FY 2012 Annual Reports for National Program 108 Food Safety

Executive Summary

Food Safety falls under Goal 4 of the Agency Strategic Plan**: Enhance Protection and Safety of the Nation's Agriculture and Food Supply**. For the Nation to have safe and affordable 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 encompasses a diverse, extensive, and easily accessible system that is open to the introduction of pathogens (bacteria, viruses and parasites), bacterial toxins, fungal toxins (mycotoxins), and chemical contaminants through natural processes, global commerce, and intentional means. In response to these threats, crop and livestock production systems must be protected during production, processing, and preparation from pathogens, toxins, and chemicals that cause disease in humans.

To ensure the security of production systems, Agricultural Research Service (ARS) conducts basic, applied, and developmental research resulting in new technologies, new and improved management practices, pest management strategies, sustainable production systems, and methods of controlling potential contaminants. These ARS activities are key to providing a safe, plentiful, diverse, and affordable supply of food, fiber, and other agricultural products.

Mission Statement
To provide through research, the means to ensure that the food supply is safe for consumers and that food and feed meet foreign and domestic regulatory requirements. Research seeks ways to assess, control or eliminate potentially harmful food contaminants, including both introduced and naturally occurring pathogenic bacteria, viruses and parasites, toxins and non-biological-based chemical contaminants, mycotoxins and plant toxins. Food safety is a global issue; thus, the Program involves both national and international collaborations through formal and informal partnerships. Accomplishments and outcomes are utilized in national and international strategies delivering research results to regulatory agencies, commodity organizations, industry and consumers for implementation.

Vision Statement
To increase public health through the development of technologies which protect food from pathogens, toxins, and chemical contaminants during production, processing, and preparation thus increasing the safety of the food supply.

There is one research component and six problem statements in the current Action Plan for the program:

Component 1. Foodborne Contaminants

Problems Statements

1.A Population Systems

- This area identifies and characterizes the movement, structure, and dynamics of populations throughout food production, processing and storage; hence the entire safety

continuum. Major components of emphasis and interaction include epidemiology, ecology, host-pathogen relationships.

Anticipated products

- Epidemiologic studies will provide a scientific approach for population-based studies on new detection methods and interventions, to design and evaluate risk factors for potential control or intervention strategies, and a framework to integrate genomic data with disease in populations.
- Ecologic studies will determine the attributes and changes in the ecological communities in order to understand the transmission and dissemination of pathogens and toxins in and among food producing animals and crops, and the interactions and relationships within the population community.
- Host-pathogen relationship studies will provide an understanding of the acquisition of genetic traits, such as the development and movement of resistance genes; traits connected with colonization and evolution of virulence; the role of protozoa in harboring or transmitting bacterial foodborne pathogens (Trojan horse concept); and the role of commensals.

1.B. Systems Biology

- The concept of systems biology involves a unique integrative approach to understand the basic genetic components of pathogens, their expression, and directly relate this information to the microorganism's biology.

Anticipated products

- This approach provides a unique opportunity to understand the basic genetic components of pathogens, their expression, and directly relate this information to the microorganism's biology.
- While the tools for gene expression studies are available, there needs to be an increased focus on understanding how the studies will be performed and interpreted, and how they can be used to promote food safety.
- Establish a metagenomics approach to selected research areas which will, for example, allow determination of metabolic contributions to risk.

1.C. Technologies for the Detection and Characterization of Contaminants

- Challenges arise from either uncontrolled microbes entering through raw materials, contamination during processing, or from undesired chemical contaminants including chemical residues, and bacterial, fungal and plant toxins. [Sensitive and specific] detection technologies are required at the earliest possible stage in the food chain, thus avoiding/preventing the need for processing interventions, or possible recall.

Anticipated products

- Promising technologies will be advanced. Technology transfer has to be done quickly, and where possible, and appropriate, will undergo validation through national or international bodies (FERN, Codex).
- Research that offers minimal outcome or impact will be terminated, and alternate approaches formulated. For example, detection methods related to serotyping and

subtyping pathogens are useful but outcome needs to be focused on methods for more effective identification.
- Development of technologies must yield method(s) that are more rapid, efficient, and yield improved resolution.
- In developing technologies, decisions cannot be made in isolation. There needs to be an integration of biology, epidemiology, and the physical sciences systems.

1.D. Intervention and Control Strategies

- To ensure safe food and protect public health, intervention and control strategies must be identified, implemented, and then measured as to their impact on the reduction and control of food-borne pathogen, toxins, and chemical contaminants. This approach incorporates strategies in both pre- and post-harvest systems as the science dictates, to produce a complementary and efficient approach for food safety.

Anticipated products

- Intervention strategies will be developed to eliminate and/or control microorganisms in animals and their derived products, seafood and plant production, processing and storage systems. An underlying assumption is that production control interventions reduce downstream contamination which subsequently reduces disease risk.
- Efforts will focus on developing environmentally compatible technologies.
- Strategies will be developed for operations of all sizes (large to very small).
- Pathogens may develop resistance to some interventions; thus, efforts should focus on development of combinations of new or innovative intervention technologies for (minimal) processing.
- Interventions will be developed based on an understanding of their modes of action and effects on the microbial ecology of a food product, since inadequate suppression of spoilage could create an opportunity for human pathogen growth and toxin production.

1.E Predictive Microbiology

- The behavior of any microorganism is deterministic and able to be predicted from knowledge of the microorganism itself, and the microorganism's immediate environment. Behavioral predictions are an integral part of microbial risk assessment used to support food safety measures.

Anticipated products

- The ARS Food Safety Program does not develop or conduct risk assessments (RA), where RA is defined as the determination of a quantitative or qualitative value of risk related to a specific situation and a recognized hazard.
- The Program conducts research and provides data when requested by our regulatory stakeholders (FSIS, FDA) for their use in conducting risk assessments.
- Collaborations with regulatory and public health agencies will be strengthened regarding research for RA development efforts, so as to effectively utilize the inherent ARS expertise and modeling mechanisms.
- Methods used to identify data gaps will be described and integrated into the research project.
- Data acquisition will be an ambitious interdisciplinary research challenge that will eventually translate into improved public health.

1.F. Chemical and Biological Contaminants: Methodology, Toxicology and Toxinology

- The regulation and control of veterinary drugs, residues, heavy metals, persistent organic pollutants, and biological toxins derived from bacteria, fungi and plants are an integral component of any food safety program to protect human health and the environment.

Anticipated products

- The successful implementation of technologies developed and validated through research is the major goal.
- These technologies provide tangible benefits through a more effective and efficient means of monitoring the food supply, and environment where food is grown. Better methods assist researchers conducting toxico/ toxinological studies.
- Toxico/toxinological studies provide basic and applied knowledge on the effect of exposure to biological toxins.

Selected Accomplishments for Agency Documents (2012)

Listeria monocytogenes in the ready-to-eat (RTE) foods at retail. Significant efforts have been made to control Listeria monocytogenes (Lm) in foods over the past decade. Outbreaks of foodborne illness are especially associated with ready-to-eat foods such as deli-meats, soft cheeses, raw and smoked fish, and raw or partially processed vegetables. At the request of the Food and Drug Administration and the USDA-Food Safety and Inspection Service, ARS researchers at Wyndmoor, Pennsylvania, undertook a study to determine the current prevalence and levels of Lm in deli-packaged versus pre-packaged RTE foods purchased at retail establishments in four FoodNet sites. The study indicated an observed Lm prevalence from 0 to 1.0 percent for seven product categories. This is the most comprehensive survey of Lm in retail RTE foods in the past decade, and provided data critical for policy decisions on further control for this pathogen, and its contribution to the public health burden. The study received the FDA Commissioners Award.

Latex agglutination tests (LATs) for six pathogenic non-O157 Escherichia coli. Certain Shiga toxin-producing Escherichia coli (STEC) serogroups, including E. coli O26, O45, O103, O111, O121, and O145 cause a similar illness in humans as E. coli O157:H7. The USDA Food Safety and Inspection Service (FSIS) recently declared these STECs as adulterants in beef. At the request of the FSIS, ARS researchers at Wyndmoor, Pennsylvania, developed and validated a rapid and simple testing method (LAT) for confirming presumptive positive non-O157 STECs to better protect the food supply and consumers. The reagents and test protocols were transferred to FSIS for validation, and the (LAT) agglutination method has now been incorporated into the FSIS Microbiology Laboratory Guidebook (MLG) Chapter 5B.02. Adoption of this method contributed to the implementation of the USDA 'zero tolerance policy' for the six non-O157 STECs in June 2012. The scientists who developed the LAT technology received the USDA Secretary's Award.

Novel probiotics target human food safety pathogens and improve poultry health. Campylobacter and Salmonella are the most commonly reported bacterial pathogens causing foodborne infections in the U.S. Epidemiological evidence has implicated poultry products as a significant source of these pathogens. A novel probiotic method was developed by ARS at

Fayetteville, Arkansas, capable of inhibiting growth of specific enteric pathogens. These probiotic cultures (composed of non-pathogenic "healthy" bacteria) target Salmonella and Campylobacter in the gastrointestinal system of poultry. This discovery was licensed to an Arkansas-based start-up company in cooperation with the University Arkansas. The commercial product (FloraMax-B11) is marketed in 16 countries with approximately 300 million birds dosed per/year.

Inactivation of Escherichia coli O157:H7 (ECOH) and non-O157:H7 Shiga toxin-producing E. coli (STEC). Escherichia coli O157:H7 (ECOH) and non-O157:H7 Shiga toxin producing E. coli (STEC) are the cause of many outbreaks of illnesses and deaths. Infections are generally foodborne with ground beef a major conduit. ARS researchers at Wyndmoor, Pennsylvania, evaluated the fate of E. coli O157:H7 and non-O157 strains in both flattened and wafers of ground beef in a heated water bath and commercial grills. Studies showed that regardless of the level of fat or type of heat/grill used, cooking ground beef patties to an internal temperature of ~71.1 degrees C was effective for destroying the pathogens. These data were transferred to the USDA-Food Safety Inspection Service for their use in consumer related advice for safe food handling.

Pathogens in produce growing areas in the Salinas Valley, California. Several bacteria have been linked to produce associated foodborne illness outbreaks. ARS researchers in Albany, California, in collaboration with the Food and Drug Administration and National Aeronautics and Space Administration conducted a survey of the Salinas watershed for the presence of E. coli O157, non-O157:H7 Shiga-toxin-positive E. coli (STEC), Salmonella, Listeria, and Campylobacter. Data collected indicated substantial differences in the prevalence of the various pathogens with a definite correlation to sampling region and date. Data allowed the development of a predictive geospatial risk assessment model (PGRAM), while overall the study provided industry and public health regulatory agencies with valuable epidemiological data for development of a risk assessment for this important agricultural region of the U.S.

Rapid, portable test for botulinum neurotoxins. Produced by the common soil bacterium Clostridium botulinum, botulinum neurotoxins (BoNTs) are potent toxins that can cause the severe foodborne disease, botulism, and could be used as a biological threat agent. ARS scientists in Albany, California, developed a rapid, sensitive diagnostic test for BoNTs that could be used by minimally trained personnel in the event of a foodborne outbreak or a bioterrorist threat. The simple lateral flow device, similar in design, use, and time as a pregnancy test, can detect and distinguishes between BoNT/A and B, two of the four serotypes that are known to intoxicate humans and together account for >80 percent of naturally occurring botulism. This rapid diagnostic method which has been validated and now transferred to regulatory and other biosecurity/military agency's is a valuable tool in the areas of food safety and homeland security.

Vaccine development for Escherichia coli O157:H7. Escherichia coli O157:H7 can cause life-threatening foodborne illnesses. Beef cattle are a major asymptomatic carrier of the pathogen, and development of a vaccine for cattle to eliminate the pathogen is a major goal for government and industry. E. coli O157:H7 colonize the terminal portion of the large intestine in cattle by "sticking" to a specific type of tissue. Specific bacterial proteins are required for adherence and studies have implicated the protein (intimin) responsible for adherence. However, ARS researchers at Ames, Iowa, have now determined that E. coli O157:H7 lacking the intimin protein use additional proteins for adherence. This finding is significant in the context of

developing efficacious vaccines for blocking adherence of the bacteria. Therefore, better vaccines would be those that would include not only the intimin protein but other proteins to reduce adherence. ARS will redirect its vaccine development studies to address this critically important observation.

Correctly detecting Salmonella in foodborne outbreaks. Salmonella species remain one of the leading pathogens causing outbreaks of illness. Unfortunately, the serotype implicated in actually causing any outbreak (clinical disease) is often difficult to determine since there may be many contaminating strains. During outbreak investigations it is critical to isolate the relevant strain from food and/or environmental sources. ARS researchers in Albany, California, determined that some Salmonella strains were more likely to be isolated than others. Current selective enrichment media shows a bias for Salmonella enterica strains while strains of serogroup B, which include serovars Typhimurium, Saint- Paul, and Schwarzengrund were less likely to emerge as dominant strains. This work provides critical information to public health agencies at the Federal and State level, as well as to the industry, stressing that during investigations, multiple enrichment protocols should be used to ensure isolation of target strains.

Genomic markers for identifying specific pathogenic Escherichia coli strains. The USDA-Food Safety and Inspection Service recently declared Escherichia coli strains O26, 045, O103, O111, O121, and O145 adulterants in beef trim and recently started regulatory screening for these pathogens. The current method for detecting these specific (serotypes) takes several days because there is not a specific genomic marker for each serotype. ARS scientists at Clay Center, Nebraska, identified strain specific DNA markers for each serotype by comparing portions of the DNA. The DNA markers were licensed to a company that makes diagnostic kits for foodborne pathogens and are being used as part of a commercially available assay. This assay will be useful for industry and government researchers.

Cronobacter sakazakii in powdered infant formula. Cronobacter sakazakii is a deadly foodborne pathogen found in dehydrated powdered infant formula. ARS researchers at Wyndmoor, Pennsylvania, conducted a study to investigate the growth kinetics of C. sakazakii in reconstituted powdered infant formula (RPIF), and develop predictive models. Thermal growth studies indicated that C. sakazakii grows well at temperatures between10-48C. There was no significant difference between the growth rates of non-heat-treated and heat-injured cells suggesting that any C. sakazakii in RPIF may present a risk to infants. The results will assist industry in their production of infant formula; for regulatory agencies in conducting risk assessments of RPIF exposed to various temperature-abuse conditions and defining regulatory policy, as well as for parents and other caretakers in properly storing and preparing reconstituted powdered infant formula.

Natural antimicrobials to replace antibiotics in swine diets. The use of antibiotics in animal production is a controversial issue due to the concern of transmission of antibiotic resistance genes. Young swine are often fed dietary antibiotics to improve health, reduce pathogen load, and enhance performance. Few natural alternatives have been identified to replace these compounds if producers are required to eliminate antibiotic use. ARS scientists at Clay Center, Nebraska, determined that a commercial product containing lysozyme (naturally found in eggs) could replace dietary antibiotics. The impact of this research, particularly for industry, is that the use of lysozyme in diets of young piglets could maintain a safe food supply and reduce the use of prophylactic antibiotics that are typically used for swine production.