Project Number: To be assigned by the sponsoring regional association.
Project Title: Enhancing Microbial Food Safety by Risk Analysis
Requested Project Duration: From to October 1, 2012 to September 30, 2017.

The long-term goal of this project is the establishment of a multi-disciplinary network of scientists that performs comprehensive and integrated risk-based research and outreach to improve the safety of food from farm to fork. Interested stakeholders, including food producers and/or processors, retailers and consumers, have identified the need for an approach that conducts applied research to determine the prevalence and ecology of foodborne pathogens (including antibiotic resistant bacteria) in fresh and processed foods coupling that to research aimed at establishing effective control methods to decrease pathogen contamination of foods. Several outreach objectives have also been developed in support of this project. These objectives include communication of risk-based management recommendations derived from the research aspects of this proposal to stakeholders as well as to those who interact with stakeholders. Communication strategies will be precisely tailored to the particular audience (processors, distributors, retailers, consumers). Message content will focus on risk-based strategies and microbial control opportunities deemed critical for each target audience to achieve the greatest strides in improving food safety in the U.S. Outreach to those who advise producers and consumers (*e.g*. educators, extension personnel) who are not part of the project will be achieved through ongoing symposia to disseminate key information concerning lessons learned during the course of this project.

This project has been specifically designed to address the critical needs of the fresh and processed food industries by developing a thorough understanding of how these foods become contaminated with foodborne microbial pathogens. It is well established that the heterogeneous distribution of pathogens in food makes studying the ecology of these pathogens difficult. The problems facing the food industry are also sufficiently complex such that solutions to these problems are beyond the scope of any single investigator's programmatic outputs. This means they are most efficiently addressed through multidisciplinary efforts with expertise in risk analysis, microbial ecology, epidemiology of foodborne disease, and food safety microbiology.

The results of this project will directly impact industries that handle low moisture food sector (emphasis on nuts and dried fruits), fresh, minimally and shelf-stable processed produce, dairy, fresh and further processed seafood, meat, and poultry products (including fully cooked and read-to-eat products subject to post-process contamination), as well as other multi-component and processed foods. **The studies proposed here will be the first comprehensive attempt to develop risk-based strategies leading to effective control of pathogens from the farm through consumption across all food commodities in the U.S.** Additional expected outcomes include the use of microbiological data to develop risk-based models that can be used to better predict microbial contamination and predict the reduction of pathogens in foods due to application of various control strategies. It is expected that the outcomes of this project will contribute to the long-term profitability and sustainability of the food industry as a whole by making accessible a suite of new tools with which the microbial safety of foods will be enhanced. This group will also work to standardize protocols among laboratories so that research results can be easily and directly compared. Many funding opportunities for food safety require collaboration by several universities. Having a mechanism in place prior to release of a

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formal Request for Proposal enables the scientists in this group to be more responsive and successful in acquiring external funding than if collaborations were formed *ad hoc*.

The Centers for Disease Control and Prevention (CDC) has recently reported new, more accurate estimates of foodborne illnesses that occur annually in the U.S. Approximately 48 million cases of foodborne illness, 128,000 hospitalizations, and 3,000 deaths occur each year from foodborne microorganisms (Scallan *et al*., 2011). The food safety surveillance system, FoodNet, documented in 2008 (the latest year for which data are available) that the Noroviridae were identified as the most common etiological agent of microbial foodborne disease, accounting for almost 50% of the outbreaks and 46% of illnesses. *Salmonella* spp. accounted for 23% of the outbreaks and 31% of illnesses. The commodities that led to the most outbreak-related illnesses were fruits and nuts (24%), vine-stalk vegetables (23%) and beef (13%) (Anonymous, 2011).

In addition to human suffering, foodborne illnesses also have a substantial economic impact in the United States. Based on data from Scallan *et al*. (2011) and Scharff (2010), the annual cost of foodborne illness in the U.S. is estimated at $89 billion for loss of productivity, other economic losses and medical expenditures. The most costly foodborne illnesses are caused by *Vibrio vulnificus* and *Listeria monocytogenes* (Scharff, 2010). The availability of improved microbiological methods will facilitate the goal of reducing the burden of current and emerging foodborne pathogens at all points of the food chain from farm to fork. Such methods will decrease foodborne related illnesses and deaths, and reduce economic losses to the food industry.

Finally, in addition to developing a better understanding of the microbial ecology of foodborne pathogens and methods to detect and control their presence in foods, this multi-state project will permit undergraduate and graduate students to gain experience in current and emerging methods used to identify, track, and control foodborne pathogens in the food production environment, as well as the use of modern molecular methods to identify and study emerging pathogens that may contribute to the burden of foodborne illnesses. The need for training programs to support the next generation of food safety specialists is clear, as is the need to increase the ethnic and cultural diversity among food safety researchers to reflect the ethnic and cultural composition representative of the U.S. population. Greater diversity is critical not only from the perspective of educational opportunity but also relative to food safety and public health. The prevalence of foodborne illnesses associated with culturally prepared foods and preparation practices associated with preparation of these foods is growing, making cultural competence among food safety professionals not simply attractive, but absolutely necessary.

Related, Current and Previous Work

Previous Work, S1033 10/2006 – 09/2012.

Since 2009, member of the previous S1033 group have authored over 450 peer-reviewed papers on the subject of food safety (see "2009 – 2012 Publications" in the Additional Documents section). Notably, approximately 20% (85/450) of these papers were co-authored by more two or more members of the multi-state group, providing direct and tangible evidence of effective multi-member collaboration. Moreover, funding acquired among group members supported research described in many of these papers. The impact of this research is significant. The increased understanding of the ecology, biology, epidemiology, of foodborne pathogens in pre and post- harvest environments, foods and the environment has been used to populate risk

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models of disease transmission and develop a variety of intervention strategies to control risk. In addition, the data has been incorporated into systematic reviews and meta-analytical studies which are available to inform decision makers in industry and in government positions.

The participants of this project have a very productive history of collaboration and successful research. Interactions amongst researchers from the 28 universities participating in S1033 are outlined in Table 1 (see “Table 1” in the Additional Documents Section). This table indicates collaborations (defined as funded projects, extension activities, or co-authored publications) between universities over the course of the previously active multistate project S1033 between 2006 and 2012. Outputs and deliverables among S1033 members is high, individually averaging more than 5 publications, 6 presentations, and $426,000 of research support each year. It should be noted that S1033 members have formed collaborations and developed multi-institutional, trans-disciplinary successful research programs funded by a variety of federal (USDA, FDA, NIH, USAID, and FAS), state, private, and stakeholder groups.

One of the most underrated benefits of participation in a project with so much collaboration is the opportunity to work with erudite researchers across the country. As a result, many of the grants received and goals achieved would not have been practical or possible if working alone. These relationships included, but are not limited to, obtaining samples or microbial cultures, performing analytical services and the sharing of technical guidance and advice. Although not always obvious from annual reports, meeting minutes or publications, these difficult-to-quantify benefits springing from the frequent collaborations is a key component of what has helped to make the past project so successful.

Current Work

Food safety is an important agricultural, public health, and economic concern in the U.S. and worldwide. As such, there is an emphasis regionally, domestically, and globally, to conduct research to better understand foodborne pathogens, disease transmission and prevention. For example, in 2012 alone, there were over 40,000 research papers published on the topic of the most common foodborne pathogens (10 bacterial, 3 parasitic, and 1 viral) occurring in the US (See “Table 2” in the Additional Documents Section).

In the past few years, federal funding for agricultural research has not kept pace with increasing demands, but resources for food safety food safety research have been somewhat prioritized. The availability of resources for food safety research has attracted a large number of investigators not traditional trained in or previously involved in this field. This influx of new researchers brings exciting new ideas and approaches and the opportunity for novel interdisciplinary strategies to address some of the most pressing food safety challenges. However, the competition for available resources in increased, and the new cohort of food safety researchers may not be fully aware of past food safety efforts and advances from a practical and applied perspective.

We recognize the vast amount of food safety research currently conducted in laboratories around the world. It is the purpose of this multi-state project to contribute to the coordination of food safety efforts performed at land grant institutions in the United States. The networking capability of this group permits the formation multi-state, regional, or other appropriate teams that build on the strengths of different individuals to develop innovative approaches to food safety that limits the redundancy in research focus. At the same time, this multi-state project provides investigators new to the field mentoring opportunities to better understand stakeholders needs and challenges involved with the conduct of applied research.

The objectives of our new proposal are the natural extension and expansion of the work completed on S1033, and address current and emerging food safety concerns in 2012 and beyond. We have identified seven additional universities that have expressed interest in participating in this project (See "Table 3" the Additional Documents Section). As is apparent by comparing collaborations from Table 1 between universities participating in S1033, and the rather limited collaborations obvious in Table 2, we see tremendous opportunity for future, previously uncultivated, collaborations. While these additional seven universities have already been contacted for future participation, we anticipate the efforts of the group will expand to invite participation of additional, historically underrepresented, institutions such as 1890's Universities.

Our previous objectives focused on control of foodborne pathogens in pre- and post-harvest environments, development and validation of mathematical modeling, and antimicrobial resistance in production and processing environments. As the importance placed on risk-based standards in food safety has evolved, we have modified our objective areas to integrate research, extension and teaching to cover the broad areas of Risk Assessment, Risk Management and Risk Communication. Risk Communication is an expansion of our former outreach component and is an attempt to highlight the diverse range of Extension activities at many of the participant universities. Our movement from targeted, isolated objectives to integrated, systems and risk based objectives is a logical evolution. Objective areas previously covered under S1033, will continue in this new project. For example, rather than a unique objective focusing specifically on antibiotic resistance amongst bacterial pathogens and its significance/mitigation, research and extension related to antibiotic resistance in foodborne bacteria will be covered under all three objective areas. The prevalence of and risk factors involved will be covered under 1) Risk Assessment; potential control strategies will be covered under Aim 2) Risk Management; and the knowledge obtained from objectives 1 and 2 will be transferred to stakeholders under Aim 3) Risk Communication. The adoption of this risk-based systems-type approach allows member researchers to: (i) continue to be engaged along the entire farm-to-fork continuum on a variety of food products including dairy products, meat, poultry, seafood, fruits, dried fruits and nuts and vegetables; (ii) work on a number of bacterial, parasitic, and viral pathogens; (iii) to evaluate emerging detection and decontamination technologies and processing methods; (iv) to input data into more complex and all-inclusive mathematical models; and (v) to transfer this information through innovative and evolving methodologies to stakeholders along the continuum.

Related Work

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A systematic search of electronic databases, including the USDA CRIS and NIMSS databases, yielded a larger number of past and active projects that address a wide variety of food safety topics. Of 243 active AFRI, Animal Health, NRI, and HATCH projects identified by the search term FOOD SAFETY, 72% are conducted by investigators at institutions involved in this project and are partially an outcome of previous involvement with this group. In addition, several ARS units are also involved in food safety research. The following seven other multi-state projects identified in the NIMSS search included some mention of food safety objectives:

NC1023: Engineering for Food Safety and Quality.
NC1041: Enteric Diseases of Swine and Cattle: Prevention, Control and Food Safety.
NE1028: Mastitis Resistance to Enhance Dairy Food Safety.
NC1183: Mycotoxins: Biosecurity, Food Safety and Biofuels Byproducts.
S_TEMP2882: Fly Management in Animal Agriculture Systems and Impacts on Animal Health and Food Safety
S294: Quality and Safety of Fresh-cut Vegetables and Fruits
W3122: Beneficial and Adverse Effects of Natural Chemicals on Human Health and Food Safety

A detailed table ("Table 4") of how each of the above projects compares to SDC346 is included in the Additional Documents Section.

Food systems are extremely complex and various aspects of production, quality, and animal and plant health may impact food safety. The major difference between the proposed multistate project, and other projects, that have in their title a reference to food safety, is the fact that these projects include the topic of food safety because it is often on the periphery of many non-food safety topics related to agriculture and production of food. In contrast, members of SDC346 conduct food safety research as a primary focus. Other differences include the fact that most other projects focus on a single class of food commodity (ie.g. fresh/minimally processed produce, dairy), whereas SDC346 will conduct research related to the safety of multiple food commodities.

Objectives:

To advance the sustainability and competitiveness of US agriculture, our multi-institutional team will employ innovative, integrated, multidisciplinary research and outreach approaches for risk assessment, development of risk-management strategies, and communication tools to mitigate the risks associated with hazards in food. This mission will be accomplished by addressing the following objectives:

1. Risk Assessment: Assess food safety risks in agriculture systems
2. Risk Management: Develop science-based interventions to prevent and mitigate food safety threats
3. Risk Communication: Communicate food safety messages to stakeholders

Materials and Methods:

This proposal describes a collaborative effort between researchers at multiple institutions in the US and includes basic and applied research over a wide range of food commodities with a goal of risk-based research and outreach to address the safety of food from farm to fork. The principal investigators (PIs) meet annually to help build a strong grass-roots team dynamic, and most participants are well connected regionally and nationally to the food commodity production, processing, distribution and retailing industries across the US. The PIs have and continue to work to standardize microbiological methods among laboratories so that results may be directly comparable. Whenever appropriate, standard methods such as those from the Compendium of Methods for the Microbiological Examination of Foods, the U.S. Food Aand

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W2177: Enhancing the Competitiveness and Value of U.S. Beef. ¶
NE1028: Mastitis Resistance to Enhance Dairy Food Safety.¶
S1027: The Poultry Food System: A Farm to Table Model. ¶
S294: Quality and Safety of Fresh-cut Vegetables and Fruits¶
NC1023: Engineering for Food Safety and Quality. ¶
NC1183: Mycotoxins: Biosecurity, Food Safety and Biofuels Byproducts. ¶

Deleted: The primary difference among the abovementioned projects and the current proposal is that in this project, food safety is the paramount goal. Impacts on quality, productivity, economics and marketing are all secondary benefits. Moreover, this project is unique in that it cuts across all food commodities, and is holistic in its risk analysis approach. Notwithstanding, several of the participants of this project are also members of the other abovementioned groups, an activity that even further strengthens the outputs of this proposal and builds complementarity among efforts.¶

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The objectives of our new proposal are the natural extension and expansion of the work completed on S1033, and address current and emerging food safety concerns in 2012 and beyond. We have identified seven additional universities that have expressed interest in participating in this project (Table 2). As is apparent by comparing collaborations from Table 1 between universities participating in S1033, and the rather limited collaborations obvious in Table 2, we see tremendous opportunity for future, previously uncultivated, collaborations. While these additional seven universities have already been contacted for future participation, we anticipate the efforts of the group will expand to invite participation of additional, historically underrepresented, institutions such as 1890's Universities. ¶
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Drug Administration's Bacteriological Analytical Manual (BAM), or other applicable sources (AOAC, USDA, etc.), will be used for the enumeration or identification of foodborne pathogens. The use of standardized, validated methodologies is an often overlooked but critically important aspect of collaborative studies. PIs of this group have already previously developed and validated many of the methods that we propose to use here. However, additional cross-laboratory validations of new and emerging methods are continually evolving and include evaluation of strain, inoculum preparation method and concentration, impact of laboratory humidity, and recovery methods.

Feedback from the food production and processing industries on the type of research proposed here has been that concentrations of microorganisms used in the laboratory are often unrealistically high to be of practical value. Indeed, the experience of PIs confirms that concentration and inoculation-preparation methods often have significant impact on pathogen behavior (Flessa et al., 2005; Uesugi et al., 2006; Montville and Schaffner, 2003) and thus interpretation and external validity of results. However, in other cases, inoculum levels or culture preparation plays a minor role. The ability of researchers to meet to discuss and evaluate influence of these factors is a vital and imperative component of the project.

The proposed research reflects the diversity of the member scientists and will cover food commodities including aquaculture (fish and shellfish), meat (beef, pork sheep, goat, and other), poultry and eggs, dairy, fruits, vegetables, low moisture foods (primarily nuts and dried fruits), dry, raw, ready-to-eat and processed foods and animal feeds. In addition to multiple commodities, numerous conventional and emerging pathogens, including bacterial (*Salmonella* spp., *Campylobacter* spp., *Vibrio* spp., shiga toxin producing *Escherichia coli* (STEC), *Listeria* spp., *Clostridium* spp., *Yersinia* spp., *Shigella* spp., *Staphylococcus* spp., *Enterococcus* spp., *Mycobacterium* spp.), viruses (hepatitis A, norovirus, FRNA phages), and parasites (*Cryptosporidium* spp., *Cyclospora* spp., *Toxoplasmosis* spp. and *Giardia* spp.) are investigated by members of this group. Although no current members conduct research on mycotoxigenic fungi or mycotoxins, we look forward to future inclusion of members with a specialty in this area, if they are interested. However we recognize that there is another multistate project entirely devoted to this hazard.

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General Methods Applicable to Objectives 1 and 2.
A combination of basic and applied science questions will be addressed using laboratory experiments, field trials, and epidemiological investigations.

Food Commodities. Food commodities will be obtained from producers, processors or purchased from local retailers or distributors. Occasionally, specific pathogen-free animals may be required. Samples will be stored at appropriate temperatures prior to use. Time between obtaining the food and experimental use will be minimized. Commercially appropriate varieties will be utilized.

Pathogens. Strains that have been associated with outbreaks from the commodity of interest will be used whenever possible. If not possible, other significant pathogenic strains will be selected. These strains are often available in the PIs laboratories and will be shared amongst researchers when appropriate. As appropriate, antibiotic-resistant variants of these strains have been isolated and several have been modified to produce florescent compounds, allowing enhanced detection from food systems. Validated non-pathogenic surrogate species of various microorganisms are also available for those situations where the use of such organisms may be appropriate. Strains of different genera can be engineered to contain traits noted above as required. The modifications will allow, when necessary, easy identification of the inoculated strains in the presence of high levels of background microflora.

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Inoculation. Frozen stock cultures of bacterial strains are typically stored in glycerol stock solutions at -80°C. Prior to use strains are streaked onto non-selective media supplemented with selective agents as appropriate. Inocula may be prepared from plate or broth cultures, and may or may not be washed prior to use. Appropriate carrier media will be used for inoculations at volumes, levels and methods typical for the commodity being evaluated. Standard methods will also be used to create viral or parasitic inocula. Methods for inoculation of food commodities will vary, as required, to best mimic standard commodity specific criteria and the specific hypothesis-based research questions being addressed.

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Recovery of Pathogens from Inoculated Samples. Sample sizes, buffering solutions, and maceration methods will vary depending upon commodity and experiment-specific requirements. Enumeration of bacterial pathogens following serial dilutions by standard plating techniques onto selective and non-selective media, Most Probable Number techniques or by more sophisticated molecular techniques are commonly used by project PIs. When samples fall below the limit of detection standard enrichment protocols (FDA BAM or others) will be followed. The collection of quantitative data will be encouraged whenever possible and can be used to populate risk models.

Recovery of Pathogens from Environmental and Uninoculated Food Sources. Sampling methods to recover pathogens from the environment and foods will vary depending upon the sampling scheme and source as appropriate for the experimental design of the experiment. All attempts will be made by project PIs to not only determine frequency of pathogen isolation, but also concentration of pathogens identified, as concentration is a critical variable required in Objective 2. When appropriate, concentration techniques may be used to evaluate larger than typical sample volumes/weights and enrichment techniques used to evaluate samples when low numbers of cells are present.

1. Assessment of food safety risks in agricultural systems.

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The long-term goals of this objective include (i) evaluation and modeling the relationship between environmental parameters and indicator organisms to the levels of pathogenic microorganisms; (ii) understanding prevalence and frequencies of pathogens and antimicrobial resistance within the environment, food products and food production processing, distributions and consumer systems; (iii) persistence, dissemination and traceability of the microorganisms within the environment, food products and food production processing, distributions and consumer systems.

Evaluate and model the relationship between environmental parameters and indicator/index organisms to the levels of pathogenic microorganisms. Critical to the development of risk-based approaches to food safety is the understanding of how pathogenic microorganism's presence/numbers relate to easy-to-measure physicochemical and microbial indicators.

Currently employed standards throughout the food production and manufacturing sectors involve the frequent sampling for various indicator or index organisms. However, while dogma dictates that changes in indicators or indexes result in an increased risk for a product, very little published literature on this topic is available. One of the drawbacks of testing for pathogens or microbial indicators is the interval between testing and the time of result. In many instances, this time delay can range anywhere from 12 to 120 h depending on target organism(s) that are being detected. Obviously the long detection times preclude testing from being used in real time. To address these issues, we propose to evaluate and model these relationships using available and emerging technologies.

Understanding prevalence and frequencies of pathogens and antimicrobial resistance within the environment, food products and food production processing, distributions and consumer systems. Also vital to the success of any risk assessment is a comprehensive perception of both concentration and distribution of risk factors, including foodborne pathogens and presence of antimicrobial resistance genes. Much of the currently available prevalence data is lacking critical concentration data, which while difficult to determine, is an essential piece of any risk assessment. Also commonly overlooked are the potential spatial-temporal population differences that may exist across the US, and offer a unique niche for PIs collaborating on this project to evaluate. These spatial patterns that exist along the farm-to-fork continuum provide insight into current relative risk of food products and production environments, and are a critical starting point against which all risk reduction attempts can be benchmarked. Statistically-sound sampling methods and sample sizes are of fundamental importance to all studies. These issues will be addressed by our plan to evaluate frequencies and concentrations of pathogens and antimicrobial-resistance genes and identify production, manufacturing, distribution or consumer management practices that improve public health by reducing these risks.

Persistence, dissemination and traceability of the microorganisms and antimicrobial resistance within the environment, food products and food processing, distribution, and consumer systems. In addition to understanding relationships between indicator organisms and pathogens, and concentration/frequencies of risk factors during food production, of crucial importance is an understanding of how risk factors can vary from the time a food product is conceived to consumption by a consumer, and how typical industry or consumer practices and handling can influence these risks. While a significant amount of data exists for some commodities, others remain relatively understudied, and handling practices are continually evolving with the industry. For data that do exist, a systematic review to identify critical data gaps and extraction of data for inclusion into comprehensive risk assessments is an opportunity for PIs of this project. While the term "cross-contamination" is often used, and the principle of prevention of cross-contamination taught to all facets of the industry, data to model and understand the fundamental mechanism of cross-contamination, and elucidate novel prevention strategies are lacking. Our strategy to tackle this concern rests in our multidisciplinary, systems approach of critical data gap identification, data generation, and modeling of multiple commodity, production, process, distribution and consumption patterns.

2. Develop science-based interventions to prevent and mitigate food safety threats

This section describes current and planned activities/methods related to the management of microbiological risks associated with foods arising from significant points along the food production and process continuum (e.g., "farm-to-fork"). Major food commodity groups are

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identified, along with their interaction(s) with novel intervention strategies, and food safety diagnostic technologies. The ultimate goal of these activities is to lower or reduce pathogens in foods and thus concurrently lower risks of foodborne disease.

To accomplish the tasks associated with this objective, models and a risk management framework based on commodity-specific flow diagrams and inputs from the first objective will be developed. A key component of this activity will be the use of risk modeling techniques to relate levels of microbial contamination in food to the likelihood of the occurrence of foodborne outbreaks. The information developed using this approach will then be utilized to mitigate risks at specific points along the farm to fork continuum. The data developed using the risk modeling approaches will also lead to the identification of critical data gaps, which will feed back into new projects under objective 1. For example, pre-harvest efforts may center around the identification of on farm management practices that improve food safety by reducing potential foodborne pathogens. At harvest, methods will center around the combination of effective interventions that act synergistically to reduce or eliminate pathogens from foods, with a major emphasis placed on reducing cross contamination events that occur and lead to major food contamination events.

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Models and risk management. Predictive microbiology and quantitative microbial risk assessment (QMRA) are rapidly developing scientific disciplines that use mathematical equations, numerical data, and expert opinion to estimate the presence, survival, growth, and death of microbes in foods. These models allow for the prediction of the safety of a product, based on the entire sequence of events up to consumption. They provide a framework for identifying critical data gaps and evaluating the effectiveness of risk-reduction strategies.

Under this objective, predictive models will be built and validated for appropriate commodity/pathogen pairings. Temperature is a major extrinsic factor that affects growth/death of microorganisms and temperature of food products changes drastically during processing, storage, and distribution. Mathematical models will be developed to describe the chilling and heating rates of various food commodities. These developed models will be validated using real-life scenarios, whenever possible. Microbial predictive models (e.g. Baranyi et al., 1993 neural network models) will be developed using kinetics derived from microbial growth experiments at different temperatures. Models to predict growth rate and lag time of pathogens as a function of temperature will be developed using the square root model popularized by Ratkowsky et al. (1991). The models generated for one commodity can be used to guide a series of experiments to validate the model for different, closely related commodities. Following the development of temperature models, expert opinion, industry, experimentally derived and literature data for processing and handling conditions to the point of consumption can be integrated into risk assessment models to estimate changes in microbial population dynamics. Alternatively, established models such as The Pathogen Modeling Program or ComBase can be utilized.

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Examples of approaches to QMRA can be found in Montville and Schaffner (2005). Briefly, literature-captured data are collected by searching medical and biological databases for documents related to the commodity. A “flow diagram” documenting the commodity (including its ingredients) from production through retail should be developed with expert opinion. Data from other objectives and the literature will be translated into appropriate discrete or probability

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distribution functions and assigned to processes in the flow diagram. The QMRA model can be created using Analytica (Lumina Decision Systems, Los Gatos, CA) or @risk software (Palisade Corp). Results for simulated input distributions as well as final results will be obtained by running from 1,000 to 1,000,000+ iterations of the simulation. Tornado analysis can be used to determine the relative significance of the input variables.

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Risk Mitigation. For foods that are processed, the development and validation of novel processing technologies will lead to reduced risk of the production of contaminated foods. Ongoing studies include, but are not limited to, those related to high pressure processing (HHP), UV, ozone, electrolyzed water, bacteriophages, peracetic acid, essential oils, and value-added packaging, alone or in combination, as methods to mitigate food safety risks on various food commodities. For example, the responses of various enteric viruses (hepatitis A and Norovirus surrogates) and bacteriophages (as surrogates for human viruses) inoculated into ready-to-eat food seafood products to HHP will be observed. Comparison studies will include realistic HPP experiments in tissue culture media and model food products. Experimental variables for these studies will include pressure magnitude, treatment time, and temperature of different. HPP-treated RTE products will be evaluated using consumer taste panels, allowing for consumers to be educated on foodborne viruses and the potential HPP impact on food safety and preservation.

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Maintaining proper temperature during transportation is essential to ensuring the safety of foods. In order to develop effective interventions, it is first necessary to understand the effects that cold chain temperature abuse have on the ability of bacterial foodborne pathogens to grow during transportation. The ecology of foodborne pathogens during transportation between unit operations within the food continuum is grossly understudied and misrepresented in current risk modeling simulations. For example, to address these issues, we will employ the use of wireless temperature sensors to monitor fluctuations in temperature that occur during commercial transportation of food products (pre, post and during harvest and processing), as well as transportation from retail to domestic kitchens. Data from these studies will be used in risk assessment models to predicting the growth of foodborne bacterial pathogens during various stages of transport.

A major area of concern with respect to contamination of food is the domestic kitchen, where multiple opportunities arise for abuse of foods. Similar to temperature control during various phases of transportation, consumer behaviors and actions they perform to increase or decrease food safety risks requires further study for inclusion in current risk modeling simulations. For example, while consumers are often advised to prepare their produce dish (s) before preparing raw meat or poultry, informal studies have found that most consumers may not, and those that do follow a range of methods from a quick rinse under running water to scrubbing with soap and water. Further work is needed to evaluate such methods efficacy in minimizing the survival and growth of foodborne pathogens. To address this concern, an additional evaluation of the efficacy of novel methods and products for washing produce to decrease populations of foodborne pathogens may be undertaken. Depending on the commodity, any number of methods could be evaluated. The most promising methods will be promoted through programs and educational materials developed in objective 3.

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3. Communicate food safety messages to stakeholders

Effective communication is critical to incite behavior and management changes towards a safer food supply. Instead of relying solely on passive diffusion of information through the publication of Fact Sheets and peer-reviewed journal articles, and presentations, herein we propose to use two-way exchanges of information between stakeholders and researchers to tailor risk management messages for each specific audience. Multiple criteria will be used to evaluate and assess message content and media. The efficacy of these messages to result in measurable changes in behavior and tangible impacts on food contamination will be evaluated. Based on stakeholder feedback and the assessed success or limitations of various communication strategies, changes will be made to outreach approaches to meet specific audience needs.

Risk avoidance messages should be based on data. Some of the data to support the risk message content will be derived from the research of this program. However, it is equally important information from other multi-state groups, and other individuals, both nationally and internationally, be included in crafting appropriate messages and determining the best route for message delivery.

We anticipate that each stakeholder will require unique combinations of specific information, and route of delivery (print, electronic, presentations, etc.). PIs of this group have partnerships and collaborations with a wide variety of stakeholder groups situated at all levels of the farm to table food production continuum. Targeted stakeholders include producers, processors, retailers, food service, and consumers. However, to enhance the capacity of this group to communicate food safety information to stakeholders we will expand our communication efforts in to the following groups:

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a) Seafood industry
b) Juice and beverage industry
c) Produce, dried fruit and nut industries
d) Dairy industry
e) Meat industries
f) Poultry and Egg industries
g) Ingredient manufacturers
h) Consumers
i) Food service and retail organizations
j) Public health agencies
k) Regulatory agencies

In addition, this objective will be enhanced by Technical Committee members working directly with the abovementioned groups by expanding the breadth and diversity of the multi-state team. Invitations to join this group will be sent to professional contacts of current Technical Committee members, especially other academics who are already working with stakeholders. This multi-state group offers the unique advantage to form regional working-groups to coordinate targeted information and outreach activities. Conversely, when geographically based regions are inappropriate for maximizing impact to stakeholder groups (i.e. juice safety efforts in Florida and New York; Oyster safety efforts in Washington, California, Louisiana, and Maryland; or cantaloupe safety in California, Arizona, Texas, Colorado, Indiana and Florida), the diverse geographic representation and backgrounds of participating institutions and individuals allows for maximum impact and uniform messages to be communicated.

The following approaches will be exploited:

1) Increase communication by recruiting additional university personnel with research and Extension appointments, including 1890's land-grant schools and Hispanic-speaking institutions.
2) Strengthen collaborative networks and exchange of information about integrated food safety issues, fostering communication with food industry/target audiences and other stakeholders (USDA, FDA, Departments of Agriculture and Health, etc.) on a regional and national scale.
3) Increase USDA-ARS scientist participation in group meetings and research collaborations on a regional and national scale.
4) Through stakeholder participation in meetings, conduct needs assessment/survey of stakeholders to determine current trends and food safety issues at annual meetings of IAFP, AMSA, PMA, AMI, NCBA, NRA, GMA, PSA, United Egg Producers, organic producers/processors, etc.
5) Transfer food safety knowledge to undergraduate and graduate students via training opportunities at collaborating institutions, resident education, extension and/or outreach activities nationwide.
6) Facilitate national networking and coordination amongst the users of food safety information from production to consumption (farmers, producers, processors, inspectors, researchers, consumers, etc.), to explore regional specific and national barriers and opportunities.
7) Identify and disseminate information about databases of food safety information and interactive software to support decision-making amongst food safety professionals, on a regional or national scale as necessary.
8) Disseminate (share among partners) food safety trainings, multiuser distance education programs, satellite communication, webinars, etc. to deliver food safety training on topics such as:
   i) ServSafe
   ii) Center for Produce Safety curriculum
   iii) Food Safety Modernization Act
   iv) Validation for meat and poultry industries
   v) HACCP
   vi) Food Defense
   vii) Traceability
9) Encourage Technical Committee members participation actively in professional food safety venues and acknowledge the multi-state contributions of their activities publically in programs such as:
   a) Conference for Food Protection
   b) PDG's and affiliates within IAFP
   c) IFT (FMD, MFD, Extension, F&VD, etc.)
   d) Commodity-based organizations (meat, poultry, fruit, vegetable, confectionary, ingredient, dairy, etc.)
   e) National Advisory Committee on the Microbiological Criteria for Foods

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IAFP affiliates

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10) Conduct evaluations to determine impact of educational and/or outreach activities on student and/or workshop participants' food safety knowledge, attitude, behavior, and/or skills.

In addition to the research activities performed by the group's members, the extent to which team members participate in the abovementioned outreach activities (outputs), and outcomes and impacts associated with the fulfillment of these objectives, will be documented annually, and national and regional efforts and collaborations identified. Collectively, this emphasis on two-way exchange of information and participatory decision-making will foster an increased understanding of stakeholders' goals and needs and strengthen the relationships between all partners in the food system. As an expected outcome, we anticipate a decrease in redundancy in regional efforts and a more efficient use of financial resources in food safety research and outreach, with more directed focus on current and emerging problems. Because of the increased availability of information and knowledge transfer among stakeholders, the opportunity will exist for decision-makers in industry, academia and government to make better, risk-informed, choices related to regulations and the allocation of resources.

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Measurement of Progress and Results:

Outputs:

- Increased understanding of the contamination, ecology, and risk based prevention strategies for food safety
- Validated decontamination methods that can be used by the food producers, processors, retailers and consumers to enhance the safety of their finished product
- Outreach/extension education and training materials for stakeholders including regulatory personnel, extension agents
- Engagement of minority food safety researchers and more students in discipline

Outcomes or Projected Impacts:

- Enhanced safety of fruit, vegetable, dried fruit and nut, seafood, meat, and poultry products
- Increased understanding of food safety measures by regulatory personnel, producers, processors, consumers, extension agents
- Overall enhanced food safety and health for consumers
- Increased opportunities for trade of food products
- Increased capacity to meet growing food safety intellectual capacity for the country

Milestones:

This project is specifically designed such that the specific aims are highly integrated and not co-dependent upon accomplishments of individual objectives. The discovery, synthesis and delivery of knowledge is an iterative process that will continually be refined to enhance the quality of information as it becomes available. Risk assessment typically precedes risk management and risk communications. However, the level of risk knowledge of some food commodity-hazard pairs is well established and communication efforts should begin immediately. In contrast, we anticipate new and emerging challenges to develop over the project period. Nevertheless, certain programmatic activities will take place as outlined below:

2013- Ensure that at least one representative from each State Agricultural Experiment Station has been contacted and invited to participate in this project. Achieve a membership of at least 50 individuals with broad geographic, commodity and area of representation.

2014- Enhance diversity of membership through targeted recruitment of individuals working on food safety issues at 1890 Institutions, Hispanic Serving Institutions, and Tribal Colleges and Universities.
2015- Establish a student mentoring program to recruit and mentor students into a variety of food safety related disciplines.
2016- Invite Participants from USDA ARS laboratories and other state and federal governmental laboratories and organizations with interest in food safety (FDA, EPA, etc.).
2017- Publish a white paper highlighting advantages of and detailing how participant research has evolved into risk based standards targeted for publication in Trends in Food Protection.

The milestones described are those under the control of the conference participants. The completion depth and scope of the specific sub-objects that will be accomplished is dependent upon participants acquiring additional external resources to perform laboratory and field research and develop, deliver, and evaluate novel outreach materials. Given the large degree of uncertainty in the availability of additional funding, our proposal was designed in such a way that the objectives are not co-dependent and if some of the early objective cannot be met for one reason or another, the project does not fail completely. In contrast, other aims can be addressed and while attempts are made to find alternative strategies to circumvent project roadblocks and challenges.

Projected Participation:

See Appendix E.

Outreach Plan:

Outreach activities and the evaluation/impact of this project are fully integrated into the methods of this proposal under objective 3.

Organization and Governance:

The membership of the Regional Technical Committee includes: (i) The regional administrative advisor (non-voting); (ii) A technical representative of each cooperative experiment station, appointed by the respective station director; (iii) A technical representative of each cooperative USDA research division or other Federal agency named by the director of the division or Head of the agency; (iv) An executive committee consisting of Chairman, Vice Chairman, and Secretary, elected by the Technical Committee members, is designated to conduct business of the Technical Committee between meetings and to perform other duties assigned by the Technical Committee. The term of office for each Executive Committee member is two years. The progression is Secretary, Vice Chairman, Chairman, for a total of six years.

The duties of the Technical Committee will be to coordinate planning and work of the project and make such recommendations as are necessary through the Administrative Advisor to the Southern Association of Agricultural Experiment Station Directors. The functions of the Chair will be to preside over meeting and edit the annual report. The recording secretary shall take minutes at the annual meeting and distribute these to members of the committee within a month of the meeting.

The Technical Committee will meet annually to review progress, develop research plans and coordinate research efforts in order to maintain the Committee's focus on the objectives identified in the project. During the annual meeting, the research coordinators from each of the lead states (Table 1) will summarize for the entire Regional Technical Committee the plan of work for the next year in the specified research areas in meeting the goals of each objective. In addition to the annual meeting, the coordinators are responsible for maintaining active communication with their cooperating stations

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principal investigator to maintain a current knowledge base of research accomplishment within the specified problem area. This linkage will enhance the research effectiveness and productivity, reduce duplication and unnecessary work, and strengthen the regionalism among cooperating stations. Copies of the Annual Progress Report, including major accomplishments of contributing project and minutes of the annual meeting will be distributed each year and available at the NIMSS website.

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