GRANTS PROGRAM: CENTER FOR PRODUCE SAFETY

2019 RFP Research Priorities Summary – September 11, 2018

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. CPS allocates research fund priorities to short-term applied, practical, and knowledge gap–filling projects with direct application to industry practices. A smaller portion of CPS research funds are generally allocated to longer-term fundamental research and proof-of-concept projects exploring novel solutions of broad interest to the industry and to better inform public health agencies. In this Request for Proposal (RFP), CPS will focus research questions on specific anticipated data outcomes with high potential for adoption at points across the supply chain.

To successfully fulfill the expectations of the many CPS partners in making funding available, CPS encourages principal investigators to secure committed industry collaborators* *(see page 7)* involved in the identification of research objectives and assessment of anticipated outcomes. On request, CPS will assist in finding collaborators.

With this mission in mind, the priorities provided as guidance to the 2019 CPS Request for Proposals applicants are listed below and detailed on the following pages.

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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): Current expectations for investigative 'swabathons' require sampling no sooner than 4 hours after operational start-up within typical product handling timelines, from receiving to finished product handling. However, there is no scientific evidence substantiating the minimal time interval specified or the requirement to swab while running product, in contrast to simply running the line without product and systematically swabbing to screen for resident harborage sites. Industry has identified that running product during a Zone 1 swabathon is a substantial operational and economic hardship impacting the affected business, its customers, and broader supply-chain stakeholders. As a matter of practice, when Zone 1 testing is conducted, pending test results, industry will continue to destroy the impacted lot due to perishability and quality loss or as a consequence of buyers rejecting any product handled on a line during a swabathon exercise.

- **For different operational systems, what is the optimal swabbing method required to detect dispersion of *Listeria* from intractable biofilm sites within produce packing or processing? Is a single interval or commodity-type Best Practice guidance possible?**
  - **The proposed research must address modeling biofilm development as a function of time intervals between deep cleaning of inaccessible harborage sites resulting in dispersal of blebbing/shedding environmental pathogens during operation, which will be detected in a Zone 1 swab survey.** (For the RFP expectations of addressing this research question, the identified industry issue is *not* to define the sites and traits of harborage locations.)
  - *Note*: Research designed within a credible pilot plant facility with representative packing or processing equipment is specifically requested.
- **What are the post-cleaning and sanitizing critical time and location factors to detect Zone 1 resident *Listeria* harborage and Zone 2 and 3 transference if *Listeria* spp. or Lm is established on these food contact surfaces?**
  - *Note*: Research designed within a credible pilot plant facility with representative packing or processing equipment is specifically requested.
- **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, condensation in long-term storage)?**
  - *Note*: Integrated studies, combining 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.

1.1.2 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 – including those constructed with wood or painted metal and covered by polymer tarps or panels, cushioning sheets, or other traditional materials.

- **Are there commercially viable alternatives to the current stone fruit industry practices of dewatering with sponge or brush rollers after washing? How do available or envisioned alternatives compare to**

current industry practices with respect to efficacy in dewatering, Lm harborage and transfer, and cost to acquire and operate? [1]*

- **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?**
- **A good hygiene program may include changeouts of sanitization chemicals for areas (e.g., floor drains) that are susceptible to Lm contamination, but there is a lack of scientific publications to support or refute a rotating sanitization program. What is the effect of the sanitizing agent and its performance, and what other effects may mask what is really happening with the sanitizer? Are micro-environments and/or harborage sites being built up (e.g., due to hard-water scaling) that the sanitizer may even be contributing to or cannot overcome?**
- **In harvest and packing operations, and in fresh-cut produce processing plants, what factors (operational, environmental, and temporal) determine the rate of "resident" Lm establishment on equipment and other areas at high risk for transferring contaminants to food-contact surfaces?** [1, 2, 3]*

Note: To address the questions above, integrated studies, combining 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.

- **Do pathogens develop tolerance to a sanitizer?**
  - *Note:* Studies designed to address this question may rely solely on laboratory and/or *in silico* experiments, including genomic evaluations with produce relevant isolates from packing and fresh-cut operations.

1.1.3 Science-based industry best practices in response to *Listeria* detection in RAC operations: The emerging increase in supply-chain mandated environmental monitoring programs for Raw Agricultural Commodities (RACs) has raised a number of questions regarding the optimal response to presence/absence test results across various product handling areas and non-food-contact zones. A defined response prioritization to quantitative thresholds in Zone 3 areas could be used in sanitation and deep-cleaning schedules. The operational philosophy, "You can't clean and sanitize everywhere everyday" is common sense but not currently addressed or supported by science. 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?**

1.2 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 additional 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 minimizing the disruption of animal access or use of habitat in compliance with federal and local regulations and ordinances.

- **What cost-effective and environmentally benign practices that minimize animal intrusion may be demonstrated at different farm production scales?**
- **Conduct on-farm demonstration of quantifiable animal intrusion control that involves non-lethal and habitat non-disruptive methods.**
  - *Note*: For this RFP priority, a maximum of $50,000 per site is available**.**

1.3 Postharvest Preventive Controls

1.3.1 Preventive controls for packing and holding operations:

Packing and shipping – Packinghouses are being held by the customers to new standards in food safety programs and must pay particular attention to implementing, validating, and verifying process controls during packing and holding operations that are consistent with the expectations applied under the FSMA Preventive Controls for Human Food Rule.

- **Cleaning & sanitizing: How do clean-in-place (CIP) systems compare with clean-out-of-place (COP) systems in effectiveness of preventing harborage of environmental pathogens on various food contact surfaces? How does brush, roller, or postharvest treatment applicator impact cleaning and sanitizer efficacy? Which set of options are inherently more sanitary than current industry standards while maintaining commercial performance goals.** [1, 2]*
  - **Develop or identify and demonstrate the commercial viability of CIP or COP processes capable of either sanitizing or preventing the transfer of human pathogens to stone fruit, tomatoes, cucumbers, or other commodities from inline brush beds and similar packing practices, used to de-fuzz, de-spine, clean, polish, or apply surface coatings to RACs.**
  - **Alternatively, develop or otherwise identify and demonstrate the commercial viability of methods for achieving these necessary postharvest quality management practices within a food safety program.**
- **Does the efficacy of antimicrobials vary with "wet" versus "dry" contact-time scenarios? Dry contact time: "dry" gap between wash solution with antimicrobial agent and rinse. "Wet" contact time: no gap, wash solution with antimicrobial agent is continuously applied until fruit encounters rinse section. In both cases, the time it takes for fruit to travel between beginning of wash section and rinse is often referred to as "contact time."** [1]*
  - *Note*: Proposals that may result in anticipated benefits to industry in a one-year time frame will be given priority consideration.

1.3.2 Environmental monitoring in distribution centers: Vented crates are an industry standard for packing produce products. Product exposed to wet or dry product handling environments 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 for quality. 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 crates to answer:

- **What is the appropriate approach for monitoring the environment in diverse distribution centers handling produce containers open to the environment?**
- **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)?** [2] [4]*

1.3.3 Wash water standards for FSMA implementation and audit compliance: 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 designs, the industry is asking for greatly improved clarity in answering the following questions:

- **What novel non-chlorine water disinfectant chemistries may effectively be used with current packinghouse operating conditions and practices?** [2]*
- **What are the Best Practice operating limits and the critical limits for hydrocooling and/or wash water and icing system parameters to prevent cross-contamination under typical and peak challenge conditions? What are the optimal practices and standards for current commercial system antimicrobials and monitoring systems to prevent cross-contamination from product to water and water to product?** [1, 2, 3]*

  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 (PAA) formulations at doses less than 0.60× of maximum labeled use rate and at source (make-up) water pH greater than 7.0 (an upper limit for a dose bracketed and factorial experimental design 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]

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[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".*

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

2.1 Postharvest Interventions

2.1.1 Produce surface contaminants: 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 preharvest 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 2019 RFP is requesting proposals to answer the following questions:

- **What single treatment or combination of treatments, meet regulatory requirements for use on food, 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?**

  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.

2.2 Core Produce Safety Research Objectives

Core produce safety research objectives have been streamlined and prioritized for 2019, 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. Proposed project objectives must minimally span at least two sequential links in the supply-chain, including 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 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:

2.2.1 *Cyclospora* prevalence and risks: FDA set up a multidisciplinary workgroup in 2015 to prioritize the development, validation and implementation of a method for detecting *Cyclospora* in fresh produce, and in 2018, FDA began using the newly validated *Cyclospora* testing method. The availability of this method is a significant advancement in FDA's ability to investigate outbreaks of cyclosporiasis and identify the parasite in foods. There has recently been a significant increase in the number of recalls attributed to *Cyclospora* based on this clinical method and then investigated back to produce. The number of incidents has either been triggered by some event or may have gone undetected in the past. The industry needs to understand the validated process and whether testing has caused this increase in *Cyclospora* activity, and determine the future impact of this new test method to produce crops and the industry at large.

- **Using this technique, what is the prevalence of *Cyclospora* in irrigation waters, outside of currently suspected areas (Arizona and Texas), and proof of filtration and UV/O3 technologies to eliminate risk?**
- **Are there practical techniques for the produce industry to screen positive product samples for sporulated oocysts and rates of developing to an infectious stage on product following direct human transfer to food-contact surface or product?**

*Industry Collaborators:

The number in brackets is used to identify committed industry collaborators in the project descriptions:

[1] California Fresh Fruit Association
[2] Washington Tree Fruit Industry
[3] Florida Fruit and Vegetable Association
[4] Industry Partner Available – Please contact research@centerforproducesafety.org for additional information

Many other CPS partners have offered to be industry collaborators on projects of interest. CPS encourages principal investigators to secure industry partners on their own but will assist in finding collaborators for those with limited industry contacts.