



National Center for Food Safety and Technology

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Processing & Packaging Platform

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2009 PROJECT PROPOSALS

PROCESSING AND PACKAGING PLATFORM

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging	
Title: Thermal Resistance of <i>Coxiella burnetii</i> in Dairy Products with Differing Levels of Solids and Fat Contents	
Project Leader(s): Joseph E. Schlessner	
New or Continuing: Continuing	Start: October 1, 2008 End: September 30, 2011
Background and Justification: <p>Pasteurization of dairy products is based on thermal resistance of <i>Coxiella burnetii</i>, the most resistant vegetative pathogen to this process. The research for the basis of this regulation was conducted during the 1950's. However, very little further research on the thermal resistance of <i>C. burnetii</i> was conducted. A more thorough understanding of the thermal resistance of <i>C. burnetii</i> is required to determine the minimum pasteurization requirements for dairy products with differing levels of solids and fat contents. Since <i>C. burnetii</i> is an intracellular parasite, selective media can not be used to propagate, recover or enumerate this microorganism. Therefore, thermal resistance of <i>Coxiella burnetii</i> in milk and dairy products with differing levels of solids and fat contents is currently difficult to determine. Nine Mile strain, phase II, clonal 4 of <i>C. burnetii</i> will be used as the surrogate for experimentation. Various methods to propagate and recover <i>C. burnetii</i> in tissue culture will be studied. Enumeration methods for <i>C. burnetii</i> will also be studied. Once these methods of propagation, recovery and enumeration have been established, the thermal resistance of <i>C. burnetii</i> in milk and dairy products with differing levels of solids and fat contents will be studied.</p>	
Project Objectives (and Milestones, with timeline, if a continuing project): <i>Objectives:</i> Study the thermal resistance of <i>Coxiella burnetii</i> in milk and dairy products with differing levels of solids and fat contents. <i>Milestones:</i> <ol style="list-style-type: none">1. Evaluate various methods to propagate for <i>C. burnetii</i> in mammalian tissue cell culture. March 20092. Evaluate recovery and enumeration methods for <i>C. burnetii</i>. Sept. 20093. Study the thermal resistance of <i>C. burnetii</i> in whole and skim milks. Sept. 20104. Study the thermal resistance of <i>C. burnetii</i> in dairy products with differing levels of solids and fat contents. Sept. 2011	
Benefits to Stakeholders: <p>Better understanding of the thermal resistance of <i>Coxiella burnetii</i> is needed to determine the minimum pasteurization requirements for dairy products with differing levels of solids and fat contents for the Pasteurized Milk Ordinance and other Federal Regulations as well as CODEX equivalency issues for imported milk and milk products.</p>	

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging		
Title: Validation of Microwave Pasteurization of Multiple Shell Eggs		
Project Leader (s): Greg Fleischman		
New or Continuing: Continuing	Start: October 1, 2004	End: September 30, 2010
Background and Justification: <p>In the U.S., 64 billion eggs are consumed annually. The ever present problem of transovarian Salmonella Enteritidis (SE) has caused the FDA to issue a regulation to eliminate SE through a set of extensive provisions to be taken at the production level. Producers would be exempt from all but one of these provisions if they pasteurize their eggs. However, current shell egg pasteurization approaches are plagued by low throughput and slow processing. It has been shown in previous work that microwave pasteurization of a single egg is feasible. However, it remains to be shown that multiple eggs can be pasteurized sequentially regardless of in-grade variability.</p>		
Project Objectives (and Milestones, with timeline, if a continuing project): <i>Objectives:</i> To assess the performance of various microwave applicators in reducing the count of Salmonella to where full pasteurization is effected. <i>Milestones:</i> <ol style="list-style-type: none">1. Determine if the most recent applicator can achieve consistent pasteurization.2. When achieved, examine various processing variables to determine how processing time is minimized, while maintaining pasteurization.3. Determine relationships between egg parameters and processing requirements.4. Determine if high levels of Salmonella in the egg cause changes in egg component dielectric values.		
Benefits to Stakeholders: <p>The validation of a multi-egg pasteurizer is the next step in demonstrating a viable approach to continuous pasteurization of shell eggs. While existing practices do yield pasteurized eggs, their approaches relegate them to the specialty food area because of their low output. The current approach of continuous, dry pasteurization of shell eggs has the potential of making a significant contribution to the effort of Salmonella Enteritidis elimination at the producer level.</p>		

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging		
Title: Decontamination of Dry Ingredients		
Project Leader(s): Nate Anderson		
New or Continuing: Continuing	Start: October 2008	End: June 2010
Background and Justification: <p>Pathogens have been linked to outbreaks associated with dry food ingredients including powders (e.g., infant formula), particulates (e.g., seeds for sprouts) and foods with extended surfaces (e.g., almonds). Traditional thermal approaches to decontaminating these foods can cause adverse effects to product quality; therefore, alternative processes for decontaminating dry materials are desirable.</p> <p>Cold plasma, an emerging non-thermal technology with potential for microbial destruction of vegetative cells on solid foods will be explored. Cold-plasma processes uses high-voltage electricity to ionize gas to generate a plasma field that breaks down the oxygen molecules of air passing near the electrodes of the device into reactive oxygen species. The NCFST will acquire cold plasma equipment in the near future to explore inactivation of <i>Salmonella</i> on the surface of almonds and <i>E. sakazakii</i> in infant formula.</p> <p>Pulsed UV (PUV)light technology is a powerful surface decontamination technology which has shown to be effective against a wide array of micro-organisms. PUV technology shows promise of effectively inactivating <i>Salmonella spp.</i> on raw almonds and <i>Enterobacter sakazakii</i> in infant formula.</p> <p>The use of these technologies to pasteurize other tree nuts, legumes, and dry spices may also be explored.</p>		
Project Objectives (and Milestones, with timeline, if a continuing project): <p><i>Objectives:</i> Evaluate the effectiveness of cold plasma and pulsed UV-light technologies for microbial destruction of vegetative cells attached to surfaces of low moisture foods. Evaluate qualitatively the effects of these treatment technologies on product quality. (Project requires new equipments to be obtained in 2009.)</p> <p><i>Milestones:</i></p> <ol style="list-style-type: none">1. Examine cold plasma inactivation of <i>Salmonella spp.</i> on raw almonds. December 20092. Develop methods of inoculating dry foods and food powders. March 20103. Examine the effectiveness of pulsed UV-light on inactivation of <i>Salmonella spp.</i> on raw almonds. March 20104. Cold plasma inactivation of <i>Enterobacter sakazakii</i> in infant formula. October 2010 Investigate the efficacy of pulsed UV-light on inactivation of <i>Enterobacter sakazakii</i> in infant formula. October 2010		
Benefits to Stakeholders: <p>Stakeholders will gain a better understanding of emerging approaches to decontamination of powders and other heat sensitive foods such as nuts and produce, which presently is not well known. If proven effective, emerging cold plasma systems and pulsed UV-light systems may provide stakeholders with in-line pasteurization processes for heat sensitive, dry and powdered foods.</p>		

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging		
Title: Effect of solid particles on ultraviolet disinfection <i>E. coli</i> K12		
Project Leader(s): Kathiravan Krishnamurthy, Alfredo Rodriguez		
New or Continuing: New	Start: October 2009	End: June 2011
Background and Justification: <p>Ultraviolet disinfection is a proven and widely used technology in the industry for inactivation of pathogenic microorganisms. However, ultraviolet light is ineffective for foods with large particles, as presence of these particles provide protection to microorganisms and therefore minimize the inactivation. The role of these particles on the efficiency of ultraviolet light needs to be well understood in order to optimize the system for treatments of foods with large particles. The size of the particle and the flow characteristics may play a vital role in minimizing the shadow effect of particles. Therefore, it is highly beneficial to investigate the effect of foreign particles and flow characteristics on microbial inactivation of ultraviolet light. Effect of these particles on other juice products or liquid foods may also be explored.</p>		
Project Objectives (and Milestones, with timeline, if a continuing project): <p><i>Objectives:</i> To investigate the effect of the presence of foreign particles, size of the particles, Reynolds number, and particle density on the inactivation efficiency of UV-light for reduction of <i>Escherichia coli</i> K12 in model systems. To develop a model to understand the role of these particles in providing shielding effect to microorganisms.</p> <p><i>Milestones:</i></p> <ol style="list-style-type: none">1. Role of foreign particles on inactivation efficiency of UV-light for inactivation of <i>Escherichia coli</i> K12 in model systems (12/2010)2. Development and validation of inactivation kinetics models to better understand the role of foreign particles on inactivation. (06/2011)		
Benefits to Stakeholders: <p>This study will provide better understanding of the effect of large particles and flow characteristics on inactivation efficiency of ultraviolet light to the stakeholders. As majority of the foods have large particles, a clear understanding of the role of large particles may result in further optimization of the technology to enhance the inactivation efficiency of the ultraviolet disinfection system.</p>		

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging		
Title: Analysis of microwave heating of food systems		
Project Leader (s): Gregory J. Fleischman		
New or Continuing: Continuing	Start: 10-01-08	End: 09-30-10
Background and Justification: <p>Microwave ovens have been used primarily as a convenience to reheat cooked foods. Lately, the appearance of not-ready-to-eat (NRTE) foods that include microwave preparation instructions has moved the microwave oven into the realm once occupied solely by conventional heating appliances. The dependence on microwave energy to thoroughly heat these foods presents a challenge to their producers to stipulate instructions that will lead to thorough cooking. Yet, as is well known, the complicated interaction of microwaves leads to an equally complicated temperature distribution within the food. Using a cook-and-look approach to heating instructions will not reveal the interplay of content, placement and geometry of the food system components that would affect final heating results. Therefore it is proposed to examine on a more fundamental level the interplay of these factors through mathematical modeling. Knowing the basic parameters of heat transfer and microwave absorption allows these models to be developed. Using a finite-element modeling program to implement them allows many numerical "experiments" to be performed with complete knowledge of all temperatures. Combining this with actual experiments will determine if such models are adequate in explaining the variation in heating that is observed in actual foods. If so, modeling can be used as a tool to analyze heating situations and anticipate potential problems in NRTE foods.</p>		
Project Objectives (and Milestones, with timeline, if a continuing project): Objectives: Determine the expected temperature distribution in food items composing a complex food system and how changes in food system content, placement and geometry affect this distribution. Milestones: <ol style="list-style-type: none">1. Finite element analysis software, software training, and a computer suitable to run the software are obtained. The software must be able to handle microwave energy coupled with transient heat transfer. Perform numerical experiments to determine the changes in temperature distribution as a function of content concentration, placement and size.2. An NRTE food system is identified that will serve as a guide to construct a mathematical equivalent food system that will be used to analyze heating in a microwave field. Such a food system will have a well-defined geometry and components, with their dielectric parameters known. Use actual heating experiments to determine which model is suitable for reflecting the dynamics of microwave heating.3. A mathematical model is constructed that allows coupled thermal and electromagnetic phenomena. This model includes the oven, its size and location of the waveguide entrance as well as the model food system.4. Through the use of the mathematical model, the sensitivity of the temperature distribution to changes in heating parameters is determined. This will help to define the limits of applicability of NRTE microwave heating instructions.		
Benefits to Stakeholders: <p>The food safety issues with NRTE foods prepared in microwave ovens has served as a warning that if NRTE foods are to be microwave-prepared, a more careful approach to their microwave preparation is necessary. Mathematical modelling is one tool that could allow a quick assessment of potential issues with NRTE foods.</p>		

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging

Title: Basic exploratory study of the main engineering factors of the microbial contamination of foods.

Project Leader(s): Alfredo Rodriguez

New or Continuing: New **Start: July 1, 2009** **End: June 30, 2010**

Background and Justification:
Mathematical description of the microbiological contamination of foods by pathogens is not complete and reliable enough to support the development and application of engineering tools that assist to understand and control the corresponding processes. The scope is limited to pathogens of importance and the physical and physical-chemical phenomena that drive the behaviour of the corresponding systems. The mechanisms to be considered are convection, diffusion, settling and motion. Factors selected are electrostatic phenomena, surface and interface phenomena, physical properties such as size, shape, density, etc.; and adhesivity (for the micro-organisms), and viscosity, porosity, tortuosity, roughness, electrostatic charge, etc. (for the vectors). The populations to be studied are bacteria and viruses. Availability of appropriate mathematical descriptions for the transformations driving the contamination process will enable the development of models based on the corresponding population dynamics using system analysis. These models are expected to become powerful tools to support our work and assist us to enhance food safety through a better understanding of the contamination process. Therefore, this basic exploratory study is highly desirable.

Project Objectives (and Milestones, with timeline, if a continuing project):

Milestones:

1. Literature Review – August 1st.
2. Experimental plan – September 1st.
3. Acquisition of materials and hiring student October 1st
4. Execution of experimental plan April 30, 2010.
5. Report – manuscript(s) for publication May 15, 2010.

Benefits to Stakeholders:
This is a basic exploratory study that is aimed at improving our engineering capabilities on what concerns to the mathematical description of food microbial contamination by pathogens. Stakeholders will benefit because models generated may be used as powerful tools to enhance our understanding of the contamination processes, and our capability to control the corresponding threats to food safety.

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging

Title: An Interagency Project: Determination, Analysis, and Validation Of Cooling Procedures and Options for Food Service Items Within the USDA National School Lunch Program in Order to Meet the Food Code Recommended Practices

Project Leader (s): Katie Bialka, Alfredo Rodriguez

New or Continuing: New **Start: September 1, 2008** **End: September 30, 2010**

Background and Justification:
The National School Lunch Program (NSLP) is a federally assisted meal program operating in public and non-profit private schools and residential child care institutions. It provides nutritionally balanced, low-cost or free lunches to children each school day. Over 100,000 schools participate in the program that delivers over 30 million lunches per day. Ongoing epidemiological studies indicate an association between food borne illness and poor control of cooling. Despite the recommended practices (FDA Food Code), questions about safe cooling practices are one of the most common questions asked by school caterers. This work will continue studies to determine existing practices, analyse the variability, and provide options to support the use of best practice for safe cooling. NCFST has been working on this project since Sept. 2008. Significant progress has been made as agreed initially. Stakeholders requested that the project be continued one more year and experimental work be expended accordingly.

Project Objectives (and Milestones, with timeline, if a continuing project):

Objectives:
Continue and expand work on the determination, Analysis, and Validation of Cooling Procedures and Options for Food Service Items within the USDA National School Lunch Program in Order to Meet the Food Code Recommended Practices

Milestones:

1. Continue and expand the survey of current conditions of the school lunch throughout the Nation.
2. Continue to analyse the information to define the desirable parameters for modelling work.
3. Continue to develop physical and mathematical models of the cooling process including variation and variation transmission analysis.
4. Interface the mathematical models with the predictive microbiology models from the USDA.
5. Continue to communicate key findings to steering group and participate in dissemination of key findings to stakeholders including the National Food Service Management Institute.
6. Define future research needs and consider the best procedures and tools required for implementation and monitoring of safe cooling procedures. This could include future modifications to the food code, the development of a new module within HACCP, and /or web based tools.

Benefits to Stakeholders:
This project will allow for a better understanding of the characteristics and critical elements of the systems and procedures used for cooling as they affect the safety of the school lunches. It will provide the capability to simulate mathematically and physically the cooling of school lunch items and produce valuable information to be disseminated to the stakeholders.

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging

Title: Nation-wide Survey of Raw Milk for the Presence of Four Significant Food Pathogens

Project Leader(s): Ravinder Reddy

New or Continuing: Continuing

Start: October 1, 2007

End: September 30, 2010

Background and Justification:

Risk assessment and management are tools used to assure safety of traditional products subjected to newer practices of food production. Processing parameters for safe production of milk for consumption and further processing are based on the initial microbial level of the target pathogen(s) (H_0). In this study, samples of raw milk are being collected from silos at dairy plants. FDA- BAM Methods (Most Probable Number from Serial Dilutions) in combination with the various detection test kits were adopted to enumerate the target pathogens in this study. For the pathogens, preliminary data indicates that there was a majority of positive samples. There are several possible causes for the majority of positive samples: 1) Too few samples were analyzed to give an accurate representation of the population. To increase numbers of samples, FDA has requested more state participation for the main study. 2) Preliminary data showed too many false positive samples. Testing using selective and chromogenic plates is being incorporated to confirm the presumptive positives for these pathogens. 3) Because of the cost of MPN analysis, only three levels of MPN serial dilutions were analyzed. To improve the accuracy of the viable pathogens counts, lower levels (0.025 and 0.0025 ml) of the MPN serial dilution will be added.

Project Objectives (and Milestones, with timeline, if a continuing project):

Objectives:

Determine the distribution and levels of *E. coli O157:H7*, *Salmonella* spp., *Listeria monocytogenes* and *B. cereus* in the nation's raw silo milk supply.

Milestones:

1. Conduct literature search to examine previous work reported on the determination of type of pathogens, their presence and levels in raw silo milk. Completed
2. Determine and adapt methodology for enumeration of *E. coli O157:H7*, *Salmonella* spp., *Listeria monocytogenes* and *B. cereus* in raw silo milk. Completed
3. Official survey samples will be obtained and tested weekly for a period of one year. At the end of each year, the LPET will prepare a report and determine the status of the project for year two. 9/30/09
4. Official survey samples will be obtained and tested weekly for a period of one year. At the end of each year, the LPET will prepare a report and determine the status of the project for year 3. 9/30/10
5. Utilize information in Food Safety Objective Model for Extended Shelf Life of Pasteurized Milk. 9/30/10

Benefits to Stakeholders:

Knowledge of quantitative levels of pathogens (H_0) in the nation's raw milk supply used in processing for consumption or dissemination into innumerable downstream productions will be very crucial for the regulatory authorities in determining the approaches needed to formulate food safety programs. Also, without H_0 , determination of the effectiveness of alternative processes will be difficult. NCFST/FDA is in an ideal position to leverage the expertise of the Laboratory Proficiency and Evaluation Team in collecting milk samples from dairy plant silos through out the country just prior to processing.

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging		
Title: Effects of Thermal Pasteurization on the Macro- and Micro-Nutrients in Bovine Milk		
Project Leader(s): Joseph E. Schlessner, Britt Burton-Freeman		
New or Continuing: New	Start: July 1, 2009	End: June 30, 2012
Background and Justification: An important facet of the raw milk consumption debate is the claims of decreased nutritive qualities of pasteurized milk when pasteurized milk is compared to raw milk. These nutrients include bovine lactoferrin, lactoperoxidase, lysozyme, Immunoglobulin G, B-complex vitamins such as thiamine, folate and riboflavin, fat-soluble vitamins such as A, D, E and K, and Vitamin C. Studies in the literature show little or no effect on the nutrients in bovine milk by pasteurization. However, much of the data presently available is from the early 1980's and not exactly on point with the current pasteurization conditions in the United States. Better information about the impacts of the current pasteurization conditions on the macro- and micro-nutrients in milk is needed. This study will determine if current pasteurization practices have changed any of the nutritive qualities of pasteurized milk and milk products.		
Project Objectives (and Milestones, with timeline, if a continuing project): <i>Objectives:</i> To determine the effects that current pasteurization conditions have on the nutritive qualities in pasteurized milk. <i>Milestones:</i> <ol style="list-style-type: none">1. Select chemical and bioactive methods to analyse the fat and water soluble vitamins in raw and pasteurized milk (3 months).2. Determine the effects of current pasteurization conditions on the fat and water soluble vitamins in commercial samples (9 months).3. Determine the effects of long-temperature long-time current pasteurization conditions on the fat and water soluble vitamins in samples manufactured in the lab (12 months).4. Determine the effects of high-temperature short-time current pasteurization conditions on the fat and water soluble vitamins in samples manufactured in the lab (12 months).		
Benefits to Stakeholders: Both industry and regulators will benefit from information obtained from this project, which will provide the data on the nutritive qualities of pasteurized milk.		

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging		
Title: Effects of sanitizers and processing on viral and bacterial pathogens		
Project Leader(s): Stephen Grove, Alvin Lee		
New or Continuing: New	Start: July, 2009	End: June, 2011
Background and Justification: <p>Fresh produce has come under intense scrutiny in recent times in the U.S. due to several high profile outbreaks of foodborne illness, involving both bacterial and viral agents. The presence of pathogenic microorganisms on fresh produce is a particular concern due to minimal processing or absence of thermal treatments to the produce prior to human consumption.</p> <p>This project aims to investigate disinfection and processing procedures to reduce or eliminate bacterial and viral contamination on fresh produce and in produce wash water. Pathogens of interest include <i>E. coli</i>, hepatitis A virus (HAV) and the non-culturable human norovirus (NoV) where surrogate viruses murine norovirus (MNV-1) and feline calicivirus (FCV) will be used. Antimicrobial sanitizers commonly used in commercial produce washing will be combined with high power ultrasound (HPU) to inactivate pathogens in produce wash water and on inoculated produce. The efficacy of this combined treatment will be investigated at scales between bench-top in the laboratory, to commercial-scale in the biocontainment pilot plant (BCPP) facility.</p>		
Project Objectives (and Milestones, with timeline, if a continuing project): <p><i>Objectives:</i> Determine the effectiveness of high powered ultrasound combined with chemical sanitizers to reduce <i>E.coli</i> O157:H7 and foodborne viruses when applied to leafy greens wash water.</p> <p><i>Milestones:</i></p> <ol style="list-style-type: none">1. Set up 1 kW & 8 kW HPU equipment in appropriate labs, train staff and commission for use with pathogenic microorganisms (3 mths)2. Train graduate student in tissue culture and microbiological techniques (4 mths)3. Determine optimal power & amplitude, map cavitation field produced by 1 kW unit in purpose-built vessel (6 mths)4. Develop improved methods of microbial concentration and quantification from large-scale volumes of water and produce (10 mths)5. Evaluate the combined effect of sanitizer treatments with 1 kW HPU on target microorganisms on inoculated produce and in produce wash water (18 mths)6. Scale-up combined treatments to 8 kW for use with inoculated produce in purpose-built flow cells and in the commercial-scale produce washing flume (24 m)		
Benefits to Stakeholders: <p>Information on the stability of noroviruses in the environment and during processing is not available, and will be important when considering processing strategies to destroy NoV. Determine the implications and benefits of introducing ultrasonic processing to a produce washing facility in terms of reducing the microbial load of the product and wash water. Ultrasonic washing may allow for reduction in sanitizer dosage in wash water whilst maintaining sanitizer effectiveness and efficiency. The more efficient use of wash water may lead to better conservation practices.</p>		

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging		
Title: Effect of Solids Levels on the Thermal Resistance of Listeria Species		
Project Leader (s): Susanne E. Keller		
New or Continuing: New	Start: October 1, 2007	End: September 30, 2010
Background and Justification: <p>Pasteurization parameters for milk are well established and set by regulation (PMO). However, higher solids levels are not as well addressed. As solids levels increase, an increased amount of heat is required to destroy any pathogens present. Innovations in food processing have led to a desire to create liquid products with higher levels of solids. These higher solids level products may be dairy or non-dairy in nature. Although there is some information available on the thermal resistance of <i>E. coli</i> or <i>Salmonella</i> at high solids concentrations, data at intermediate levels (ex:18 to 30%) is limited. For other foodborne pathogens such as <i>Listeria monocytogenes</i>, no data is available. In this project we propose the examination of the effect of solids levels on the thermal resistance of <i>Listeria monocytogenes</i>, using MSNF and various sugars. Since viscosity of the product may be problematic, several approaches will be used.</p>		
Project Objectives (and Milestones, with timeline, if a continuing project): <i>Objectives:</i> Determine thermal resistance of <i>Listeria monocytogenes</i> related to solids levels. <i>Milestones:</i> <ol style="list-style-type: none">1. Examine thermal resistance of <i>Listeria monocytogenes</i> at solids levels between 30 and 50 % using sugars and best test system. Target date Sept 20092. Examine effect of water activity on <i>Listeria monocytogenes</i> Target date Sept 30, 2010		
Benefits to Stakeholders: <p>New products are being developed, such as ultrafiltered milk, where no thermal process is used to increase milk solids. Such products must still be heat treated to destroy any pathogens present. The effect of increased solids levels on the thermal; resistance of many foodborne pathogens such as <i>Listeria monocytogenes</i> is unknown. In this study, effect of solids levels on thermal resistance of <i>Listeria monocytogenes</i> will be established enabling processors to properly heat treat new products with increased solids levels.</p>		

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging

Title: Application of the Food Safety Objective Concept to Extended Shelf-life Refrigerated Foods

Project Leader (s): Nate Anderson, Guy Skinner, John Larkin

New or Continuing: New **Start: July 1, 2009** **End: September 30, 2011**

Background and Justification:

ICMSF (International Commission on Microbiological Specifications for Foods) has developed the FSO approach to managing food safety. FSO helps translate the public health risks associated with particular hazards into goals that are more easily definable at the manufacturing level. The ICMSF states that FSOs are the “maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection”. With consumer demands of high quality, nutritious and convenient foods, there has been growth of 20-25% per year of refrigerated, extended shelf life foods (usually low acid). In order to meet the consumer’s needs for a high quality product, the food industry must be able to produce these types of products with minimal or no chemical preservatives and with milder processing treatments. When establishing processing criteria for processing technologies intended to produce extended shelf life refrigerated products, the initial microbial level of the target pathogen(s) (H_0) must be taken into account. The level of reduction ($\sum R$) required ensuring product safety and thus meet the FSO will be based on the H_0 of the target pathogen, as well as the level of growth or recontamination expected throughout the food production and distribution chain ($\sum I$).

Project Objectives (and Milestones, with timeline, if a continuing project):

Objectives:

1. To write a ‘white paper’, suitable for submission to the Codex Food Hygiene Committee and for publication, which describes the framework for establishing an FSO for the manufacture of Extended Shelf Life Refrigerated Foods) utilizing new risk assessment approaches, including those of the International Commission on the Microbiological Specifications for Foods (ICMSF). This document will be based on the approach set forth in the NCFST FSO guidance document on Sterilized foods.

Milestones:

1. Organize a working group meeting to establish expert teams and a suitable risk-based framework for establishing an FSO for ESL foods. Oct. 2009
2. Teams submit content for first full draft review by steering committee. March 2010
3. Complete first full draft document returned for review and comment– October, 2010
4. Final draft submitted for publication – October, 2011

All milestone dates will be contingent on when the Sterilization FSO project is completed.

Benefits to Stakeholders:

Using this framework, the food industry will have a scientifically sound basis for development, validation and commercialization of new or novel food processing technologies as well as traditional processes, which while ensuring safety, will allow for the production and marketing of higher quality (sensory and nutritional quality) food products. This framework will allow for the development and evaluation of different, yet equivalent, processes.

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging		
Title: Inhibitory Growth Boundary Conditions for <i>Clostridium botulinum</i>		
Project Leader(s): N. Rukma Reddy, Guy Skinner		
New or Continuing: New	Start: October 1, 2009	End: September 30, 2013
Background and Justification:		
<p>The International Commission on Microbiological Specifications for Foods (ICMSF) has proposed the use of the FSO system for managing food safety. FSO helps translate the public health risks associated with particular hazards into goals that are more easily definable at the manufacturing level. ICMSF states that FSOs are the “maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection”. The hazard of <i>C. botulinum</i> toxin formation continues to exist with shelf-stable foods and extended shelf life refrigerated foods, an area which is rapidly growing in the marketplace.</p> <p>When establishing processing criteria for processing technologies intended to produce a food product, the initial microbial level of the target pathogen(s) (H_0) must be taken into account. The level of reduction ($\sum R$) required to ensure product safety and thus meet the FSO will be based on the H_0 of the target pathogen, as well as the level of growth or recontamination expected throughout the food production and distribution chain ($\sum I$). There are many questions regarding the likelihood of a particular load of <i>C. botulinum</i> spores producing toxin at levels on the verge of being inhibitory. For example, it is often assumed that at higher pH levels, between 6 and 7, one hundred percent of <i>C. botulinum</i> spores would germinate in a food. At pH levels below 4.6 it is assumed that no strains of <i>C. botulinum</i> would germinate, grow and produce toxin. To answer questions related to the establishment of an appropriate FSO, it may be necessary to know the likelihood of a particular inoculum of <i>C. botulinum</i> spores that would result in toxin formation at pH levels 4.65 or 4.7. This study is designed to test boundary conditions of intrinsic properties of foods such as pH, water activity (a_w), NaCl, and others to obtain probabilistic values for use in FSO evaluations of a process.</p>		
Project Objectives (and Milestones, with timeline, if a continuing project):		
<p><i>Objectives:</i></p> <p>Determine the probability of proteolytic <i>C. botulinum</i> toxin formation as a function of inoculum at various boundary conditions of inhibition. This data will be useful in FSO determinations.</p> <p><i>Milestones:</i></p> <ol style="list-style-type: none">1. Determine what data exists for <i>C. botulinum</i> spores and toxin formation as a function of pH, a_w, NaCl.2. Identify the types and strains of <i>C. botulinum</i> to be used in the project.3. Identify the chemical media or model food system.4. Identify intrinsic parameters to test, i.e. pH (and specific acid), a_w, NaCl, etc.5. Obtain or grow spores of the <i>C. botulinum</i> strains identified for use in the project.6. Perform inoculation studies using spores that have been exposed to various elevated temperature histories that may represent real abuse situations in foods. Subsequent to this preconditioning, inoculation studies will be performed at temperatures between 10 and 35°C to test the effect on temperature exposure history on the ability of <i>C. botulinum</i> to form toxin in model systems.7. Validate the results using selected food systems		
Benefits to Stakeholders:		
<p>Gaining insight into the ability of <i>C. botulinum</i> to produce toxin in foods under conditions of pH, a_w or NaCl that are almost inhibitory will help provide data for utilization in the FSO approach to food safety by helping to model the $\sum I$, or probability of growth or recontamination through product production and distribution.</p>		

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging		
Title: Thermal Characterization of Botulinum Neurotoxin using Differential Scanning Calorimetry		
Project Leader(s): Greg Fleischman		
New or Continuing: Continuing	Start: October 1, 2005	End: December 31, 2009
Background and Justification: <p>Differential Scanning Calorimetry (DSC) is a powerful technique that heats substances in a highly controlled manner for the purpose of uncovering thermal transitions. In microbiology, such a transition indicates protein denaturation. Previous work examined the thermal inactivation of Botulinum Neurotoxin (BoNT--acid mud) in various liquid foods using a submerged coil apparatus. A kinetic model was applied to the data relating toxin inactivation to temperature. However, kinetic parameters could not be correlated with temperature. We anticipate that the DSC, being more of an analytical instrument than the submerged coil, will give us a consistent picture of toxin destruction and relative stability in different foods. Furthermore, it may be possible to use the DSC as a direct means of assessing BoNT toxicity in samples.</p>		
Project Objectives (and Milestones, with timeline, if a continuing project): <i>Objectives:</i> Determine if BoNT thermal events as measured by DSC can be linked to results of the mouse bioassay. <i>Milestones:</i> <ol style="list-style-type: none">1. The effect of fruit juices and milk on the inactivation of BoNT is determined. The question here is if liquid foods offer some protection to BoNT, making it more resistant to thermal inactivation. A comparison will be made using DSC results between toxin suspended in buffer and in different liquid foods: milk and two fruit juices. This milestone depends on a successful outcome of work in the 2008-09 year showing the toxin thermal event detected by DSC is related to toxicity.2. The kinetics of BoNT are determined, including kinetic model, constants, and their temperature dependence. Reaching this milestone will make extensive use of the mouse bioassay. DSC will be used as a very precise heater to treat samples, the post-treatment toxicity of which will be assayed using the mouse bioassay		
Benefits to Stakeholders: <p>Botulinum Neurotoxin (BoNT) is a natural toxin that can be suspended in liquid foods, which, if consumed and untreated, will lead to death. It is, however, very sensitive to heat. Thus any processing that pasteurizes, sterilizes or otherwise heat treats a liquid food can significantly reduce or eliminate the toxicity of the BoNT that may be present. The current work is undertaken to better define the degree to which thermal processing succeeds in deactivating the toxin.</p>		

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging		
Title: Inactivation of <i>Clostridium botulinum</i> spores using high pressure processing		
Project Leader(s): N. Rukma Reddy, Guy Skinner		
New or Continuing: Continuing	Start: October 1, 2007	End: September 30, 2010
Background and Justification: <p>The application of high pressure processing (HPP) for food processing was first examined in 1899. Since the mid 1980's, use of HPP as a food preservation and processing method became a subject of renewed interest because it can be used to inactivate microorganisms in foods and food ingredients without adversely affecting product quality. There is very little published data on the resistance of <i>C. botulinum</i> type A spores by HPP. No published data is available on the effect of bacteriocins or other preservatives in combination with HPP on inhibition of <i>C. botulinum</i> type A spores. Type A strains produce heat resistant spores that are a primary concern in processing of low-acid foods. Biological validation of a HPP process for low-acid canned (LACF) foods can be very time consuming. There is a need for a kinetic based process delivery calculation procedure. This project will measure the high pressure/temperature resistance of <i>Clostridium botulinum</i> spores for use in setting and validating the process for LACF shelf-stable foods and establishment of recovery procedures. HPP also has many applications for Extended Shelf Life products by reducing the vegetative microflora and extending product shelf-life. Eliminating vegetative cells while leaving viable spores results in a risk of outgrowth of <i>C. botulinum</i> in some ESL products. HPP treatments yielding equivalent reductions for nonproteolytic <i>C. botulinum</i> spores in ESL products would reduce the botulism risk in such foods.</p>		
Project Objectives (and Milestones, with timeline, if a continuing project): <i>Objectives:</i> Measure the high pressure/temperature resistance of <i>C. botulinum</i> spores for use in setting and validating the process for LACF shelf-stable foods. To determine the commercial feasibility of producing safe, high quality, extended shelf life, chilled, low-acid food products (such as meals) via high pressure-mild temperature processing (i.e. 90°C, 10 min equivalent) where nonproteolytic <i>C. botulinum</i> spores are the target pathogenic microorganism. To develop validated predictive inactivation models for nonproteolytic <i>C. botulinum</i> spores which can be broadly used to determine the processing conditions required to produce a safe, high quality, ESL chilled food product. <i>Milestones:</i> <ol style="list-style-type: none">1. Select packaging system for packaging spores and determine heating profiles for the PT-1 for use with the inactivation studies, May 2009.2. Perform preliminary screening inactivation experiments using mixtures of type A and proteolytic type B strains spores for the selection resistant strains and process pressures and temperatures to be used in the kinetics studies, November 2009.3. Prepare spore crops of <i>Bacillus cereus</i> and selected <i>Clostridium botulinum</i> strains of 10-15 nonproteolytic type B and type E spores using biphasic method, December 2009.4. Perform preliminary screening inactivation experiments using mixtures of nonproteolytic strains spores for the selection of most resistant strains and process pressures and temperatures to be used in the kinetic studies, February 2010.		
Benefits to Stakeholders: <p>Results of this study will benefit FDA, Industry, and NCFST in the application of HPP for inactivation of <i>C. botulinum</i> spores in various LACF foods and ESL foods and still result in foods with improved product quality, appearance, and nutritive value.</p>		

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging

Title: Evaluation of enzyme-based time-temperature for validation of thermal sterilization of low-acid foods.

Project Leader(s): Susanne Keller

New or Continuing: New

Start: October 2009

End: October 2011

Background and Justification:

Biological validation of thermal processes designed and established for the production of safe ambient stable low-acid foods is necessary to ensure a safe product. For this purpose, the use of widely recognized test microorganisms (WRTMs) as surrogates for *Clostridium botulinum* has historically been the validation method of choice by industry. However, this method is highly time-consuming and resource-demanding. Alternatively, enzyme-based time-temperature indicators (TTIs) have proven to be a feasible and reliable tool for validation and optimization of pasteurization processes, ranging from a few minutes at 70°C (158°F) to up to several minutes at 93°C (200°F). Recent studies indicate the range of application of these TTIs can be successfully extended to time-temperature levels typical of commercial sterilization processes. Several enzymes from *Pyrococcus furiosus* have been characterized on the basis of their heat inactivation kinetics, and have been shown to have z-values in the same range as those of bacterial spores. Tests for quantification of residual enzymatic activity are typically direct, colorimetric, assays that take only a few minutes offering a clear advantage over spores of bacterial surrogates. This project will validate the use of the enzymes derived from *Pyrococcus furiosus* by directly comparing their heat inactivation kinetics with those of known WRTMs under established processing conditions for shelf-stable low acid foods.

Project Objectives (and Milestones, with timeline, if a continuing project):

Objectives:

Compare the thermal resistance properties of two enzymes from the hyperthermophilic organism *Pyrococcus furiosus* with those of widely recognized test organisms.

Milestones:

1. Complete set-up, acquire enzymes, run test systems: June 2010
2. Run comparison tests: Oct 2010
3. Run pilot plant studies (in both conventional and novel heating systems): August 2011
4. Perform statistical evaluation: Oct 2011

Benefits to Stakeholders:

Rapid, easy-to-use tools that can provide accurate estimates of lethality are needed to facilitate innovation and increase speed to market of heat preserved foods. To this end, enzyme-based time-temperature integrators (TTIs) offer a cost-effective alternative to the traditional microbiological validation methods.

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging

Title: Determination of organic and inorganic chemicals released from polymer-clay nanocomposite food packaging

Project Leader(s): Timothy Duncan

New or Continuing: New

Start: October 1, 2009

End: September 30, 2011

Background and Justification:

Polymer-clay nanocomposites (PCNs) are plastics in which nanoclays are homogeneously dispersed. Nanoclays are found in some natural clays as agglomerated bundles of platelets with an individual thickness of about one nanometer. PCNs have had some commercial successes in barrier applications. In particular, the enhanced barrier and mechanical properties of nylon 6 and PET nanocomposites exhibited great potential for use in food and beverage packaging, including boil-in bags, microwavable retort pouches, vacuum packs, paperboard cartons, and bottles. Recently, interest from the food industry has expanded to other polymers such as polyethylene, polypropylene, and ethylene vinyl alcohol (EVOH). The PCNs can be used commercially in both coatings and multilayer structures. When placed in a polymer matrix, nanoclays are hard to be separated or distinguished from the host polymer. However, there has been some concern that nanoparticles can be released from nanoclay packaging materials when they are physically abused and/or exposed to high cooking temperature, or that they may change the migration properties of the host polymer(s). If nanoparticles and other residual products migrate into foods in direct contact with the materials, they could possibly become a concern to public health. Therefore, it is necessary to evaluate the potential migration issue in PCN for food packaging applications.

Project Objectives (and Milestones, with timeline, if a continuing project):

Objectives:

To determine migration of organic and inorganic chemicals into food simulants from PCN packaging materials.

Milestones:

1. Characterize PCN packaging materials in aspects of particle size and distribution (6 months).
2. Develop and validate analytical procedures to qualify and quantify organic and inorganic residuals in food simulants by using ICP and GC/HPLC-MS (6 months).
3. Determine inorganic compounds migrated into food simulants from PCN packaging materials during microwave heating conditions by using an ICP (9 months).
4. Determine nonvolatile organic compounds migrated into food simulants from PCN packaging materials during microwave heating conditions by using GC/HPLC-MS (9 months).

Benefits to Stakeholders:

This proposed research will help the FDA and the industry to decide whether safety issues should be addressed concerning the use of PCN packaging materials for food products. The research could lead to increased confidence and use of nano-engineered packaging materials for food markets.

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging

Title: Evaluation of a Non- Destructive High Voltage Technique for the Detection of Pinhole Leaks and Delamination in Trays and Foil-Laminated Pouches for Foods

Project Leader(s): Yoonseok Song

New or Continuing: New **Start: July 1, 2009** **End: June 30, 2010**

Background and Justification:

High-voltage leak detection (HVLD) is a technology that has successfully been used to test the integrity of hermetically sealed packages in the medical industry. It allows for non-destructive, fully automatic, and 100% on-line detection of pinholes as small as 5m in diameter. Recently, research studies in the NCFST demonstrated that the HVLD is a promising technique to detect pinhole defects and delamination in flexible pouches containing various foods. Among critical factors, package surface area has the greatest effect on detection of the defects, followed by material thickness, pinhole size, and food conductivity. For both plastic and metallized pouches, the HVLD has detected pinholes as small as 10µm, even under worst case scenario conditions.

Preliminary results from the NCFST showed that, with a modification of testing electrodes, the HVLD can be applied for the inspection of semi-rigid food containers heat-sealed with plastic and foil-laminated lids. The applicability of this high-voltage technique to various semi-rigid containers and bottles with different types of foods and beverages is of great interest to food industry, and thus requires further investigation. In addition, there's a concern that a defective package, in particular made of foil-laminated films may be further damaged due to high voltages applied during the inspection. It is therefore necessary to examine potential impact of high voltages on packaging materials and their physical properties.

Project Objectives (and Milestones, with timeline, if a continuing project):

Objectives:
To Evaluate a HVLD System for the inspection and integrity assurance of semi-rigid containers, bottles, and foil-laminated pouches for foods.

Milestones:

1. To determine the effect of high voltage on physical properties of foil-laminated films (i.e. WVTR, OTR, pinhole size, degree of delamination, and surface structure) after an exposure to high voltages.
2. To perform screening studies to determine the applicability of a modified HVLD system for the detection of pinholes and delamination in semi-rigid cups, trays and bottles, containing model foods, sealed with different plastic and foil-laminated lids.
3. To determine minimum sizes of pinhole leaks, which the HVLD system can detect, as a function of processing variables.
4. To perform factorial design experiments to evaluate the effect of processing variables of significance on detection of pinhole leaks in food packages.
5. To validate the HVLD system for the detection of pinholes and delamination in semi-rigid cups, trays and bottles containing foods through blind studies.

Benefits to Stakeholders:

A working knowledge of advanced technologies for package integrity inspection is essential to the FDA and the food industry because of their potential to impact food safety. If the HVLD technique can be applied for online culling of imperfectly sealed LACF containers, it would have many applications in the food industry. In particular, the expense, uncertainty and lost production time for human inspection could be avoided. A more reliable and therefore safer system of package inspection would result. The information obtained from this study can be implemented in industrial SQC (statistical quality control) systems to enhance efficiency in removing defective packages, to reduce the risk of product recalls and subsequent outbreaks, and to improve overall security of the food supply.

NEW (OR CONTINUING) PROJECT PROPOSAL (2009-2010)

Science Platform: Processing and Packaging

Title: Migration database of additives and contaminants in food packaging systems for use in predictive migration models

Project Leader(s): John Koontz, Yoonseok Song

New or Continuing: New

Start: July 1, 2009

End: June 30, 2012

Background and Justification:

Several migration models are currently used by the FDA to screen migration claims made in a FCN. In these models, both diffusion coefficient (D) and partition coefficient (K) play a crucial role in determining the level of total migration in real food packaging applications. However, a significant data gap still exists on D values for organic compounds in PET, nylon-6, nylon-66, nylon-MXD6, PET/nylon-MXD6, and polymer-clay nanocomposites. This is mainly attributed to the inherent low diffusivity of these high barrier polymers. Over the past several years, the NCFST has collected a limited quantity of diffusion data for several organic compounds in PET. Recent studies at the NCFST showed that the models may lead to the underestimation of migration for some small compounds ($MW < 200$) at low temperature ranges (25-60°C). Therefore, it is necessary to determine D values for organic compounds in question to further validate the models. In addition, no good source of K values exists for additives/migrants that can be used to evaluate migration potential. Migrants of interest include incidental contaminants that may be present in recycled PET intended for food use, chemical and radiolysis products detected in irradiated polymers such as PET, PS and others, as well as thermal degradation products generated in PP, PET, and CPET packages during microwave heating. Gathering K values in a systematic way to improve FDA's migration database is a prerequisite to generating realistic dietary exposure estimates for these migrants.

Project Objectives (and Milestones, with timeline, if a continuing project):

Objectives:

To determine diffusion coefficient (D) and partition coefficient (K) values of potential migrants to substantiate the use of existing migration models for regulatory reviews.

Milestones:

1. Continue to develop (or modify) and validate analytical procedures to determine D of volatile and non-volatile surrogate compounds by using the MAS 2000 organic permeability analyzer, PermeGear cells, GC-MS, and/or HPLC (6 months).
2. Determine D of volatile surrogate compounds in nylon-66, nylon-MXD6, PET/nylon-MXD6 blends, and/or PET/nylon nanocomposites at temperatures of 40, 66, 100, and 121°C by the dynamic permeation technique using MAS 2000 (12 months).
3. Determine D of non-volatile surrogate compounds in nylon-66, nylon-MXD6, PET/nylon-MXD6, and/or PET/nylon nanocomposites at temperatures of 40, 66, 100, and 121°C by the static PermeGear migration cells coupled with HS-GC-MS (24 months).
4. Complete selection of potential migrating compounds, polymers, food simulating systems, and test conditions for K migration experiments (3 months).
5. Produce test samples for partition coefficient migration experiments by loading selected additives and incidental contaminants into polymer films (3 months).
6. Conduct migration experiments of selected chemicals under the predetermined test conditions (24 months).
7. Test D and K data to determine what the limits of applicability are for each migration model (36 months).

Benefits to Stakeholders:

The ultimate purpose of the work will examine and validate predominant migration models for their applicability across broad properties of possible migrating compounds. FDA's confidence to assess FCN will be increased by providing a simple means to check the reasonability of migration values submitted with the FCN. Industry FCNs will potentially take less time to prepare and require less laboratory effort and experimental cost.