GRANTS PROGRAM: CENTER FOR PRODUCE SAFETY
2017 RFP Research Priorities Summary – October 20, 2016

The Center for Produce Safety sets its highest priorities in supporting research towards ready-to-use, data-based solutions or information which catalyze and support science-based actions and decisions to prevent or minimize produce safety vulnerabilities across the supply and marketing chain. To a significant degree, the sustainability of CPS to provide this resource and function demands that the greatest share of research award funds be allocated to investments in applied, practical, and knowledge gap–filling projects. These near-term research questions also must be supported by longer-term fundamental research and limited objective proof-of-concept projects to explore novel solutions or to complete translation research of products or services of broad interest and adoption by the industry. While some priorities remain broad, other priorities are re-drafted for 2017 to capture and emphasize the input that CPS has received to more tightly focus the research question with specific anticipated data outcomes. With this mission in mind, the following priorities are provided as guidance to applicants to the 2017 CPS request for proposals.

Part I. Listeria monocytogenes (Lm)

1. Lm Prevalence and Persistence: To inform risk-based decision making, research is warranted to determine the prevalence and persistence of *Listeria monocytogenes* (Lm) in various environments and micro-environments throughout the produce supply chain, including but not limited to:

- Produce on farm/orchard at the time of harvest,
- Packinghouse and warehouse dry environments,
- Produce coolers and distributions centers, and
- Produce micro-environs (e.g., HVAC units and motors that create elevated temperature micro-environments; condensation that creates a wet surface in otherwise dry operation, etc.)

Determine procedures, practices and factors that influence the rate of "resident" Lm establishment on produce farms, and in harvest operations, packing operations and fresh-cut produce processing plants.

2. Lm Basic Biology:

2.1. Lm Growth or No Growth in Foods: Determine which raw agricultural commodities and fresh-cut produce products will support the growth of Lm at recommended and abusive storage temperatures. This information is important to assess the potential for Lm proliferation, which is an important factor in assessing public health risk from a contaminated food product, and helps inform the entire produce supply chain regarding safe handling best practices.

2.2. Metagenomics (PROOF OF CONCEPT ONLY FOR FUTURE GRANT LEVERAGING): Produce, produce farms, harvesting, packing and processing environments have diverse microbial communities. Understanding how these diverse and often un-culturable communities of microbes may enhance or reduce the potential for establishment of "resident" Lm (e.g., by competitive exclusion) may lead to better environmental monitoring strategies or use of microbial antagonists to prevent or reduce the likelihood of the establishment of "resident" Lm. (Note: Proof-of-concept proposals ONLY)

3. Lm Risk Assessment:

3.1. Risk-Based Corrective Actions: Currently, commonly used *Listeria* spp. and Lm environmental monitoring program test techniques are qualitative or semi-quantitative. Development of quantitative *Listeria* spp. and/or Lm environmental monitoring technologies would be helpful in assisting operators to prioritize and determine the magnitude of corrective actions when Lm or *Listeria* spp.–positive test results occur.

3.2. Equipment Risk Assessment and Sanitation Frequency: If equipment is of less-than-optimal sanitary design and cannot easily be refurbished or retrofitted, effective cleaning methods and frequencies should be determined to minimize risk. This would include an evaluation and prioritization of different pieces of equipment based on persistence data and the rate at which Lm can establish residence in/on the different pieces of equipment. Cleaning frequencies and methods could be established that reduce the likelihood of Lm establishing residence.

3.3. Rate of Transference in Produce Facilities: Conventional thinking is that finding a *Listeria* positive sample in Zone 4 is of lower risk than finding one in Zone 3, and that Zone 3 is lower risk than Zone 2, etc. Understanding how *Listeria* travels through a facility can aid in the development of optimal facility design and environmental testing strategies.

3.4. Probability for Transference: Define system-wide and system-specific probabilities of Lm for transference from non-food–contact surfaces and areas (Zone 2 to 4) to food-contact surfaces and products.

4. Lm Preventive Controls (Cleaning & Sanitation / Interventions):

4.1. Sanitizers: Investigation is warranted to identify chemical sanitizers (conventional, green and organic) that are effective at disinfecting common food-contact surfaces found in raw agricultural commodity packinghouses such as wood and painted metal surfaces. Additionally, as hot water may not be universally available at all produce operations for cleaning and sanitation, the effect of temperature on the efficacy of various aqueous-based food-contact cleaning and sanitizing chemicals is warranted.

Part II. Core Produce Safety Research Objectives

Core produce safety research objectives have been streamlined and prioritized for 2017 but research concepts and objectives not specifically listed will be considered. The desire for science-based advancements to bridge or close our knowledge gaps and practical technological solutions in risk reduction cut across all fresh fruit, vegetable and nut crops. Research that will enhance produce safety systems span all phases of production, harvest, cooling, packing, fresh-processing, storage, transportation, receiving and point-of-sale environments. These research objectives are typically broad in scope and are written with the intent to encourage creative approaches to research that will improve our understanding of potential produce safety hazards, risks and routes of contamination, and aid in development of more effective, science-based risk identification and characterization. In some cases, priority is given to very specific research topics and a structured set of anticipated outcomes that align with industry input for a public source of data to support preventive control validation or the efficacy of corrective actions to food safety risks. It is hoped that both approaches to solicit research proposals lead to increased knowledge and practical technologies that support evolving strategies and food safety management tools throughout the entire supply chain.

For 2017, the following core produce safety research priorities are provided as the focal point for program needs but are not intended to preclude submission of topics within the broadest context of produce safety. Principal investigators submitting a Pre-Proposal are highly encouraged to review this information before submitting proposals. Principal investigators submitting a Research Proposal may also submit clarifying questions by telephone to (530) 554-9706 or by sending an email to research@centerforproducesafety.com.

1. Prerequisite Produce Safety Research: Produce safety research requires expanded development of produce safety–specific research tools, techniques, materials and methods to address complex produce safety issues in the farm, adjacent farmscape and watershed environments, harvest operations, cooling facilities, packinghouses, re-pack operations, fresh-cut processing, transportation, distribution, retail or foodservice environments. While open to broad application of applied and more fundamental research proposals, specifically requested are research and development of tools and technologies regarding:

1.1. Remote Sensing of Risk Factors: Proof of Concept proposals are requested to develop baseline efficacy information and demonstration of data capture, analysis, and practical predictive modeling for the detection of presumptive risk of contamination and corrective action alert systems.

1.2. Closing Knowledge Gaps in FSMA Produce Rule–Related Metrics: Die-off of pathogens, primarily but not limited to bacterial pathogens, has proven challenging to confidently predict, particularly in preharvest environments and conditions. The Produce Safety Rule provides a management option in which produce growers may apply an assumed die-off rate, based on limited studies, for pathogens between an irrigation or foliar-application event (using source water that does not meet the statistically determined standards) and harvest, or between harvest and reasonably anticipated shortest storage and distribution interval prior to food preparation or point of purchase. A broad diversity of science-based assessments under tightly-controlled conditions are need to develop data and broaden knowledge critical to modeling die-off under conditions that represent and reflect the diversity of industry practices and environmental norms. CPS is requesting proposals specifically designed to provide standardized, multi-regional projects that will provide foundational evidence for predictive modeling of pathogen die-off, which either strengthen and support current regulatory metrics for agricultural water or demonstrate the need for modifying this approach in view of clear limitations of these allowances to protect public health.

1.3. Developing Science-Based Evidence for Principles of Co-Management: In many regions and, frequently, in operations under certified organic crop management, produce is grown on farmscapes in smaller production blocks and surrounded by woodlands or other wildlife habitat. As the Produce Safety Rule or ancillary retail industry and direct–market buyer expectations engage a broader community of growers, this is likely to become an increasingly important business sustainability and management consideration. Although ongoing research is addressing risk potential and mitigation characteristic of these numerous small-scale farms, CPS is committed to solicit complimentary research that identifies practical, economical and effective measures to divert or direct animal foraging and movement away from production areas, with minimal disruption of animal access or use of their habitat and also compliant with federal and local regulations and ordinances. For example:

- What is the quantitative effectiveness and cost:benefit of diversion and/or food source cropping to prevent deer intrusion into fresh produce fields and crop contamination with zoonotic pathogens?
- How can falconry be a viable co-management strategy to control nuisance birds and minimize crop loss in fields? Ravens and other birds may arrive before leafy greens fields are harvested, which sometimes eliminates a complete field from harvest. The Southwest Desert produce industry is interested in project collaboration. (Note: Scientists should check the CPS website for previously funded research in this area.)

2. Indicators and Index Microorganisms: Identify a singular or suite of culturable or non-culturable microorganisms, or biological or chemical markers that could quickly, easily and reliably indicate the presence or absence of human pathogenic viruses in agricultural inputs, within the on-farm agricultural environment, in/on produce commodities and in produce handling facilities.

3. Factors Affecting Human Pathogen Persistence: Related to Core Priority 1.3 – Research is needed to identify guidance principles to better predict the persistence and growth potential of human bacterial pathogens within the practical and realistic range of produce production, postharvest handling, and distribution environments to the point of purchase or food preparation. These principles should be generally transferable and translatable to diverse systems and scales of production and handling operations. Research results should include recommendations and/or guidance for system-wide preventive controls to reduce, control, or eliminate human pathogens in these environments and marketing channels. For 2017, CPS is specifically requesting research clearly elucidating:

3.1. Human Pathogen Persistence in the Produce Production Environment: Special attention is called to determining the prevalence, persistence and transference of *Cyclospora* to produce during production and in marketing channels. Concept Proposals which include clear evidence for the capacity to study survival and transference from endemic sources of *Cyclospora*-contaminated soil, water, or other environmental sources, whether on-site or in model systems, will be given priority.

4. Understanding Produce Risks: Industry practitioners and government regulators are limited in their ability to formulate truly science-based and risk-based produce safety best practices and policies. This limitation stems from their inability to integrate all the available information into a useable tool to assist in risk-ranking various hazards and routes of contamination and to most effectively deploy limited food safety resources. Specifically, development of qualitative and/or quantitative microbial risk assessment data to populate risk-ranking tools in both unique and regional operations is needed. Systems-based research is first needed to establish data fundamental and suitable for the development of a QMRA analysis, which would lead to prioritization of preventive controls and interventions that optimally reduce public health and business risk.

4.1 Risk Assessment of Use-By Labeling and Second-Quality Fresh Produce in Relation to Retail Donations to Food Banks:

Background – In alignment with expanding industry initiatives to reduce food waste and address concerns surrounding food injustice and urban food deserts, many retailers are increasing long-standing food donation programs or initiating new programs with diverse community support groups. Many of these donations, including large quantities of packaged salads and salad kits at the labeled Use-By/Best Enjoyed By dating are provided to food banks and related organizations. These groups distribute much of this produce to individuals who fall into high susceptibility demographics for foodborne illness, with potential for severe post-infection consequences. Similar large volumes of other value-added produce and second-quality commodities (fully ripe, well mature, bruised, minor mold/decay) are also provided to the centers. Recently, retailers have been asking for guidance in understanding the specific risks of foodborne illness as product reaches the labeled dating or has visible evidence of minor handling injuries and spoilage. Specific questions surround the increased risk to recipients as the expected shelf-life quality is exceeded, the residual risk of cutting away or discarding spoiled parts or components of produce intended for consumption without cooking, and the best practice for cutting off damaged or slightly spoiled areas of various commodities.

Several research reports over the past 25 years have identified the potential for increased risks of foodborne bacterial pathogens with wounded, spoiled and decayed produce. The interaction between superficial molds and internalization of pathogens has also been reported. However, eliminating the practice of these donations is not the desired outcome, and a data-fulfilling request is to better understand the qualitative and quantitative risks with highest priority in the label-dated packaged salads and salad kits categories.

The successful proposal will combine the existing scholarly and lay-practical information most relevant to specific risk assessment and discovery-based data to learn more about the biology of pathogen interactions with host and associated microbiota and to define incremental risk variables in the dynamic cold-chain handling from retailer to food bank distribution and end-user practices.

5. Proof of Concept Mitigation Technologies and Preventive Controls: Proof of Concept proposals are requested to demonstrate the critical information needed to suggest longer-term investment in pre- and postharvest interventions that significantly reduce pathogens to non-detectable levels.

6. High Priority Objectives:

6.1 Product Testing Risk Modeling: Develop a risk-based model for the impact of product testing (inclusive of all positions within the supply chain) to provide insight into risk management alternatives for a range of produce items (i.e., baby greens, whole head greens, cole crops, tomatoes, onions, peppers, celery, pome fruits, stone fruits and tropical fruits). The model should examine the probabilities of pathogen detection as a matrix of sample size, sample number as a function of the frequency of contamination, and the severity of contamination. The model should address how this relationship is impacted by lot size, location of sampling, multiple sampling points across the supply chain, etc. The net result should be an explanation of residual risk remaining in a process in its totality as well as how the individual components contribute toward the reduction of the residual risk. The specific variables and assumptions that drive the model must be clearly articulated and evaluated for the impact of their individual variance. The impact of prior knowledge about a key variable and how such knowledge might drive an alternative risk management approach also must be addressed. Note: Essential criteria for the principal investigator would include an intimate understanding of the testing scenarios and lot definitions currently used by the produce industry.

6.2. CPS is requesting proposals for a comprehensive but limited timeline-scoping study to develop a White Paper consolidating the breadth of published research in the past 1.5 years of this RFP and all awarded research in the public domain, which should be systematically utilized in defining new priorities or directions in general RFP funding or specific research award placement for critical data needs. The proposal should be limited to a six-month period unless compelling justification is provided for a phased reporting approach, up to a one-year maximum.

6.3. Does application of approved and economically viable sanitizers achieve adequate and compliant disinfection of diverse fabrication and construction materials utilized in current packing, cooling and handling equipment and facilities?

6.4. Development of Best Practice Guidance for Measuring Key Water Sanitizers: Broad assessment of the variability in measurement of delivered and steady-state sanitizer dose across the fresh produce supply-chain and within the various scales of operation and diverse applications have taught us that meeting desired set-points and outcomes is harder to achieve for many commercial operations than bench-top testing would predict. Equally, reported sanitizer doses from preharvest to postharvest do not uniformly correlate with the expected outcomes in microbiological assessments of different bacterial groups in the treated water. While many systems are being used in good faith and according to standard, available protocols, it is clear that a greater understanding of in-practice dose measurement in relation to water quality constituents and commodity-specific parameters is needed to differentiate among practical Test Methods, which are sorely needed to define the required or allowable Accuracy and Precision. Whether compliance is determined by industry standards, customer specifications, or regulatory standards the protection of public health and the integrity of produce enterprises will increasingly require a greater level of performance in dose management and accurate documentation. CPS specifically requests a multi-state, multi-institution proposal to address the following Priority Objective:

Develop a matrix of best practice guidance for measurement of sanitizer dose among various test kit options, which fit practical application expectations from small-scale to medium-scale applications on-farm to packinghouse, and determine the fully associated costs. A broad diversity of actual in-use water quality constituents must be included. Test kit performance in accuracy and precision must be compared to technical analytical measurement of constituents, temperature, pre and post microbiological profile, and dose, including but not limited to hypochlorites, chlorine dioxide, ozone, and peracetic acids. Comparative assessments among reasonably paired operations across multiple states, locations, crops, scale of operation, and seasonal conditions are expected. The anticipated outcome is the development of a concise guidance document that better informs produce industry operations, audit-scheme holders and developers, regulators, and buyers of the realistic expectations for managing sanitizers in water-based applications, by measurement and treatment-adjustments that fit the characterized performance in microbiological control of cross-contamination for their scale of operation and economic resources.

6.5. Develop a detailed design and comprehensive cost analysis of a large-scale daily water reconditioning and re-use system for water-use efficiency and conservation in primary packing operations, with data developed specifically in relation to food safety process controls and routine verification and monitoring of physicochemical and microbiological constituents. Close alignment and participation with a company collaborator is essential, but anticipated engineering design elements and management outcome principles should be broadly transferable regionally and to comparable scale commodities.

6.6. Much empirical and anecdotal information has been circulated among the produce industry regarding the efficacy of various EPA-labeled, non-labeled, and GRAS compound preharvest surface sanitizers to significantly reduce risk when applied several days preharvest, especially on leafy greens and pole-tomato fields. Definitive data is need to guide the industry to informed decisions regarding the cost:benefit of this practice for any science-based assessment of these formulations, alone or in comparative studies.

Part III. Commodity Specific

Pacific Northwest Tree Fruit – All projects must include: a strong written, oral and web-based outreach component; sound statistical design suitable for applied projects; utilization of fruit and supplies directly from PNW sources; and science-based knowledge to improve practices and decision-making industry wide.

1. Agricultural Water: Agricultural water is used in various ways for tree fruit production in the Pacific Northwest. Among other uses, it may be applied for overhead sprinkler orchard irrigation and to apply fruit and foliage crop protection sprays on apple, pear, cherry and other stone fruit (apricot, nectarine, peach). To reduce damage from sunburn in apples, agricultural water may be applied by overhead sprinkler irrigation (also called overhead cooling). In these cases, agricultural water directly contacts fruit throughout the growing season. It is currently unclear if there is a public health risk associated with the use of agricultural water contaminated with human pathogens when that water directly contacts tree fruit in the orchard.

Specifically, additional research is needed to:

- Determine how long human pathogens will persist (survive, die and/or grow) on tree fruit that have been directly sprayed in the orchard with agricultural water containing human pathogens (especially *E. coli* and *Salmonella*). Special consideration should be given to the further development of fruit inoculation protocols (materials and methods) that will yield meaningful, repeatable and applicable results for tree fruit grown in the Pacific Northwest.

- Identify what intrinsic and extrinsic factors (e.g., production practices and agro-ecological conditions) may influence persistence of human pathogens on tree fruit that have been directly sprayed in the orchard with agricultural water that contains human pathogens. Development of a model system to systematically evaluate the intrinsic and extrinsic factors that may affect the risks associated with the diverse production practices and agro-ecological growing conditions encountered in the Pacific Northwest is encouraged.

  Based on recent events related to apple food safety concerns we would like to specifically know:
  a. Does the calyx end of the fruit harbor any human pathogens?
  b. If so, how does one go about consistently reducing the pathogen load in that location?
  c. Are there any varieties currently grown in the PNW that are more prone to support bacterial attachment?
- Characterize agricultural water systems in the Pacific Northwest regions for the potential to establish low-cost water sampling scenarios for producers under FSMA. This could include, but is not limited to: pooled sampling, collaboration with irrigation districts, and on-farm water sampling consolidation.

2. Tree Fruit Packinghouse Operations: Tree fruit are routinely sorted, washed and packed for further distribution and sale in packing facilities. Cherry fruits are frequently run through a hydro cooler to remove field heat and thus aid postharvest fruit quality retention. Tree fruit packinghouse operations provide an opportunity for packers to reduce microbial loads of human pathogens on tree fruit but conversely provide an opportunity for tree fruit to be contaminated by cross contact with contaminated water or food-contact surfaces. With many tree fruit packinghouses falling under the Preventive Controls for Human Food rule, attention should be paid to validation of preventive controls that will be accepted by FDA under the requirements of this rule.

Specifically, research is needed to:

- Determine how effective current packinghouse preventive controls are in reducing the cross-contamination potential for water to fruit in hydro coolers, dump tanks, and water flumes. Specific emphasis should be given to identifying conditions that are likely to transfer human pathogens to fruit during packinghouse operations, and determining if there are more effective equipment design, technology, chemical, or material options available.
- Determine how effective current packinghouse preventive controls are in reducing the cross-contamination potential for food-contact surfaces to fruit during the packing process (brush beds, rollers, dryer, belts, etc.). Specific emphasis should be given to identifying and ranking niches, harborages, and food-contact surfaces that are likely to transfer human pathogens to fruit during packinghouse operations, and determining if there are more effective equipment design, technology, chemical or material options available.
- Identify methods and materials for cleaning and sanitation of enclosed, recirculated water systems as used in packing facilities (e.g., dump tank recirculation systems, hydro cooler recirculation systems, cherry water flumes). Determine process efficacy for reduction of human pathogens and biofilms.
- Determine efficacy of sanitation and disinfection products for reduction of human pathogens in the packing facility or on the fruit surface. Special emphasis should be given to identifying packinghouse operations and operating variables that maximize the reduction of human pathogens on tree fruit.
  - Investigation of water disinfectants that may effectively be used with current packinghouse operating conditions and practices is encouraged, particularly alternatives to chlorine.

3. Tree Fruit Storage Operations: Tree fruit is typically stored for up to 12 months in either refrigerated air or controlled atmosphere cold storage. While in storage, fruit may be treated with maturation inhibitors such as 1-methyl cyclopropane, antioxidants such as diphenylamine or ethoxyquin, and fungicides such as pyrimethanil, fludioxonil, thiabendazole, and/or ozone. Application methods include fogging or continuous treatment throughout storage.

Specifically, research is needed to:

- Determine survival and growth of human pathogens, including *Listeria monocytogenes*, on fruit surfaces during common storage periods and when employing common storage practices, with special emphasis on technologies that may reduce the persistence of human pathogens in storage. Examples include ozone treatment and air filtration systems.
- Determine impact of postharvest treatments on survival and growth of human pathogens on fruit surfaces during storage.
- Determine if current cleaning and sanitation programs are effective for control of human pathogens in the storage facility and refrigeration equipment. Specific emphasis should be given to identifying and ranking niches, harborages, and potential for cross contamination to fruit during storage.

California Fresh Fruit Association (CFFA) – The CFFA is seeking proposals to address the following questions related to postharvest handling of peaches, plums, and nectarines grown in the San Joaquin Valley of California, with special emphasis on developing greater risk reduction knowledge towards preventive controls for *Listeria monocytogenes.* Successful proposals will clearly identify and demonstrate how the proposed research objectives will advance, rather than duplicate or be limited to derivative model research, existing or in-progress studies identifiable in the public domain. Furthermore, proposals that may result in anticipated benefits to industry in a one-year timeframe will be given priority consideration.

Research questions:

1. Develop or identify and demonstrate the commercial viability of clean-in-place (CIP) or clean-out-of-place (COP) processes that are capable of either sanitizing or preventing the transfer of human pathogens to fruit from inline brush beds used to de-fuzz, clean, or apply surface coatings to whole, fresh stone fruit. Alternatively, develop or identify and demonstrate the commercial viability of methods for de-fuzzing, cleaning, or applying surface coatings to stone fruit that are inherently more sanitary than current industry standards while maintaining commercial performance goals.

2. Are there commercially viable alternatives to the current industry practices of dewatering stone fruit with sponge rollers after washing? If yes, how do those alternatives compare to current industry practices with respect to the harborage and transfer of human pathogens?

California Leafy Greens Research Program – Irrigated agriculture in the West provides an attractive environment for amphibians such as the Pacific Treefrog (now designated as the Sierran Treefrog). Water containment systems, including irrigation reservoirs, tail-water ponds, and sediment containment structures, combined with extremely dry climatic conditions in neighboring non-irrigated lands, may be contributing to an ongoing issue with amphibians, a possible source of foodborne pathogens. On occasion, frogs found in finished leafy greens products are reported, usually by a traumatized consumer. When found on a processing line, work is halted, product is disposed of, and a sanitation crew cleans the line. Additionally, on-ranch water features host numerous flying insects that serve as a food source for frogs and can be a source of contamination in leafy greens.

Research questions:

- Would a better understanding of amphibian behavior within leafy greens production environments lead to possible control measures?
- Are there environmentally friendly management practices for reservoirs and ponds that would limit reproduction?
- Do lined or unlined ponds make a difference?
- How do fluctuating water levels in ponds and reservoirs impact amphibian populations?
- Where large numbers of flying insects are an issue at the water's edge, can they be controlled and would a drop off of insect populations lead to fewer amphibians? What other measures could be developed to limit intrusion into fields?