HACCP principles, and to evaluate the effectiveness and efficiency of prevention strategies already in place.

Enhance and Expand Foodborne Disease Active Surveillance

CDC, FDA, and FSIS support five FoodNet sites at state health departments to track cases of foodborne infections and to determine the sources of the most common ones. The existing sites will be strengthened, and their number increased to seven in FY97, and to at least eight in the following year. The sites and federal food-safety agencies will be electronically linked to create a powerful new network to detect, respond to, and prevent outbreaks of foodborne illness. Adding additional sites will improve geographic and demographic representation, making this network more likely to detect diseases and outbreaks that are regional rather than national in distribution.

FY97 Activities

- Two new active surveillance sites, in New York and Maryland, will begin FoodNet activities.

FY98 Activities with Food-Safety Initiative Funds

- CDC, FDA, FSIS, and the Council of State and Territorial Epidemiologists (CSTE) will add at least one site to FoodNet, and CDC will enhance personnel resources at all sites to improve surveillance, analysis of data, and timely and appropriate release of information.
- CDC and the FoodNet sites will develop and conduct case-control studies of *Campylobacter* and *Cryptosporidium* infections to guide control efforts.

Enhance Early Detection of Foodborne Disease Nationwide

The early-warning system will enhance improved early detection of foodborne disease in additional states in FY98 by providing resources for improved surveillance, investigation, control, and prevention of foodborne disease outbreaks. Although sophisticated laboratory studies can identify causes of illness and show relationships among pathogens, laboratory methods are insufficient without investigators who can collect samples, interview people, and trace the source of contamination to find out why the illness occurred. New electronic tools need to be developed to enable rapid detection of outbreaks and to enhance communication about outbreaks to appropriate agencies. CDC also should provide additional resources to states to increase their

surveillance and response capacity for the serious long-term consequences of foodborne disease, such as hemolytic uremic syndrome (HUS).

FY97 Activities

- CSTE and CDC, in conjunction with FDA and FSIS, will develop a protocol for evaluating epidemiologic outbreak data. The group will also develop criteria for local and state health officials to provide information on outbreaks to federal authorities for review and necessary action.
- FoodNet sites will gather epidemiologic data on cases of HUS.

FY98 Activities with Food-Safety Initiative Funds

- CSTE and CDC, in conjunction with FDA and FSIS, will define critical capacity elements that state and local health departments require to conduct surveillance, investigation, control, and prevention of foodborne illnesses; CDC will help states remedy identified deficiencies.
- CDC and CSTE will develop an electronic module for collecting and transmitting data to CDC on outbreaks of foodborne illness.
- CDC will begin a case-control study of hepatitis A to determine the proportion of cases due to contamination of food so that optimal control strategies could be determined. Recognized foodborne outbreaks account for about 2 to 5% of annually reported hepatitis A cases and are usually caused by an infected food handler.
- Epidemic assistance for outbreaks of foodborne disease will be expanded when states request direct CDC participation in investigations.
- CDC and, where appropriate, FDA and FSIS, will collaborate with state health departments to improve diagnostics, outbreak detection, and electronic communications.
- *Vibrio* surveillance will be strengthened by CDC, FDA, and states by increasing personnel, epidemiologic, and laboratory resources devoted to the Gulf Coast *Vibrio* surveillance program.

Long-term Activities

- Surveillance and investigative systems should continue to be enhanced to improve the ability of state and local health departments to promptly and accurately identify foods that are the source of foodborne illness.

Modernize Public-Health Laboratories

CDC should provide resources and training to upgrade public-health laboratory capabilities in FoodNet sites and in states without those sites so the laboratories can rapidly identify a broad range of foodborne pathogens, including parasites and viruses, and can use new techniques like DNA fingerprinting. The new capacities would allow rapid identification of the cause of some outbreaks that currently go undiagnosed.

FY97 Activities

- CDC will collaborate with FoodNet sites to determine serotypes of *E. coli* other than O157:H7 that cause HUS in children.

FY98 Activities with Food-Safety Initiative Funds

- The Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) and CDC will improve diagnostic assays and provide additional resources to improve the capacity of state laboratories to detect foodborne pathogens, including selected viruses and parasites.
- CDC will provide sufficient funds to states to support the production of serotyping reagents for *Salmonella*, which are critical for outbreak identification.
- CDC will develop DNA amplification-based tests for foodborne pathogenic bacteria that are difficult to detect by culture (e.g., Shiga-like toxin-producing *E. coli* other than *E. coli* O157:H7 and other disease-causing *E. coli*) and will provide resources and technical assistance to states to improve their capacity in diagnosing those pathogens.

Long-term Activities

- CDC should begin developing molecular alternatives to serotyping for *Salmonella*.

Create a National Electronic Network for Fingerprint Comparison

CDC should fund a new computer network and database system that would capture fingerprints of pathogens in a national database, linking CDC, FDA, FSIS, and states that have that new capacity into a national network. This technology would, for example, permit rapid recognition that an *E. coli* O157:H7 bacterium cultured from a patient in Washington was indistinguishable from one isolated from another patient in California. That might suggest to public-health investigators that a product distributed in California and Washington was contaminated with the same organism.

In addition to identifying, investigating, and reporting cases of foodborne disease in humans, microbiological surveillance of pathogens in foods, in food animals and their manures, and in animal feed, is important to control and prevent foodborne diseases and to evaluate the measures that reduce the risk of exposure. Therefore, to make the early-warning system fully operational and to translate its findings into long-term improvements in the safety of the food supply, additional surveillance activities would be required.

FY97 Activities

- CDC will provide resources and technical assistance to state health departments for DNA fingerprinting of *E. coli* O157:H7, and begin to establish a centralized national electronic database of DNA fingerprint patterns.

FY98 Activities with Food-Safety Initiative Funds

- The national electronic database of DNA fingerprint patterns of *E. coli* O157:H7 will continue to be expanded.
- In collaboration with participating state health department laboratories, FDA and FSIS, CDC will develop standardized methods for DNA fingerprinting of *Salmonella* serotypes Typhimurium and Enteritidis and will transfer the techniques to selected state health departments.
- CDC, ASTPHLD, and CSTE will develop guidelines for maximizing the utility of DNA fingerprinting at state health departments in foodborne disease surveillance and outbreak investigations.
- CDC, FDA, and FSIS will set up centralized national electronic databases of DNA fingerprint patterns of *S. Typhimurium* and Enteritidis.

Long-term Activities

- CDC should continue to develop standardized DNA fingerprinting methods for other foodborne disease-causing bacteria as appropriate and should transfer the standardized methods to state health departments and appropriate federal laboratories.
- CDC should begin implementing automated foodborne disease outbreak detection algorithms based on the DNA fingerprint patterns submitted by state health department laboratories.

Increase National Surveillance for Antimicrobial Resistance of Foodborne Pathogens

The problem of foodborne disease is increasing, in part, because foodborne infections are becoming more serious. One of the ways foodborne pathogens become more virulent is by acquiring resistance to antimicrobial agents, making such infections very difficult to treat. Therefore, CDC should expand surveillance for antimicrobial resistance in *Campylobacter*, *Salmonella*, and *E. coli* O157:H7 isolated in humans, and FDA and FSIS should take similar steps for those bacteria isolated from food-producing animals and their manures and from food products in a way that permits those data to be compared. CDC, FDA and FSIS should develop standard procedures for sharing information and for responding to increases in resistance or other "red-flag events" such as the discovery of an important new resistant bacterium.

FY97 Activities

- CDC, FDA, and FSIS will conduct surveillance of antimicrobially resistant *Salmonella* and *E. coli* O157:H7 isolates.

FY98 Activities with Food-Safety Initiative Funds

- CDC, FDA, and FSIS will initiate surveillance of antimicrobial resistance in isolates of *Campylobacter* from humans and animals, including poultry.
- FDA and CDC will conduct surveillance and epidemiologic studies to monitor and reduce the incidence of foodborne disease associated with emerging and drug-resistant pathogens.

Long-term Activities

- CDC, FDA, and FSIS should continue monitoring and comparing the antimicrobial resistance of *E. coli* O157:H7, *Salmonella*, and *Campylobacter* strains in humans and animals.
- FDA and CDC should conduct physician and veterinary drug-prescribing surveys, including patients and animal producers, to assess the effect of antimicrobial drug use on resistance patterns and prevalence to guide regulatory policy and educational campaigns.
- FDA should assist the World Health Organization (WHO) in the development of a veterinary database within the WHONET system. (WHONET is a system for standardized international reporting of antimicrobial resistance to WHO.)

**Conduct Surveillance of Human Pathogens
in Food-Animal Populations and Enhance Oversight of Animal Feedstuffs,
Feeds, and Manures for the Effect of Drugs and Other Therapies**

FY98 Activities with Food-Safety Initiative Funds

- USDA, CDC, FDA, and EPA will convene a working group to discuss how to conduct surveillance of human pathogens in food animals and their manures, and should target one pathogen on which to begin surveillance in FY99.

Long-term Activities

- FDA should increase the monitoring of animal-feed processing to determine the nature and extent of pathogen contamination and the effect of control strategies on pathogen reduction in animals.

INTERSTATE OUTBREAK CONTAINMENT AND RESPONSE COORDINATION

Background

Four federal agencies are charged with responding to outbreaks of foodborne illness (including waterborne illness): FDA and CDC (at HHS), USDA, and EPA. All states, and many local governments, with widely varying expertise and resources, share responsibility with the federal government for response to such outbreaks. When an outbreak occurs, all of the relevant entities must work together to efficiently and effectively prevent deaths and minimize the number of illnesses. The better coordinated the response, the more quickly the outbreak will be contained.

Each of the four federal agencies has a potentially critical role when an outbreak occurs. CDC's primary responsibility is to assist state and local health departments in investigating outbreaks of illness and in identifying the cause of the outbreak. FDA, FSIS, and EPA also have responsibility for determining whether a product they regulate may be causing illness, and of halting the spread of illness by taking regulatory action against the suspect products, or wastes (other than animal manures) that have the potential to contaminate the air, land, or waters used to produce the food product. The type of food affected determines which regulatory agency has primary jurisdiction: FSIS regulates meat, poultry, and egg products; FDA regulates all other foods including shell eggs; and EPA regulates water and pesticides and manages organic and inorganic wastes used or disposed of on agricultural land. While each agency has clearly defined areas of responsibility, the successful containment of many outbreaks of foodborne illness involves more than one agency.

The states and many local governments also have a critical role. Identification and investigations of foodborne illness often begin at the community or state level. States share with the federal government the legal responsibility for protecting the health of their residents. Although foodborne outbreaks are sometimes local, most outbreaks implicate federal agency jurisdiction. Illnesses cross state borders, and most foods or food ingredients are processed or produced in another state or by international trading partners. Federal involvement is also necessary when contaminated food from a common source has been distributed to grocery stores, restaurants, and homes in more than one state.

In many outbreaks of foodborne illness, federal agencies work with state and local health authorities in their investigations and in implementation of control measures through consultation, diagnostic assistance, and by regulatory action against the products. In some instances, on-site assistance is requested by the local and state authorities from the CDC to establish the cause of an outbreak, and from other agencies to help find the source of the problem. For large or multistate outbreaks, federal agencies play a critical coordination role to ensure consistency of approach and implementation of needed control measures.

Companies responsible for affected products also have a critical role to play. Food companies are sometimes the first to recognize that their product is causing illness. In addition, food-product

recalls are voluntary, although FDA may request a company to recall products. Federal and state agencies can benefit from industry's expertise about food products and their distribution patterns.

Problem

Although significant coordination already occurs among federal, state, and local agencies, better coordination is needed to meet new and growing threats to the nation's food supply. More than one agency is involved in virtually every large foodborne outbreak. Joint efforts are often hindered by a lack of communication or a misunderstanding of each agency's role in a particular situation.

Recommendations

Federal, state, and local governments should improve the coordinated management of interstate outbreaks. Improved coordination among the federal agencies, among federal, state, and local agencies, among the various state agencies, and between state and local agencies would enhance the level of public health protection, leverage agency resources and experience, and avoid duplication of effort.

The early-warning capability, comprised of FoodNet and strengthened state-surveillance capacity, and improved federal-state communications will enhance appropriate involvement of federal agencies in the investigation of foodborne disease outbreaks. Communication and exchange of information among the appropriate federal, state, and local government agencies must be improved.

Improve Outbreak Containment Through Better Federal-State-Local Coordination of the Evaluation of and Response to Foodborne Illness

There are probably hundreds of times a year when at least one federal agency, working with state and local agencies, plays a role in detection, investigation, and containment of illnesses that may be caused by contamination of food. Occasionally (typically once or twice a year) the outbreak is sufficiently significant and complex to require the involvement of the highest level officials in the responsible federal agencies. When this occurs, it is essential that federal agencies speak with one voice.

A critical element of an effective, rapid response to a foodborne illness outbreak is ready communication by all the involved parties at the federal, state, and local level. Although there are communication systems in place, they need to be expanded and coordinated to achieve rapid exchange of information and data between key outbreak-response personnel in each agency at the federal, state, and local levels. This strengthened system will complement the data and information exchange systems described in the "Early Warning for Foodborne Disease Surveillance" section of this report.

As part of this initiative, the agencies have streamlined their outbreak-response procedures. The departments with a role in any foodborne illness outbreak will be determined by public-health responsibility and regulatory jurisdiction over the food products (or water) implicated in the outbreak. Each department with public-health responsibility and regulatory jurisdiction over food products (or water) implicated in an outbreak will designate a Coordinator responsible for that department's activities related to the outbreak.

This new management system will provide a common set of objectives and strategies and one spokesperson that will speak on behalf of the federal government. Once there are indications to federal or state agencies of a large-scale problem, the staff will tell the Coordinator who will then coordinate the response among federal and state agencies.

Each agency has specific mechanisms in place to aid in this effort. FSIS has established an Emergency Response Program to prevent and control foodborne disease outbreaks involving meat, poultry, and egg products. Likewise, FDA's Division of Emergency and Investigational Operations serves this function for all other food products. Both FDA and FSIS maintain 24-hour telephone service staffed with a duty officer trained to respond to emergencies and ongoing illnesses, including foodborne illness and outbreaks, who have access to emergency personnel throughout the agency, as well as with emergency contacts in other agencies. FDA's Division of Emergency and Investigational Operations will serve to coordinate with other agencies. CDC provides 24-hour emergency consultation for botulism and other foodborne disease clinical emergencies and stations Epidemic Intelligence Service officers in 15-20 states each year to support surveillance and emergency response at the state level.

In order to improve communications with state agencies, FDA has adopted a fax-on-demand and fax broadcast system. The fax broadcast system, containing a database of more than 900 state officials, permits messages to be sent any time of day or night to any list of state contacts, providing an early alert or update to foodborne illness investigations. The fax-on-demand system provides access to press releases from federal agencies, press releases from firms about their recall, as well as other information. FSIS communicates with state departments of health and coordinates outbreak response through CDC WONDER (Internet) and both FDA and USDA maintain liaisons at CDC to facilitate food-safety activities, including outbreak investigations. CDC has established rapid communication links with all state and territorial epidemiologists and public health laboratory directors providing rapid group electronic mail and group fax links, and conference calls in outbreak settings.

FDA has also instituted a 50-state conference call system to keep all state agencies up-to-date on major foodborne outbreaks. This system was first used for the outbreak involving *E. coli* O157:H7 in apple juice and was most recently used for the hepatitis A outbreak associated with frozen strawberries. FDA and CDC jointly participate in these calls to assure more effective follow up and control of outbreaks. FDA will modify the conference call system to involve appropriate states in the very early stages of any multistate outbreak, as well as continuing the 50-

state update conference calls, in order to ensure better communication among state and federal agencies.

FY97 Activities

- To further strengthen our outbreak-response systems, CDC, EPA, FDA, and FSIS will establish an intergovernmental group, the Foodborne Outbreak Response Coordinating Group (FORCG), to improve the approach to interstate outbreaks of foodborne illness. FORCG will provide for appropriate participation by representatives of state and local agencies charged with responding to outbreaks of foodborne illness. This group will also review ways to more effectively involve the appropriate state agencies when there is a foodborne outbreak.
- FORCG will review and evaluate outbreak response. FORCG will undertake these reviews after appropriate consultation with industry and consumer representatives. Based on these deliberations, FORCG will assess the infrastructure for outbreak response, make recommendations for improving the current system, and work with federal, state, and local governments, the food industry, health professionals, and consumer advocates to implement beneficial changes. FORCG will meet several times a year for this purpose.
- Under the new initiative there will be one person/position designated as the outbreak coordinator for each department or agency that has a role in the outbreak response. This position will be established as a formal institutional position, with appropriate backup designees. For outbreaks that fall within the purview of HHS, HHS will designate the Assistant Secretary for Health to be the primary person in charge of coordination for HHS. For outbreaks that fall within the purview of USDA, the Under Secretary for Food Safety will coordinate for USDA. EPA will designate the Assistant Administrator for Water as the primary person in charge of coordination for EPA when drinking water is involved.
- Standard procedures will be developed for the rapid exchange of data and information associated with foodborne illness outbreaks between involved agencies and for dissemination to the public. The procedures will be developed by FORCG and representatives from the appropriate state agencies. The procedures will cover the exchange of data and information associated with an outbreak and will complement systems established for exchange of information about day-to-day occurrences of foodborne illness. (See "A New Early-Warning System for Foodborne Disease Surveillance" section.) The procedures will also provide for rapid dissemination of accurate information to the public by the agency spokesperson.

Enhance State and Local Infrastructure for Foodborne Outbreak Detection, Evaluation, and Response Coordination

The epidemiology offices and laboratories within state and local health departments are charged with the surveillance of infectious and non-infectious conditions, and, along with other state and local officials, with the investigation of outbreaks. They collect surveillance data from physicians, laboratories, local health departments, and other sources. Yet, the resources available in many states and communities for the surveillance and investigation of foodborne diseases are limited and decreasing, thereby limiting the effectiveness of their response. As a result, outbreaks may go undetected or are never investigated.

CDC, EPA, FDA, and FSIS will address the problem first by assessing and cataloguing available state resources, and then by working with states and providing support for foodborne-disease-surveillance programs and assistance to better investigate outbreaks of foodborne illness.

FY97 Activities

- FORCG, with assistance from the Association of Food and Drug Officials, the Association of State and Territorial Health Officials, the Association of State and Territorial Public Health Laboratory Directors, the Council of State and Territorial Epidemiologists, and the National Association of State Departments of Agriculture, will begin a nationwide audit to catalogue the existing state and local food-safety program infrastructure.
- FORCG, in consultation with the appropriate outside organizations, will establish working groups with appropriate participation of federal, state, and local officials to develop recommended procedures for outbreak-response coordination at the state and local level.

FY98 Activities with Food-Safety Initiative Funds

- CDC, EPA, FDA, and FSIS will assist states and local governments in developing the infrastructure necessary to ensure proper detection, evaluation, and coordinated response to foodborne outbreaks.

RISK ASSESSMENT

Background

The impact of increased funding for development of methods and models directed at improving risk assessments will be to focus public resources on reducing those risks that have the greatest consequences for human health. Risk assessment provides a strong foundation upon which efficient allocation of scarce food-safety resources can be made. While obvious severe hazards in the food supply will be addressed through the larger food-safety initiative, risk assessment provides an objective foundation upon which efficient allocation of scarce food-safety resources can be established. Furthermore, risk assessment often plays a central role in the development of any science-based system of preventive controls.

There has been a long history of performing safety assessments or risk assessments for foods, particularly chemicals and drug residues. Risk assessments, cost-benefit analyses, and evaluations of alternative risk-management strategies are required for all major regulations in USDA, a requirement imposed by the Federal Crop Insurance Reform and Reorganization Act of 1994 (P.L. 103-354). EPA is developing methods for required risk assessments under the Safe Drinking Water Amendments of 1996, including both microbial and chemical hazards. Sound risk assessments are important in various aspects of international trade, including the provisions of Codex Alimentarius and the World Trade Organization, the international bodies that govern standards for food safety, among other issues. Carefully formulated risk assessments based on high-quality data and scientific information generated from research lead to more informed risk management and better decisions.

Risk assessment also provides essential information for estimating and analyzing the costs and benefits of policy alternatives. Risk estimates are used to characterize the state of the world in the baseline and the alternative states expected to occur after taking action, whether through regulation, guidelines, or education campaigns. Ideally, results of risk estimates are in the form of distributions that capture the scientific uncertainty and population variability, but where that is not possible, point estimates of risk need to reflect the impact on the entire population.

Risk management and risk assessment must mutually inform each other but must remain separate and independent entities. Risk communication must be an integral part of all risk-related activities, including the public, industry, and all affected parties.

Good risk assessment requires good risk communication. Participation from industry, academia, and private risk organizations will be ensured in the interagency consortium's risk-assessment activities. Good risk communication must be ensured by interfacing with educators. Active communication between the risk assessment consortium and the research community is crucial to a successful initiative.

Risk assessment characterizes the nature and size of the risk to human health associated with hazards, and to make clear the degree of scientific certainty of the data and the assumptions used to develop the estimates. Risk assessments require specific information on the hazard and on the exposed population to provide meaningful information for those making risk-management decisions. Even for chemical hazards, for which risk-assessment methods have been most thoroughly developed, data gaps force the use of assumptions about exposure, hazard potency, and characteristics of the population at risk.

Problem

Risk assessment is far less developed for foodborne pathogens. Intensive commitment is necessary to develop critically needed methods of analyzing the available data and addressing its uncertainty; methods that account for variability, specifically of living microbial pathogens, are essential. Chemical and radiological risks do not pose these special challenges, so extending these established methods to microbial risk is not sufficient.

The research needed to develop improved methods and models that will make it possible to perform quantitative microbial risk assessments to the degree of complexity required for most food-safety issues will require the integration of work in biological sciences, predictive microbiology, and applied mathematics. In some instances, the research needs overlap with those identified in the research section of this document. However, to reflect the multidisciplinary nature of the needed research programs and to highlight the critical nature of the research needs, research needs related to risk assessment are being presented as a separate item for consideration.

Recommendations

This initiative emphasizes the development, testing, and validation of microbial risk assessment and foodborne illness valuation methods. These efforts should support effective and efficient public response to foodborne illness concerns, whether the response is improved surveillance plans, better prevention strategies, or stronger inspection models. The initiative's activities focus on developing models for improving risk assessment, thereby more precisely targeting the prevention of foodborne disease by informing surveillance plans, prevention strategies for process-control systems and for food inspections based on HACCP principles, and research programs to fill critical food-safety information gaps. Recommendations are being made in three areas.

Establish a Risk Assessment Consortium

All federal agencies with risk-management responsibilities for food safety will establish jointly a consortium at which federal agencies can collectively advance the science of microbial risk assessment, and to assist agencies in fulfilling their specific food-safety regulatory mandates. The consortium should be inclusive in its risk-assessment activities, seeking expertise from risk-assessment professionals and scientists from public and private sources, as well as industry and

consumer groups. The goal of the consortium would be to improve the quality of risk-assessment research by coordinating research priorities, eliminating redundancies of effort, and encouraging multidisciplinary research efforts. The consortium will have three primary functions:

- Develop a scheme for setting methodological research priorities based upon the value of information expected from each research activity.
- Serve as a clearinghouse for information about current and planned research projects pertinent to microbial risk-assessment techniques.
- Foster and, where possible, augment the research activities of the member agencies to accelerate particularly critical research projects.

FY97 Activities

- The consortium, which will include all interagency partners, will be established in 1997 as part of the Joint Institute for Food Safety and Applied Nutrition, a collaborative activity of FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine and the University of Maryland. The initial focus of the initiative will be on pathogenic microorganisms.
- The consortium will begin the process of establishing a clearinghouse that will collect and catalogue available methodology, specifically simulations necessary to address microbial growth and death variables offered by the private sector, trade associations, federal and state agencies, and international sources. The consortium will work with its member agencies to catalogue their microbial risk-assessment-research advances and identify data sets that would provide the scientific data needed to develop new models. The consortium will be inclusive in its risk-assessment activities, seeking expertise from risk-assessment professionals and scientists from public and private sources, and industry and consumer groups.

FY98 Activities with Food-Safety Initiative Funds

- A series of public meetings will be held to develop a strategy to address long-term research needs for the analysis of farm-to-table scenarios, including potential pathogen introduction at each level (e.g. farm, processing, transportation, home, restaurant, and retail food handling), food-consumption data, and computer modeling. A strategic plan will be developed for research into dose-response calculations, chronic sequelae, biomarkers, and adapting surveillance data. This process will include a broad spectrum of academic, industry and government expertise that will be obtained through an acceptable process such as an advisory committee.

- Begin a comprehensive review of existing data and federal information-collection programs to determine the extent to which they may fill existing data gaps, and suggest additional data needs to better support risk assessments.

Long-term Activities

- The consortium will continue to collectively identify critical research needs, propose effective research on analytical approaches and methods, and reach consensus on the priority of these needs based on their potential to reduce the uncertainty of risk-management decisions in food safety and provide the greatest positive impact. Research supported and conducted through this initiative would cover several areas critical to developing our ability to conduct risk assessments for foodborne disease-causing organisms and to assess the effectiveness of control measures.

Develop and Validate Exposure Assessment Models Based on Probabilistic Methodology

Risk assessment of foodborne illness is dependent on accurately estimating the probability that various quantities of a toxin or pathogen will be ingested by the consumer (i.e., exposure assessment). This initiative addresses numerous data and modeling deficiencies in estimating exposure to microbial and chemical contaminants. Specifically, research will be conducted into the development of models and simulations based on probabilistic methods for the occurrence of microbial pathogens and chemical hazards in food at all stages of the food chain; typical behaviors of commercial and home preparation operations; validation of dynamic exposure assessment models; evaluation of intake data regarding food-consumption patterns of the general population and sensitive subpopulations; and specific data on microbial behavior in food vehicles of sporadic and epidemic disease. Research on how to incorporate data related to biomarkers should be pursued. (Biomarkers are surrogates that indicate that exposure has occurred or that some effect has occurred, particularly when actual evidence of exposure or effect is difficult or impossible to obtain.)

FY98 Activities with Food-Safety Initiative Funds

Working with FDA, EPA, and USDA, the consortium will identify priority research programs in two areas that are in need of augmentation: exposure assessment methods, and techniques for acquisition and analysis of experimental data for model development. Initial areas identified include:

- Addressing the dynamics of foodborne pathogens in agricultural environments (e.g. pathogen reservoirs, feed, and animal manure).
- Quantifying effects of key processing steps on levels of pathogens.

- Quantifying effects of key commercial food service preparation procedures, marketing facilities, and home food-handling practices.
- Designing and proposing ways to integrate the collection of exposure and dose-response data into outbreak investigation.

Long-term Activities

Future initiatives would be fluid to adjust to results of short-term research, emerging food-safety needs, and changes in the direction of research programs within individual agencies. Additional research would likely include the development of modeling techniques to assess human exposure resulting from the subtherapeutic use of veterinary antibiotics in food-producing animals. To reduce uncertainties in exposure estimates, the consortium will work with researchers who are conducting focused food-consumption surveys targeting foods consumed by a variety of subpopulations (e.g., the elderly, children).

Develop and Validate Dose-Response-Assessment Models for Use in Risk Assessment

Research is needed to accurately estimate the relationship between the quantity of a biological agent and the frequency and magnitude of adverse human health effects in a population. Dose-response assessments typically include estimates of the rates of infection, morbidity, and mortality.

FY98 Activities with Food-Safety Initiative Funds

Working with FDA, EPA, and USDA, the consortium will identify priority research programs in dose-response-assessment methods and models that need to be augmented. Initial areas identified include:

- Methodology to incorporate the use of biomarkers in exposed populations into risk-assessment models.
- Identification and development of criteria for objective models that permit high-to-low-dose extrapolation.
- Development of criteria that will be used to select or weight alternative models (theories) for extrapolating from empirical data to quantitative descriptions of risk.

Long-term Activities

Risk-assessment research priorities in this area will be collectively established by the interagency consortium. Additional research includes studying whether threshold or non-threshold models for infectivity are more appropriate for describing low-dose infectivity rates for infectious and toxicoinfectious microorganisms. Further research is also needed into the use of biomarkers of susceptibility, chronic sequelae, microbiological toxicokinetics, and infectious dose.

RESEARCH

Background

Food-safety research is critically needed to develop the means to identify and characterize more rapidly and accurately foodborne hazards, to provide the tools for regulatory enforcement, and to develop effective interventions that can be used as appropriate to prevent hazards at each step from production to consumption. FDA, CDC, EPA, NIH, ARS, and CSREES, conduct research related to pathogenic microorganisms and other contaminants that threaten the safety of food. That research supports the needs of both the federal and state food-safety agencies and the many food industries.

Problem

New foodborne pathogens have emerged over the past ten years. Other microorganisms, previously thought to be innocuous, have been linked to life-threatening diseases after acquiring new virulence genes and antimicrobial resistance. Many of those organisms cannot be detected readily due to either a lack of suitable methods or their sporadic occurrence in foods. Certain foodborne pathogens are increasingly associated with resistance to time-tested controls, such as heating, refrigeration, and acid. In some cases, that ability appears to be linked with increased virulence or new ways to evade our immune defenses. The various research programs of FDA, ARS, CSREES, CDC, EPA, and NIH need to better coordinate their research efforts on the highest-priority issues and work together more effectively to leverage each other's resources.

Recommendations

Prevention of foodborne pathogens in foods requires an understanding of how foods become contaminated during their production, processing, and distribution, and the availability of practical interventions to control or eliminate the biologic agent. Selection of target pathogens and foods ideally are guided by risk assessment. Research is also needed to support HACCP implementation to verify that critical control points in HACCP systems are working, and to target the data gaps that hamper HACCP and risk assessment. Among the recognized data gaps, the following areas were identified as priority research needs. (Research activities listed for FY97 and FY98 are not necessarily completed in those years. Therefore, activities listed as long-term are additional activities.)

Improved Detection Methods

Many pathogens cannot be easily detected in foods, e.g., *Cyclospora* in raspberries. Among the needs for improved diagnostics, methods are needed for rapid, cost-effective testing for pathogens in food animals and their manures, in agriculture and aquaculture products, animal feeds, and processed food products. Methods development must address the low-level, sporadic incidence of many pathogens in foods. Research will be coordinated with EPA's efforts to develop better

test methods for *Cryptosporidium* and other pathogens in water and drinking water. Improved methods are needed for the identification and subtyping of foodborne pathogens in human and animal clinical specimens. The development of effective sampling plans and enrichment techniques are vital parts of detection methodology.

FY97 Activities

- EPA, CDC, ARS, CSREES, and FDA, in conjunction with states and academia, will conduct research to develop detection methods and control measures for *Cyclospora*.

FY98 Activities with Food-Safety Initiative Funds

- ARS, FDA, and EPA will enhance ongoing research to develop test methods for *Campylobacter*, *Salmonella*, *Toxoplasma*, *E. coli* O157:H7 and other Shiga-like toxin-producing *E. coli*, *Cryptosporidium*, hepatitis A and Norwalk viruses, and naturally occurring mycotoxins and marine toxins in foods.
- FDA will expand its ongoing research on the development of methods for detecting foodborne pathogens in animal feeds.

Long-term Activities

- FDA, ARS, CSREES, and EPA should undertake research to develop test methods for *Vibrio vulnificus* in foods.

Understanding Resistance to Traditional Preservation Technologies

Microorganisms that are resistant to antimicrobial agents and processing techniques that have been relied on traditionally to eliminate or prevent the growth of foodborne pathogens have become increasingly important causes of serious foodborne disease. Research is needed to determine how microorganisms associated with foodborne disease become tolerant to various types of antimicrobials and to traditional food-safety safeguards, such as heat or cold, low pH, high salt, and disinfectants, and to elucidate factors in animal- and plant-production systems and processing environments that influence the development of resistance. The physiological and genetic bases of resistance are not understood well enough to prevent breakthrough of newly emerging pathogens. Such research will help identify food production, processing, and handling practices that are likely to contribute to pathogen contamination or proliferation. That research is also needed to guide improvement of traditional techniques and the development of new interventions.

Long-term Activities

- ARS, CSREES, and FDA should undertake research into physiological, genetic, and other factors that cause foodborne-disease-causing microorganisms to develop resistance to preservation technologies.

Understanding Antibiotic Drug Resistance

Pathogens in food-producing animals and their manures may become resistant to antibiotics and drugs, particularly when used improperly. One possible solution might be to modify drug withdrawal periods. Such an approach would require scientific data to be developed on how the resistance profiles of microbial populations in animals changes in response to the elimination of a drug. Work involving resistance to traditional preservation technologies and antibiotic drug resistance must be based on a sound understanding of microbial, physiologic, and genetic adaptive mechanisms.

FY98 Activities with Food-Safety Initiative Funds

- FDA and ARS will conduct research to identify and characterize the factors that lead to the development of multiple drug (antibiotic) resistance in foodborne pathogens in farm and aquaculture animals, including establishing the gene-transfer mechanisms and selective pressures.
- ARS and FDA will investigate techniques for manipulating the microbial ecology of the intestinal tract of agricultural and aquaculture animals to prevent the development of antibiotic resistance or select for nonresistance. Research will emphasize competitive exclusion techniques (probiotics) and the use of extended drug-withdrawal periods. Probiotics are benign bacteria that can be used to out-compete pathogenic bacteria.

Prevention Techniques: Pathogen Avoidance, Reduction, and Elimination

Contaminants are introduced into the food supply at numerous points along the way from farm to table. Food animals and their manures can carry human pathogens, without any clinical manifestations. Likewise, fresh fruits, fresh vegetables, and grains can harbor pathogens or mycotoxins without any discernable loss of quality. In such cases, traditional approaches of segregating contaminated foods are ineffective, and active interventions are needed. In particular, new interventions are needed to prevent and control the pathogens listed below in raw agricultural commodities and seafood. Developments in this area would be expected to provide new approaches for controlling a variety of other foodborne contaminants.

FY98 Activities with Food-Safety Initiative Funds

For *Campylobacter*, *Salmonella*, *Toxoplasma*, *E. coli* O157:H7, and other Shiga-like toxin-producing *E. coli*, and *Cryptosporidium*, FDA and ARS, often in partnership with universities and industry, will:

- Expand research into the microbial ecology of foodborne pathogens and how initial colonization in plants and animals can be prevented.
- Expand research on new methods to reduce or eliminate pathogenic microorganisms and mycotoxins from agricultural and aquaculture animals before slaughter or harvest, including the use of probiotics.
- Develop new methods to reduce or eliminate pathogenic microorganisms and mycotoxins from plants before harvest.
- Develop new disinfection methods and systems for improved sanitation of production (including on-farm) processing and marketing equipment and facilities.
- Expand research on new methods of decontamination of meat, poultry, seafood, fresh produce, and eggs.
- Initiate research to develop new techniques for eliminating animal feeds as a source of foodborne pathogens.

Long-term Activities

- ARS, CSREES, and FDA should undertake research to develop new decontamination methods for contaminants such as *Vibrio* and Norwalk virus on or in marine-harvested and aquaculture-reared seafood, and for *Cyclospora* and hepatitis A virus on fresh produce.
- ARS, CREES, and FDA should work with industry and academia to develop new techniques that provide alternatives to traditional thermal processing for eliminating pathogens. Collaboration among these parties, particularly with industry participation, will facilitate rapid evaluation of the safety and effectiveness of new technologies, and ultimately, approval of processes.
- FDA, FSIS, and EPA should work with industry and academia to develop criteria for evaluating the efficacy and safety of the new intervention technologies.

Food Handling, Distribution, and Storage

Food production, processing, and consumption often occur thousands of miles apart. Stresses associated with the transportation of live animals and fresh produce can contribute to the dissemination of foodborne pathogens. Effective packaging and proper food-storage conditions are critical to maintaining the level of safety achieved by processing.

Long-term Activities

- ARS, CSREES, and FDA should undertake research to identify factors that contribute to the spread of microorganisms during transportation of live animals and fresh produce and develop techniques for eliminating cross-contamination.
- FDA, ARS, and CSREES should work with industry and academia to develop and assess the effectiveness of in- or on-package sensors of storage conditions to alert consumers of products not stored safely.

Charge an Interagency Committee Convened by the Office of Science and Technology Policy (OSTP) to Coordinate Federal Research Priorities and Planning

Numerous opportunities exist for collaboration and the development of research partnerships among federal and state agencies, the private sector, and academia. A mechanism is needed to coordinate food-safety research among federal agencies, to link research with the activities and needs of the agencies, to better leverage agency resources and experience, and avoid duplication of effort. Such a coordination mechanism could be provided by an OSTP-convened interagency committee. That committee would review food-safety responsibilities and research programs of the various agencies with a view to recommending direction of research funds and programs in accordance with those responsibilities.

IMPROVING INSPECTIONS AND COMPLIANCE

Background

Inspection of commercial food processors is an integral part of the food-safety assurance system. Inspections are carried out by federal, state and local authorities. In addition to other food-inspection responsibilities, state and local officials also have primary responsibility for inspecting restaurants, supermarkets, and other retail establishments. At the federal level, FSIS has responsibility for meat and poultry inspection in slaughter and processing plants and egg-product-processing plants, and for all imported meat, poultry, and egg products. FDA conducts periodic, random inspections of all other food-processing plants; that entails fewer than 700 inspectors and laboratory personnel for 53,000 U.S. plants and for all other imported foods.

Problem

The number of inspections conducted by FDA has decreased steadily since 1981, when 21,000 inspections were conducted, so that today resources exist to carry out only about 5,000 inspections per year. An FDA-regulated plant is inspected by FDA, on average, only once every 10 years. FDA also relies upon the states to conduct some inspections under contract, but that number has dropped from 12,000 in 1985 to 5,000 now. Moreover, because the number of imports has doubled over 5 years, with no real increase in inspectors, a smaller percentage of imports are inspected at entry.

Given the limited inspection coverage, FDA is finding an increasing number of problems--the number of products recalled for life-threatening microbial contamination has increased almost five-fold since 1988. Federal budget constraints will likely prohibit significant funding increases in the future, so FDA must find new ways to provide adequate inspection coverage.

Recommendations

Scientists and other food-safety experts have concluded that the most effective and efficient mechanism to ensure that food processors identify and control hazards that could threaten food is the application of HACCP principles. FDA's seafood HACCP regulations go into effect in December 1997. FSIS began to implement its HACCP and Pathogen Reduction Requirements for the meat and poultry industries in 1997 with phase-in to be completed in 2000. HACCP programs allow government and industry resources to be used more appropriately, allowing the government and industry to focus on the greatest risks. To ensure that HACCP is properly implemented, and to ensure more efficient and effective monitoring of the safety of the food supply, recommendations are being made in the following areas.

Enhance Development of HACCP Procedures

FY97 Activities:

- Based on the best science available, FDA will propose appropriate regulatory and non-regulatory options, including HACCP, for the manufacture of fruit and vegetable juice products.
- Based on the best science available, FSIS will propose appropriate regulatory and non-regulatory options, including HACCP, for egg products.
- FDA and USDA will immediately identify preventive measures to address public-health problems, such as those recently associated with fruits and vegetables, e.g., hepatitis A virus associated with frozen strawberries. This will be accomplished through a comprehensive review of current production and food-safety programs including inspection, sampling, and analytical methods.
- FSIS and FDA will jointly publish an ANPR in which they will evaluate the public-health, food-technology, and regulatory issues involved in reducing the risk of human illness from *Salmonella* Enteritidis in shell eggs. The ANPR will solicit information and comment on all elements of risk in the farm-to-table chain to ensure any resulting regulatory actions will be both reasonable and effective in reducing risk.
- FDA will evaluate whether and how to propose to require the use of HACCP in other appropriate food commodities and animal feeds.
- FDA will provide additional training in seafood HACCP and FSIS will complete HACCP training of inspectors in large meat and poultry plants.
- FSIS and FDA will evaluate expanding existing cooperative agreements so that plants producing meat and nonmeat foods are inspected by FSIS inspectors trained in FDA inspection standards. FSIS inspectors are already in these plants, and their presence could be better used to maximize use of federal resources without loss of inspection coverage for FSIS-regulated foods.
- FSIS will conduct a series of public meetings to discuss:
 - How HACCP requirements will be implemented in slaughter plants and how the roles and responsibilities of inspection personnel will change with that implementation.

- The design and testing of new inspection concepts consistent with HACCP principles to achieve food-safety and other consumer-protection objectives through distribution and retail channels to consumers.
- FSIS and state associations will complete development of HACCP-based control measures for meat and poultry processing at the retail level.

FY98 Activities with Food-Safety Initiative Funds

- FDA and USDA will cooperate in evaluating the feasibility of HACCP for commodities such as fresh fruit and vegetables. The process could also consider whether it is appropriate to use USDA inspectors to inspect plants that manufacture products regulated by both agencies or even products that must meet different regulatory requirements from the two agencies, such as fresh produce used in the school lunch program.
- FDA will implement seafood HACCP by hiring approximately 80 investigators to conduct inspections to ensure proper implementation of seafood HACCP.
- A performance-based organization (PBO), will be created, with Congressional approval, as the organizational structure for the voluntary fee-for-service seafood program currently located at the Department of Commerce's National Marine Fisheries Service. The Departments of Commerce and Health and Human Services will consider whether to locate the PBO at FDA, which would consolidate voluntary and mandatory seafood programs within one agency and provide limited additional resources for implementation of seafood HACCP, while continuing the voluntary fee-for-service program.
- FSIS will continue to propose changes to current regulations to harmonize with HACCP.

Long-term Activities

- FDA should further the use of HACCP principles, as appropriate, for other foods, including animal feeds, and use risk-assessment techniques where possible.

Enhance the Safety of Foods in Retail Food Establishments Particularly at State and Local Levels

More than 3,000 state and local regulatory agencies have primary responsibility for monitoring retail food establishments to ensure that consumers are protected. U.S. retail establishments include approximately 785,000 commercial and institutional food establishments, 128,000 grocery and convenience stores, and 1.5 million vending operations. Workers in these establishments have highly diverse backgrounds and training.

FY97 Activities

- FDA and FSIS will hold a series of meetings with state and local regulators in five regions to establish retail program standards in accordance with the 1997 model state code (the Food Code) to enhance national uniformity.

FY98 Activities with Food-Safety Initiative Funds

- FSIS and FDA will provide HACCP training to state and local inspectors that will augment the training program for federal inspection personnel, more fully covering the farm-to-table process.
- See also "Education: Improve Retail Food-Service and Institutional Education."

Long-term Activities

- The Food Code should be adopted by all 50 states.

Enhance Federal-State Inspection Partnerships

State inspection programs are an important component of the nation's food-safety inspection system. The move toward HACCP will pose a challenge to the states that federal agencies can help the state system to meet. If HACCP is to be an effective program for ensuring that food processors have modern, state-of-the-art food-safety procedures in effect, FDA must improve its inspection capabilities, so that the highest-risk food plants are inspected at least once per year. New federal-state partnerships focused on coordinating inspection coverage (particularly between FDA and the states), are major steps in this direction.

FY97 Activities

- FSIS will hold two public meetings on the issue of interstate distribution of state-inspected meat and poultry products. The purpose of these public meetings is to obtain information and comment from all stakeholders on this issue.

FY98 Activities with Food-Safety Initiative Funds

- FDA will develop additional federal-state partnerships to improve coordination between the federal food-safety agencies and state regulators for the training of state inspectors in food-safety standards applicable at all levels, including retail. FDA is currently involved in 92 partnerships with states; approximately 30 of those deal with inspection activities.
- FDA will expand the number of federal-state partnerships to include more extensive HACCP training of state inspectors, the seafood industry, and the retail food industry.

- FSIS will initiate HACCP training for state inspectors with respect to meat and poultry products.

Long-term Activities

- FDA and FSIS should work more closely with industry, professional and trade associations, and academia to ensure effective implementation of HACCP principles, particularly at the production, processing, and retail levels.
- FDA should create a data system to compile inspection data from federal and state inspections, as well as provide the states with equipment and technology for the rapid sharing of inspection results.

Enhance Coverage of Imported Foods with Specific Attention to Foods Regulated by FDA

Wharf examinations and sampling of foods being offered for import into the United States have dropped by 50% in just the past four years. Today, FDA is responsible for about 2.2 million import food entries (i.e., shipments), an increase from 1.5 million entries just 5 years ago, with the same number of staff.

FY98 Activities with Food-Safety Initiative Funds

- FDA will work to increase the number of mutual recognition agreements (MRAs) with trading partners. Under MRAs, the trading countries ensure that food is produced and manufactured under equivalent systems that provide a comparable level of safety.
- FDA will initiate a federal-state communication system through which states can inform federal agencies of problems found with imported products in their jurisdictions.
- FDA will initiate a system for certifying and accrediting private laboratories, including use of a quality-assurance procedure, that will be authorized to test samples of food products for contaminants. Such private parties would provide a service to food firms wishing to demonstrate that their products meet applicable federal standards.
- When FDA and FSIS become aware of possible public-health problems associated with a regulated food product (e.g., through occurrence of foodborne illness outbreaks, sample analysis, or inspections), the agencies will provide technical assistance to the foreign country importing the product.

Long-term Activities

- FSIS should continue to verify foreign government-inspection progress for conformance with the new HACCP and Pathogen Reduction Requirements; that activity will begin in 1997 and should be completed in 2000.
- The laboratory-certification process should be extended to include assessing the utility of existing accrediting bodies with FDA providing performance standards and oversight to the process.
- FDA should expand the federal-state communication system states use to inform federal agencies of problems found with imported products in their jurisdictions. As part of that expansion, FDA should evaluate the feasibility of combining the communication system with the federal-state inspection data system discussed above, making the data and information more widely accessible.
- FDA should review and evaluate ways to increase coverage of imports through such means as increased personnel, increased partnerships, or innovative information-sharing with the states.

Enhance Safety of Foods During Transportation

In considering whether and how to regulate the transportation of meat, poultry, seafood, eggs, and other foods to safeguard the public from pathogenic microorganisms and other hazards, FSIS and FDA published an ANPR on November 22, 1996.

FY98 Activities with Food-Safety Initiative Funds

- FDA and FSIS will evaluate the comments and information received in response to the ANPR as a basis for determining what, if any, regulatory approach to take, including development of guidelines. These guidelines may include such elements as suggested performance standards for temperature control, providing information on prior cargo, and cleaning information for the food-shipper's use, to ensure the safety of the food at its destination.

Long-term Activities

- FDA and FSIS, through partnerships with states, should provide training and training materials to the transportation industry on safe food transportation. (See "Education: Improve Industry Education in the Transportation Area.")

EDUCATION

Background

An integral part of the overall food-safety initiative is providing food-safety education to a variety of audiences: consumers (the general public and specific groups at risk for foodborne illness); public-health professionals and physicians; retail, food-service, and institutional food preparers; veterinarians, animal and other food producers; and food-transportation workers. The challenge is to create educational messages that address the risks relevant to each audience throughout the food chain. Research and risk assessment are important elements in identifying these risks and devising appropriate messages. Realizing that educational efforts are cost-effective investments, federal, state and local governments, private organizations, consumer groups, and industry have fostered educational programs to address foodborne illness.

Problem

Despite educational efforts, foodborne illness remains prevalent throughout the United States. For example, from 1988 to 1992, *Salmonella* caused 69% of the 796 bacterial foodborne disease outbreaks; 60% of those *Salmonella* outbreaks were caused by *Salmonella* Enteritidis. *S.* Enteritidis also resulted in more deaths than any other pathogen, with 85% of these deaths occurring among residents of nursing homes.

One reason is that food preparers and handlers at each stage of the food chain lack the knowledge of risks involved and the related safe food-handling practices. Food preparers in the retail sector must be made aware of how they can prevent food contamination and reduce pathogen growth, particularly by preventing cross-contamination with other foods and by properly cooking foods such as eggs. Without the knowledge of food-safety practices and proper food-handling procedures, foodborne illness cannot be significantly reduced. Food-safety messages should be developed to reach individuals at each stage from the farm to the table.

Risk assessment and research are needed to determine the most effective ways to overcome barriers to use of safe food-handling practices and to ensure use of safe food-handling practices by specific audiences. Consumers' food-handling practices and the choices they make in the foods they eat will either increase or decrease the chances of foodborne illness. Studies show that more than 50% of the public eats raw or undercooked eggs, 23% eats undercooked hamburger, 17% eats raw clams and oysters, and 26% do not wash cutting boards after using them for raw meat or poultry.

Health professionals and physicians also need specific knowledge about causes and effects of foodborne illness to more effectively detect and treat the illnesses. Producers of animals used in human food production and veterinarians treating such animals must be made aware of food-safety aspects of drugs and drug residues. Finally, those responsible for the transportation of food are often unaware that mishandling of food during shipment can result in contamination.

Recommendations

The goal of this initiative is to target and change unsafe food-handling practices by people throughout the food chain, including food-service workers, and especially those providing food to populations at high risk of foodborne illness. Objectives include: 1) forming partnerships and alliances to maximize resources and broaden the impact and scope of educational efforts; 2) designing messages by conducting research to identify barriers to safe food handling, upon which educational programs will be centered; and 3) expanding the use of innovative outreach methods, including the use of new technologies.

Implementation of the education goals and objectives of the initiative combined with the other elements of the initiative will significantly increase the number of consumers and food-service workers being reached with effective and persuasive food-safety messages.

Improve Consumer, Retail, and Food Service Education

FY97 Activities

The 1997 Consumer Food-Safety Education Partnership

A memorandum of understanding was signed in May 1997, formalizing a food-safety education partnership that includes industry, consumer groups, FDA, CDC, USDA, and the Department of Education. Participants in the partnership will launch a nationwide food-safety education campaign for the general public. The campaign will center on four key food-safety concepts tested for maximum consumer understanding and will include a slogan, logo or identifiable character. At present, the Partnership is reviewing proposals from national public-relations and communications firms to conduct a public awareness and education campaign. The industry groups have contributed almost \$500,000 to date. Plans for the nationwide campaign will be announced at the food-safety education conference, "*Changing Strategies: Changing Behaviors*," sponsored by FSIS, CSREES, FDA, and CDC to be held June 12-13 in Washington, DC. The partnership will promote September as National Food Safety Month, as already designated by industry, and launch the food-safety education campaign during the month.

Identify key food-safety education principles through establishment of an expert council

Convene the National Food Safety Education Council, an independent scientific review board to periodically review food-safety education messages. The Council, which will include food scientists and educators, will serve to identify emerging food-safety risks that require public education. Risk assessment will be used to identify at-risk audiences for targeted food-safety education programs.

Other FY97 Activities

- The agencies will form alliances with industry, consumer, trade, state and local food-protection agencies, and academic organizations to share food-safety education materials and conduct joint food-safety education activities in order to leverage resources and expand the reach of the alliances. For example, FDA, FSIS, and CSREES will form an alliance, joining expertise of federal, state and local agencies, industry, and professional and trade associations to promote and implement the 1997 Food Code and develop multilingual communication techniques targeted to specific groups to overcome communication barriers.
- See "Inspections: Enhance Safety of Foods in Retail Food Establishments."

FY98 Activities with Food-Safety Initiative Funds

- FDA, CDC, FSIS, and CSREES will promote and incorporate food-safety education into school programs.

Conduct Research to Identify Barriers to Safe Food-Handling, Upon Which Educational Programs Will Be Centered

FY97 Activities

Under the auspices of the National Food Safety Education Council:

- HHS and USDA will develop national safe-food-handling guidelines like the Dietary Guidelines and review them periodically.

FY98 Activities with Food-Safety Initiative Funds

- Conduct additional research necessary to determine the best way to communicate key food-safety principles in order to achieve behavior change.
- Conduct research necessary to develop a visual communication tool that conveys food-safety principles, as the food guide pyramid does for nutrition principles.

Long-term Activities

- Through partnerships and alliances, implement an education campaign to use the new educational tools especially targeted to school programs and specific at-risk audiences.

Expand Existing Information Systems

FY97 Activities

- Expand existing information systems, such as the existing Foodborne Illness Education Information Center, while laying the groundwork for a National Clearinghouse for Food Safety Education. Innovative methods for sharing food-safety information will be explored, including the consolidation of government food-safety Internet sites to reach larger audiences and provide easier access to information through a single site.

FY98 Activities with Food-Safety Initiative Funds

- Establish the National Clearinghouse for Food Safety Education.
- Consider use of food labels and other point-of-sale materials to convey food-safety information.
- In food service, develop and initiate a highly focused multilingual program to change food workers' unsafe food-preparation behaviors. The programs will address the impact of the high turnover in food-service workers and target teenage workers, small businesses, and new entrepreneurs.

Long-term Activities

- Evaluate program and continue to support those programs initiated in FY97 and FY98.

Improve Veterinarian and Producer Education

Long-term Activities

- Use existing mechanisms, such as the Cooperative Extension Service and professional associations, to strengthen and implement programs to educate producers, veterinarians, and state and local regulators about proper drug use and the incorporation of HACCP principles into industry quality-assurance programs to reduce foodborne pathogens.
- Encourage the evaluation and improvement of veterinary and producer education at veterinary and agriculture colleges to address foodborne pathogens in animals and their manures.
- Develop and disseminate guidelines and educational materials through existing networks to food producers and the veterinary medical community.

Improve Health-Professional Education

Long-term Activities

- In cooperation with FDA , FSIS, and CSREES, CDC should train public-health professionals on foodborne disease and clinical microbiology and foodborne illnesses with nontraditional symptoms by using multimedia and distance-learning techniques and the National Laboratory Training Network.

Improve Industry Education in the Transportation Area

Long-term Activities

- Form an alliance among government agencies and the private sector to develop educational materials and train food-transportation vehicle owners and operators and food-processing establishments on hazards associated with the transportation of food products, particularly hazards associated with temperature control, prior cargo, and sanitation methods.
- See also: "Inspections: Enhance Safety of Foods During Transportation."

A BLUEPRINT FOR A BETTER FOOD-SAFETY SYSTEM

Background

The actions described in this report will significantly improve the safety of the nation's food supply, but the agencies recognize that this 90-day report does not address a number of critical issues facing our food-safety programs. The agencies recommend a longer-term strategic planning effort to consider how to best address important challenges and make the best use of the agencies' limited resources. This process will involve all public and private stakeholders, including consumer groups, affected families, state and local governments, and industry. One function of the strategic-planning process is to consider how to make the best use of each agency's limited resources.

Through this initiative, and previous activities, we have laid the groundwork for a strategic planning effort. For example, federal agencies, consumer groups, and industry have worked together to incorporate HACCP into meat, poultry, and seafood regulatory programs. And there is now a broad recognition of the need to carefully implement these programs, and to consider how to apply preventive measures in other areas of concern. A strategic-planning effort could build on this common ground, and tackle some of the difficult public-health, resource, and management questions facing federal food-safety agencies.

As discussed throughout this report, USDA, HHS, and EPA have responsibilities for ensuring the safety of the U.S. food supply. USDA and HHS also have ancillary responsibilities for the quality of our food. These responsibilities include the grading of agricultural commodities and grain by the Agricultural Marketing Service and the Grain Inspection Service, the importation of foreign plants and animals by APHIS, and the quality and wholesomeness of food purchased by the federal school lunch program. FDA sets standards of quality for a variety of food products. Regulatory requirements applicable to food products are largely established by FSIS for meat, poultry and egg products, and by FDA for all other products.

In recent years, there has been increasing evidence that foodborne diseases can be caused by microbial contamination in seafood, fresh fruits, vegetables, and other products. Moreover, during the Clinton Administration, both agencies have looked to a new and similar approach to food regulation. FSIS has adopted HACCP for the products that it regulates and FDA has adopted HACCP for seafood products, and is considering the HACCP approach for other products. During the next few years, the HACCP regulations that these agencies have adopted will go into effect, and more may well follow.

Developing a Strategic Plan

Over the past 90 days, the federal food-safety agencies have engaged a wide range of stakeholders in discussions about food-safety issues through a series of public meetings and through written comments to public dockets. Although these discussions have identified some ideas for

approaches to strategic planning, they have more clearly established the need for continuing discussions about the process for developing a strategic plan.

Therefore, the agencies will initiate a longer-term strategic planning process to develop a strategic plan for improving the food-safety system. The process will facilitate the participation of all interested parties. Extensive, structured discussions will be needed to build trust in the process, and to obtain agreement on priorities, strategies for achieving change, and ways for measuring progress.

Because it is critical that the process be inclusive and equitable, the agencies will give interested parties an opportunity to comment on the possible approaches for structuring the dialogue before its implementation. The agencies will provide specific information regarding the general objective, scope, and conduct of the dialogue and strategic-planning process, management of the process, selection criteria for participants, and other relevant factors. Unanimous agreement is unlikely. Therefore, the agencies will use a general consensus to shape the planning process.

Broad participation of stakeholders is central to the success of the discussions. The achievement of such broad participation can be accomplished in a number of ways. The agencies will hold meetings in various regions of the United States, which will also ensure broad participation. These meetings will involve multiple sectors to ensure broad and balanced participation of all stakeholders in the food-safety system. The meetings will be open and their proceedings, products, and the process for producing those products transparent.

Issues for Consideration

A major challenge in developing a strategic plan will be attaining consensus on priorities for action to enhance food safety within the highly complex food-safety oversight system. Reaching agreement on priorities is compounded by the complexity of the food supply and the different perspectives of the various oversight agencies and groups. Federal and state agencies have established programs in research, risk assessment, education, surveillance, and inspection, and agencies are working to better coordinate activities within these programs. Nevertheless, a better system of identifying and setting priorities within these areas is essential to maximizing the use and effect of limited agency resources in reducing the incidence of foodborne illness and enhancing the safety of the food supply.

During the course of the stakeholder discussions, a variety of issues, ranging from specific to broad, surfaced as priority topics for discussion. A number of stakeholders suggested the need to consider such broad policy questions as:

- Key public-health, resource, and management questions facing federal food-safety agencies.
- Structure of strategic, coordinated, long-range risk-assessment and research agendas.

- Consideration of improvements for coordination and planning of food-safety regulation to optimize federal and state prevention, intervention, and control actions.
- Means to improve exchange of information about foodborne disease outbreaks.

More focused, technical issues were also suggested for consideration, among them:

- Technical and policy issues associated with agricultural manures (important potential sources of microbial contaminants of foods). Animal manures are currently excluded from regulation. Therefore, an EPA regulatory mechanism to control human health impacts resulting from improper application to or burial of manures in farm and other lands does not exist.
- Technical and policy issues associated with microbial-control technologies, including food irradiation.
- Developing a global approach to evaluating new, emerging, and potential foodborne diseases such as Transmissible (Bovine) Spongiform Encephalopathy--T(B)SE--and a process for responding to prevent the spread of such diseases.

Prepare a 3- to 5-Year Strategic Plan

Participants in the planning process would be charged with developing a strategic long-range agenda that could be used to help set priorities, improve coordination and efficiency, identify gaps in the current system, and enhance and strengthen prevention and intervention strategies, and identify measures to show progress. Each agency will incorporate the relevant parts of the strategic plan into its Government Performance and Results Act (GPRA) strategic plan, commensurate with its budget.

Measure Progress to Evaluate the Effectiveness of the Plan in Reducing the Annual Incidence of Foodborne Illness

After the plan's implementation, progress would be reviewed to determine the strategic plan's effect on reducing the annual incidence of foodborne illness. Measurable goals and objectives would provide a basis for establishing progress. Measurements could be based on a decline in the number of foodborne illnesses and deaths, a decline in the number of outbreaks, more effective prevention and intervention programs, more rapid, coordinated, and effective responses to foodborne illness outbreaks, increases in inspection coverage for domestic and imported products, changes in behavior, and better detection and quantification methodologies.

APPENDIX B

SOME IMPORTANT MICROBIAL PATHOGENS ASSOCIATED WITH FOODBORNE ILLNESS

Bacteria

Salmonella

Salmonella species cause diarrhea and systemic infections, which can be fatal in particularly susceptible persons, such as the immunocompromised, the very young, and the elderly. Animals used for food production are common carriers of salmonellae, which can subsequently contaminate foods, such as meat, dairy products, and eggs. Foods often implicated in outbreaks include poultry and poultry products, meat and meat products, dairy products, egg products, seafood, and fresh produce. An estimated 800,000 to 4 million infections occur each year in the United States, most of them as individual cases apparently unrelated to outbreaks. Between 128,000 and 640,000 of those infections are associated with *Salmonella* Enteritidis in eggs. Over the past decade, more than 500 outbreaks have been attributed to *S. Enteritidis* with more than 70 deaths. In 1994, an estimated 224,000 people became ill from consuming ice cream in one outbreak alone.

Campylobacter

The bacterium *Campylobacter* is the most frequently identified cause of acute infectious diarrhea in developed countries and is the most commonly isolated bacterial intestinal pathogen in the United States. It has been estimated that between 2 and 4 million cases of campylobacteriosis occur each year with an associated 120-360 deaths. *Campylobacter jejuni* and *Campylobacter coli* (two closely related species) are commonly foodborne, and are the infectious agents most frequently described in association with Guillain-Barré syndrome, as frequently as 1 in 1000 cases. Several prospective studies have implicated raw or undercooked chicken as major sources of *C. jejuni/coli* infections. Unpasteurized milk and untreated water have also caused outbreaks of disease.

Shiga-like toxin-producing *Escherichia coli*

Several strains of the bacterium *E. coli* cause a variety of diseases in humans and animals. *E. coli* O157:H7 is a type associated with a particularly severe form of human disease. *E. coli* O157:H7 causes hemorrhagic colitis, which begins with watery diarrhea and severe abdominal pain and rapidly progresses to passage of bloody stools. It has been associated with HUS, a life-threatening complication of hemorrhagic colitis characterized by acute kidney failure that is particularly serious in young children. *E. coli* O157:H7 is found in cattle, but there may be other reservoirs; the dynamics of *E. coli* O157:H7 in food-producing animals are not well understood. Approximately 25,000 cases of foodborne illness can be attributed to *E. coli* O157:H7 each year with as many as 100 deaths resulting. *E. coli* O157:H7 outbreaks have recently been associated with ground beef, raw milk, lettuce, and minimally processed and fresh fruit juices. The most recent outbreak in the Fall of 1996 in three western states and British Columbia was associated with unpasteurized apple juice, sickened 66 people, and caused the death of one child.

Vibrio

Vibrio species are gram-negative bacteria most commonly associated with seafood-containing dishes. *Vibrio parahaemolyticus* is the species that is most commonly reported as a cause of foodborne disease; it generally causes watery diarrhea and abdominal pain lasting 1-7 days, and commonly follows consumption of improperly handled cold-seafood salads. *V. vulnificus* is one of the more serious foodborne pathogens, with a case-fatality rate for invasive disease that exceeds 50%. Most cases of foodborne *V. vulnificus* infections occur in persons with underlying illness, particularly liver disorders, who eat raw molluscan shellfish. Since the late 1980s, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Gulf Coast states have intensified efforts to collect information on *Vibrio* infections, and on the microorganisms' ecology, to improve our ability to prevent foodborne infections.

Protozoa

Toxoplasma gondii

T. gondii is a parasitic protozoan. Some 1.4 million cases of toxoplasmosis occur annually with an associated 310 deaths. Healthy adults who become infected usually have no symptoms but might get diarrhea. Pregnant women who become infected can pass the disease to their fetuses. In infants infected before birth, fatality is common. Should the infant survive, the effects of infection are typically severe (i.e., mental retardation). The disease can be life-threatening in persons with weakened immune systems and often is fatal to people with HIV/AIDS. *T. gondii* has been found in virtually all food animals. The two primary ways that humans become infected are consumption of raw or undercooked meat containing *T. gondii* or contact with cats that shed cysts in their feces during acute infection. Under some conditions, the consumption of unwashed fruits and vegetables can contribute to infections.

Cryptosporidium parvum

C. parvum is a parasitic protozoan. The most common consequence of infection in healthy people is profuse watery diarrhea lasting up to several weeks. Children are particularly susceptible. Cryptosporidiosis can be life-threatening among people with weakened immune systems. The largest recorded outbreak of Cryptosporidiosis was a waterborne outbreak in Milwaukee, Wisconsin, in 1993, affecting more than 400,000 people. More recently, a waterborne outbreak in Las Vegas resulted in at least 20 deaths. The first large outbreak of cryptosporidiosis from a contaminated food occurred in 1993. That outbreak was attributed to fresh-pressed apple cider. *Cryptosporidium* also is found in animal manures.

Viruses

Norwalk virus

Norwalk viruses are important causes of sporadic and epidemic gastrointestinal disease that involve overwhelming, dehydrating diarrhea. An estimated 181,000 cases occur annually with no known associated deaths. In January 1995, a multistate outbreak of

viral gastroenteritis due to Norwalk virus was associated with the consumption of oysters. A 1993 Louisiana outbreak of Norwalk virus gastroenteritis involved 70 ill people and was associated with the consumption of raw oysters. In 1992, another outbreak resulted in 250 cases. Outbreaks of Norwalk virus intestinal disease have been linked to contaminated water and ice, salads, frosting, shellfish, and person-to-person contact, although the most common food source is shellfish. Several such outbreaks are believed to have been caused by oysters contaminated by sewage dumped overboard by oyster harvesters and recreational boaters.

Hepatitis A

Hepatitis A (HAV) is a virus that infects the liver and causes hepatitis A, an illness with an abrupt onset that can include fever, malaise, nausea, abdominal discomfort, dark urine, and jaundice after a prolonged incubation period (e.g., more than 2 months). In children less than 6 years old, most (70%) infections are asymptomatic, but in older children and adults, infection is usually symptomatic, with jaundice occurring in more than 70% of patients. Signs and symptoms of hepatitis A usually last more than 2 months, and there are no chronic consequences. About 130,000 infections with HAV and 100 deaths occur each year in the United States. The primary mode of transmission for HAV is person-to-person by the fecal-oral route. Recognized foodborne hepatitis A outbreaks account for only 2% to 5% of hepatitis A cases reported in the United States each year, most of which are caused by an infected food handler. Outbreaks due to foods contaminated before preparation, while uncommon, have been associated with widely distributed products such as shellfish, lettuce, frozen raspberries, and frozen strawberries. Hepatitis A can be prevented by good personal hygiene and safe food-handling practices. It can also be prevented before exposure by hepatitis A vaccine, and after exposure by immune globulin, if given within 14 days of exposure.



**Partnership For
Food Safety Education**

FIGHT BAC!



About the Partnership for Food Safety Education



Who We Are and What We Do

The Partnership for Food Safety Education is an ambitious public-private partnership created to reduce the incidence of foodborne illness by educating Americans about safe food handling practices. The following summarizes the mission, structure and activities of this unique coalition of industry, government and consumer groups:

- Committed to making safe food handling meaningful to consumers through communications that are positive, upbeat and inherently empowering to foster behavior change.
- Combines the resources of the federal government, industry and several consumer organizations to conduct a broad-based food safety education campaign designed to reach men, women and children of all ages.
- Formed in 1996 and officially launched with a Memorandum of Understanding signed on May 12, 1997 by Agriculture Secretary Dan Glickman, Health and Human Services Secretary Donna Shalala and Education Secretary Richard Riley, together with seven food trade associations, three consumer/public health organizations and the Association of Food and Drug Officials.
- Formed as a direct response to a 1996 independent panel report - "Putting the Food Handling Issue on the Table: The Pressing Need for Food Safety Education" - which specifically called for a public-private partnership to educate the public about safe food handling and preparation.
- Uses public opinion research and expert scientific and technical review to develop campaign concepts, messages and graphics so that they are accurate, understandable and persuasive.
- Utilizes multiple information channels - the mass media, public service announcements, the internet, point-of-purchase materials, and school and community outreach efforts - to bring Americans face-to-face with the problem of foodborne illness and to motivate

them to take action.

- Enlists a national network of public health, nutrition, food science, education and special constituency groups to support the campaign and greatly extend its reach.
- Currently funded by the contributions of industry trade associations with technical assistance and in-kind support provided by government agencies and consumer organizations.

Members of the Partnership for Food Safety Education are:

- American Egg Board
- American Meat Institute
- Association of Food and Drug Officials
- Canadian Partnership for Consumer Food Safety Education
- The Centers for Disease Control and Prevention (CDC)
- Consumer Federation of America
- Food Marketing Institute
- Food Safety and Inspection Service
- Food and Drug Administration
- International Food Safety Council (National Restaurant Association)
- National Association of State Departments of Agriculture
- National Cattlemen's Beef Association
- National Chicken Council
- Produce Marketing Association
- Public Voice for Food and Health Policy
- The Soap and Detergent Association
- U.S. Poultry and Egg Association
- U.S. Department of Agriculture

- [U.S. Department of Education](#)
- [U.S. Department of Health and Human Services](#)



Return to About the Partnership



GLICKMAN UNVEILS PROPOSED LAW TO STRENGTHEN MEAT, POULTRY RECALLS

Release No. 0297.97

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GLICKMAN UNVEILS PROPOSED LAW TO STRENGTHEN MEAT, POULTRY RECALLS

WASHINGTON, Aug. 29, 1997--Agriculture Secretary Dan Glickman today unveiled proposed legislation designed to provide consumers better protection from meat and poultry products that may be contaminated.

"USDA needs more authority to act quickly and decisively to remove suspect products from the marketplace," Glickman said at a press conference to discuss his proposed bill, "The Food Safety Enforcement Enhancement Act of 1997."

Specifically, Glickman's bill would authorize the Secretary of Agriculture to do the following:

- stop the distribution and order the recall of adulterated or misbranded meat and poultry in situations that pose a reasonable probability of a threat to public health;
- refuse or withdraw inspection based on any willful or repeated violation of federal meat or poultry laws; and
- impose civil monetary penalties for violations of the meat and poultry laws.

"Our proposal will enable us to ensure that the industry adheres to the high food safety standards the Clinton Administration is implementing," Glickman said. "Giving me the power to impose fines on violators, order recalls and halt operations by withdrawing federal meat inspectors from plants that willfully or repeatedly violate food safety laws will put more teeth in our oversight over the industry and better help protect consumers."

Glickman's proposal follows this month's recall of 25 million pounds of ground beef made at the Hudson Foods Company's Columbus, Nebraska meat processing plant. Frozen hamburger patties from the plant were found to be contaminated with E.coli O157:H7 and the cause of an outbreak of foodborne illness in Colorado. USDA is continuing its investigation of record keeping and manufacturing practices in Hudson's Columbus, Nebraska plant.

"The implications of this recall have led us to ask Congress for prompt approval of this legislation," Glickman said. "I also call on Congress to fund fully the President's food safety initiative. In addition, USDA will continue to look at food safety issues concerning the reprocessing of meat products from one shift to another, the use of microbiological testing and lessons learned from the recent recall."

Glickman said the proposed legislation would strengthen USDA's authority under the Federal Meat Inspection Act and the Poultry Products Inspection Act. USDA now has no authority to require product recalls in the event of contamination. USDA relies on voluntary recalls. Mandatory recall authority would speed up the process and permit the department to take more effective action to head off bad production practices that could endanger public health.

"Currently, companies can try to get recalls on their terms instead of ours," Glickman said. This legislation will permit USDA to move more quickly to protect the public from food products contaminated with dangerous bacteria such as E. coli O157:H7."

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NOTE: USDA news releases and media advisories are available on the Internet. Access the USDA Home Page on the World Wide Web at <http://www.usda.gov>



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D. C. 20250

SEP 4 1997

Honorable Albert Gore, Jr.
President of the Senate
Washington, D. C. 20510

Dear Mr. President:

In order to protect the public from foodborne illness or death from meat products contaminated with *E. coli* O157:H7, the Department of Agriculture (USDA) has recently initiated its largest food recall in American history. This recall incident highlighted weaknesses in USDA's food safety enforcement authorities. Congressional action would help to provide the additional authorities the Secretary could use to ensure food safety.

Today, I am transmitting to Congress a draft bill to improve public health and food safety by providing USDA with enhanced enforcement powers. This draft bill is an important part of the Clinton Administration's initiative to improve food safety for American consumers. The Administration recommends that the draft bill be promptly enacted.

The draft bill would give the Secretary of Agriculture a more complete range of enforcement tools with which to protect the public health. The bill would amend the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) by adding three new enforcement sections providing for mandatory recall of meat and poultry products, more explicit authority to refuse or withdraw inspection, and the power to assess civil monetary penalties.

Specifically, the bill authorizes the Secretary of Agriculture:

- ◆ to stop the distribution and order the recall of adulterated or misbranded meat and poultry in situations that pose a reasonable probability of a threat to public health;
- ◆ to refuse or withdraw inspection based on any willful or repeated violation of the FMIA or the PPIA; and
- ◆ to impose civil monetary penalties for violations of the FMIA and the PPIA.

Although the recent recall was done at the Department's request, compliance with that request was voluntary. Until the Department has mandatory authority to require the recall of products at any point in the production and distribution chain, establishments and others can refuse to comply. Such mandatory recall authority would enable the Secretary to move

effectively in case of delay by the industry to a voluntary recall to stop the distribution of adulterated products and to protect the public from food products contaminated with dangerous bacteria like *E. coli* O157:H7.

In addition, this legislation would clarify USDA's existing authority to withhold inspection by providing the Secretary the authority to refuse or withdraw inspection when a company has either willfully or repeatedly violated USDA laws or regulations.

Finally, the legislation would give the Secretary the authority to impose civil penalties for violations of the FMIA or the PPIA. Currently, USDA is limited to seeking criminal penalties in the Federal courts. Civil penalty authority will better protect public health and improve food safety by providing a more timely and effective remedy against those who violate USDA meat and poultry laws.

The January 1993 outbreak of *E. coli* O157:H7 in Washington State affected more than 700 people and resulted in four deaths. That outbreak was a tragic reminder of the potential consequences of illness due to foodborne pathogens. Since then, the Clinton Administration has taken aggressive steps to improve food safety, by implementing science-based inspection systems for meat, poultry, and seafood and by expanding foodborne illness surveillance. Additionally, the Administration's Food Safety Initiative contained in the 1998 budget proposes a comprehensive strategy for enhancing food safety. The Administration's efforts over the past four years to improve food safety contributed significantly to the successful containment of the recent outbreak.

The Clinton Administration has made great progress in improving food safety, but more work remains to be done. We continue to investigate the cause of this recent recall incident and, if necessary, will propose additional program and policy changes that will aid in ensuring the U.S. food supply remains the safest. We look forward to working with Congress to achieve this critical goal.

The Office of Management and Budget advises that enactment of this proposed legislation would be in accord with the President's program.

A similar letter is being sent to the Speaker of the House.

Sincerely,

A handwritten signature in black ink, appearing to read "Dan Glickman". The signature is fluid and cursive, written over the word "Sincerely,".

DAN GLICKMAN
Secretary

A BILL

To amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to provide for improved public health and food safety through enhanced enforcement.

Be it enacted by the Senate and the House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "The Food Safety Enforcement Enhancement Act of 1997."

SEC. 2. The Federal Meat Inspection Act (21 U.S.C. 601, et seq.) is amended:

(1) by redesignating section 411 as section 414, and

(2) by inserting after section 410 the following new sections:

NOTIFICATION AND RECALL

"SEC. 411 (a) Any person, firm, or corporation, excluding household consumers, which has a reasonable basis for believing that any carcasses, parts thereof, meat, or meat food products are adulterated or misbranded shall immediately notify the Secretary, in such manner and by such means as the Secretary may by regulation prescribe, of the identity and location of such articles.

"(b) (1) If the Secretary finds, upon such notification or otherwise, that (A) any carcasses, parts thereof, meat, or meat food products are adulterated or misbranded and (B) there is a reasonable probability that human consumption of such articles presents a threat to public health, as determined by the Secretary, the Secretary shall provide the person, firm, or corporation with an opportunity to: (i) cease distribution of such articles,

1 (ii) notify all persons, firms, and corporations transporting, storing, or distributing such
2 articles, or to which such articles have been transported or sold, to immediately cease
3 distribution of such articles, (iii) recall such articles, and (iv) provide, in consultation with
4 the Secretary, notice to consumers to whom such articles were, or may have been,
5 distributed. (2) If such person, firm, or corporation refuses to or does not voluntarily
6 cease distribution, make notification, recall such articles, and provide notice to
7 consumers, within the time and in the manner prescribed by the Secretary, the Secretary
8 shall, by order, require, as the Secretary deems necessary, such person, firm, or
9 corporation, to: (i) immediately cease distribution of such articles, and (ii) immediately
10 notify all persons, firms, and corporations transporting, storing, or distributing such
11 articles, or to which such articles have been transported or sold, to immediately cease
12 distribution of such articles. (3) The Secretary shall, as the Secretary deems necessary,
13 provide notice to consumers to whom such articles were, or may have been, distributed.

14 "(c) The Secretary shall provide any person, firm, or corporation subject to an
15 order under subsection (b) with an opportunity for an informal hearing, pursuant to such
16 rules or regulations as the Secretary shall prescribe, to be held as soon as possible but not
17 later than two days after the issuance of the order, on the actions required by the order
18 and on why the articles that are the subject of the order should not be recalled.

19 "(d) (1) If, after providing opportunity for an informal hearing under subsection
20 (c), the Secretary determines that there is a reasonable probability that human
21 consumption of the articles that are the subject of an order under subsection (b) presents a
22 threat to public health, the Secretary, as the Secretary deems necessary, may: (i) amend

1 the order to require recall of such articles or other appropriate action, and (ii) specify a
2 timetable in which the recall will occur, require periodic reports to the Secretary
3 describing the progress of the recall, and provide notice to consumers to whom such
4 articles were, or may have been, distributed. (2) If, after such a hearing, the Secretary
5 determines that adequate grounds do not exist to continue the actions required by the
6 order, the Secretary shall vacate the order.

7 (e) The remedies provided in this section shall be in addition to and not exclusive
8 of other remedies that may be available.

9 **REFUSAL OR WITHDRAWAL OF INSPECTION**

10 "SEC. 412 (a) The Secretary may, for such period, or indefinitely, as the Secretary
11 deems necessary to effectuate the purposes of this Act, refuse to provide or withdraw
12 inspection under title I of this Act with respect to any establishment if the Secretary
13 determines, after opportunity for a hearing is accorded to the applicant for, or recipient of,
14 such inspection, that the applicant or recipient, or any person responsibly connected with
15 the applicant or recipient (as defined in section 401), has committed any willful violation
16 of this Act or the regulations promulgated thereunder or repeated violations of this Act or
17 the regulations promulgated thereunder.

18 "(b) The Secretary may deny or suspend inspection under title I of this Act,
19 pending opportunity for an expedited hearing, with respect to an action under subsection
20 (a) to refuse to provide or withdraw inspection, if the Secretary deems such denial or
21 suspension in the public interest to protect the health or welfare of consumers or to assure
22 the safe and effective performance of official duties under this Act.

1 (c) The determination and order of the Secretary with respect to the refusal or
2 withdrawal of inspection under this section shall be final and conclusive unless the
3 affected applicant for, or recipient of, inspection files application for judicial review
4 within thirty days after the effective date of such order and simultaneously sends a copy
5 of such filing by certified mail to the Secretary. Inspection shall be refused or withdrawn
6 as of the effective date of such order pending any judicial review of such order unless the
7 Secretary directs otherwise. Judicial review of any such order shall be in the United
8 States Court of Appeals for the circuit in which the applicant for, or recipient of,
9 inspection resides or has its principal place of business or in the United States Court of
10 Appeals for the District of Columbia Circuit, and shall be on the record upon which the
11 determination and order are based.

12 (d) The remedies provided in this section shall be in addition to and not exclusive
13 of other remedies that may be available.

14 **CIVIL PENALTIES**

15 "SEC. 413 (a) Any person, firm, or corporation that violates any provision of this
16 Act or any regulation or order issued under this Act may be assessed a civil penalty by
17 the Secretary of not more than \$100,000 for each such violation. Each violation and each
18 day during which a violation continues shall be a separate offense. No penalty shall be
19 assessed by the Secretary under this section unless such person, firm, or corporation is
20 given notice and opportunity for a hearing on the record before the Secretary in
21 accordance with sections 554 and 556 of title 5, United States Code. The amount of such
22 civil penalty shall be assessed by the Secretary by written order, taking into account the

1 gravity of the violation, degree of culpability, size and type of business, and any history
2 of prior offenses; and may be reviewed only as provided in subsection (b).

3 "(b) An order assessing a civil penalty under subsection (a) shall be final and
4 conclusive unless the person, firm, or corporation files, within thirty days from the
5 effective date of the order, an application for judicial review in the Court of Appeals of
6 the United States for the circuit in which such person, firm, or corporation resides or has
7 its principal place of business or in the United States Court of Appeals for the District of
8 Columbia Circuit by filing a notice of appeal in such Court and by simultaneously
9 sending a copy of such notice by certified mail to the Secretary. The Secretary shall
10 promptly file in such Court a certified copy of the record upon which such violation was
11 found and such penalty assessed. The findings of the Secretary shall be set aside only if
12 found to be unsupported by substantial evidence on the record as a whole.

13 "(c) If any person, firm, or corporation fails to pay an assessment of a civil penalty
14 after it has become a final and unappealable order, or after the appropriate Court of
15 Appeals has entered final judgment in favor of the Secretary, the Secretary shall refer the
16 matter to the Attorney General, who shall institute a civil action to recover the amount
17 assessed in an appropriate district court of the United States. In such collection action,
18 the validity and appropriateness of the Secretary's order imposing the civil penalty shall
19 not be subject to review.

20 "(d) All penalties collected under authority of this section shall be paid into the
21 Treasury of the United States.

22 "(e) If any person, firm, or corporation fails to pay an assessment of a civil penalty

1 after it has become a final and unappealable order, or after the appropriate Court of
2 Appeals has entered final judgment in favor of the Secretary, the Secretary may refuse to
3 provide inspection to, or suspend inspection from, any such person, firm, or corporation
4 until the assessed civil penalty is paid or until otherwise ordered by the Secretary.

5 "(f) Nothing in this Act shall be construed as requiring the Secretary to report for
6 prosecution, or for the institution of libel or injunction proceedings, violations of this Act
7 whenever the Secretary believes that the public interest will be adequately served by
8 assessment of civil penalties.

9 "(g) The remedies provided in this section shall be in addition to and not
10 exclusive of other remedies that may be available."

11 **SEC. 3.** The Poultry Products Inspection Act (21 U.S.C. 451 et seq.) is amended:

12 (1) in section 5 (c) by deleting "and 12-22 of this Act" and inserting in lieu thereof "12-
13 22, and 31-33 of this Act", and

14 (2) by inserting after section 30 the following new sections:

15 **NOTIFICATION AND RECALL**

16 "SEC. 31 (a) Any person, excluding household consumers, which has a
17 reasonable basis for believing that any poultry or poultry products are adulterated or
18 misbranded shall immediately notify the Secretary, in such manner and by such means as
19 the Secretary may by regulation prescribe, of the identity and location of such poultry and
20 poultry products.

21 "(b) (1) If the Secretary finds, upon such notification or otherwise, that (A) any
22 poultry or poultry products are adulterated or misbranded and (B) there is a reasonable

1 probability that human consumption of such poultry or poultry products presents a threat
2 to public health, as determined by the Secretary, the Secretary shall provide the person
3 with an opportunity to: (i) cease distribution of such poultry or poultry products, (ii)
4 notify all persons transporting, storing, or distributing such poultry or poultry products, or
5 to which such poultry or poultry products have been transported or sold, to immediately
6 cease distribution of such poultry or poultry products, (iii) recall such poultry or poultry
7 products, and (iv) provide, in consultation with the Secretary, notice to consumers to
8 whom such poultry and poultry products were, or may have been, distributed. (2) If such
9 person refuses to or does not voluntarily cease distribution, make notification, recall such
10 poultry or poultry products, and provide notice to consumers, within the time and in the
11 manner prescribed by the Secretary, the Secretary shall, by order, require, as the Secretary
12 deems necessary, such person to: (i) immediately cease distribution of such poultry or
13 poultry products, and (ii) immediately notify all persons transporting, storing, or
14 distributing such poultry or poultry products, or to which such poultry or poultry products
15 have been transported or sold, to immediately cease distribution of such poultry or
16 poultry products. (3) The Secretary shall, as the Secretary deems necessary, provide
17 notice to consumers to whom such poultry or poultry products were, or may have been,
18 distributed.

19 “(c) The Secretary shall provide any person subject to an order under subsection
20 (b) with an opportunity for an informal hearing, pursuant to such rules or regulations as
21 the Secretary shall prescribe, to be held as soon as possible but not later than two days
22 after the issuance of the order, on the actions required by the order and on why the

1 poultry or poultry products that are the subject of the order should not be recalled.

2 "(d) (1) If, after providing opportunity for an informal hearing under subsection
3 (c), the Secretary determines that there is a reasonable probability that human
4 consumption of the poultry or poultry products that are the subject of an order under
5 subsection (b) present a threat to public health, the Secretary, as the Secretary deems
6 necessary, may: (i) amend the order to require recall of such poultry or poultry products
7 or other appropriate action, and (ii) specify a timetable in which the recall will occur.
8 require periodic reports to the Secretary describing the progress of the recall, and provide
9 notice to consumers to whom such poultry or poultry products were, or may have been,
10 distributed. (2) If, after such a hearing, the Secretary determines that adequate grounds
11 do not exist to continue the actions required by the order, the Secretary shall vacate the
12 order.

13 (e) The remedies provided in this section shall be in addition to and not exclusive
14 of other remedies that may be available.

15 **REFUSAL OR WITHDRAWAL OF INSPECTION**

16 "SEC. 32 (a) The Secretary may, for such period, or indefinitely, as the Secretary
17 deems necessary to effectuate the purposes of this Act, refuse to provide or withdraw
18 inspection under this Act if the Secretary determines, after opportunity for a hearing is
19 accorded to the applicant for, or recipient of, such inspection, that the applicant or
20 recipient, or any person responsibly connected with the applicant or recipient (as defined
21 in section 18(a)), has committed any willful violation of this Act or the regulations
22 promulgated thereunder or repeated violations of this Act or the regulations promulgated

1 thereunder.

2 "(b) The Secretary may deny or suspend inspection under this Act, pending
3 opportunity for an expedited hearing, with respect to an action under subsection (a) to
4 refuse to provide or withdraw inspection, if the Secretary deems such denial or
5 suspension in the public interest in order to protect the health or welfare of consumers or
6 to assure the safe and effective performance of official duties under this Act.

7 "(c) The determination and order of the Secretary with respect to the refusal or
8 withdrawal of inspection under this section shall be final and conclusive unless the
9 affected applicant for, or recipient of, inspection files application for judicial review
10 within thirty days after the effective date of such order and simultaneously sends a copy
11 of such filing by certified mail to the Secretary. Inspection shall be refused or withdrawn
12 as of the effective date of such order pending any judicial review of such order unless the
13 Secretary directs otherwise. Judicial review of any such order shall be in the United
14 States Court of Appeals for the circuit in which the applicant for, or recipient of,
15 inspection resides or has its principal place of business or in the United States Court of
16 Appeals for the District of Columbia Circuit, and shall be on the record upon which the
17 determination and order are based.

18 "(d) The remedies provided in this section shall be in addition to and not exclusive
19 of other remedies that may be available.

20 **CIVIL PENALTIES**

21 "SEC. 33 (a) Any person that violates any provision of this Act or any regulation
22 or order issued under this Act may be assessed a civil penalty by the Secretary of not

1 more than \$100,000 for each such violation. Each violation and each day during which a
2 violation continues shall be a separate offense. No penalty shall be assessed by the
3 Secretary under this section unless such person is given notice and opportunity for a
4 hearing on the record before the Secretary in accordance with sections 554 and 556 of
5 title 5, United States Code. The amount of such civil penalty shall be assessed by the
6 Secretary by written order, taking into account the gravity of the violation, degree of
7 culpability, size and type of business, and any history of prior offenses; and may be
8 reviewed only as provided in subsection (b).

9 "(b) An order assessing a civil penalty under subsection (a) shall be final and
10 conclusive unless the person files, within thirty days from the effective date of the order,
11 an application for judicial review in the Court of Appeals of the United States for the
12 circuit in which such person resides or has its principal place of business or in the United
13 States Court of Appeals for the District of Columbia Circuit by filing a notice of appeal in
14 such Court and by simultaneously sending a copy of such notice by certified mail to the
15 Secretary. The Secretary shall promptly file in such Court a certified copy of the record
16 upon which such violation was found and such penalty assessed. The findings of the
17 Secretary shall be set aside only if found to be unsupported by substantial evidence on the
18 record as a whole.

19 "(c) If any person fails to pay an assessment of a civil penalty after it has become
20 a final and unappealable order, or after the appropriate Court of Appeals has entered final
21 judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney
22 General, who shall institute a civil action to recover the amount assessed in an

1 appropriate district court of the United States. In such collection action, the validity and
2 appropriateness of the Secretary's order imposing the civil penalty shall not be subject to
3 review.

4 "(d) All penalties collected under authority of this section shall be paid into the
5 Treasury of the United States.

6 "(e) If any person fails to pay an assessment of a civil penalty after it has become
7 a final and unappealable order, or after the appropriate Court of Appeals has entered final
8 judgment in favor of the Secretary, the Secretary may refuse to provide inspection to, or
9 suspend inspection from, any such person, firm, or corporation until the assessed civil
10 penalty is paid or until otherwise ordered by the Secretary.

11 "(f) Nothing in this Act shall be construed as requiring the Secretary to report for
12 prosecution or for the institution of libel or injunction proceedings, violations of this Act,
13 whenever the Secretary believes that the public interest will be adequately served by
14 assessment of civil penalties.

15 "(g) The remedies provided in this section shall be in addition to and
16 not exclusive of other remedies that may be available."



**Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700**

Speeches

The Food Safety Research Agenda-- Emerging Microbial Pathogens and Issues

Remarks prepared for delivery by Dr. Catherine Woteki, Under Secretary for Food Safety, before the Beef Safety Symposium sponsored by the National Cattlemen's Beef Association and the American Meat Science Association, December 3, 1997, Chicago, Ill.

It's a pleasure to join you today to discuss emerging pathogens and issues in beef and how they affect the future agenda for food safety research. Before I was confirmed as Under Secretary for Food Safety, I served as Acting Under Secretary for Research, Education, and Economics, where I oversaw all food and agricultural research carried out by USDA. So I have a great interest in food safety research.

We especially appreciate *your* interest in food safety research, because we recognize that our efforts alone cannot be expected to address all food safety research needs. We must involve other government agencies, academic institutions, professional organizations, and the industry, to meet our research objectives in a timely manner. Meetings such as this one provide a forum for us to discuss what those needs are and how we can best achieve our goals.

Public Health Goals

Of course, all of our activities, whether they involve research, regulation, or education, focus on the important goal of reducing the incidence of foodborne illness. And that is indeed a formidable challenge. In the United States, the Centers for Disease Control and Prevention estimate that foodborne microbial pathogens account for up to 33 million cases of foodborne illness each year, and up to 9,000 deaths.

At the same time, the solutions to food safety problems are also becoming more and more complex, for many reasons. We have new food products with new food safety concerns. We have an increase in elderly and immune-compromised persons who are at higher risk of severe illness.

Emerging Pathogens

And, as the theme of your conference indicates, we have emerging pathogens and other emerging issues related to food safety. At a recent conference at Georgetown University on *E. coli*, I discussed how that pathogen is responsible for changing the Nation's mind set about foodborne pathogens. It's such a tiny organism, but is responsible for such a large impact. Less than a decade ago, the pervasive attitude among industry--and even among some regulators--was that bacteria, including pathogens, are a natural part of the environment and can't be controlled. The idea that government would begin setting standards for pathogen reduction, and testing raw products for bacterial contamination, was beyond belief.

Today, things have changed. We must focus on emerging pathogens such as *Salmonella typhimurium* DT104 and new strains of *E. coli*. We must be vigilant to trends in other countries, such as the emergence of BSE in Europe.

We also must be open to new paradigms regarding pathogens. What worked in the past may not necessarily work now or in the future. For example, we are finding pathogens on foods initially thought of as "safe." Produce, eggs, and fruit juices are examples. We are also encountering emerging antimicrobial resistance. And pathogens are adapting to traditional processing procedures and developing the ability to survive changes in pH, heat, and drying.

Food Safety Strategy

USDA has embarked on a number of changes to address these challenges.

First, we are making significant changes in our regulatory programs for meat and poultry by placing a new emphasis on controlling microbial pathogens. The final rule on Pathogen Reduction and HACCP, which was published in July 1996, sets new requirements for meat and poultry slaughtering and processing plants. By January 1997, all plants were required to implement standard operating procedures for sanitation, and slaughter plants were required to begin testing for generic *E. coli*, as a means of evaluating process control. In January 1998, plants will begin implementing Hazard Analysis and Critical Control Point (HACCP) systems and will be required to meet performance standards for *Salmonella* in raw products.

USDA is also implementing a farm-to-table strategy. From the very beginning of developing the HACCP rule, we have known that an effective food safety strategy must address the entire farm-to-table chain, not just what goes on within inspected plants. Our authority outside of plants is limited, but we are making progress by working closely with other government agencies, professional groups, academia, and industry.

The Food Safety and Inspection Service also recently underwent a reorganization to better operate in a HACCP environment that emphasizes the prevention of foodborne illness. One objective of the reorganization was to strengthen the Agency's focus on public health. Within the new Office of Public Health and Science, we have established several new divisions responsible for addressing epidemiology and risk assessment, emerging pathogens, food hazard surveillance, and emergency response to outbreaks of foodborne illness.

Food Safety Research Today

Research is very important to the success of these food safety initiatives. In order to effectively address the safety of meat, poultry, and egg products, we need to know more about the hazards in these foods and their relation to illness. Our programs must be responsive to new information and new data. And because our food safety strategy has broadened to cover the farm-to-table continuum, our research agenda must also address the entire continuum.

Agricultural research is now a shared responsibility of both the public and private sectors, and I'd like to take a few minutes to look at the current state of food safety research conducted today.

The Federal government has played a major role in supporting agricultural research for over a century. While farming was the traditional focus of Federal agricultural research during the last century, the demands placed on the U.S. agricultural research system are changing. Today, society's interest in agricultural research is more complex, with consumers expecting a wider set of issues to be addressed, including consumer health, food safety, and environmental protection.

(Slide #1)

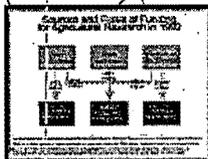
Research, Education and Economics Agencies include:

	Staff Years (ceiling)	FY \$97 Budget (millions)
ARS	7,901	\$800
CSREES	399	\$912
ERS	620	\$53
NASS	1,130	\$101
Total - REE	9,950	\$1,848

1. Current Estimate

The Federal government supports intramural research through the Agricultural Research Service, the Forest Service, and the Economic Research Service. It also funds extramural research at State institutions, which is administered by the Cooperative State Research, Education, and Extension Service. This strong intramural research base is needed because there are research problems and issues of national importance that may receive too little attention from individual States or regions. This research also serves the needs of the regulatory and action agencies.

(Slide #2) (Click image to view entire slide)



In 1992, nearly two-thirds of the \$1.55 billion spent by the Federal government for agricultural research went for in-house research at USDA agencies. The remaining third was distributed to State institutions. The private sector funded \$3.8 billion in research conducted in their own facilities or by universities.

(Slide #3) (Click image to view entire slide)



However, the lack of growth in Federal agricultural research expenditures constrains the ability of the public agricultural research system to respond to new demands. Federal expenditures have not grown in real terms since the mid-1970's.

(Slide #4) (Click image to view entire slide)



It is difficult to determine how much of the public funds for agricultural research are devoted specifically to food safety, because this research is often incorporated into other areas such as food science and animal health. It is clear, however, that food safety receives a very small percentage of research dollars.

(Slide #5)

CRIS

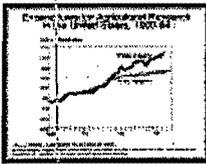
	Total Public Ag R&D (gross)	Total USDA R&D Agencies/1
RPA 701: Insure Food Products Free of Toxic Contaminants, Including Residues from Agricultural and Other Sources	\$21,387,994	\$15,840,773
RPA 702: Protect Food and Feed Supplies from Harmful Microorganisms and Naturally Occurring Toxins	\$56,417,002	\$32,221,082
RPA 707: Prevent Transmission of Animal Diseases and Parasites to Man	\$4,060,107	\$692,175
Total Agricultural R&D	\$3,168,751,751	\$1,130,638,508

Source: Inventory of Agricultural Research Fiscal Year 1995, Current Research Information System, CSREES, USDA, 1996

1. USDA research agencies include Agricultural Cooperative Service, ARS, CSREES, NRI Competitive Grants Program, ERS, Forest Service, Small Business Innovation Research Grants

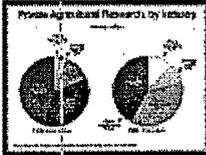
Data from the Current Research Information System (CRIS) maintained by USDA, shows three categories where research monies for food safety were allocated in 1995. ARS priorities include bacterial physiology, ecology, pathogenesis, growth dynamics of pathogens, and methods of predictive microbiology in various food matrices. ARS is carrying out approximately 35 projects at FSIS request.

(Slide #6) (Click image to view entire slide)



Turning to the private sector, it is also difficult to really know how much food safety research is done in private industry, but we do know that private research tends to be more commercially oriented than public research. And we also know that over the past 30 years, the importance of the private sector in both funding and conducting agricultural research is growing.

(Slide #7) (Click image to view entire slide)



There has also been a shift in emphasis in the type of agricultural research conducted in the private sector, with the private sector developing significant research capacity in areas such as farm chemicals, plant breeding and animal health.

Agricultural research will continue to require involvement by the Federal government in areas where private incentives are weak, and many aspects of food safety research fall into this area. But I believe the growing importance of food safety and the impact it can have on businesses are providing a growing incentive for private industry to support fundamental, as well as applied, food safety research. I believe this mutual interest in food safety research provides opportunities for partnerships in the future.

(Slide #8)

FOOD SAFETY RESEARCH AGENDA DIRECTIONS FOR THE FUTURE

Food Safety and Inspection Service
U.S. Department of Agriculture
May 1997

Food Safety Research Agenda

FSIS is not a research agency, however, and it must reach out to other research agencies within the Federal government, and to the private sector, to meet its research needs.

For that reason, in 1996, the Agency developed a Food Safety Research Agenda as one means of communicating with those outside the Agency about its priorities in food safety research.

As a first step, FSIS established a Food Safety Research Working Group, which was composed of scientists representing a broad base of expertise. The group included representatives from various USDA agencies as well as from the Food and Drug Administration, the Centers for Disease Control and

Prevention, the National Institutes of Health, and the Department of Defense. The group's task was to establish a research agenda that supports the changes FSIS is making in its food safety programs.

(Slide #9)

Criteria Used to Develop the Research Agenda

1. Incidence of Adverse Health Outcome
2. Causes of Adverse Health Outcome
 - a. Chemical
 - b. Physical
 - c. Biological
3. Linkage (etiological/vehicle linked to food)
4. Outcomes
 - a. Sequela
 - b. Deaths
 - c. Distribution (demographics/populations)
 - d. Costs
 - * Medical
 - * Productivity Losses
 - e. Public Sensitivity/Perceptions

The working group used human health effects as the basis for determining FSIS research needs, which is consistent with the risk assessment framework recommended by the Council for Agricultural Science and Technology (CAST) and the National Academy of Sciences (NAS).

Using the criteria, the working group reached a consensus on the major research questions that needed to be answered. They identified general research questions as well as research needs that are unique to the following pathogens--*Salmonella*, *Campylobacter*, *Listeria*, and Enterohemorrhagic *E. coli*, including *E. coli* O157:H7. Page 7 of the report lists 10 general research questions applicable to all pathogens.

(Slide #10) These are the questions that were developed for *E. coli*.

E. coli Research Questions

- What is the incidence of EHEC and *E. coli* O157:H7 disease/infection in humans and animals in the United States? What is the relative incidence among different subpopulations?
- What are the virulence factors associated with EHEC? Are all Shiga toxin-producing *E. coli* (STEC) pathogenic for humans, i.e., are all STEC also considered EHEC? Which virulence factors are associated with bloody diarrhea, hemolytic uremic syndrome, or other sequelae?
- How do EHEC colonize both animals and humans?
- What is the infectious dose and dose-response relationship of EHEC and *E. coli* O157:H7 for humans and animals? Does a threshold exist below which illness does not occur? Is a zero tolerance standard supportable by scientific evidence? Can dose response data calculated for *Shigella sp.* or *S. dysenteriae* type 1, be used for EHEC and *E. coli* O157:H7?
- What is known about microbial ecology of EHEC and *E. coli* O157:H7? What are the environmental reservoirs for EHEC and *E. coli* O157:H7 along the farm-to-table continuum? What are survival and growth characteristics before and after cooking?
- Should we be screening *E. coli* from human disease, and/or from food, for toxin production, or for the presence of stx, eae, hyl, EHEC plasmid, adhesins, etc.? Should we be screening human fecal specimens and/or foods for the presence of Shiga toxins?

The questions that the working group developed are important for several reasons. First, because the group used public health criteria as a means of determining research priorities, we can consider the pathogens identified by the group to be the major pathogens of concern for future research. Thus, *Salmonella*, *Campylobacter*, *Listeria*, and Enterohemorrhagic *E. coli* and *E. coli* O157:H7 are the pathogens about which we are most concerned. I encourage you to consult the research agenda for the specific research questions for each of these pathogens.

(End of slides)

Second, the research agenda reflects the direction taken by the President's Food Safety Initiative, which was announced in January of this year. The President's initiative supports the use of risk assessment as a means of characterizing risks to human health associated with foodborne hazards and assisting regulators in making decisions about where in the food chain to allocate resources to control those hazards. It targets virtually all of the pathogens emphasized in our research agenda as areas requiring short- and long-term research goals. And it supports the inclusive process through which the research agenda was developed. A wide spectrum of government agencies, including those with public health expertise, were involved in the process of determining research needs.

Our research agenda is also in keeping with the Government Performance and Results Act of 1993,

often referred to as the Results Act, which calls on all Federal agencies and departments to coordinate their activities to be more effective, efficient and to avoid duplication.

Challenges for the Future

The challenge for the future will be to integrate all of the research needs stated in the FSIS Research Agenda and the President's Food Safety Initiative, into an operational plan that reflects the emphasis on cooperation and partnerships. To assist in this process, the President's Food Safety Initiative calls for the convening of an interagency working group by the White House Office of Science and Technology Policy, to coordinate Federal research priorities and planning. The goal of this working group will be to develop a coordinated Federal food safety research plan, which will extend to our research partners in States, industry, and academia. This committee is now in the process of being formed, and we hope to hold the first meeting of the working group this month.

Closing

I would like to end my remarks with a few words about risk assessment.

Risk assessments are vitally important to our ability to determine the public health hazards associated with pathogens. Because risk assessment is a relatively new science, we need investment at the ground level. USDA's Agricultural Research Service is doing a lot of work in computer modeling, which is enabling us to be able to conduct these risk assessments, and FDA is making a major investment in a new center with the University of Maryland to focus on risk assessment. But in addition to the technology, we need the funds to develop new methods and to carry out such assessments. Appendix 2 in the Research Agenda--a Fault Tree Analysis for *E. coli* O157:H7 in ground beef--highlights areas where data are missing and we need to target research.

In closing, I hope I have succeeded in providing USDA's perspective on food safety research and in describing our research priorities. For the future, we would like to see industry determine what direction it wants to take in food safety research. Is the traditional division of labor and responsibilities for the private and public sectors consistent with making the best use of valuable research dollars? Should we continue to follow the tradition of more fundamental research questions being left to the Federal government and universities? Is the current Federal investment sufficient to meet food safety concerns and are our priorities appropriate?

I look forward to hearing the answers to these, and many more questions, as we work together to meet our food safety research goals.

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