GRANTS PROGRAM: CENTER FOR PRODUCE SAFETY

2018 RFP Research Priorities Summary – September 13, 2017

The Center for Produce Safety's highest priority is to support research resulting in ready-to-use, data-driven solutions or information that catalyze and support science-based actions and decisions to prevent or minimize produce safety vulnerabilities across the supply chain. This requires CPS to allocate most of its research funds to short-term applied, practical, and knowledge gap–filling projects with direct application to industry practices. A smaller portion of CPS research funds are allocated to longer-term fundamental research and proof-of-concept projects exploring novel solutions or completing translational research of products or services of broad interest and use to the industry. In this Request for Proposal (RFP), some priorities presented in prior years remain and are included in broad longer-term projects, while other prior year priorities have been re-drafted for 2018 to capture and emphasize the input CPS has received to more closely focus research questions on specific anticipated data outcomes.

CPS wishes to thank the following industry collaborators for contributing their research needs for this RFP: California Fresh Fruit Association (1); California Cantaloupe Advisory Board and the California Melon Research Board (2); Washington Tree Fruit Research Commission (3); and Florida Fruit and Vegetable Association (4). The number in parentheses is used to identify industry collaborators in project descriptions below; however, similar research in collaboration and partnership with commodity groups not mentioned in the RFP's commodity-specific research questions are also welcome. Many projects described in this RFP will require cooperation with industry partners. CPS encourages principal investigators to secure industry partners on their own but will assist in finding collaborators for those with limited industry contacts. With this mission in mind, the following priorities are provided as guidance to the 2018 CPS Request for Proposals applicants.

PART 1. SHORT-TERM PROJECTS (MAXIMUM OF 1 YEAR) WITH DIRECT APPLICATION TO INDUSTRY PRACTICES

1.1 *Listeria monocytogenes* (Lm) in the supply chain

1.1.1 Environmental monitoring program best practices (Zone 1): With an increasing number of FDA/USDA/military 'swab-a-thons', regulators require production lines to run product for four hours prior to swabbing. There is no scientific proof substantiating the time interval used for *Listeria* detection with rapid tests or the requirement to run product in contrast to simply running the line without product and swabbing higher risk areas/high cell density niches to screen for resident harborage sites. Understandably, industry has identified this as a substantial operational and economic hardship impacting customers and broader supply chain stakeholders. As a matter of practice, when zone 1 testing is conducted, industry will continue to hold product, pending test results, or destroy it due to the perishability and quality loss.

- **What are the post-cleaning and sanitizing critical time and location factors to resolve the potential for Zone 1 resident *Listeria* harborage?**

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

- Produce on farm or in orchard at the time of harvest (3),(4)
- Packinghouses and warehouses especially conditions in wet environments (3),(4)
- Produce coolers and distribution centers (3)
- Retail and foodservice operations

  - o Produce micro-environs (e.g., HVAC units and motors that create elevated temperature micro-environments and condensation that creates a wet surface in an otherwise dry operation, etc.) (3)

Integrated studies, which combine foundational laboratory research with a strong work plan involving commercial or pilot plants, are specifically requested. Studies designed strictly for laboratory experiments will not be considered.

- **In harvest and packing operations and fresh-cut produce processing plants, what are the factors (operational, environmental, and temporal) determining the rate of "resident" Lm establishment on equipment and other areas at high risk for transferring contaminants to food-contact surfaces?**

1.1.3 Lm preventive controls (cleaning & sanitation / interventions): If equipment or diverse food-contact surfaces are fabricated with less-than-optimal sanitary design or materials, are there cost-effective alternatives that can minimize food safety risk? If they cannot easily be refurbished, retrofitted, or economically replaced due to the operational scale, effective cleaning methods and harmonized cleaning frequency and performance expectations are needed to minimize risk. Investigation is warranted to identify equipment design features, cleaning processes, and chemical sanitizers (conventional, green, and organic) that are effective at disinfecting food-contact and non-food-contact surfaces, drains, and other structures frequently found in raw agricultural commodity packing operations – especially those constructed with wood and painted metal.

- **What data-based guidance in the form of prioritization is possible based on Lm persistence data and the rate at which Lm can establish residence in/on different pieces of equipment and types of food-contact surfaces (e.g., areas where wax or lubricants accumulate, or condensation in long-term storage, etc.)?**
  - o **Are there commercially viable alternatives to the current industry practices of dewatering stone fruit (peaches, plums, and nectarines) with sponge rollers after washing? If yes, how do those alternatives compare to current industry practices with respect to Lm harborage and transfer?** (1)
  - o **What role do biofilms play in contamination in cantaloupe field-packing operations and how might biofilm formation be controlled most effectively in these settings? Is biofilm development and transfer to produce, such as cantaloupe, from food-contact surfaces during field-packing operations a relevant concern based on risk potential and risk exposure?** (2)
- **Considering commodity type, hours, volume, and other operating variables that can help inform effective sanitation schedules, what are best practices for cleaning and cleaning followed by sanitizing intervals, methods, and suite of efficacious chemistries for surfaces commonly found in produce industry facilities?**
- **What is the effect of temperature on the efficacy of various aqueous-based food-contact surface cleaning and sanitizing chemicals?**
- **What combination of sanitary preventive controls meets or exceeds EPA requirements for qualifying a hard surface sanitizer for *non-stainless steel* solid surfaces?**
- **What is the practical efficacy and optimized guidance for use of dry quaternary ammonium sanitizers (QUATs) or other powder-type sanitizers in wet produce processing/packing?**

1.1.4 Science-based industry best practices in response to *Listeria* detection: The emerging increase in supply-chain mandated environmental monitoring programs has raised a number of questions regarding the optimal response to presence/absence test results across various product handling areas and food-contact and non-food-contact zones. The industry is interested in having on-site data to answer the following questions:

- **Is there a science-based and logical foundation for differential responses to *Listeria* spp. detection within a facility operational and spatial swab-detection matrix, including environmental location(s) and quantitative recovery levels?**

- **Does determination of population size of *Listeria* within these different areas/zones allow for differential approaches to cleaning and sanitizing frequency and sanitizer selection?**

1.1.5 Expanding knowledge on *Listeria* growth potential and kinetics: Knowledge gaps remain that adequately characterize the growth of *Listeria monocytogenes* on fruit and vegetable surfaces, both intact and fresh cut, for a wide variety of items in relation to current regulatory policies for environmental monitoring requirements and expectations. Although some commodities have a fairly rich body of knowledge in peer-reviewed journal publications and FDA guidance documents, an expanded profile of diverse commodities and product formats, conducted under optimal, typical, and sub-optimal/abusive conditions for up to double the shelf life of the product, is specifically requested.

- **What is the survival and growth of *Listeria monocytogenes* on fruit and vegetable surfaces, both intact whole produce as well as fresh cut, held under typical and abuse conditions for up to double the shelf life of the product?**
- **Industry Focus Question – What is the survival and growth of human pathogens, including *Listeria monocytogenes*, on tree fruit surfaces during common storage periods and when employing common storage practices?** (3)

1.2 Hazards in the Production Environment

1.2.1 Animal intrusion: In many regions, produce is grown 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 characteristics of small-scale farms, CPS is committed to research that identifies practical, economical and effective measures to divert or direct animal foraging and movement away from production areas while at the same time minimalizing the disruption of animal access or use of their habitat in compliance with federal and local regulations and ordinances.

- **Taking into account prior research on animal populations in produce production areas, what are the specific risks with animal intrusion and fecal material in the produce production environment?** (4)
- **Based on research that quantifies the spread of human pathogens in animal excrement, what are the buffer zones necessary to prevent contamination of adjacent crops considering factors such as crop and soil type, weather conditions, topographical features of the growing area, etc.?** (4)

1.3 Post-Harvest Preventive Controls

1.3.1 Preventive controls for packing and holding operations: With many packinghouses falling under the Preventive Controls for Human Food rule, operators must pay particular attention to implementing, validating, and verifying preventive controls during packing and holding operations that will be accepted by FDA under the requirements of this rule.

- **Packing equipment: During which specific tree fruit packing operations and under what conditions are human pathogens likely to transfer from food-contact surfaces to fruit? Which packinghouse operations and operating variables maximize the reduction of human pathogens on tree fruit? Are there equipment design, technology, chemical, or material options available that are more effective at reducing pathogen transfer?** (3)
- **Cleaning and sanitizing: How effective are current tree fruit packinghouse preventive controls in reducing food-contact surface-to-fruit transfer on brush beds, rollers, dryer, belts, etc. and biofilm formation on enclosed, recirculated water systems (e.g. dump tank and/or hydrocooler recirculation systems, cherry**

water flumes)? Is steam cleaning an effective alternative to traditional cleaning and sanitation regimes for tree fruit packing equipment? If so, what are the best practices for the use of steam (i.e., effective temperature and moisture range, clean-in-place, clean-out-of-place, use of sanitizers after steam cleaning, cost effectiveness compared to traditional cleaning procedures)? (3)

  - **How do clean-in-place systems compare to clean-out-of-place systems? Develop or identify and demonstrate the commercial viability of clean-in-place (CIP) or clean-out-of-place (COP) processes capable of preventing the transfer of human pathogens to fruit from inline brush beds used to de-fuzz, clean, or apply surface coatings to whole, fresh tree /stone fruit (peaches, plums, and nectarines). Alternatively, develop or identify and demonstrate the commercial viability of methods for de-fuzzing, cleaning, or applying surface coatings to fruit that are inherently more sanitary than current industry standards while maintaining commercial performance goals.** (1),(3)

- **<u>Storage and holding</u>: Are current cleaning and sanitation programs effective for controlling human pathogens in storage facilities and industrial refrigeration systems? Are there technologies (e.g., ozone treatment and air filtration systems) that may reduce human pathogen persistence in storage (i.e., prevent condensation formation)?** (3)
- **<u>Cooler</u>: Are there cost-effective, lower risk methods for use as an alternative to icing produce, such as broccoli, at the cooler?**

<u>1.3.2 Wash water standards for FSMA implementation and audit compliance:</u> In produce packing operations, fruit and vegetables are routinely sorted, washed, and packed for further distribution and sale. Many produce items are run through a hydrocooler to remove field heat and thus help retain postharvest quality. Produce packing operations provide an opportunity to reduce human pathogens on product but conversely provide an opportunity for produce to be contaminated by contact with contaminated water. Across diverse commodities and system design, the industry is asking for greatly improved clarity in answering the following questions:

- **What are non-chlorine water disinfectant chemistries (e.g., ozone, PAA, new chemistries, etc.) that may effectively be used with current tree fruit packinghouse operating conditions and practices?** (3)
- **What are the best practice operating limits and the critical limits for hydrocooling and/or wash water system parameters to prevent cross-contamination under typical and peak challenge conditions? What are the optimal practices and standards for commercial system monitoring to prevent cross-contamination from product to water and water to product?** (3),(4)

  Additional requirements: Proposals are open as to commodity and region, but experimental design must accurately reflect the prevailing industry practices for immersive wash systems and any system using recirculated and re-conditioned water, including but not limited to antimicrobial dose, temperature, and residence time in the water. Proposals do not need to include a comprehensive comparative Work Plan to address multiple antimicrobials, but any sanitizing agents must be currently EPA-labeled for this purpose and recognized as allowable by FDA, or similar country authority outside the U.S. In addition, proposals must include an assessment of the rates of cross-contamination under conditions at and, at least, 0.1× below the defined critical limit. Proposal budgets must not exceed $50,000.[1]
- **What is the efficacy of peroxyacetic acid formulations at doses less than 0.60× of maximum labeled use rate and water pH greater than 7.0 (upper recommended limit is pH 8.5)?**

  Additional requirements: Proposals must include an assessment of the rates of cross-contamination under conditions at and, at least, 0.75× below the defined labeled rate. Proposal budgets must not exceed $25,000.[1]

---

[1] CPS anticipates funding multiple projects on diverse commodities and regional efforts within this objective, among qualifying proposals. CPS will consider funding more than one proposal on the same commodity in different regions, but will require the PIs for all funded proposals to engage in a directed and coordinated planning meeting to standardize experimental design parameters, challenge strains, and definition of "prevents cross-contamination" to the extent practical.

<u>1.3.3 Environmental monitoring in distribution centers:</u> Vented crates are an industry standard for packing produce products. Product exposed to the environment is subject to hazard-analysis and risk-based preventive controls, including an evaluation of environmental pathogens. This has created concerns for storage and distribution operations with food safety plans that have, prior to FSMA regulations, primarily focused on more limited good manufacturing practices and time/temperature controls. While these products may be considered "exposed to the environment" for regulatory purposes, few if any distribution centers have considered contamination of these products with environmental pathogens to be a known or reasonably foreseeable hazard. To help clarify uncertainties around the vulnerability of produce in vented crates to environmental pathogens, retail and foodservice distribution operations are asking for research evaluating the potential transfer of bacteria from the storage and warehouse environment through and into vented food crate to answer:

- **What is the appropriate approach for monitoring the environment in diverse distribution centers handling produce containers open to the environment?**

PART 2. FUNDAMENTAL RESEARCH AND LIMITED OBJECTIVE PROOF-OF-CONCEPT PROJECTS

2.1 Mitigating *Listeria monocytogenes* Growth on Produce

<u>2.1.1 Preemptive exclusion by microbial consortia</u> (PROOF OF CONCEPT ONLY FOR FUTURE GRANT LEVERAGING): Produce, produce farms, and harvesting, packing, and processing environments have diverse microbial communities. Understanding how these diverse and often non-culturable microbial communities may enhance or reduce the potential for "resident" Lm establishment (e.g., by competitive exclusion) may lead to better environmental monitoring strategies or use of microbial antagonists to prevent or reduce the likelihood of "resident" Lm establishment.

- **Are there novel listeristatic and listericidal processing aides suitable for use on fresh and minimally-processed produce?**
- **Is directed development of a listericidal microbial community a realistic strategy for risk reduction?**

2.2 Postharvest Interventions

<u>2.2.1 Produce surface contaminants:</u> In recent years, much of the research and resulting industry policies around wash water management have focused on defining critical parameters for minimizing cross-contamination. This is recognized as the primary achievable approach to addressing residual risk from pre-harvest food safety programs. However, the long-term need is to continually improve or create innovative systems to lethally treat pathogen-contaminated surfaces of incoming product. Towards this goal, the 2018 RFP is requesting proposals to answer the following questions:

- **What single treatment or combination of treatments can provide a consistent 2-log reduction in comparison to a standard commercial-scale chlorine wash system on the surface of minimally processed leafy greens and pre-cut vegetables? What effect does the treatment(s) have on the quality and sensory aspects of the product? Does the product meet regulatory requirements for use on food?**

  Additional requirements: Proposals to address this RFP question may be framed as a three-year, progressive program of up to $150,000 per year. Continuation funding will be contingent on an annual research and practical accomplishments review with CPS. The successful proposal will include a cogent and compelling justification for the incremental 2-log reduction, in direct comparison to a standard commercial wash process, in relation to naturally occurring epiphytes and inoculated challenge isolates. A clear relationship with an entity capable of conducting a commercial-scale pilot wash line and/or capacity to conduct scientifically valid tests in a commercial facility is required.

2.3 Core Produce Safety Research Objectives

Core produce safety research objectives have been streamlined and prioritized for 2018 but research concepts and objectives not specifically listed will be considered. Of interest are projects with the potential of bridging or closing our scientific knowledge gaps or ones with practical technological solutions leading to risk reductions across all fresh fruit, vegetable, and nut crops. Research should enhance produce safety systems spanning all phases of production, harvest, cooling, packing, fresh-cut processing, storage, transportation, receiving, and point-of-sale environments. Principal investigators submitting a proposal are also encouraged to submit clarifying questions by telephone to (530) 554-9706 or by sending an email to **research@centerforproducesafety.org**.

Prerequisite 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 farm-scape, and watershed environments, harvest operations, cooling facilities, packinghouses, re-pack operations, fresh-cut processing, transportation, distribution, and 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:

2.3.1 Defining quantitative and spatial risks in production fields: The leafy greens industry has 10 years of experience in making dynamic and evolving harvest decisions based on pathogen testing. It is widely recognized that practical levels of routine preharvest testing cannot provide the detailed information necessary to improve our understanding of the comparative risk profiles of "field lots" which pass or fail these assessments. This knowledge is desired to:

- Support risk model improvements by populating these schemes with true field data
- More systematically define sampling regimes
- Better establish the common root-cause and distribution of contamination events
- Challenge the current approaches to defining the scope of "failed-test" crop destruction.

Towards this goal, the 2018 RFP is requesting proposals to answer the questions:

- **Are the field-level differences in harvest decisions and lot acceptance for leafy greens between a negative test outcome (passed) and a positive test outcome (failed) real or merely a reflection of inadequate sampling design and execution?**
- **At what frequency can environmental analysis and highly saturated sampling of a "failed" field provide clear identification of root-cause/pathogen source-tracking? If contamination is present in low levels, how far does it spread?**
- **Are there cost-effective methods and technologies to optimize sample collection and preparation in-field that definitively distinguish potentially positive samples from negative samples?**
- **Are the comparative outcomes between "passed" and "failed" fields different between conventional and organic production sites and practices?**

The successful proposal may be developed individually or as a consortium of qualified researchers to conduct a regional approach to addressing these questions within a tightly coordinated logistical plan of access with a commercial partner(s). Proposals should plan to incorporate a detailed analysis of multiple fields and regions across two seasons.

2.3.2 Product testing risk modeling: Develop a risk-based model for the impact of product testing (must include all positions within the supply chain) to provide insight into risk management alternatives for a range of produce items (e.g., 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 matrices of sample size and sample number as a function of the frequency of contamination and the severity of contamination (e.g., pathogen concentration). The model should address how these relationships are affected by lot size, location of sampling, multiple sampling points across the supply chain, etc. The net result should be a realistic and practical 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 and clear opportunities for commercial implementation. 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: It is essential for the principal investigator to have an intimate understanding of the testing scenarios and lot definitions currently used by the produce industry.

2.3.3 Factors affecting human pathogen persistence: 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, distribution, and retail 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.

2.3.4 Understanding produce risks: Risk-ranking is essential for setting priorities to most effectively deploy limited food safety resources. Without a quantitative standard as a target for measurements, industry practitioners and government regulators are limited in their ability to formulate truly science- and risk-based produce safety best practices and policies. Confounding this limitation is the inability to integrate all the available information into a useable tool (i.e., model) to assist in risk-ranking various hazards and contamination routes. Specifically, quantitative microbial risk assessment (QMRA) data is needed to populate models that can be used in both unique and regional operations to determine which currently employed practices are most effective at reducing contamination risk. Systems-based research is first needed to establish fundamental and suitable data for QMRA analysis – essential for prioritizing preventive controls and interventions to optimally reduce public health and business risk.

Industry Collaborators:

(1) California Fresh Fruit Association (CFFA)

(2) California Cantaloupe Advisory Board and the California Melon Research Board

(3) Washington Tree Fruit Research Commission

(4) Florida Fruit and Vegetable Association