United States Department of Agriculture
Cooperative State Research, Education, and Extension Service
Office of the Administrator

Self-Review for 2005 Portfolio Review Expert Panel

Portfolio 3.1: Reduce the Incidence of Food Borne Illnesses and Contaminants

Supporting Objective 3.1: Reduce the Incidence of Foodborne Illnesses and Contaminants through Science-Based Knowledge and Education

CSREES Goal 3: Enhance Protection and Safety of the Nation's Agriculture and Food Supply

For the period 1999-2004

Executive Summary

The portfolio review document for the Food Safety Program of Cooperative State Research, Education, and Extension Services (CSREES) was developed as a means to effectively review the overall effectiveness and impact of the program. The overall goal of the program is to improve the safety of the nation's food supply. The data supplied in this self study document, primarily represented in the numerous Success Stories, provide strong evidence that the program has relevance, quality, and performance, that it is working as designed, and that it is having a significant *impact* on improving the US food systems. Reference is made, in several places in the document, to data from the Centers for Disease Control (CDC) indicating that the incidence of food borne illnesses is decreasing. This overall improvement in public health is due to many federal programs including the CSREES Food Safety program. Food safety is a partnership of numerous agencies and evidence is provided that the CSREES Food Safety team is effective in its interactions with other agencies and is having a positive effect on improving the safety of food.

This report is comprised of two major sections. The first section describes the mission and goals of CSREES and cites the many enabling legislative actions directing the goals of the agency. ***[Deleted in the web published version, as repetitive across portfolios.]*** The second part of the report is a high level description of the Food Safety program in detail. In the second section, we elected to discuss each of the major funding programs separately. Included in this section are descriptions of the National Research Initiative (NRI) food safety programs (32.0 and 32.1), the National Integrated Food Safety Initiative (NIFSI), Special Grants, and the Small Business Innovation Research (SBIR) program. In each description, program mission is stated followed by a statement of program scope, and numerous program success stories. The separation of the specific funding programs was deliberate to simplify the review process. However, it should be understood that none of the programs are independent and each contributes to the overall goal of improving the safety of the nation's food. Furthermore, there are numerous examples of interactions between the programs and grantees within the programs. These interactions demonstrate that the programs are effectively integrated.

In addition to this report, a third component is represented by the Evidentiary Materials. This component is provided separately and contains documents and articles that more provide greater amounts of data on each program. The Evidentiary Materials have been divided into sections that aid in the overview of the Food Safety Program. This is followed by additional data on each of the funding programs.

In considering the outcomes from the Food Safety program as described in this report, we want to emphasize the significance of the outcomes as they relate to federal investment. Several projects including those related to actual interventions (e.g. product irradiation guidelines, diagnostic assays, and analysis of the benefits of good agricultural practices on food safety) demonstrate the strong commitments of the programs to the development of real world applications. As well, several studies have resulted in basic science

information that have the potential to challenge our thinking and study of food safety (e.g. use of geographic information systems tracking *S. enterica* and antibiotic resistance in the environment, analysis of closed systems in studying the epidemiology of *C. jejuni* in Iceland, and the development of "ropes" to track *E. coli* O157:H7 in beef feedlots). While these are but a few examples of impacts, we believe that the evidence provided in this report, which represents the entire food safety portfolio, demonstrate the food safety programs operate at a high level. Program performance has been excellent and the quality of the work has been outstanding. However, we believe that the most significant aspect of the portfolio is the data that demonstrates the performance of the funded work has led to significant impacts in the food safety system. This has led to an improvement in the safety of the foods produced through the US agricultural systems. The work has led to a spectrum of discoveries that range from that of a basic understanding of the principles of food safety through to the development of interventions, to tools for the detection of adulterants in foods. These accomplishments are remarkable and are strong indicators of success of the Food Safety program.

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SECTION II -- Portfolio Description

This self-study report was developed by the Plant and Animal Sciences (PAS) unit, Cooperative State Research, Education, and Extension Service (CSREES), United States Department of Agriculture (USDA). It is submitted to the Portfolio Review Panel, which is convened by the CSREES Administrator, in order to assess the effectiveness of the NRE unit as it leads efforts to address national problems and/or issues related food safety and biosecurity. The report covers a wide variety of programs conducted from 1999–2003 that are related to CSREES Strategic Goal 3: and Objective 3.1: *Reduce the Incidence of Food borne Illnesses Through Science-Based Knowledge and Education*.

This self-study is presented in two volumes. Volume One is a description of the portfolio and its programs. The second volume is Evidentiary Materials that are organized in a separate notebook. The notebook has been tabbed to provide overview materials followed by materials pertinent to each of the Food Safety programs. The following two Problem Areas (PA) are covered in this portfolio. However, since they are closely related, they are merged in the portfolio description:

PA 711. Ensure food products free of harmful chemical, including residues from agricultural and other sources.
PA 712. Protect food from contamination by pathogenic microorganisms, parasites, and naturally occurring toxins.

The Problem Area discussion is composed of research, education, and extension activities across various units within CSREES. A specific program, often conducted by a single program unit or even a single National Program Leader (NPL), may address several Problem Areas and several objectives of the CSREES Strategic Plan. Descriptions of these areas are compressed and do not cover all the activities within a portfolio. Additional information can be found in the Evidentiary Materials that will be available at CSREES review. The CSREES website (http://www.csrees.usda.gov) also contains information on the programs covered under this portfolio.

For the Nation to have affordable and safe food, the food system must be protected at each step from production to consumption. The production and distribution system for food in the United States is diverse, extensive, and easily accessible. This open system is vulnerable to introduction of pathogens and toxins through natural processes, global commerce, and by intentional means. Crop and livestock production systems must be protected from the ravages of diseases whether domestic or exotic. The food supply must be protected during production, processing, and preparation from contamination by pathogens and toxins that cause disease in humans.

The possibility of intentional contamination of the food supply or pathogen attacks on crops and livestock defines the need to conduct research to keep the U.S. food supply safe by incorporating a biologically-based (biodefense) strategy to reduce vulnerabilities. Novel scientific strategies must be developed to meet new threats.

The agencies within the Research, Economics, and Education (REE) Missionary Area will provide producers, manufacturers, regulatory agencies, and consumers scientific information and technologies, to support their efforts to provide affordable and safe food.

This portfolio supports Objective 3.1: "Reduce the Incidence of Food Borne Illnesses Through Science-Based Knowledge and Education" of CSREES Goal 3: "Enhance Protection and Safety of the Nation's Agriculture and Food Supply."

Central to providing a safe food supply is preventing the contamination of food by pathogens or toxins throughout production, processing, and distribution. Contamination of food can result from complex and diverse factors such as agricultural practices, the use of manure, water quality, weather, plant and animal genetics, industrial hygiene, storage and packaging, transportation, and food preparation. The safety of the food supply has long been a priority; the increased threat of the intentional introduction of pathogens and toxins has placed more emphasis on food safety in general and specifically on methods to prevent and detect contamination during processing and distribution.

Basic science and the resulting technology are keys to both preventing and detecting contamination of the food supply by pathogens and toxins. Training and information are essential for everyone from producer to consumer to carry out their role in promoting food safety.

Performance Goal: Provide scientific information to better understand and control the introduction of pathogens into the food system from production to consumption.

Performance Goal: Develop and transfer to USDA and other government agencies and to the private sector systems that rapidly and accurately detect, identify, and differentiate the most critical and economically important food borne pathogens.

Performance Goal: Provide the timely release of chemical usage statistics for fruits and vegetables.

Performance Goal: Provide education and training to producers, the workforce, and consumers on their role in promoting food safety and responding to threats to the safety of the food supply.

Actionable Strategies:

- Support and conduct microbial genomic research to provide the basis for detection, diagnosis and mitigation of food borne pathogens.

- Develop information on the ecology of human pathogens and understanding pathways to contaminate food. Focus on *Listeria, E.coli 0157:H7, Salmonella* , and *campylobacter* .
- Develop tests to detect pathogens that can be used by producers, processors, and regulatory agencies, such as the Food Safety Inspection Service (FSIS) and the Food and Drug Administration.
- Develop new on-farm and processing systems and practices to reduce pathogen contamination.
- Work with Federal food safety agency partners, FSIS and the Food and Drug Administration, to evaluate available food borne illness data and develop more accurate measures on the effectiveness of regulatory strategies in reducing preventable food borne illness.
- Develop scientific information and risk assessment models, in cooperation with the Food Safety mission area, that permit regulatory agencies to develop risk assessments for production, processing, and distributions systems
- Collect and disseminate science based information on chemical usage during the production and processing of food
- Provide the general public with food safety and biosecurity information and education through expanded outreach programs that address all aspects of food safety and mitigation strategies.
- Assist in developing the next generation of research scientists, educators, and technicians in the food and agricultural sciences.
- Design and develop intervention strategies that will aid regulatory agencies, including FSIS, in establishing the basis for regulations under Hazard Analysis and Critical Control Point (HACCP).

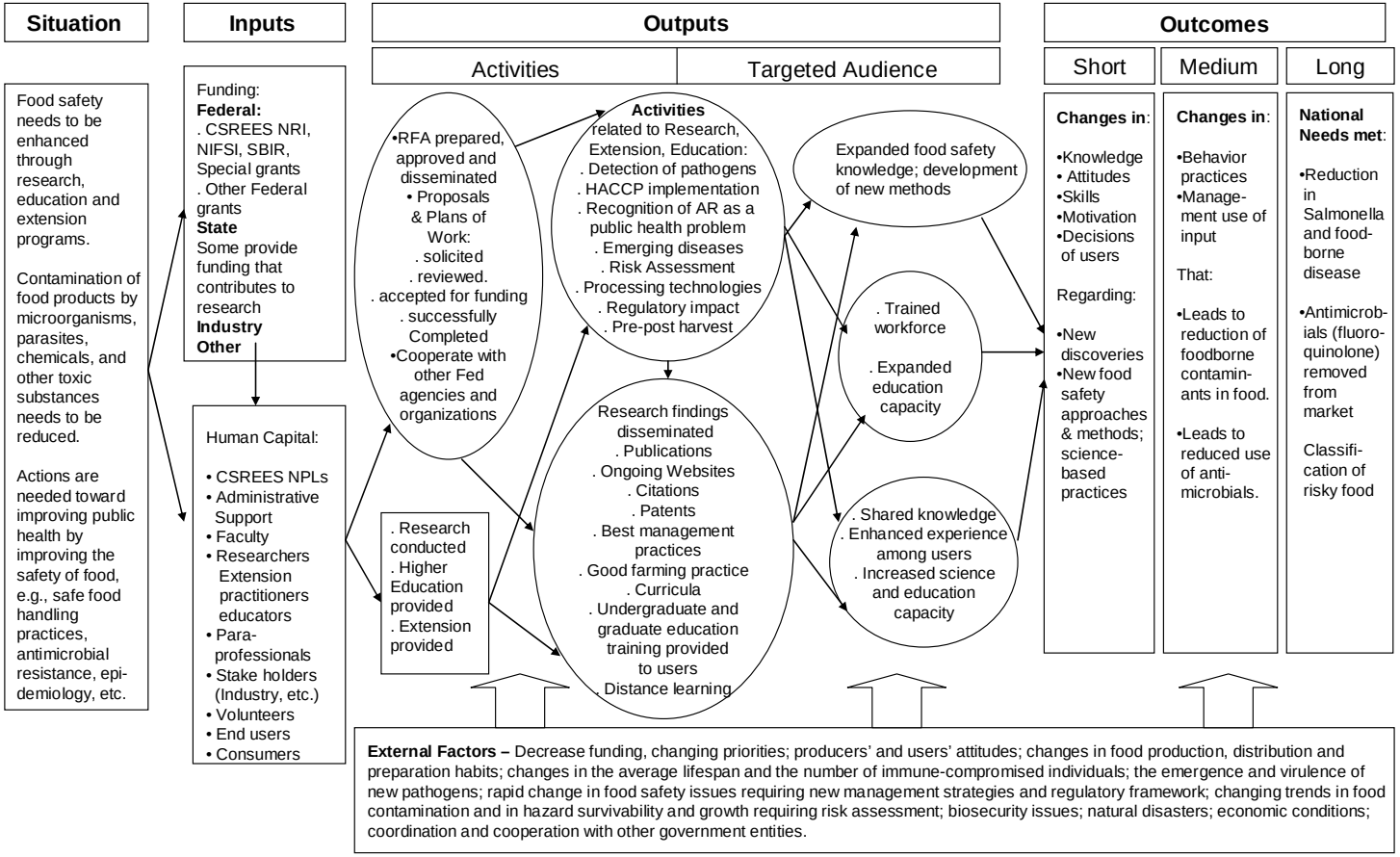
Overview of the Nation's Food Safety Issues

While the food supply in the United States is one of the safest in the world, the Center for Disease Control (CDC) estimates that 76 million people get sick, more than 300,000 are hospitalized, and 5,000 Americans die each year from food borne illness. Preventing food borne illnesses and death remains a major public health challenge. The nation's food system(s) are large and highly complex, which increases the difficulty in addressing this societal issue. It also mandates government involvement.

In 1997 in response to increased concerns about food borne illnesses, President Clinton introduced the Food Safety Initiative (FSI). The initial focus and goal of FSI was to reduce the number of illnesses caused by microbial contamination of food and water. The responsibilities for different aspects of food safety are necessarily shared among various government agencies. Consequently, there is a need for close coordination of activities. The initiative stimulated the formation of numerous task forces, committees, initiatives, and funding incentives over the following years. Some of the actions included major reports and recommendations on food safety in the U.S. such as "Food Safety from Farm to Table: A National Food Safety Initiative- A Report to the President, a report of the National Academy's findings "Ensuring Safe Food from Production to Consumption", and the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and

Vegetables. Other activities included the formation of many national and interagency task forces and working groups such as the Joint Institute for Food Safety Research, the Risk Assessment Consortium, and the National Food Safety System. Major initiatives included the implementation of the 1996 Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) rule, which was passed to help reduce microbial pathogens in processing plants and to clarify federal and industry roles. The culmination of these efforts was the signing of the National Strategic Food Safety Plan in January 2000. The broad goal of the strategic plan was "the protection of public health by significantly reducing the prevalence of food borne hazards through science-based and coordinated regulations, surveillance, inspection, enforcement, research, and education programs." The plan also established an outcome measurement. The goal by 2004 was a 25% decline in the incidence of the most common food borne illnesses and a 50% reduction in residues of carcinogenic and neurotoxic pesticides on foods. In 2002, The Food Safety Council became the Presidential Food Safety and Security Council, which was redefined to include the threat of bioterrorism. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 has changed the focus of some activities and initiatives. See (http://www.fda.gov/oc/bioterrorism/bioact.html). During the time period of the current peer review, several new research, outreach, and educational initiatives within CSREES were developed to address the need for new information to be able to make decisions based on sound science. These new programs included the National Integrated Food Safety Initiative (NIFSI) and the Epidemiologic Approaches in Food Safety initiative.

CSREES Food Safety Logic Model

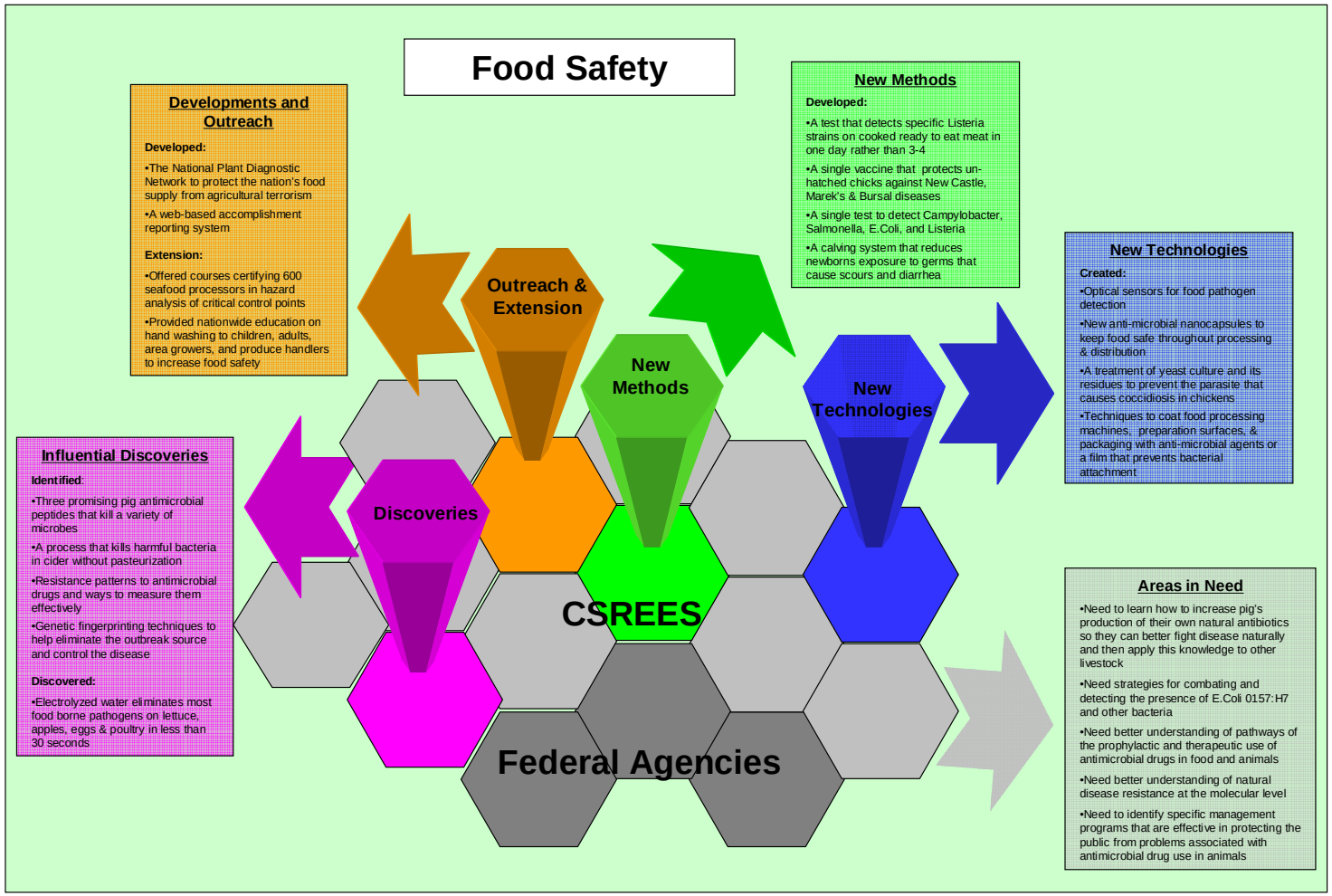


Source: Planning & Accountability Portfolio Review Expert Panel, 2004

The goal of this portfolio review is to critically evaluate the directions and successes of the CSREES food safety programs. The parameters driving the program include the important situations, inputs, outputs, and outcomes (short, medium, and long term) are listed in the portfolio Logic Models. The food safety programs are conceptualized in the first logic model. The logic model provides a *high level* illustration and analysis of the food safety strategy. The program descriptions that follow are geared to the logic model organization. In this document, each type of program in the food safety portfolio is separately highlighted: NRI 32.0, NRI 32.1, NIFSI, Special Grants, and SBIR grants. In addition to the comprehensive food safety logic model, separate logic models are shown for the NRI programs, NIFSI, and a combined NRI-NIFSI model. The combined NRI-NIFSI logic model is presented as an example that recognizes that none of the food safety programs are free standing and that strategic goals and activities are inherently tied to each other. It is clear that the separate programs are components of a cohesive and well coordinated research and education system. In the following portfolio descriptions, when necessary, aggregate data are presented. In other situations, the individual programs, particularly their successes, are individually showcased. It is important to note that while the individual programs are described separately in this portfolio review document, this separation is meant to simplify the review process. It is recognized that this perspective is a somewhat artificial view of the portfolio.

An additional graphical representations of the food safety programs are shown in a "honey comb" illustration. The illustration has been developed to graphically present the relationship between functions within the program, and their relationship to other programs within and outside of CSREES.

CSREES Strategic Goal 3: Enhance Protection and Safety of the Nation's Agriculture and Food Supply
CSREES Objective 3.1: Reduce the Incidence of Food borne Illnesses and Contaminants through Science Based Knowledge and Education
Portfolio 3.1: Reduce the Incidence of Food borne Illnesses and Contaminants



Stakeholder Input

All of the food safety programs in the CSREES have been developed and modified using extensive stakeholder input. The discussion of stakeholder input is presented as an aggregate discussion. The NIFSI Program Directors have sponsored three interagency food safety planning sessions since the inception of the Initiative. Partners and stakeholders from other Federal food safety agencies have been active participants in these planning sessions, helping to shape the direction of the CSREES food safety programs, while eliminating duplication in programming among the agencies. Joint program initiatives have been established, and grant funds have been made available to support these interagency initiatives. For example, the Presidential Produce Initiative to Ensure the Safety of Fresh Fruits and Vegetables is an interagency program. The Initiative worked cooperatively with Federal partners at the Food and Drug Administration (FDA) to quickly incorporate fresh fruit and vegetable safety into its competitive program portfolio.

Within the two NRI Food Safety program (32.0 and 32.1) stakeholder information is obtained in several ways. One is through the sponsorship of science meetings where the entire spectrum of stakeholders is present. For example, two colloquia were sponsored: one on food safety and biosecurity and the other on agricultural uses of antibiotics. Participants at these colloquia were invited and the number at each was limited to about 30. Careful attention was paid to the participant lists to insure representation of the science disciplines, other government agencies, and industry commodity groups (all are stakeholders). The outcomes from both colloquia were summary reports that included recommendations for future research, educational programs, and policies within the subject area. As of April 2004, over 15,000 copies of the summary from the antibiotics colloquium have been circulated. These documents are available on the web page (www.asm.org).

Financial support also was provided for other national workshops or conferences including the 2003 Mycotoxins and Phycotoxins Gordon Conference.

The grantees represent another stakeholder group. The Epidemiologic Approaches for Food Safety program was the first National Research Initiative (NRI) program to require annual meetings of the grantees. This was in part to facilitate communication but also to get "feedback" on the program, emerging research issues, and academic stakeholder input. The meetings also represent a means for scientists to leverage samples collected in their studies and to develop synergistic collaborative research projects.

Additional examples of stakeholder input are listed below.

● A public listening session was held in November of 2000. Stakeholders included university partners, representatives from industry, a consumer advocate, and federal partners from FSIS, FDA, and ARS. Participants presented food safety priorities from their representative organizations. In small group break-out sessions, participants identified overall food safety priorities common to all those working in food safety.

● A consortium of approximately 20 Federal agencies met to solicit the collective and individual needs of each agency in the area of risk assessment.

● *A joint CSREES/ARS stakeholder workshop held in November of 2001*:

In a format similar to a public listening session, university, industry, consumer, and federal partners presented their food safety and animal agriculture priorities, and worked to develop overall program priorities. The workshop highlighted complementary research between CSREES and Agricultural Research Services (ARS).

● *NASULGC recommendations provided in a published report to USDA*:

Recommendations from the National Association of State Universities and Land Grant Colleges (NASULGC) were provided in a report published in 2001 entitled *"A Science Roadmap for Agriculture."* Recommendations provided guidance for food safety program priorities in CSREES.

● *A CSREES-sponsored interagency brainstorming session held in August of 2002*:

Federal stakeholders from Food Safety Inspection Services (FSIS), Food and Drug Administration (FDA), and Agricultural Marketing Services (AMS) participated in a planning activity intended to help guide priority-setting for integrated food safety programs in CSREES. Federal stakeholders provided agency updates, and discussed areas where each agency could work together to strengthen overall food safety programs throughout the government.

● *A Stakeholder Listening Session on Food Safety Research Priorities*:

CSREES and ARS took the lead in hosting a national stakeholder session in June 2003 for the Office of the Research, Economics, and Education (REE) Under Secretary. The session was held in Denver, Colorado. Industry, university, consumer, and federal stakeholders ranked their top 5 food safety research priorities. The input that was gathered at this session was compiled and summarized in a report published by USDA entitled, *"The USDA Food Safety Research Agenda for 2004-08."*

Overview of CSREES Food Safety Portfolio Funding and Priorities

Overview: *Current Funding and priorities within CSREES***:** Research, education, and extension programs are funded by CSREES through several programs: The National Research Initiative Competitive Grants Program, The Integrated Food Safety Program, Special Grants, grants from SBIR, and Hatch and other formula funds. In the 5 years covered by this review, over $108 million have been provided through CSREES for food safety research. In addition, funds secured through CSREES have been used to leverage other funding opportunities and vice versa. Funding for Food safety remains steady although newer priorities have emerged since the bioterrorism act. In the Federal

budgets, it is more difficult to determine what funding is for food biosecurity versus food safety, especially since many of the activities overlap. However, increases in funding have been used for increased surveillance, inspections, and enforcement activities. Other initiatives include the registration of food processing plants, and numerous rules and guidelines.

Food safety research remains essential since many data gaps exist and food borne disease is still a significant public health burden. Furthermore, the continual increase in the number of multiply antibiotic resistant bacteria is of growing concern. There are significant data gaps in the risk assessment models and, while there are several good farming practice approaches, effective science-based on farm interventions are still lacking. Consequently, research is needed to determine better interventions and better control and prevention measures along the entire food safety continuum and tools need to be developed that measure the effectiveness of these interventions at the farm, processor, and public health levels. Furthermore, new infectious diseases have emerged (or re-emerged) and antibiotic resistance has become a major issue in food safety. Most of these new diseases are zoonotic and some are food- related (including BSE).

Another major initiative is in epidemiology with the availability of funding specifically for epidemiologic research in food safety. There is an important need to develop data to determine how food borne pathogens enter the food chain with the expectation that such information will provide ways to break the transmission process. This requires the inclusion of epidemiologic methods. With the initial increase in food safety research funding in the late 1990's, a new granting program was established in 1999 by the CSREES. Epidemiologic Approaches for Food Safety provides epidemiologists and microbiologists with an opportunity to obtain research funding. This program established a new paradigm of mandated interdisciplinary research. Since 1999, this program has provided over $23 million in funding for epidemiologic research.

CSREES also developed a mechanism to translate basic research into action via the NIFSI. The goal of this Initiative is to link basic and applied research and to move the outcomes of research funded through this program to the main stream. The Initiative also is unique in that it also mandates a link to educational and outreach activities, which include education of producers and consumers. Consequently, NIFSI is the applied wing of the food safety portfolio.

In addition to the food safety programs within CSREES, other agency programs are charged to improve food safety. In particular, scientists studying microbes that cause food borne illnesses now are aided in their investigations because of the availability of genome sequences of food borne pathogens. Some of this sequence data has been obtained through research derived from other CSREES supported research programs (Animal Health and Well-Being and Microbial Genomics). The remainder is from NIH, DOE, NSF, other non profit organizations, as well as numerous international sources. The genome sequences are being used to develop a spectrum of outcomes from new, rapid diagnostic tests for food borne pathogens, to the development of animal vaccines to break the transmission cycle of food borne pathogens in animals.

In the April 30, 2004 issue of Morbity and Mortality Weekly Report, it was stated that "During 1996--2003, the estimated incidence of *Campylobacter*, *Cryptosporidium*, *E. coli* O157, *Salmonella*, and *Yersinia* infections declined substantially. The decline in *Campylobacter* and *E. coli* O157 infections demonstrates that meeting the 2010 national health objectives of 12.3 and 1.0 illnesses per 100,000 persons, respectively is likely. Although the incidence of *Salmonella* infection has declined, it remains above its objective, and among the five most common *Salmonella* serotypes, only *S*. Typhimurium demonstrated a sustained decline in incidence." These results indicate that the fruits of the multi-pronged attack to improve the safety of foods are working. In the following sections information and data will be provided that describes the breadth and depth of the CSREES programs, the success stories, and their impacts. The approach taken in this report is to describe the individual programs and to show how the various programs interact with each other as well as other governmental and stakeholder programs. As stated previously, the individual programs are highly interactive and interdependent. The approach taken in this report is to simply the review.

The Problem Areas (PA) that are considered part of the food safety portfolio include PA 711 (Ensure food products free of harmful chemicals, including residues from agricultural and other sources) and 712 (Protect food from contamination by pathogenic microorganisms, parasites, and naturally occurring toxins). Because PA 711 is a small component of the food safety portfolio, we elected to merge the two PAs into a single report. Furthermore, it was felt that both PAs represent important food safety concerns that are interrelated. For the information below describing the food safety programs, we elected to describe the NRI programs (32.0 and 32.1), the NIFSI, and special grants/SBIR grants individually.

Inputs

The major type of input data is the number of projects funded, the total dollars provided, and the number of graduate students and postdoctoral fellows supported through CSREES funds within the Food Safety objective. The data presented in the following series of graphs and tables represent inputs from the CRIS database and is sorted by Subject of Information (SOI) categories. To aid in the interpretation of the data we elected to present only the top 5 of 10 SOI's since these represent that greatest percentage of fund allocation. The number of trainees supported with CSREES funds from competitive grants only includes NRI-based funds.

Table 1

Top Funding Trends by SOI 1999-2003
(in 000)

	1999	***2000***	***2001***	***2002***	***2003***
Microorganisms	$4,875	$4,626	$8,675	$11,826	$7,091
Poultry	$3,388	$3,767	$2,755	$5,980	$5,261
Vegetables	$2,052	$4,250	$1,619	$1,292	$1,340
Food	$2,042	$2,549	$5,887	$4,567	$4,453
Beef cattle	$1,729	$2,154	$1,619	$3,353	$2,226

Figure 1

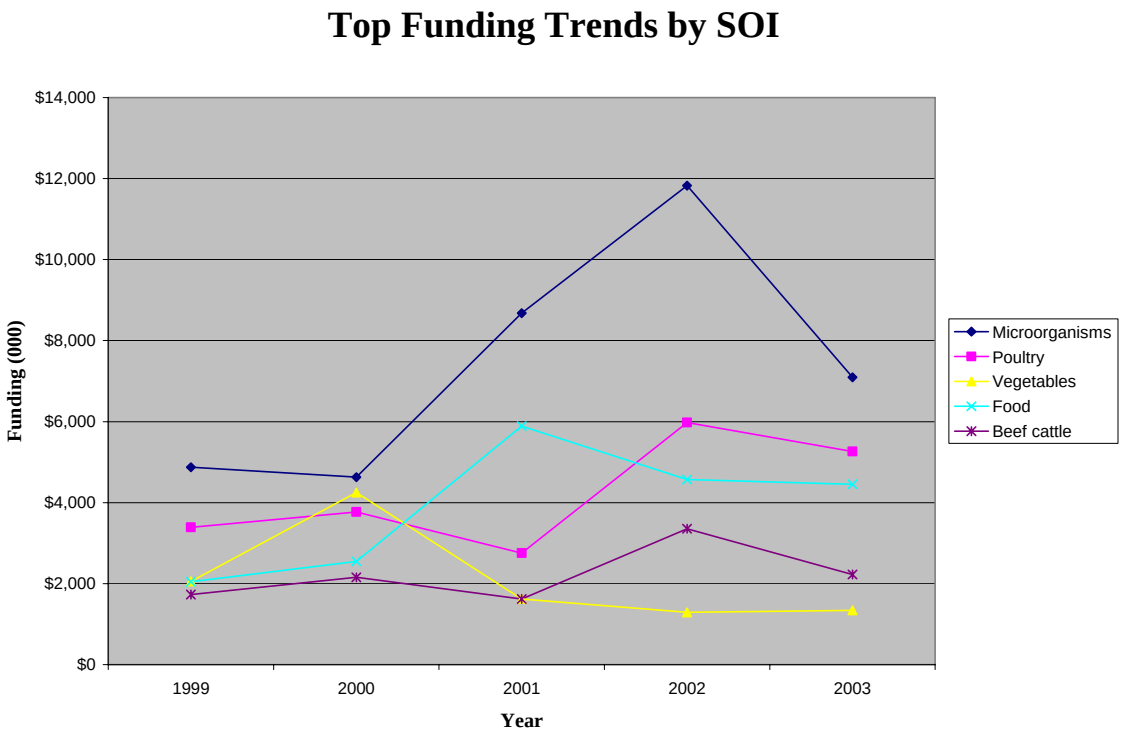


Figure 2

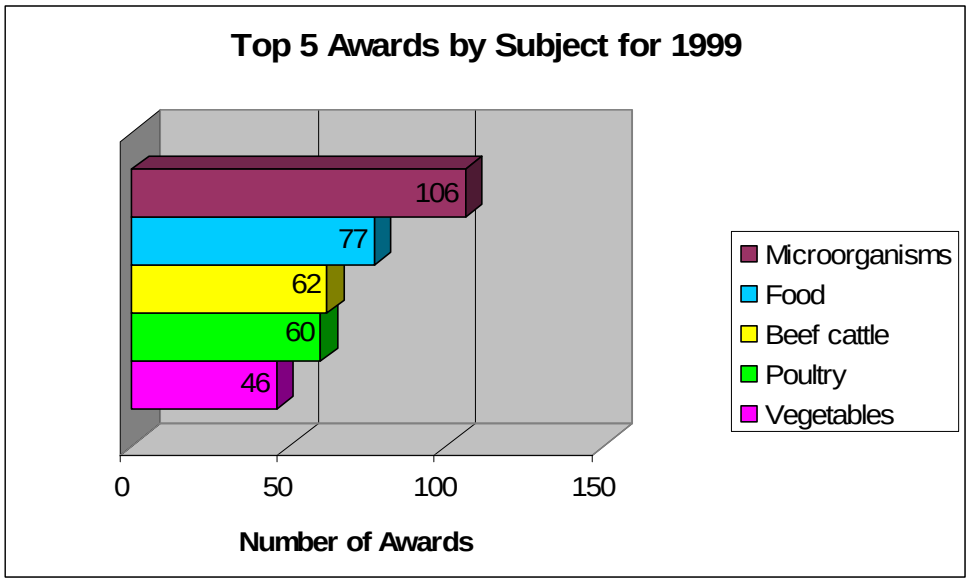
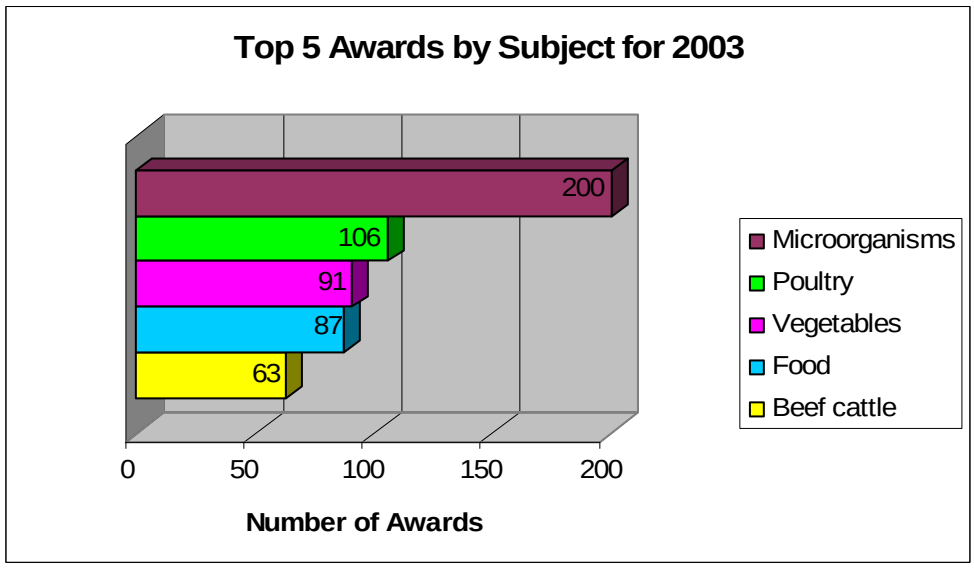


Figure 3

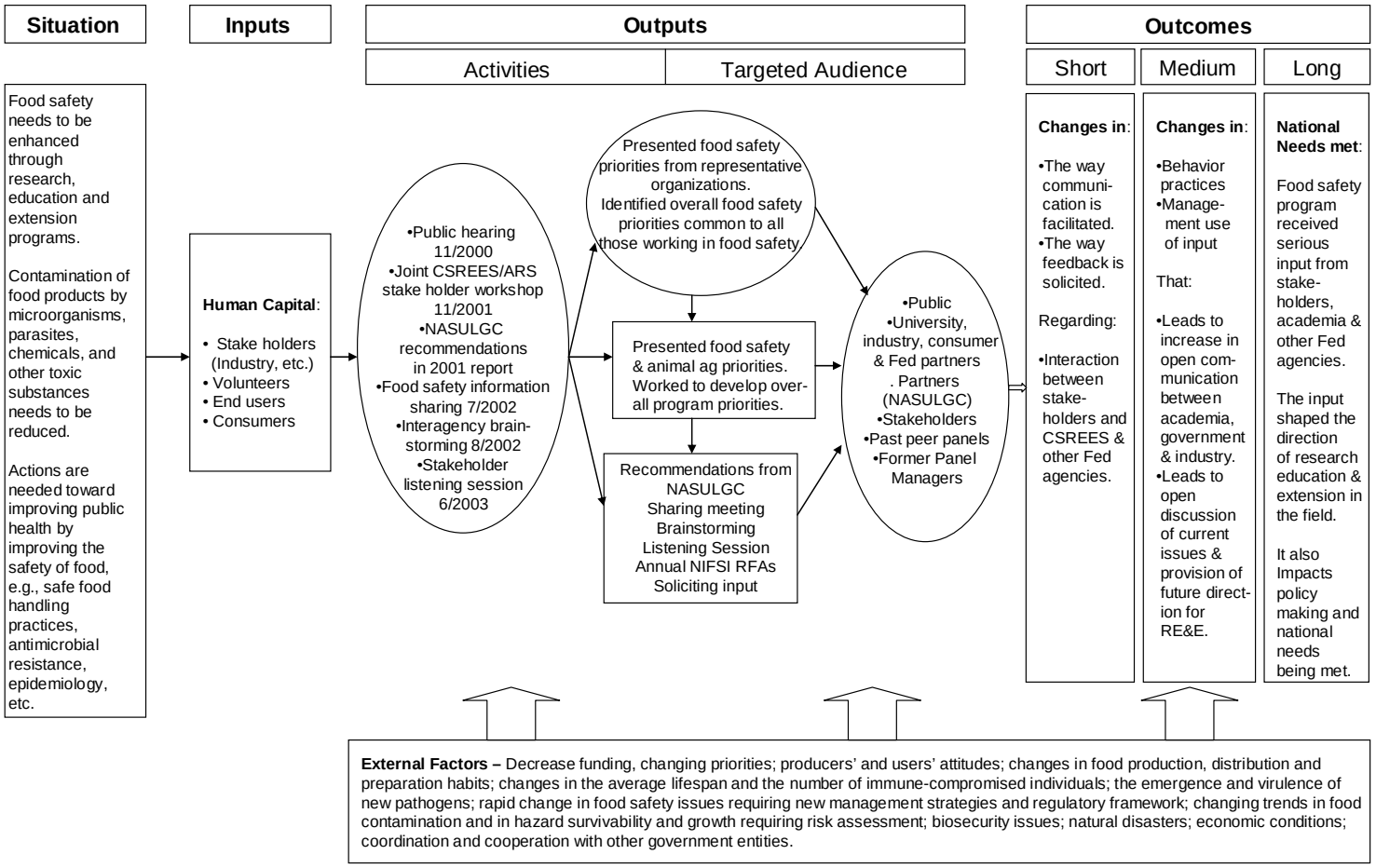


SECTION III – FOOD SAFETY PROGRAMS

Introduction to NRI and NIFSI

CSREES shapes the future of food safety through research, education, and extension. These three components are crucial in allowing food safety researchers, educators, and communicators to move from theory, to data gathering, to data analysis, to testing, to program development, to implementation, and, finally, to evaluation. This comprehensive approach provides the basis for an overall "integrated" food safety program. Food safety program components within CSREES are addressed through two of the Agency's flagship competitive grant programs –NIFSI and the NRI (Sections 32.0 and 32.1). While NRI focuses on *developing* new knowledge, NIFSI focuses on *applying* new knowledge. Thus, both programs complement each other, rather than being duplicative. Basic research generated through NRI provides baseline data to support the development of NIFSI's educational interventions. In addition, NRI basic research will provide new detection methods, prevalence data, or identification of new risk factors that can then be integrated into education or extension programs funded through NIFSI. This ensures that research results are disseminated to appropriate end-users.

CSREES Food Safety Logic Model (NRI&NIFSI Stakeholder Interaction)



Source: Planning & Accountability Portfolio Review Expert Panel, 2004

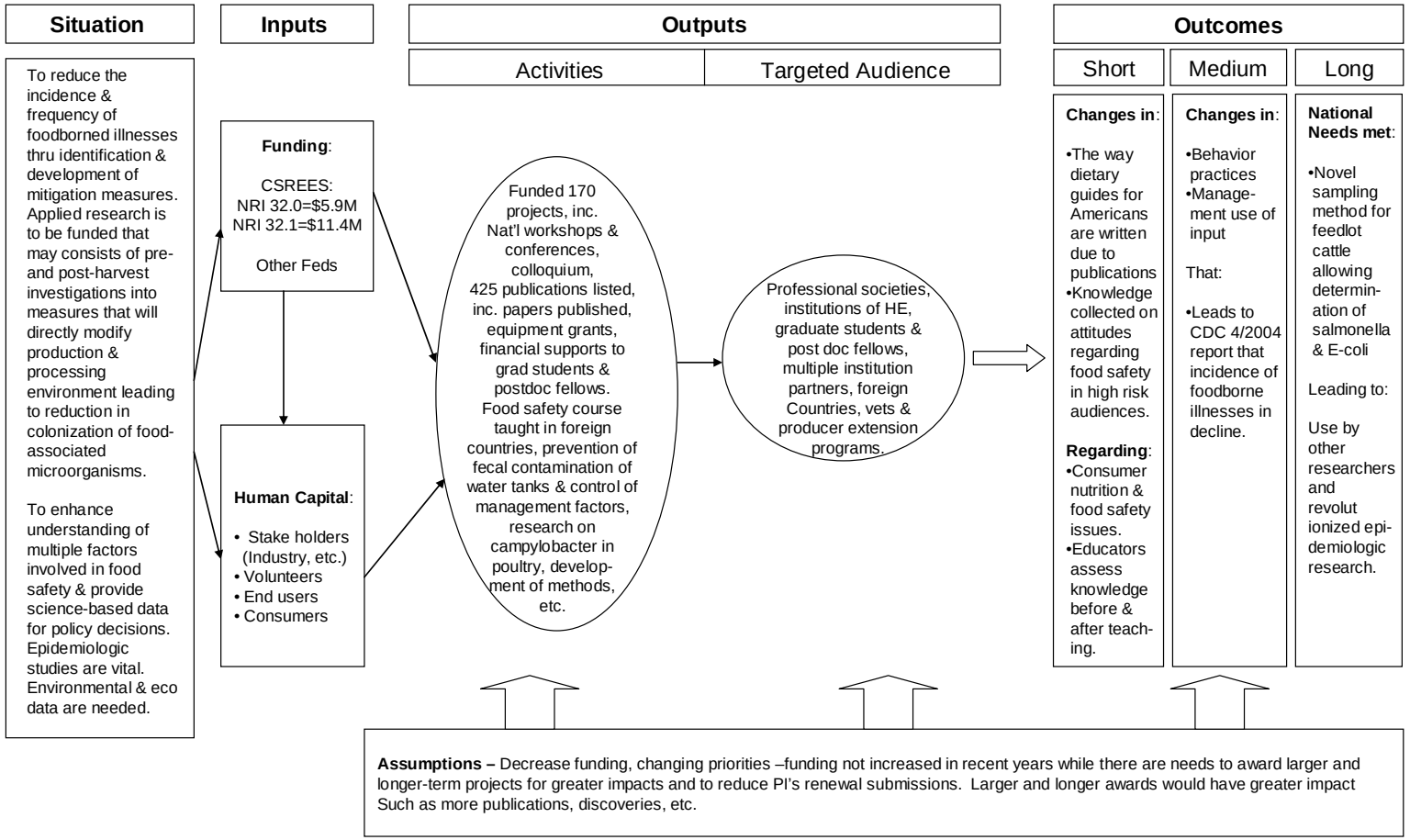
NRI Food Safety Program

The NRI Food Safety Program covers both program parts (32.0 and 32.1). One logic model is provided to graphically describe this program. However, for each part, honey comb illustrations are provided. NRI has also provided funding for a number of graduate students, as presented in Table 2.

Table 2
Graduate Students and Post Doctoral Fellows
Funded through NRI Research Grants
1999-2003

	Graduate Students	Post Doctoral Fellows
1999	14	12
2000	13	10
2001	14	11
2002	16	16
2003	30	18
Total	87	67

CSREES Food Safety Logic Model (NRI)



Source: Planning & Accountability Portfolio Review Expert Panel, 2004

NRI Food Safety Program (32.0)

Overview – Mission and Goals:

The 32.0 Food Safety Program seeks to enhance the knowledge of mechanisms of food borne illness from the standpoint of both basic and applied research efforts with the goal of developing risk mitigation measures. This includes, but is not limited to, investigations of vector-based transmission of pathogens, toxins and contaminants; identification of critical control points in food production and processing; development of novel vaccines to preclude pathogen colonization; molecular and biochemical approaches to understanding the genetic and physiological mechanisms influencing pathogen virulence; model development to predict aspects of food production and processing wherein mitigation will be most effective; socioeconomic factors affecting food safety; and genetic modification of crops to mitigate toxin producing microorganisms.

Situation -- Program Objectives:

The overall objective of the Food Safety Program (32.0) is to reduce the incidence and frequency of food-borne illness through identification and development of mitigation measures. The mechanisms that lead to a reduction in food-borne illness may consist of what is considered as basic research into mechanisms of pathogen virulence, genetic variance in pathogen populations, and physiological mechanisms influencing toxin production among other areas. Applied research also is funded under this program and may consist of pre-harvest or post-harvest investigations into measures that will directly modify the production or processing environment leading to a reduction in colonization or survival of food-associated microorganisms. Mitigation measures investigated through this program may be biological, chemical, physical or may rely on a change in behavior or food handling methods.

In addition to colonization of foods with microbial contaminants, chemical contaminants are also considered as food safety issues and research into reducing this contamination may be funded under the 32.0 RFA. This includes pesticidal chemicals wherein residues exceed EPA-determined levels for a particular pesticide on a specific commodity, but may also include inadvertent chemical contaminants that may be of environmental origin or as a result of human actions.

Outputs

Between Fiscal Years 1999 and 2003 the NRI Food Safety Program provided grants for more than 136 separate projects. Highlights from these grants are presented below.

- Partial financial support was provided for 7 national workshops or conferences. Examples include the 2001 Symposia on Microbial Food borne Hazards; the American Academy of Microbiology colloquium, Antibiotic Resistance and the Role of Antimicrobials in Agriculture: A Critical Scientific Assessment, in 2001; and the 2003 Mycotoxins and Phycotoxins Gordon Conference.

- Over 425 publications have been listed in USDA's Current Research Information System (CRIS) as resulting from NRI-funded projects. This only includes papers published or in press up to December, 2003. Selected examples are cited under Success Stories.
- Six equipment grants were made to strengthen the capacity for food safety research in small to mid-size institutions and institutions less successful in obtaining NRI funds. These included purchase of a spiral plating system for the University of Maine; pulsed-field gel electrophoresis equipment for Mississippi State University; and LC/MS equipment for the University of Wyoming.
- In Fiscal Year 2003, NRI-funded projects provided financial support for 24 graduate students for 678 months and for 2 postdoctoral fellows for 58 months.
- Of the 136 projects funded by NRI during this time period, at least 15 included partnerships between multiple institutions. Examples are partnerships between researchers at the University of Nebraska and Cornell University on a project entitled "Population Genomics of *Listeria monocytogenes*" and collaboration between researchers at the U.S. Food and Drug Administration and University of Maryland on several projects relating to antimicrobial resistance.

Outcomes

Short-term outcomes

The 2005 Dietary Guidelines Advisory Committee (DGAC) report cited publications by a CSREES-funded collaboration of researchers from the Ohio State University, Washington State University, and Colorado State University. The committee's report will be used by the Departments of Agriculture and Health and Human Services to write the 2005 Dietary Guidelines for Americans, which is the major policy statement for consumer nutrition and food safety issues. This group has received two NRI grants, as well as a grant from the NIFSI.

Additionally, a publication resulting from the CSREES-funded projects was featured as a cover story of the November, 2004 *Journal of the American Dietetic Association* (Medeiros, L.C., Hillers, V.N., Chen, G., Bergmann, V., Kendall, P. and Schoeder, M., Design and Development of Food Safety Knowledge and Attitude Scales for Consumer Food Safety Education. J. Amer. Diet. Assoc., 104:1671-1677, 2004). The researchers developed and pilot-tested knowledge and attitude questions regarding food safety with groups of low-income nutrition education program participants and college students. They used reliability and validity tests of individual items to reduce the scales to 18 knowledge questions and 10 attitude questions. The knowledge questionnaire may be used by educators to assess subject matter knowledge before and after instruction. The attitude scale can be used by researchers and educators to assess outcomes of food safety educational programs. This group is continuing their research by working with high-risk audiences (e.g. older adults, pregnant women and persons with compromised immune function).

Researchers at Texas Technical University have demonstrated that plant tissues besides green leafy vegetation may contribute to total perchlorate exposure among humans and livestock. Concern over animal exposure to perchlorate has largely centered on drinking water. This research highlights the need to further consider plant ingestion as an exposure route. In addition, other plant tissues besides green leafy vegetation may also contribute to total perchlorate exposure among humans and livestock. These data demonstrate that food items may be a significant source of perchlorate exposure in humans and livestock, but exposure via food may not produce the same degree of effect as exposure via drinking water. The EPA is using this data in revising standards for human perchlorate exposure. Publications resulting from this NRI-funded research include:

Medium-term outcomes

The April 2004 issue of CDC's Morbidity and Mortality Weekly Report states that the incidence of food borne illnesses is in decline. This is the result of a multi-agency, multi-prolonged approach to enhance microbial contamination of food and services as an indicator that these programs are working.

New Directions

Current program funding is centered on bacterial-based food borne illness mitigation. These proposals reflect the predominance of bacterially-mediated food safety issues confronting producers and processors. Antibiotic resistance also has been a major area of research funded by this program. Despite significant advances from these projects, it is likely that the major food borne illnesses will continue and increases in antibiotic resistant will occur. Consequently, these areas will remain important themes in our food safety funding portfolio. In addition to these food safety concerns, other research areas will continue to evolve and be in need of financial support to address food safety issues. While bacterial pathogens represent the area garnering the largest amount of funding, enteric viruses represent the largest cause of food borne illnesses and emphasis needs to be placed on this area. Other areas that may need better science-based information include prions and related spongiform encephalopathies. Studies on chemical contaminants of foods (*e.g.*, dioxins, perchlorate, pesticide residues), mycotoxins, and risk assessments needed for products of biotechnology (*e.g.*, toxicology and allergenicity of transgenic proteins) also need to be considered.

Success Stories

One of the impacts of the NRI competitive grants programs is the support of new scientists who are beginning their careers in the area of food safety. For example, Muhfahzur Sarker of Oregon State University received the Presidential Early Career Award in Science and Engineering for his NRI-funded project "The Molecular Basis for *Clostridium perfringens* Spore Heat Resistance." Dr. Sarker received this award because his proposal was considered to be the best proposal from a New Investigator funded by the NRI in Fiscal Year 2002. The goal of this project is to determine the molecular basis

for the differences in heat resistance between spores of *C. perfringens* isolates carrying chromosomal versus plasmid enterotoxin (CPE) genes. These studies will provide important insights into the pathogenesis of enterotoxigenic *C. perfringens* isolates and may improve our abilities to prevent *C. perfringens* type A food poisoning, which currently affects over 600,000 Americans per year.

Another example of how young scientists are supported by NRI funding is demonstrated by Dr. Sangwei Lu, who received a New Investigator Award from the NRI Food Safety Program in Fiscal Year 2003 for her proposal, "Genetic Determinants of Resistance of *Salmonella Enteritidis* to Chicken Egg Albumen." The goal of her research is to determine how *S. enteritidis,* a major food borne pathogen, is able to survive and persist in eggs. Dr. Lu had previously served as a postdoctoral associate in an NRI-funded grant to Dr. L. Riley at the University of California, Berkeley entitled "Resistance of *Salmonella Enteriditis* to the Antimicrobial Stress of Egg Albumen." In the original study, the researchers established an in vitro assay of bacterial survival in egg albumen and identified a novel mechanism of bactericidal activity of egg albumen, and a gene, yafD, that is necessary for *S. enteritidis* to survive in egg albumen. Dr. Lu is now continuing this work to screen a transposon mutant library to systematically identify genes necessary for *S. enteritidis* to survive in egg albumen and characterize the mechanisms of resistance mediated by these genes.

Jan Sargeant and colleagues at Kansas State University have received CSREES-funded Special Grants, an NRI Food Safety grant and an NRI Epidemiological Approaches for Food Safety grant. This research group is working on effective strategies to control *E. coli* O157:H7 in feedlot cattle. They have studied the distributional patterns of *E. coli* O157:H7 in agricultural range environments and found that persistent subtypes were found in different types and groups of cattle, in natural free-flowing water and in wildlife sources. They have also studied management practices related to fecal shedding of *E. coli* O157:H7 in feedlot cattle and found that preventing fecal contamination of water tanks and controlling vermin and house flies in cattle pens may reduce fecal shedding of this organism.

Dr. Don White of the University of Illinois at Champaign-Urbana has been active in breeding maize for resistance to *Fusarium* spp and other fungi associated with mycotoxin production in grain. A proposal was funded in FY 2003 to support the identification of maize germplasm with practical levels of resistance to *F. moniliforme*, *F. proliferatum* and related fusaria. The primary objective of the project is to reduce or eliminate fumonisins in maize grain such that maize-based food products contain little or no fumonisin. This task was partially accomplished through the identification of molecular markers associated with resistance genes in a variety of maize inbreds. To date, four resistant inbreds with particular promise have been identified and evaluated in the field for resistance to *Fusarium* ear rot and fumonisin levels in grain at three different locations (North Carolina, Illinois and Indiana). Inbred lines CG1, TBA76125, GE440 and FR1064 have all been demonstrated to result in significantly lower levels of fumonisin in maize grain. All of these genotypes are undergoing molecular marker analysis and generation means analysis to aid in the localization of these resistance loci to

chromosomal locations. The germplasm developed from this project will be available to public and private plant breeders who wish to incorporate this resistance into commercial hybrids.

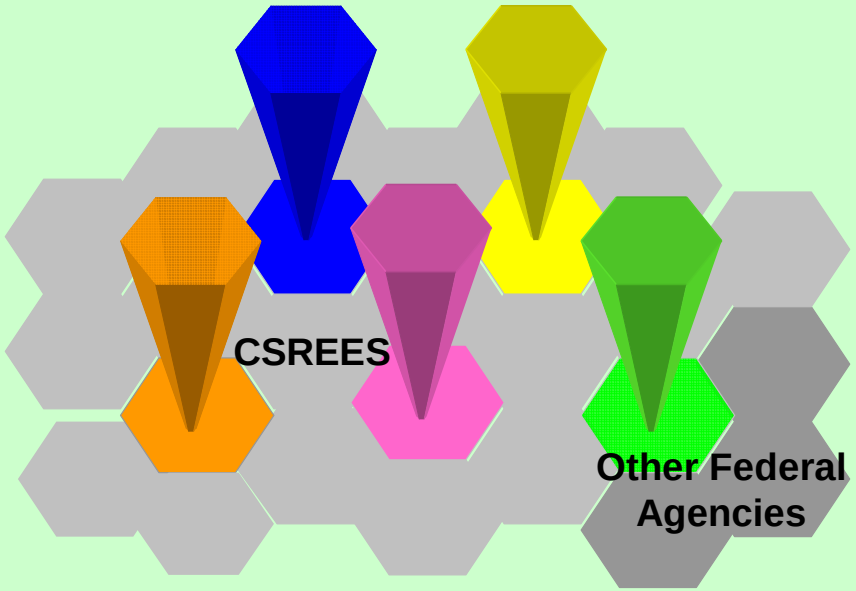
CSREES Strategic Goal 3: Enhance Protection and Safety of the Nation's Agriculture and Food Supply

CSREES Objective 3.1: Reduce the Incidence of Food borne Illnesses and Contaminants through Science Based Knowledge and Education

Portfolio 3.1: Reduce the Incidence of Food borne Illnesses and Contaminants

NRI Food Safety Program (32.0)

Funding Sources



Accomplishments

- Established an in vitro assay of bacterial survival, identified a novel mechanism of bactericidal activity, and a gene, yafD, that is necessary for S. enteritidis to survive in egg albumen
- Found that persistent subtypes of E.Coli 0157:H7 were found in different types and groups of cattle in natural free-flowing water and in wildlife sources
- Found that preventing fecal contamination of water tanks and controlling vermin and house flies in cattle pens may reduce fecal shedding in feedlot cattle.
- Identified molecular markers associated with resistance genes in a variety of maize inbreeds
- Demonstrated that inbred lines CG1, TBA76125, GE440, and FR1064 result in significantly lower levels of fumonisin in maize grain

Additional Work Needed

- Need further research on bacterial-based foodborne illness mitigation
- Need funding and emphasis to be placed on enteric viruses
- Need better science-based information on prions and related spongiform encephalopathies, chemical components of foods, and mycotoxins
- Need risk assessment for products of biotechnology

NRI Food Safety Program- 32.1: Epidemiologic Approaches for Food Safety

Overview- Missions and Goals

The mission of the CSREES NRI Epidemiologic Approaches for Food Safety is to enhance food safety by providing the opportunity for large scale population-based studies including studies at the farm level. It also is to foster research that will increase our understanding of the epidemiology of food borne pathogens, identify risk factors, and provide science-based analysis of interventions and control strategies. Projects funded through this initiative must be multidisciplinary.

Situation- Program Objectives

The program's objective is to enhance the understanding of the multiple factors involved in food safety and provide the science-based data for policy decisions. Significant gaps exist in the knowledge base for food safety and the risk factors involved in the entire continuum of food production, from farm to table. Epidemiologic studies of pre- and post-harvest areas are vital to identify and characterize pathogenic organisms, including their sources and reservoirs; and to understand the transmission of the pathogen along the entire continuum. The identification of risk factors for exposure to and infection by these pathogens can be accomplished by several different epidemiologic research methodologies. These methodologies can be applied at any stage of food production. Environmental and ecological data are needed to increase our understanding of disease-causing microorganisms, their products, and naturally occurring contaminants in meats, poultry, seafood, and fresh fruits and vegetables. Studies that elucidate these data or information, or provide a "value of information" analysis, can provide important information on where research is needed and could be useful for risk assessments.

The current emphasis of this program is any population-based epidemiologic study that involves identifying risk factors and evaluating strategies to reduce food borne contamination, whether pre- or post- harvest. It also involves the identification of potential sites of contamination from farm to fork; the development of optimal sampling strategies; and the development of outcome measures for the impact of intervention or management strategies.

Outputs

Between Fiscal years 1999 and 20003, The Epidemiologic Approaches for Food Safety program has funded 34 proposals for a little over $23.5 million. Highlights from these grants are:

- Results from the study on microbial contamination of produce will be relevant for resolving the current embargo on the importation of Mexican cantaloupe into the U.S.
- Results from a study of *Campylobacter* suggest that effective control of *Campylobacter* in poultry should use multiple approaches (including

immunology-based and management-based strategies) that target different segments of the poultry production system.

- A food safety course was taught in Chile that was based on current research of *Salmonella* in dairy cattle.
- Prevention of fecal contamination of water tanks and control of vermin in cattle pens may reduce *E. coli* O157. However, control of management factors alone will not completely prevent fecal shedding of *E. coli* O157 in feedlot cattle. Research has shown that water chlorination alone will not reduce *E. coli* 0157. The geometry of the water source is an important factor.
- Research on *Campylobacter* in poultry in Iceland has produced the potential to create a standard for allowable levels of *Campylobacter* in poultry rinses supported by both FSIS and the North American poultry industry. This research has shown that freezing poultry carcasses reduce *Campylobacter* because of its sensitivity to freezing. Iceland has adopted this practice of freezing chicken if it is contaminated with *Campylobacter*. Food borne cases have decreased significantly. Both Norway and Sweden are considering this practice.
- Development of a statistically validated method for spatial sampling of abattoir holding pens.
- Presentation of data on *Salmonella* spread on farms to dairy industry groups and to veterinarian and producer extension programs. Consequently, these researchers have been involved with producers to reduce on-farm *Salmonella* contamination by changing water use practices.
- Participation in several workshops on the role of on-farm use of antibiotics and providing guidance for prudent use of antibiotics.
- Several investigators have contributed their research results in chapters in a new microbial food safety book.

Outcomes

Short-Term

- The entire March Issue, 2005 of the Journal of Food borne Diseases will have published research that was funded by this program. Thirteen research papers will cover various emerging epidemiologic research in food safety.
- A continued significant presence at national meetings. From 2001-04, epidemiologic research has been presented at the Annual meeting of the American Veterinary Medical Association and the Conference of Research Workers in Animal Diseases. These activities help to disseminate new knowledge generated through the program.
- A workshop on Epidemiologic Approaches for Food Safety was convened in 2000 as a result of this program. This workshop was supported by CSREES, CDC, Association of Teachers of Veterinary Preventive Medicine and Public Health, and the American College of Veterinary Preventive Medicine and was held in conjunction with the U.S. Animal Health Association. This was the first workshop to specifically address epidemiologic methods and their application in food safety research. This workshop served as a catalyst for new food safety

research and technology transfer by: 1) strengthening the existing network of epidemiologists, microbiologists, and other food safety specialists; 2) increasing awareness about epidemiological approaches that integrate with other scientific disciplines; and 3) building consensus about the significant food safety research questions facing the U.S. and approaches to address those questions.
- Significant progress has been made in understanding the epidemiology of *Campylobacter* and *E.coli* at the pre-harvest level. Some hypothesized interventions or control methods have been shown no effect.
- A new sampling strategy has been developed to measure the prevalence of *Salmonella* (and the effect of stress) on swine at the abbatoir.

Medium-term

- Because the nature of this research is large population studies, other Federal agencies have been able to use our existing research studies to collect additional data for their missions. For example, CVM (FDA) added funds to an existing microbial contamination in produce study so that *Enterococci* samples could be collected and tested for antimicrobial resistance.
- A novel sampling method (a rope device) for feedlot cattle allows the determination of prevalence of *Salmonella* and *E.coli* in feedlots with minimum stress and handling of the animals. This rope device, which is being patented, is being used by other researchers and has revolutionized epidemiologic research at the feedlot level.
- Two research projects have determined that vertical transmission of *Campylobacter* in poultry does not occur. Therefore, interventions can be targeted toward horizontal transmission of the organism.
- Research has determined that poultry litter plays a significant role in the movement and transference of resistance integrons for *Salmonella*. This may help understand further the epidemiology of antimicrobial resistance and help focus certain intervention programs.

New Directions

Epidemiologic research will help provide the scientific approach to look at public health issues as well as food safety. This would include, for example, the linkage of food safety at the preharvest level to public health outcomes.

Food Safety-Coordinated Agriculture Project- This research program is not included since it has started in 2004, but this large coordinated "network" is a natural extension from the epidemiologic program. This CAP will contain over 17 universities and 40 researchers with expertise in microbiology and epidemiology in various food borne organisms and diseases. The importance of this innovative program is that it will address various needs for CSREES. This program will be able to respond quickly to emerging new areas since there is flexibility in the grant. This program also has an education component that will allow support of graduate students and young faculty. There is

enormous potential for collaborative projects among other networks, centers, or consortia and with international partnerships.

Success Stories

A PECASE award was presented in Food Safety from the Epidemiologic Approaches for Food Safety program in 2000. Dr. Randy Singer received the PECASE for his grant proposal entitled, "Epidemiology and ecology of antimicrobial resistance determinants on dairy farms". Dr. Singer has received additional funding from NSF and the NRI because of his success.

Dr. Zhang at Iowa State University is supported by 2 different grants that will provide important data to understand *Campylobacter* in poultry. These grants have helped them obtain an NIH RO1 grant to study the antibiotic efflux mechanisms in *Campylobacter*. The research revealed that vertical transmission is not a major mode of contamination by *Campylobacter* on poultry farms, indicating that control should be focused on environmental sources. The work also found that *Campylobacter* is highly mutable after exposure to fluoroquinolone antibiotics used in chickens, indicating that prudent measures need to be taken in treating *Campylobacter*-infected flocks with fluoroquinolone antimicrobials.

Dr. Norman Stern (ARS) was funded to study the sources and risk factors for *Campylobacter* in poultry and the potential impact on human disease in a closed system (production in Iceland). All poultry consumed in Iceland are produced in Iceland and this provides an opportunity to identify risk factors for food borne diseases. The US poultry industry and USDA are setting guidelines/standards for exposure level to *Campylobacter* in US produced chicken based upon data from this study. In addition, the significant impact is finding that freezing chicken will eliminate viable *Campylobacter* from the carcass. Therefore, Iceland now uses a direct plating enumeration method to measure the level of contamination with *Campylobacter.* When a threshold level is exceeded a freezing intervention is imposed that reduces the potential for disease in humans. Because of this, there has been a 70% decrease in domestically-acquired infections. Denmark and Norway are now considering this same practice.

E. coli remains a significant food safety organism and FSIS has emphasized the need for interventions at the feedlot level. CSREES has maintained a large number of research projects related to *E.coli* interventions and management practices at the feedlot level. For example, the project entitled, "Epidemiological aspects of combining *E.coli* 0157:H7 control programs and feedlot performance" at Kansas State University (Sargeant et al) evaluated different management practices related to fecal shedding of *E.coli* in feedlot cattle and quantified the relations between management practices that foster the shedding of *E.coli* and feedlot cattle performance. This is one of the first studies looking at the effect of management practices on average daily gain, feed efficiency, and food safety issues. This study was pivotal in that the risk factors identified are not amenable to mitigation. For example, the main risk factors identified were season when slaughter occurred and feed lot stocking density.

A third significant study of *E.coli* being performed by David Smith at University of Nebraska is based on the detection and prevention of *E. coli* O157:H7 in cattle. Through a population-based study, Dr. Smith tested a simple detection method for feedlot cattle (that would lower stress and handling) for *E.coli*. This rope device has proven to be useful for other pathogens as well and is in the process of being patented. It has been used by other investigators in other research studies as well.

In parallel, another study entitled "Effect of water chlorination on prevalence of *E.coli* 0157:H7 and *Campylobacter* in Feedlot Cattle being performed at Washington State University (Besser et al) evaluated the commonly believe hypothesis that chlorination of cattle water sources can significantly reduce the prevalence of infection of cattle with *E.coli* and *Campylobacter* sp. by prevention of new infections with these agents. The results of this project are significant and are often sited by other. This research was the first to demonstrate that chlorination alone or together with manual cleaning is insufficient to affect contamination of water troughs with these enteropathogenic microbes. These results indicate the urgent need to analyze the design of cattle water supplies (tanks).

A multi-institutional epidemiologic project at Washington State University and the University of California, entitled, "Clonal Dissemination of Antimicrobial Resistant *Campylobacter jejuni* and *E.coli*". These researchers have provided ground-breaking research in the areas of resistance genes, resistant organisms and their existence and movement through the environment. Their hypothesis is that antimicrobial resistance in the enteric flora of cattle is clonally disseminated on a regional basis and stable over time. This hypothesis predicts that a limited number of genetic strain types will account for most frequently occuring antimicrobial resistance profiles. In conjunction with this project Dr. Sischo at the University of California-Davis also has another research project on *Salmonella* Typhimurim and Newport and emerging antimicrobial resistance. His work has provided important spatial, geographic (GIS), and temporal data on the movement of *Salmonella* on farm, in the environment, and in water. He was specifically asked to present his research at a CDC conference on the emergence of multi-resistant strains of *Salmonella* Newport.

An epidemiologic study on risk assessment is in progress. The scope of this project is to cover the entire farm to fork continuum. The overall goal of this project is to identify measurable risk factors in the production process and access the impact the risk factors have on the occurrence of *Salmonella* and *Campylobacter* on broiler carcasses at the end of processing. The research follows the birds from the breeder-hatchery, grow-out, transportation from farm to plant, and processing. This research is unique in that it is evaluating the risk factors from each segment so it can evaluate the effect of each segment on the end product. The measurable risk factors in the production process and their impact on the occurrence of *Salmonella* and *Campylobacter* on broiler carcasses at the end of processing will help the poultry industry to comply with the HACCP requirements.

CSREES Strategic Goal 3: Enhance Protection and Safety of the Nation's Agriculture and Food Supply

CSREES Objective 3.1: Reduce the Incidence of Food borne Illnesses and Contaminants through Science Based Knowledge and Education

Portfolio 3.1: Reduce the Incidence of Food borne Illnesses and Contaminants

NRI Food Safety Program (32.1): Epidemiological Approaches for Food Safety

Funding Sources

Accomplishments

- Found that vertical transmission is not a major mode of contamination by Campylobacter on poultry farms
- Found that Campylobacter is highly mutable after exposure to fluoroquinolone antibiotics used in chickens
- Found that freezing chickens will eliminate viable Campylobacter from the carcass. Led to a 70% decrease in domestically acquired infections
- Quantified the relations between management practices that foster the shedding of E.Coli and feedlot cattle performance. Found that risk factors identified are not amenable to mitigation
- Demonstrated that chlorination alone or together with manual cleaning is insufficient to affect contamination of water troughs with enteropathogenic microbes.
- Assessed innovative rope device for detection of E.Coli in feedlot cattle that would lower stress and handling. This method has proven useful for other pathogens and is being patented

Additional Work Needed

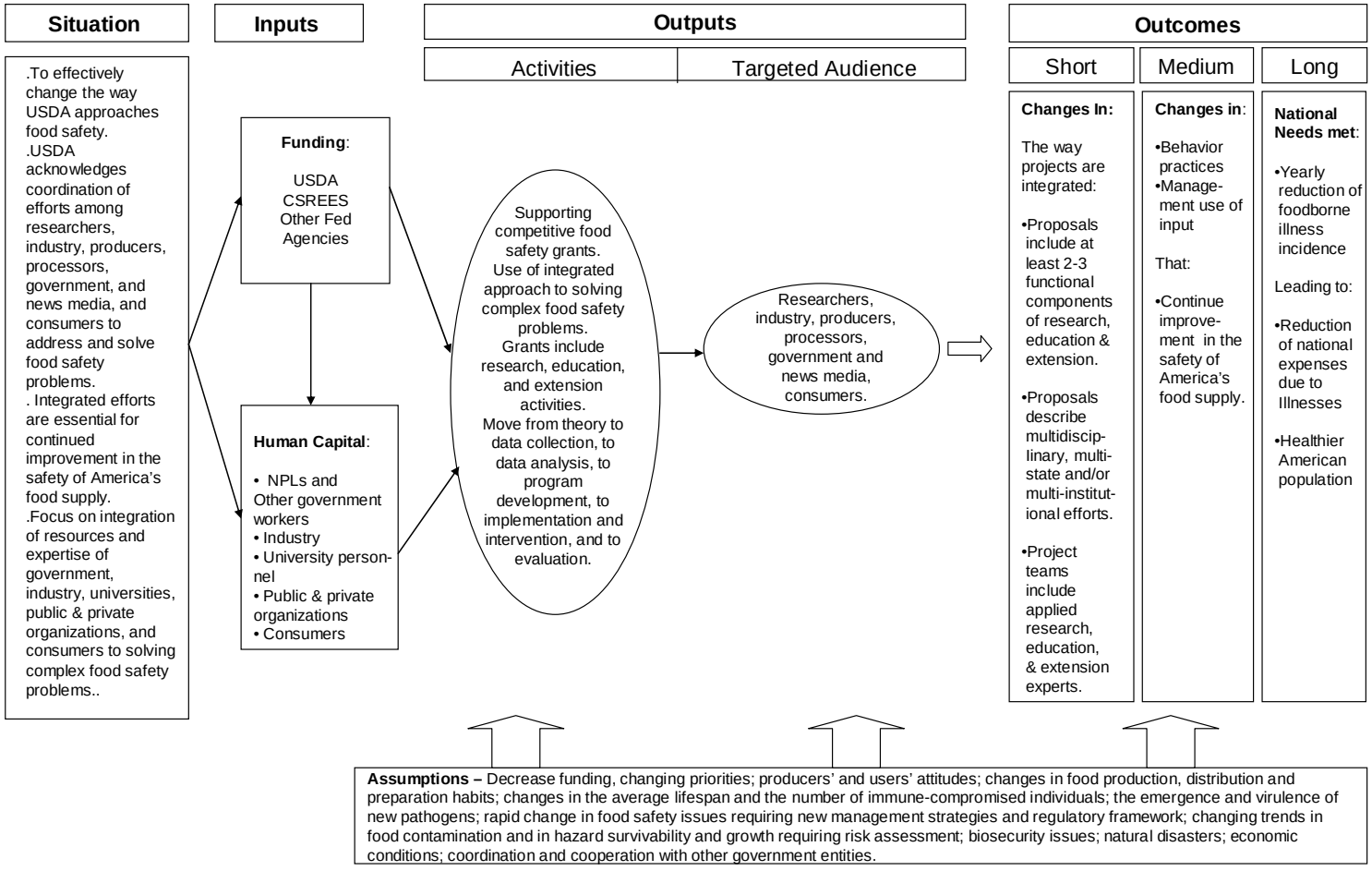
- Need to use epidemiological research to link food safety at the preharvest level to public health outcomes
- Need to design water cattle supplies (tanks) less susceptible to contamination with enteropathogenic bacteria
- Need to establish the CAP research program, containing over 17 universities and 4 0 expert researchers, to respond quickly to emerging issues and to facilitate collaborative projects

The National Integrated Food Safety Initiative (NIFSI)

Overview – Mission and Goals

To effectively address the changes in the food safety system, there have been sweeping changes in the way USDA approaches food safety. USDA has acknowledged coordination of efforts among researchers, industry, producers, processors, government, the news media, and consumers to address and solve food safety problems. These coordinated efforts – or *integrated efforts*- are essential for continued improvement in the safety of America's food supply. NIFSI was developed to address major changes in the food safety system by focusing on integration of resources and expertise of government, industry, universities, public and private organizations, and consumers to solve complex food safety problems. The overall purpose of NIFSI is to fund competitive grants that use *an integrated approach* to solving complex food safety problems. By definition, integrated grants include research, education, and extension activities. The crucial key here is that integrated, competitive grants allow USDA and CSREES to fund food safety efforts that move from *theory, to data gathering, to data analysis, to testing, to program development, to implementation and intervention, and finally, to evaluation.* This comprehensive approach provides the basis for an overall integrated food safety program.

CSREES Food Safety Logic Model (NIFSI)



Source: Planning & Accountability Portfolio Review Expert Panel, 2004

Outputs

Since its inception in Fiscal Year 2000, NIFSI has awarded more than 160 competitive grants. Grants are awarded for up to 4 years, with the average grant funded at $500,000. On-going integrated activities described in annual CRIS reports are widely varied and include:

- Conducting workshops, seminars, conferences, national and international meetings
- Developing interactive websites that provide answers to commonly-asked consumer food safety questions
- Curriculum and course development for education and training of a variety of food safety audiences
- Training of migrant farm workers across the U.S. using modified GAPS (Good
- Agricultural Practices) guidelines
- HACCP training and education for meat and poultry processors
- HACCP model development for fruit and vegetable growers

Outcomes

Federal data from the Centers for Disease Control and Prevention have indicated that there has been a decrease in food borne illness incidence over the past 7-8 years. NIFSI has contributed to this overall decrease in the incidence of food borne illness its unique and innovative an integrated approaches that brings together the resources of the government, universities, and the food industry to solve complex food safety problems.

New Directions

Input from stakeholders is solicited annually ensuring that the ever evolving needs of stakeholders are met. As emerging issues and other new program priorities are identified (or as existing priorities are modified), there is a subsequent expansion of the contemporary knowledge base for food safety, and a strengthening of overall food safety programs within CSREES and USDA.

Success Stories

Successful development of strategies aimed at controlling this *E. coli* O157:H7 depend on coordinated efforts from a wide cross-section of scientists and researchers. Using conference grant funds researchers at the University of Nebraska sponsored a *Governor's Conference on Ensuring Meat Safety: E. coli O157:H7 Progress and Challenges*. The conference brought together national and international experts involved in basic and applied research, extension educators, and industry representatives. Although recent research progress was detailed, the overwhelming emphasis was placed on addressing future challenges and on integrating the full spectrum of the *E. coli* problem, from farm to table. Invited speakers included veterinary scientists, medical researchers, geneticists, and applied food scientists. Extension specialists and food industry research directors

also addressed conference attendees from the university and industry perspectives. The conference attracted over 200 attendees. New research strategies emerged and innovative collaborations were developed as a result of bringing together such a diverse group of individuals.

Over the past several years, the NIFSI has awarded over $800,000 to investigators focusing on food biosecurity issues. For example, at the University of Georgia, investigators are assessing current Good Agricultural Practices and HAACP programs used by produce growers to study points of vulnerability to intentional contamination. Investigators are assessing whether deliberate contamination of produce with food bore pathogens remains with the produce after harvest. Their results will be incorporated into a training curriculum for produce industry personnel. The curriculum will be used as a model across the U.S. and its territories for similar programs and audiences. In addition, investigators at New Mexico State University are developing a distance education program in food biosecurity for minority farmers. Their goal is to help farmers assess their potential risks, while adopting practices that reduce their risk for food safety threats, both intentional and unintentional. Assessment tools have been developed and are currently being tested.

Prediction of hazards is at the heart of food safety. If researchers could predict the likelihood of an unsafe condition during food processing, storage, or distribution, they could then look for ways to prevent such contamination before it happens. Such prediction, however, is difficult due to tremendous variation in types of food, how it is handled and processed, transported, stored, prepared, etc. A rational, comprehensive, quantitative, science-based, and easy-to-use prediction tool would go a long way toward reducing intentional and/or unintentional food hazards. NIFSI has funded a grant that uses advances in engineering and computer simulation to develop a tool for researchers, educators, and Extension professionals that will allow easy and accurate prediction of unsafe food hazards. The grant enables researchers at Cornell University to first develop computer simulations of food processes that are as close as possible to real-life situations. Growth of harmful bacteria, or formation of harmful chemicals due to the cooking process, is then estimated inside this simulation software. To do this, engineering simulation software needs to be linked with food and microbial properties that have been developed by different universities and government laboratories. This multi-disciplinary, multi-institutional, and multi-country (US and the UK) collaboration greatly enhances the capacity of the software. Researchers anticipate that this quantitative tool will allow decision-making and problem-solving that will significantly enhance food safety resources and outreach programs.

Special grants

Special grants are unique in the CSREES Food Safety research portfolio. These grants are legislative mandates that are usually negotiated between the grantee and Congress. Special Research Grants are awarded on a discretionary basis as well as through the use of competitive scientific peer and merit review processes. The grants tend to be applied projects that address specific problems. These projects frequently relate to regional

issues, although they have applicability to our national needs in the food safety system. One of the advantages of special grants is the ability to fund research on rapidly emerging issues. Since RFAs are not issued for special grants, the program has funded a wide array of topics. There are many success stories associated with this program area. Described below are selected examples of successful and meaningful research projects.

Success stories

Auburn University's Detection and Food Safety Center has developed a method of food inspection that involves the placement of a sensor chip on food items with a high moisture content (i.e. meat and poultry surfaces). The goal is for these chips to automatically inventory and assess food safety of appropriate fresh food products at any point by measuring the presence of food borne pathogens. In addition to the chip, a hand-held bacterial detection device is being developed. Interim results have produced a hand-held biosensor that will allow food processors to detect the presence of bacterial pathogens and toxins within 100 seconds. Current industrial methods require that a food sample be taken to a lab where tests require a minimum of 6 to 48 hours to determine if the food is safe to eat. The new technology can identify harmful levels of *Salmonella*, for example, and will be packaged as a portable hand-held unit that may be used on the food production line. Researchers at Auburn are currently field-testing this hand-held device. If the hand-held device, and the radio frequency identification sensor chip are successful, the potential savings to the food industry will be large.

Another project is aimed at preventing contamination of milk and milk products by *Listeria*. A research team at Pennsylvania State University is developing a Multi Locus Sequence Typing method for molecular tracking of *Listeria monocytogenes* in dairy processing plants to track the path of contamination and identify critical control points for HACCP intervention. This project is a good example of integrating research with outreach activity since the objective is to prevent microbial contamination of diary products in the processing plant. The investigators also will identify non-microbial indicators (alkaline phosphatase and other enzymes) of pasteurization by high pressure processing and ultrasound and develop biosensors for the best non-microbial candidate.

Special research grants were awarded to Iowa State University to investigate food irradiation. These studies have had significant impacts in the development of new regulations by FSIS and the FDA for food irradiation. The outputs from these grants provided a sound scientific basis for these regulatory agencies to develop regulations in irradiation of meat and poultry products. The investigators also collaborated with ARS in providing the science basis for the regulations.

The Food Safety Consortium is a multi-institutional, multi-disciplinary program funded by a special grant. This Consortium includes Iowa State University, Arkansas State University, and Kansas State University. Each of these universities concentrate on food safety research, education, and extension issues in the pork (IA), beef (KS), and poultry (AK). (http://www.uark.edu/depts/fsc). There are specific success stories within this consortium project that need to be mentioned.

- Recently, research done on biosensors at University of Arkansas-Fayetteville has led to collaboration with Biodetection Device Inc. for a new company and received a grant from NSF-SBIR. These devices will be scaled up and show an ability to detect as few as 90 cells of *E.coli* O157:H7 in 2.5 hours with no enrichment using a chemiluminescent fiber optic-based sensor.
- The FSC designed and maintained a Food Safety Web Page that includes a HACCP demonstration site for small meat processors (http://www.iowahaccp.iastate.edu). In addition, they now have web-based food safety lessons and on-line presentations on biotechnology issues (http://www.extension.iastate.edu/food safety/biotech/slideshow/index.htm). An average of 30 high school teachers visit the site per month.
- In collaboration with Sandia National Labs, FSC developed Decon Foam- 100 for use against resistant *B. anthracis* spores in ready to eat foods. This is a potential application in biosecurity.

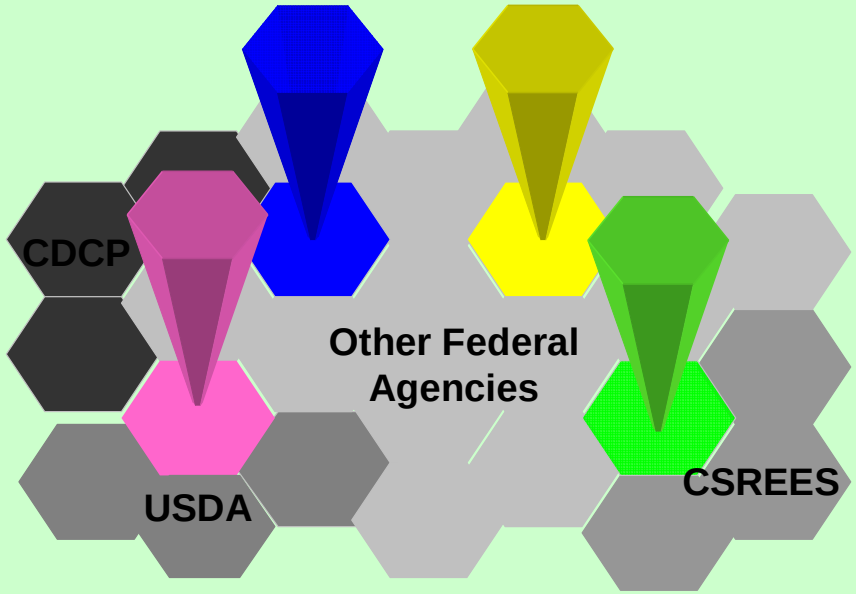
CSREES Strategic Goal 3: Enhance Protection and Safety of the Nation's Agriculture and Food Supply

CSREES Objective 3.1: Reduce the Incidence of Food borne Illnesses and Contaminants through Science Based Knowledge and Education

Portfolio 3.1: Reduce the Incidence of Food borne Illnesses and Contaminants

NIFSI: The National Integrated Food Safety Initiative

Funding Sources



Accomplishments

- University of Nebraska sponsored a Governor's Conference on Ensuring Meat Safety: E.Coli 0157:H7 Progress and Challenges which attracted over 200 attendees
- Developed a diagnostic surveillance strategy (rope) to easily monitor large cattle populations for the presence of E.Coli 0157:H7 in the feed lot
- Showed that vaccination of cattle under conditions of natural E.Coli 0157:H7 exposure reduced the proportion of cattle shedding the organism
- Awarded over $800,000 to investigators focusing on food biosecurity issues

Additional Work Needed

- Developing a training curriculum for farmers to assess their potential risks so they can reduce food safety threats.
- Developing software to simulate food process and allow for easy and accurate prediction of unsafe food hazards.

Small Business Innovation Research Program (SBIR)

The SBIR program was developed to provide a source of funding to small businesses to test the feasibility of concepts through a proof of concept process. These 1 year phase I grants can be followed with longer phase II grants to actually develop the proven concept into a product or process. The very nature of SBIR grants is to translate or apply knowledge into commercial entities. While academic institutions frequently are cooperators on SBIR projects, these grants are given directly to small businesses as a means for them to develop into viable companies. The SBIR program has been a significant source of funding for food safety projects. The projects described below are representative examples of success stories with applications in food safety.

Success Stories

An SBIR Phase II grant was provided to XTRANA, Inc, in FY 2000, to develop a low complexity genetic-based assay of high sensitivity and specificity for detection of *L. monocytogenes*. XTRANA anticipated that following minimal enrichment times, the assay will be run directly without the usual selective culture and subculture. Since the assay would only detect viable organisms, it would provide information on the effectiveness of microbial kill steps in processing, as well as sanitation of product and environmental surfaces. This should permit more effective design of HACCP systems and could reduce the frequency of outbreaks due to *L. monocytogenes.* XTRANA indicated that it has attracted a potential strategic partner that is interested in commercializing this assay. Their Phase II results indicate that their methods will detect *Listeria monocytogenes* at high sensitivity and specificity with much quicker turnaround that current methods in the market.

Current FSIS guidelines call for monitoring for the presence of various food-borne pathogens, such as *Salmonella* and *Escherichia coli O157:H7*, to improve the safety of the food supply. In FY 1999, a Phase II SBIR grant was provided to Immunological Associates of Denver, Inc. to develop a rapid detection method capable of being performed on site at food processing plants in association with HACCP. It was expected that the successful development of the proposed assay will result in safer food supply, reduced incidence of food-borne infections, and avert large recalls. The method integrates the steps of bacterial cell lysis, nucleic acid extraction, amplification and detection. The company identified several potential strategic partners that have expressed interest in exploring possible phase III collaboration.

Maintaining fruits and vegetables safe to eat with good physical appearance is extremely important to the produce industry. A phase I study successfully demonstrated that the use of bubbleless O_3 delivery could be used to effectively control microorganisms. A delivery system developed by Compact Membrane System is the basis for this study. A follow-up phase II proposal was funded in FY 2002.

An SBIR Phase II grant provided to Diachemix, LLC in FY 2003 will help the company develop the fluorescence polarization assays for fumonisins, aflatoxins and DON vomitoxins. These assays will offer an efficient way for grain producers and processors to check for these mycotoxins before bringing the grains to the market. The assays can be performed in the field, at grain elevators or in remote laboratories without submitting samples to a central laboratory.

Higher Education

Education programs support all CSREES National Emphasis Areas. These programs promote teaching excellence, enhance academic quality, and develop tomorrow's scientific and professional workforce. In cooperation with public institutions, private sector partners, and the Land-Grant University System, CSREES provides national leadership to address critical educational issues. CSREES provides funding opportunities to support educational programs through several venues including: 1890 Institutions Teaching and Research Capacity Building Grants Program, Food and Agricultural Sciences National Needs Graduate and Postgraduate Fellowship Grants Program, and Higher Education Challenge Grants Program.

Success Stories

California State University, Los Angeles through the Department of Kinesiology and Nutritional Science is committed to develop an undergraduate program in Food Science and Technology (FST) with emphasis in Food Safety. This proposed project will support the FST program in three fundamental ways: 1) by creating a state-of-the-art quality assurance and food safety laboratory; 2) by providing key faculty members with advanced training in the rapidly evolving field of food safety; and 3) by enabling undergraduate FST students to become involved in related research programs that will enhance their education. This project will help CSULA in recruitment and retention of Hispanic students and will also help to correct the disparity between the proportion of Hispanics currently entering the food industry and the Hispanic population at large. The Hispanic graduates of this program will be among the best trained in Southern California in issues related to food quality and food safety to make an important difference to public well-being. This project will help CSULA in recruitment and retention of Hispanic students and will also help to correct the disparity between the proportion of Hispanics currently entering the food industry.

The United States has a good record of food safety. In spite of this good record, there are still many reported cases of food borne illnesses recognized as significant public health issues. The objectives of the proposed study being performed by Tennessee State University are: (1) to determine the effectiveness of different types of food safety information in educating rural consumers about food safety risks and precautions, (2) to investigate whether there are any differences in the effectiveness of the different types of food safety information (for example the USDA's safe handling labels on meat and poultry or the program to educate consumers to use thermometers when cooking hamburgers), in educating rural populations about food safety risks and precautions, (3)

to develop educational and informational materials on food safety for rural residents in Tennessee, North Carolina, and Alabama, and (4) to educate members of selected ethnic groups and rural residents on important food safety issues. Through participating in this project, students' research at Tennessee State University will be enhanced. In addition to learning how to conduct research, students will be encouraged to write scientific papers for presentation at national and/or regional conferences. Faculty from Tennessee State University will be able to strengthen their research capacity in food safety research. The collaborative initiatives will expose the agency to the 1890 academic and research programs and assist the University train students for future workforce needs.

SECTION IV: Summary and Conclusions

The intent of this report was to provide reviewers with an objective view of the CSREES Food Safety Program. The data presented in this report demonstrate a high degree of research and educational activities supported through the various funding mechanisms of CSREES. More importantly, as can seen in the Success Stories, the Food Safety programs have wisely selected projects for funding and these projects have made an impact in understanding the science behind food safety and have contributed to the reduction in food borne illnesses. While we elected to describe the funding avenues separately, we want to stress that the programs are interactive. They are not stand-alone programs and build upon each other's stakeholder and user base.

In considering the outcomes from the Food Safety program as described in this report, we want to emphasize the significance of the outcomes as they relate to federal investment. Several projects including those related to actual interventions (e.g. product irradiation guidelines, diagnostic assays, and analysis of the benefits of good agricultural practices on food safety) demonstrate the strong commitments of the programs to the development of real world applications. As well, several studies have resulted in basic science information that have the potential to challenge our thinking and study of food safety (e.g. use of geographic information systems tracking *S. enterica* and antibiotic resistance in the environment, analysis of closed systems in studying the epidemiology of *C. jejuni* in Iceland, and the development of "ropes" to track *E. coli* O157:H7 in beef feedlots). While these are but a few examples of impacts, we believe that the evidence provided in this report, which represents the entire food safety portfolio, demonstrate the food safety programs operate at a high level. Program performance has been excellent and the quality of the work has been outstanding. However, we believe that the most significant aspect of the portfolio is the data that demonstrates the performance of the funded work has led to significant impacts in the food safety system. This has led to an improvement in the safety of the foods produced through the US agricultural systems. The work has led to a spectrum of discoveries that range from that of a basic understanding of the principles of food safety through to the development of interventions, to tools for the detection of adulterants in foods. These accomplishments are remarkable and are strong indicators of success of the Food Safety program.

To assist the panel in assessing the Food Safety portfolio using the three research investment criteria of relevance, quality, and performance, the following summary is offered:

Relevance

Scope
The Food Safety portfolio has funded research in all the areas of highest priority food-borne organisms identified by the Center for Disease Control and Prevention (CDCP),

including salmonella, E.coli, etc. The funded research also covers all food and animal issues, including emerging issues in sea food and produces, as well as sources of food-borne diseases.

Portfolio Ability to Remain Focused on Critical Needs of the Nation
The portfolio has received inputs from stakeholders, individuals, the academia, and other agencies. The NPLs in the portfolio are active on national and international food safety committees. They regularly attend meetings of these committees to discuss and establish national needs.

Identification of Emerging Issues Relevant to the Portfolio
The NPLs in the portfolio stay active on food safety national committees, regularly reviewing the literature on emerging issues, interacting with CDCP and the Food and Drug Administration (FDA).

Integration of CSREES Education, Research, and Extension Efforts in the Portfolio
The portfolio integrates research, education, and extension in its grant program that compliments the other two NRI research programs.

Multidisciplinary Balance of the Portfolio
The portfolio NPLs are involved with other food scientists, animal health specialists, epidemiologists, microbiologists, biologists, and food safety specialists in the extension network. This is particularly in the NRI Food Safety Program (32.1), Epidemiological Approaches to Food Safety.

Quality

Significance of Portfolio Outputs and Findings
Investment in the food safety research program has made it possible for the portfolio to provide information and make recommendations to regulatory agencies for changes in food safety practices. For example, chickens contaminated with Campylobacter, when frozen, will reduce the risk to consumers. This practice has been adopted by several countries in the world.

Stakeholder/Constituents Assessment of Portfolio
The portfolio regularly holds multiple stakeholder meetings to solicit priorities. Simultaneously, the NPLs hold annual meetings to exchange information with FDA and other Federal agencies.

Alignment of Portfolio Projects with Current State of Science-based Knowledge and Previous Work
The projects funded by the Food Safety portfolio reflect the recommendations recently made by the National Academy of Sciences and the American Academy of Microbiology.

Appropriate Methodology of funded Portfolio Projects
The projects funded by the portfolio, such as the NRI Food Safety Program (32.1), the national integrated food safety program, etc. were rigorously reviewed by individual experts and Peer Review Panels and ad hoc review panels for scientific merit, innovation, impact, national significance, and potential for success. Their proposed research methodologies have met approval of expert panels and ad hoc review panels.

Performance

Portfolio Productivity
The projects funded under the Food Safety portfolio have generated numerous scientific publications, book chapters, etc., and made significant expansion of science programs at national meetings. They have also contributed to potential action for reducing food-borne disease.

Portfolio Completeness
The Food Safety portfolio covers the entire spectrum of food production chain "from farm to table" in all three areas of research, education, and extension.

Portfolio Timeliness
The portfolio does not only focus its research activities on current issues of food-borne disease. It is, indeed, future oriented looking at viral causes of food-borne diseases. For example, it focused research activities on BSC before it occurred in the US.