U.S. FOOD & DRUG ADMINISTRATION

HUMAN FOODS PROGRAM

2024 2025

UNIVERSITY CENTERS OF EXCELLENCE ANNUAL REPORT

Western Center for Food Safety WCFS UCDAVIS

Joint Institute for Food Safety and Applied Nutrition — University of Maryland — U.S. Food & Drug Administration

The University of Mississippi — National Center for Natural Products Research

IFSH Institute for Food Safety and Health — Illinois Tech — Innovation Through Collaboration

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Introduction

The Human Foods Program (HFP) is one of six product-oriented organizations, in addition to a nationwide field force, that carry out the mission of the Food and Drug Administration (FDA). FDA is a scientific regulatory agency responsible for the safety of the nation's domestically produced and imported foods, cosmetics, drugs, biologics, medical devices, and radiological products. HFP's vision is to ensure that food is a source of wellness for all U.S. consumers, and our day-to-day activities are focused at protecting and promoting the health and wellness of all people through science-based approaches to prevent foodborne illness, reduce diet related chronic disease, and ensure chemicals in food are safe. To help achieve this vision, HFP recognizes the value of fostering collaborations with external partners to leverage research and regulatory resources in support of our science and capacity building activities. These partnerships assist the FDA in accomplishing its public health mission and in expanding the science base upon which future regulatory programs are developed.

HFP's university Centers of Excellence (COE) program is one of several approaches HFP uses to collaborate with external partners to fulfill its public health mission. The university COE program consists of formal partnerships with four academic institutions and provides opportunities to build diversified channels for infusing innovative ideas and knowledge, encourages dialogue among government, academia and industry, and develops novel approaches to solve complex public health issues. University COEs also partner and collaborate with other domestic and international organizations to conduct food safety research and capacity building. This collaboration leverages HFP's resources and enhances our ability to ensure public health. It also allows HFP to reach a larger portion of the global food safety community. HFP currently supports four university COEs; 1) the Institute for Food Safety and Health (IFSH)/National Center for Food Safety and Technology (NCFST) at Illinois Tech (IIT), 2) the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) at the University of Maryland, College Park, 3) the National Center for Natural Products Research (NCNPR) at the University of Mississippi, Oxford, and 4) the Western Center for Food Safety (WCFS) at the University of California, Davis.

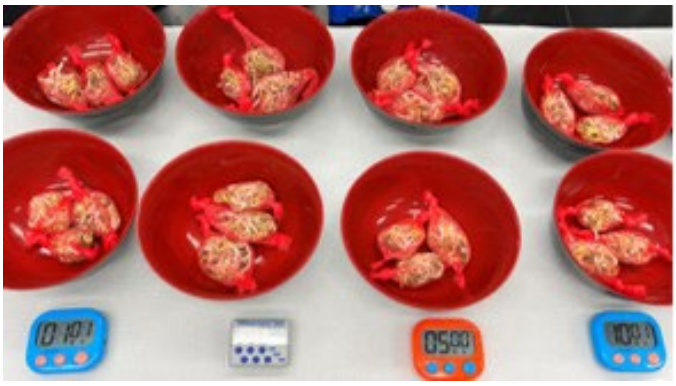
This report highlights selected research and capacity building efforts conducted by the university COEs during the 2024-2025 Cooperative Agreement budget period.

Institute for Food Safety and Health (IFSH)/National Center for Food Safety and Technology (NCFST) - Illinois Tech (IIT)

The National Center for Food Safety and Technology (NCFST) was established in 1988 at the Illinois Tech Moffett Campus in Bedford Park, IL, to bring together scientists from the FDA, academia, and industry to work collaboratively on food safety issues. The NCFST is a part of Illinois Tech's Institute for Food Safety and Health (IFSH) and is a unique food research consortium of Illinois Tech faculty and students, HFP's Division of Food Processing Science and Technology (DFPST), and food and food-related industries. NCFST's research addresses the safety of fresh and processed foods, food safety implications of emerging technologies in food processing and packaging, nutrition quality, and laboratory method performance. In addition to the NCFST, other Centers within the IFSH structure include the Center for Processing Innovation, the Center for Nutrition Research, the Center for Specialty Programs, and the Center for Food Chemistry and Packaging. IFSH also coordinates FDA Food Safety Modernization Act (FSMA) training programs through the IFSH-led Food Safety Preventive Controls Alliance (FSPCA) and Sprout Safety Alliance, including Preventive Controls for Human Food, Preventive Controls for Animal Food, Foreign Supplier Verification Programs, Intentional Adulteration, and Sprout Safety. The FSPCA also provides a Technical Assistance Network to industry on non-rule-interpretation inquiries which are related to FSMA rule implementation.

IFSH Executive Director - Dr. Brian Schaneberg
IFSH Associate Director – Dr. Jason Wan
HFP Project Officer - Dr. Les Smoot

Evaluation of the Inactivation of *Listeria monocytogenes* and *Salmonella enterica* on Noodle Soup Garnishes Based on Broth Formulation and Temperature

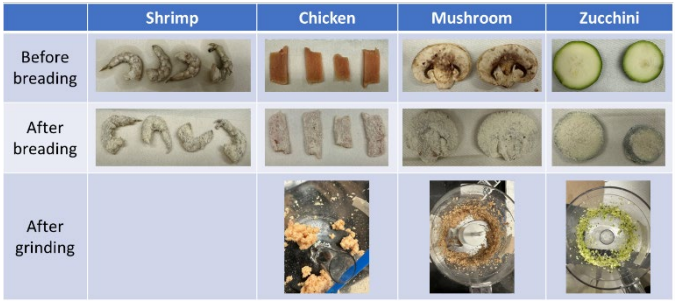


In 2020, there was an outbreak of listeriosis in the U.S. linked to contaminated enoki mushrooms. From the traceback investigation, some ill individuals indicated that they had consumed raw enoki mushrooms used as garnishes on ramen noodle soup. This was the first time that *Listeria monocytogenes* was linked to enoki mushrooms, thus a novel pathogen-commodity pairing. The outbreak prompted questions regarding the risk of fresh mushroom and other vegetable garnishes on soups. A subsequent inactivation study was conducted on specialty mushrooms resulting in identifying that ramen broth at temperatures lower than 90-100 °C were insufficient to properly inactivate pathogens, such as *L. monocytogenes* and *Salmonella enterica*, on these specialty mushrooms when submerged in

broth. Therefore, the question remained whether pathogen inactivation would be similar for other garnishes commonly found on ramen noodle soup.

In this study, the inactivation of *L. monocytogenes* on four fresh garnishes (corn, green onion, Bok choy, and mung bean sprouts) was assessed when the garnishes were submerged in ramen soup broth at 70, 80, 90, or 100 °C for up to 1 h. In addition to *L. monocytogenes*, the inactivation of *S. enterica* and *Escherichia coli* O157:H7 on mung bean sprouts (contaminated via seeds) were also evaluated. The corn, green onion, and bok choy garnishes were also held at 5 or 25ºC for 24 h after the initial 1 h inactivation study to assess the possibility of proliferation after the initial inactivation treatment. Results of this study determined that using broth temperatures of 70 or 80 °C only resulted in a 1-2 log CFU/g *L. monocytogenes* population decrease on corn, green onions, and Bok choy garnishes. However, pathogens behaved differently on the mung bean sprouts samples; using 80 °C broth resulted in a >5 log CFU/g reduction of all three pathogens. This research was funded through HFP's Cooperative Agreement with IFSH and the DFPST operating budget.

Transfer of Seafood Allergens to Frying Oil and Subsequent Fried Products



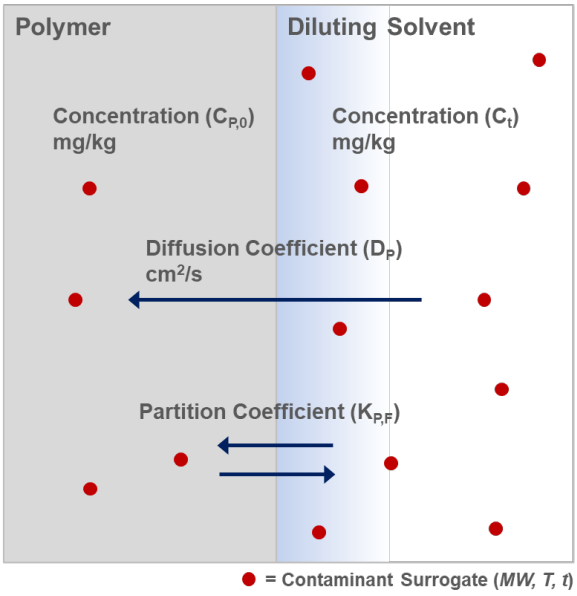
In retail and food service operations, the reuse of frying oil is a common practice for economic and operational efficiency. However, this raises concerns regarding the unintended transfer of food allergens, to allergen-free foods – a critical issue for individuals with food allergies. This study addressed these concerns by focusing on: (1) gluten cross-contact from reused frying oil, and (2) seafood allergen transfer from reused breading mix.

In Part I of the study, the oil used to fry 10 batches of par-fried breaded shrimp at 180 °C for 3 min was used to fry French fries, tater tots, and chicken breast bites. The used oil was passively filtered under gravity through sieves and cellulose filter papers. As for active filtration, response surface methodology was employed to identify optimal conditions that minimized gluten content, and these conditions were then validated for oil used to fry breaded shrimp. Gluten levels in oil increased with more frying batches and transferred to subsequently prepared gluten-free foods, exceeding the 20 mg/kg threshold for "gluten-free" labeling. Passive filtration using filter paper (25 µm pore size) decreased the residual gluten protein content in the oil by over 80%. Active filtration using 0.5% (w/w) filter aids with a 30 min mixing time further reduced gluten residues by at least 99.7% compared to untreated oil.

In Part II of the study, twenty batches of shrimp and cod (25-30 g/batch) were prepared separately in a mixing bowl containing 200 g of breading mixture. After the 1st, 5th, 10th, 15th, and 20th batches, 0.5 g samples were collected from three distinct locations in the bowl and analyzed by using ELISAs. Shrimp protein concentrations progressively increased with repeated

use, reaching approximately 1.0 ± 0 ppm, 5.5 ± 0.4 ppm, and 10.6 ± 0.2 ppm after 10, 15, and 20 batches, respectively. For cod, a similar trend of increasing fish protein concentrations with repeated reuse of the breading mixture was observed. After 20 batches, cod protein concentrations reached 628.7 ± 11.2 ppm in the breading mixture and estimated exposures to fish protein could surpass established reference doses for fish associated with appreciable risk to health. This project directly addresses food safety and allergen management in the retail/food service setting. It helps to better understand allergen cross-contact risks associated with reusing breading/frying systems. This research was funded through HFP's Cooperative Agreement with IFSH and the DFPST operating budget.

Sorption Behavior of Surrogate Chemical Contaminants in Polyethylenes for Use as Post-Consumer Recycled Food Contact Materials

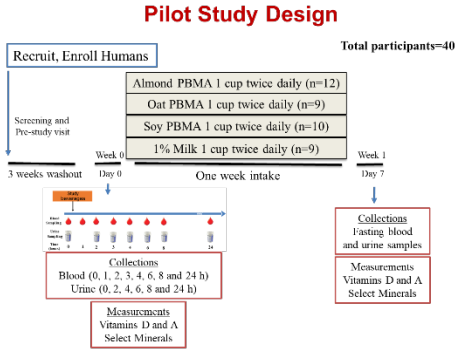


The use of recycled materials for food packaging is restricted due to the possibility of contaminants migrating into the food. FDA operates a review process for recycled plastics which primarily focuses on experimental data to demonstrate that the recycling process results in material of a purity suitable for the intended use. The potential fast diffusion of large molecular weight (MW) contaminants into polyethylene (PE) materials in comparison to other plastic resins requires additional safety evaluation since considerable sorption is expected in PE materials. This study's objective was to evaluate the sorption behavior of various chemical contaminant surrogates in High-Density Polyethylene (HDPE), Low-Density Polyethylene (LDPE), and Linear Low-Density Polyethylene (LLDPE) and optimize FDA surrogate test conditions that are specific to PE.

Eight nonvolatile compounds were selected as potential contaminant surrogates for PE based on MW and polarity. Low MW surrogates (152-184 g/mol) were methyl salicylate, benzophenone, phenylcyclohexane, and n-tridecane. High MW surrogates (275-391 g/mol) were diphenyl phthalate, bis (2-ethylhexyl) terephthalate, tetradecylbenzene, and bis (2-ethylhexyl) adipate. 2-Propanol was selected as the most appropriate diluting solvent for use during surrogate testing of PE. The sorption of the 8-surrogate mixture, each surrogate at 1% concentration, from 2-propanol into HDPE film at 40°C was sampled at 12 time points over a total of 28 days and quantified by gas chromatography-mass spectrometry (GC-MS). Equilibrium sorption of all surrogates into HDPE occurred by 14 days. The polar surrogates (methyl salicylate, benzophenone, diphenyl phthalate, and bis (2-ethylhexyl) terephthalate) resulted in lower sorption in the range of 300-1100 mg/kg, while most nonpolar surrogates (phenylcyclohexane, n-tridecane, and tetradecylbenzene) had higher sorption in the range of 2200-3300 mg/kg. Within

the nonpolar group, the more intermediate polarity bis (2-ethylhexyl) adipate experienced very low sorption (400 mg/kg). Diffusion coefficients (D_P) and partition coefficients ($K_{P,F}$) of surrogate contaminants into HDPE from 2-propanol were determined by nonlinear curve fitting optimization of experimental sorption data. Migration modeling of surrogate sorption into HDPE using partition coefficient estimation ($K_{P,F}$=1) highlighted the critical importance of using experimental $K_{P,F}$ values for accurate evaluation of surrogate sorption into polyolefins. This study identified chemistry issues that FDA will recommend in updated industry guidance that a recycled plastics manufacturer should consider during their evaluation of a recycling process for its decontamination efficacy in producing material suitable for food-contact applications. This research was funded through HFP's Cooperative Agreement with IFSH and the DFPST operating budget.

Relative Absorption of Fat-Soluble Vitamins D and A and Minerals from Select Plant-Based Milks in Human Subjects: A Pilot Trial



Plant-based milk alternatives (PBMAs) now account for around 10% of the total milk market and the sales of PBMA are predicted to increase. The different types of PBMAs on the market shelf include almond, oat, soy, coconut, cashew, pea, hemp, and rice; however, they are often nutritionally unequal. Most of the PBMAs are fortified with minerals and vitamins to mimic bovine milk composition with added sugars and flavorings to mask off-flavors. The Dietary Guidelines, 2020-2025 identify the Dairy Group, which includes milk, as a key contributor of calcium (Ca), protein, vitamin A, vitamin D, magnesium (Mg), phosphorus, potassium (K), riboflavin, vitamin B-12, zinc, choline, and selenium. The bioavailability of these nutrients (inherent and fortified) in PBMAs has not been investigated in humans. However, due to the presence of some components (i.e., oxalates, phytates, tannins) and the processing methods used in production, the bioavailability of nutrients from PBMAs is believed to be low. Moreover, there are no standards of identity for PBMAs in the U.S. and the nutritional quality of different types of PBMAs is quite variable.

A human clinical trial was conducted to study the relative absorption of vitamin D and minerals after acute and short-term intake (up to 24 h and 1 week) of almond, oat and soy PBMAs in humans. Bovine milk was used as positive control. Plasma/serum and urine samples were collected after 3-week washout from milk products (baseline, 0 h), and then periodically at 1 h, 2 h, 4 h, 6 h, 8 h, 10 h and 24 h, and 1 week post daily consumption for the analysis of vitamin A, D, and select minerals (calcium, potassium, magnesium). A total of 62 participants were screened with 44 participants randomized for each study arm. The digestion and analysis methods were developed and validated for Ca, Mg and K in human plasma and urine using microwave assisted digestion followed by Inductively coupled plasma optical emission

spectrometry (ICP-OES). These minerals (Ca, Mg and K) have been analyzed in over 500 plasma samples. The preliminary data suggest no differences in the plasma absorption profiles of minerals from PBMAs compared to bovine milk after acute or 1 week intake. The urine samples (~ 450) have been analyzed, and the data are being evaluated. This information from these studies will help in the formulation and fortification of products as well as in providing regulatory agencies with a better understanding of these products for setting up the dietary guidelines. This research was funded through HFP's Cooperative Agreement with IFSH and the DFPST operating budget.

Detection of Highly Pathogenic H5N1 Avian Influenza (HPAI) in Milk

In response to the emergence of Highly Pathogenic H5N1 Avian Influenza (HPAI) in dairy cattle, the FDA Veterinary Laboratory Investigation and Response Network (Vet-LIRN), IFSH NCFST, HFP Moffett Center, and USDA National Animal Health Laboratory Network (NAHLN) conducted an Inter-laboratory Comparison Exercise (ICE) in July 2025. The objective of the exercise was to evaluate the analytical proficiency of participating laboratories in detecting HPAI virus RNA in milk samples using various PCR-based methodologies.

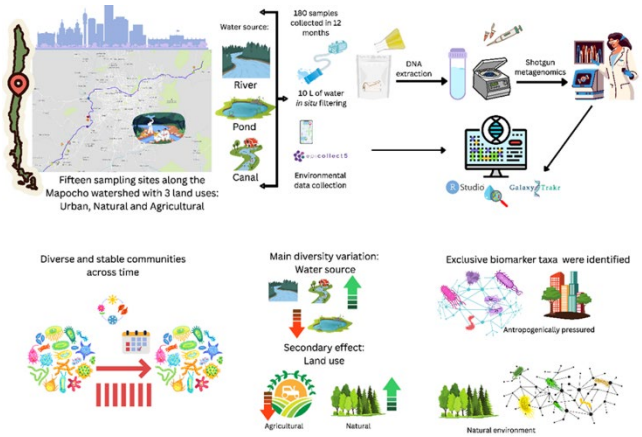
The study design consisted of 16 blinded samples containing HPAI virus RNA spiked into milk at multiple concentrations. These samples were distributed to 46 analysts in pre-registered laboratories for analysis under BSL-2 conditions. All results were reported by end of July 2025, and a preliminary summary report was circulated for review at the end of August 2025. Comparative evaluation of the submitted results was undertaken to identify opportunities for methodological improvement, assess reproducibility across laboratories, and characterize detection thresholds. The Moffett PT Laboratory and FDA's Vet-LIRN are collaborating with QuoData statistical experts to develop the final report. This report will include a comprehensive statistical analysis of laboratory performance, comparative assessment of the PCR-based methods employed, and evaluation of Levels and Probabilities of Detection (LOD/POD) to provide an evidence-based assessment of laboratory proficiency and methodological robustness. This report will be made available early Fall 2025. This initiative addresses the critical need for reliable HPAI diagnostic testing in milk, thereby supporting animal health, safeguarding public health, and ensuring the integrity of the food supply. Funding was provided through the HFP Cooperative Agreement with IFSH and the DFPST operating budget.

Joint Institute for Food Safety and Applied Nutrition (JIFSAN) - University of Maryland, College Park

The Joint Institute for Food Safety and Applied Nutrition (JIFSAN) was established in 1996 at the University of Maryland, College Park (UMD). The Institute is a jointly administered, multidisciplinary research, education, and outreach program. The research program includes genome sequencing and genomic analysis, bioinformatics, foodborne pathogens, development of training metrics, and risk assessment modeling. Additionally, JIFSAN's undergraduate internship program supports the science and research programs at HFP. JIFSAN's education and outreach programs serve the FDA internally, domestically, and internationally. The International Training Center is a train-the-trainer program and includes Food Safety Preventive Controls Alliance and Produce Safety Alliance training. It also provides training on Good Agricultural Practices, Good Aquacultural Practices, Good Fishery Vessel Practices, Commercially Sterile Packaged Food, Food Inspector Training Course, and Collaborative Food Safety Training Centers. The Food Safety Risk Analysis Professional Development Program provides courses that focus on risk assessment methods and analysis to address food safety issues worldwide, and hosts FoodRisk.org that offers online resources for food safety risk analysis.

JIFSAN Director – Dr. Jianghong Meng
HFP Project Officer – Dr. Kelly M. Randolph

Environmental Surface Water Surveillance Through Genomics and Metagenomics



Initiated in 2018, this international collaborative project aims to isolate and sequence *Salmonella* from surface waters associated with agricultural environments. Our partners at the University of Chile (UCh), Pontifical Catholic University of Chile (PUC), Federal University of Paraíba (UFPB), Federal University of Rio de Janeiro (UFRJ), and the National Autonomous University of Mexico (UNAM) have collected a total of 5,105 surface water samples. These samples were collected from diverse aquatic sources linked to agricultural activities, including rivers, dams, ponds, lakes, streams, creeks, and irrigation canals, and have yielded over 7,000 *Salmonella* isolates. A total of 6,151 *Salmonella* isolates were sequenced and cataloged on the Pathogen Detection platform of the National Center of Biotechnology Information (NCBI). The universities have also recovered *Listeria monocytogenes* from the surface waters, with Chilean universities already collecting over 1,300 isolates, of which 490 genomes have been sequenced and uploaded onto the NCBI platform.

In 2024, two additional institutions - the University of Costa Rica (UCR) and Universidad Nacional del Centro de la Provincia de Buenos Aires (UNICEN, Argentina) joined the project. Both universities have successfully established sampling and laboratory protocols for *Salmonella* isolation. UCR has collected 160 samples to date and reported a notable *Salmonella* prevalence of 50% during the most recent sampling. UNICEN has collected 90 samples, and confirmed 92 *Salmonella* isolates, with an overall prevalence of 65%. Both universities reached the goal of 240 samples each by June 2025. We also conducted metagenomic analysis, revealing microbial communities inhabiting surface water bodies and their associated functional potentials. Our international collaborators used Modified Moore swabs to collect samples from a subset of designated sites monthly throughout the 2024-2025 budget period. DNA extraction was conducted and shipped directly to JIFSAN for library preparation and sequencing at FDA's Human Foods Program. Over 600 samples have already been sequenced and deposited on NCBI.

The project has resulted in numerous research presentations and publications including nine technical oral presentations and 60 posters in scientific meetings. Moreover, 11 manuscripts have been published in scientific journals, two were recently submitted, and at least three more are in preparation. This collaborative effort has created one of the largest collections of *Salmonella* data from surface water in Latin America. This data helps us better understand how *Salmonella* spreads in the environment and the genetic differences between strains in the region. The information can help food safety investigators trace contamination sources more quickly by providing genetic data from Latin America—a region that sends a lot of food to the United States but has been underrepresented in the GenomeTrakr database. This program was funded through HFP's Cooperative Agreement with JIFSAN.

Shrimp Mandate International Training Programs - Good Aquacultural Practices (GAqP) Presentation Project

In compliance with the 2021 Appropriations Act, Congress mandated the FDA to consider options for regulating the import of shrimp into the United States with a focus on the three largest exporting countries by volume of shrimp: India, Indonesia, and Ecuador. In supporting FDA, JIFSAN has provided various training programs for the harvesting and handling of seafood, to establish good aquaculture practices, and to ensure the safety of imported foods regulated by the FDA. Jointly, JIFSAN has conducted international training courses on Good Aquaculture Practices (GAqP), Seafood HACCP, Water Sampling, and Sensory Decomposition.

In order to enhance the effectiveness and relevance of the GAqP training, particularly for international audiences, JIFSAN also conducted a comprehensive review and update of its

current GAqP training materials. JIFSAN contracted with PMG Learning Solutions, a professional content provider, with expertise in instructional design and adult learning, to update and standardize the GAqP training materials. A team of JIFSAN trainers, consultants**,** and FDA subject matter experts worked with PMG to produce an off-the-shelf ready product for future trainers to conduct GAqP training programs. This project kicked off in October 2024 with three phases and was completed in June 2025. The initial phase encompassed a comprehensive systematic review and substantive updating of existing training presentation materials to ensure alignment with current GAqP standards and regulatory requirements. The second phase involved the development and creation of a specialized GAqP train-the-trainer presentation modules designed to equip instructors with the necessary tools and subject matter expertise to effectively deliver GAqP training content to diverse audiences. The final implementation phase focused on the design and completion of a comprehensive assessment instrument specifically developed to systematically evaluate both the educational efficacy of the training course content and the instructional performance of certified trainers. JIFSAN is also exploring the possibility of creating a video component to complement and enhance the training experience. This program was funded through HFP's Cooperative Agreement with JIFSAN.

Undergraduate Student Internship Program

JIFSAN's undergraduate internship program enables UMD students to enhance their knowledge of and experience in science, particularly in the regulatory environment. FDA scientists, who serve as the students' mentors, also highly appreciate the contributions of these talented young people to the Human Foods Program's research and science program. The 2024-25 projects ranged in area and focus (biological sciences, chemistry, nutritional sciences, public health, as well as media and communications) and produced several presentations and posters at scientific conferences.

The 2024-25 cohort was comprised of 24 undergraduate students that collectively contributed ~13,000 hours of time and effort across the program for the academic year. Notable intern accomplishments included but were not limited to poster presentations at the 2024 International Association for Food Protection (IAFP) conference in Long Beach, CA, the Association of Official Analytical Collaboration (AOAC) 13th Annual Meeting and Exposition in Baltimore, MD, the 2024 FDA Foods Program Regulatory Science Conference in College Park, MD, the 2024 Celebrating OARSA's Regulatory Research meeting in College Park, MD, and the 2024 FDA Annual Student Scientific Research Day in Silver Spring, MD. In addition, interns presented their research at the 2024 Annual JIFSAN Spring Orals in College Park, MD, and were co-authors on multiple publications in scientific journals including the Journal of Food Protection and Drug Testing and Analysis. This program was funded through HFP's Cooperative Agreement with JIFSAN. In addition to HFP funding, the Rosina Barone JIFSAN Educational

Fund supported two paid internships for the 2024-25 year, allowing two continuing interns to participate in their projects for a second year. This scholarship fund provides support for educational, experiential, and professional opportunities for UMD students including paid undergraduate internships, training programs including risk analysis or laboratory training, and research opportunities for undergraduates and graduates at FDA facilities.

National Milk Drug Residue Database (NMDRD)

The database, which has been in place since 1991, is an effort of FDA and the National Conference on Interstate Milk Shipments to improve control over drug residues in the milk supply and to be able to demonstrate the amount and results of collective industry and government milk testing. The database serves as an important resource for regulators, the U.S. dairy industry, and consumers by providing insights into trends and the prevalence of animal drug residues in the national milk supply. The database includes information on the source of samples, when analyses are conducted, numbers of analyses, methods used, and results by drug and methods. The data are recorded, summarized, and distributed to interested parties in the form of an annual report. Additionally, the NMDRD offers comprehensive summary data that supports international reporting efforts on the monitoring of Beta-lactam and other drug residues. This information is essential for maintaining and expanding U.S. dairy export capabilities. Without these testing data, the industry risks losing access to international markets. The NMDRD has helped strengthen global trade relationships by providing assurance to foreign regulators, and as international audits continue, the database remains indispensable for sustaining milk and dairy product exports.

In 2023, JIFSAN took on the critical responsibility of managing and maintaining the NMDRD. This role includes ensuring the quality, accuracy, and integrity of data collected from industry and state agencies on drug residue testing in milk samples. JIFSAN's efforts led to all 50 states, Puerto Rico, and two Third Party Certifiers authorized under the International Certification Program, submitting test results in 2024. The database recorded 3,668,308 samples of cow's milk and pasteurized milk products and the results showed a continued downward trend of positive test results in the 2024 period. JIFSAN also updated the test kit list by changing the status of CHARM ROSA Gentamicin kits from Active to Not Active. Active status indicates that the manufacturer is still producing and supporting the test kit. When a kit has a Not Active status, it is no longer available and should not be used. In December 2024, JIFSAN updated the NMDRD website and produced an annual report for the FDA, the National Conference on Interstate Milk Shipments (NCIMS), dairy industry stakeholders and Antibiotic Drug Residue test kit manufacturers. JIFSAN also provided quarterly updates on delinquent reporting. JIFSAN's work in maintaining data accuracy, broadening participation, and delivering timely updates reinforces the continued success and credibility of this vital food safety database. This program was funded through HFP's Cooperative Agreement with JIFSAN.

The JIFSAN Advisory Council (AC) Annual Symposium and Webinars

JIFSAN organized and held a webinar entitled "Ultra Processed Foods" on August 21, 2024, with an attendance of 372 participants. With a global public health focus on addressing obesity and cardiometabolic and other chronic health conditions, an emphasis has been placed on promoting healthy diets, and there are a number of questions that need to be investigated in regard to ultra-processed foods. The webinar addressed this important topic and provided two perspectives on the function of processing in food manufacturing and ongoing research to address the relationship between ultra-processed foods and human health.

On October 29-30, 2024, the JIFSAN Advisory Council held its Annual Symposium entitled "Risk Communication: Science vs. Perception" in College Park, MD. This symposium garnered an attendance of 107 participants. This symposium was designed for individuals with a professional or personal interest in food safety and risk communication. The event explored critical issues at the intersection of science, public perception, and effective communication, topics that are increasingly important in today's information landscape. The presentations discussed how misinformation and disinformation spreads in the era of social media and the challenges of communicating science in this era. The symposium also included an interactive workshop-type format where communication experts and symposium participants discussed communication strategies and recommendations to address misinformation.

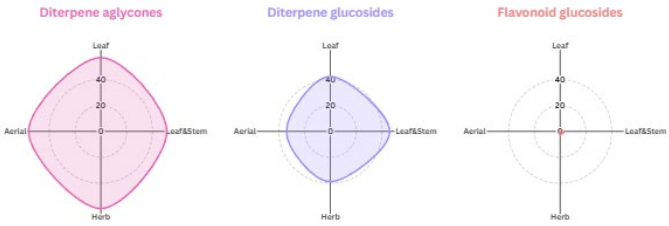
On June 25, 2025, JIFSAN organized and held a webinar entitled, "From Basics to Breakthroughs: What Do We Mean by AI, and How Is AI Changing Food Safety" with an attendance of 350 participants. Artificial Intelligence is reshaping the future of our society, including numerous possible applications within the food sector. The webinar discussed different AI technologies (e.g., machine learning, natural language processing, robotics and provide a foundation for understanding AI), which is a precursor to evaluating the possibilities, limitations, and considerations for AI applications. This AI overview was followed by a presentation that shared a real-life example of how AI is being used for signal detection and surveillance of food safety risks at the FDA. This webinar provided some AI basics along with a case example that helped us think about AI applications in the food and nutrition space. The webinars and symposium were funded by the JIFSAN Advisory Council.

National Center for Natural Products Research (NCNPR) - University of Mississippi, Oxford

The National Center for Natural Products Research (NCNPR) was established in 2001 at the University of Mississippi, Oxford, to assist the FDA with the regulatory framework that was created for dietary supplements under the Dietary Supplement Health & Education Act of 1994 (DSHEA). The cooperative research, education, and outreach programs developed by the NCNPR address scientific issues related to the safety of botanical dietary supplements (BDS) and botanical ingredients and complement the diverse activities of both the public and private sectors. Specifically, the NCNPR: 1) assists in the identification and development of a list of BDS and botanical ingredients, based on safety concerns, trends, and knowledge of botanicals being marketed in the U.S., to prioritize further research; 2) acquires, validates, and characterizes authenticated reference materials, including raw and processed plant materials and purified natural products of relevance to the FDA, for evaluation of their safety; 3) exchanges technical and scientific information, analytical methods, and reference material with the FDA scientists and other stakeholders; 4) collaborates with the FDA scientists in research areas of mutual interest; and, 5) coordinates scientific workshops and conferences on BDS-related topics of public health relevance to address high priority science and research needs.

NCNPR Director - Dr. Ikhlas A. Khan
NCNPR Assistant Director - Dr. Amar G. Chittiboyina
HFP Project Officer - Dr. Gregory O. Noonan

Analytical Investigations to Assure the Overall Quality of BDS



The extraction, purification, and characterization of standard phytochemical compounds from authentic botanical extracts are vital for developing analytical methods, measuring individual components within those extracts, and creating unique analytical fingerprints to verify the authenticity, quality, and safety of various dietary supplements. Having authenticated reference materials for botanicals is the first step in developing analytical techniques for identifying and quantifying botanical products. The NCNPR has successfully established formal agreements with several international academic and government institutions from Southeast Asia, China, Europe, South Africa, and Central and South America. Additionally, NCNPR has established strong relationships with potential partners to obtain relevant, authenticated herbs and spices to meet the COE's botanical research needs.

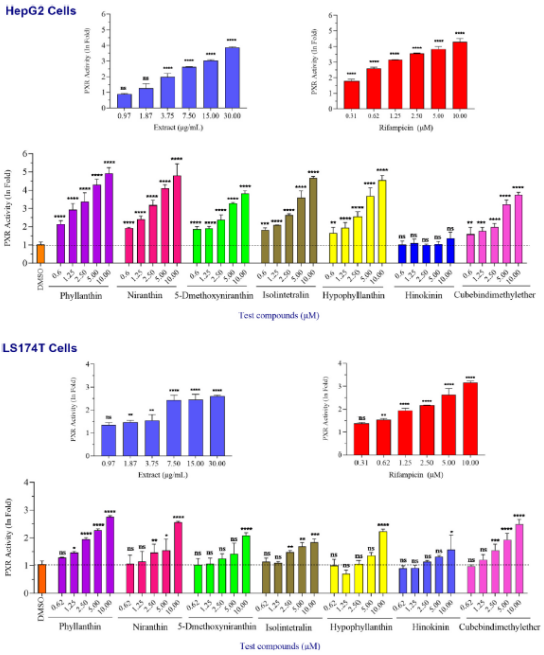
The NCNPR continues its focus on developing analytical techniques to both verify reported botanical materials and identify unknown ones. For example, to better assess the quality of *Andrographis paniculata*, purported to be an immune boosting herb, the COE team created a

comprehensive testing method. Unlike traditional methods that depend on a single quality marker, this new approach uses ultra-high performance liquid chromatography coupled with a photodiode array detector (UHPLC-PDA) and liquid chromatography/quadrupole time-of-flight mass spectrometry (LC-QToF-MS) to analyze three main classes of compounds: phenolic acids, diterpenoid lactones, and flavonoid glycosides. When tested on various commercial supplements, the new method revealed that over 25% of the products failed to meet official pharmacopeia standards. Analysis showed substantial variation in the levels of key compounds, with some products containing very low amounts of diterpene lactones (common quality marker compounds). Additionally, the study found a major discrepancy in the amount of andrographolide, a standard quality marker, between raw plant material and finished supplements. A specific finding was that some capsules showed signs of dehydration caused by processing, which reduced the amount of the active compound, andrographolide. These results highlight the limitations of relying on a single marker for quality assurance and emphasize the need for comprehensive testing to ensure the quality of *Andrographis paniculata* supplements.

Growing consumer demand and changing regulations have fueled a rapidly expanding market for psychedelic mushroom products in some U.S. states. The introduction of new edible forms, such as gummies and chocolates, presents significant challenges for ensuring product quality and safety. The NCNPR team developed an LC-QToF-MS method to detect five key mycochemicals; ibotenic acid, muscimol, muscarine, psilocin, and psilocybin to address potential quality issues associated with these consumer products. Testing of 27 commercial items made from psychedelic mushrooms including gummies, chocolates, capsules, tablets, and powders revealed widespread inconsistencies. For instance, 11 of 14 gummies claiming to contain *Amanita muscaria* extracts lacked the main compound ibotenic acid, and one gummy labeled “no psilocybin” actually contained both psilocin and psilocybin. Additionally, five products contained none of the target compounds. These findings highlight the need for uniform product standards to ensure product quality and consumer safety. The new testing method offers a reliable means of evaluating the overall quality of such products.

After the recent tara flour health scare, potentially linked to the toxic compound baikiain, ensuring the quality and safety of related products is more critical than ever. To proactively combat the risk of unintentional exposure to toxic amino acids, the NCNPR team developed a comprehensive analytical method. Using LC-MS, the team precisely mapped the distribution of both toxic non-proteinogenic amino acids (NPAAs) and beneficial proteinogenic amino acids (PAAs) in various commonly consumed legumes. At least 7 to 14 NPAAs were identified in every single legume sample tested, a discovery that underscores the need for not only vigilant quality control but also highlights assessing the safety levels of such analytes in various plant protein-based consumer products. By combining this advanced LC-MS technique with other methods, such as gel electrophoresis, this new approach offers a vital tool to help prevent future food safety incidents and protect consumers. The NCNPR has also been working to develop reliable methods for authenticating noble kava (*Piper methysticum*) and distinguishing it from two commonly substituted species, *P. auritum* and *P. excelsum*. This research was funded through HFP’s Cooperative Agreement with the NCNPR.

Adverse Effects of BDS – Modulation of Drug-Metabolizing Enzymes and Transporters (DMET) and Implications to Herb-Drug Interactions



The increasing co-administration of BDS with conventional medications presents a public health concern due to potential herb-drug interactions (HDIs). These interactions can disrupt the pharmacokinetics of pharmaceutical drugs, leading to altered efficacy or increased toxicity. As part of our long-standing commitment to ensure the safety of botanical supplements, the NCNPR investigated the HDIs potential for *Phyllanthus amarus*, a widely used botanical, by examining its effects on key drug-metabolizing enzymes and transporters.

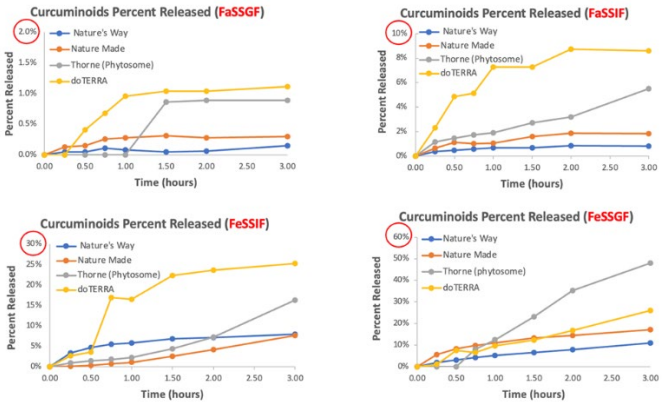
Using a combination of *in vitro* assays, the team evaluated how *P. amarus* extract and its constituent lignans modulate xenobiotic-sensing receptors and their downstream genes. The findings revealed a complex and paradoxical effect on the cytochrome P450 (CYP) enzyme system. The extract and its lignans were found to activate both the aryl hydrocarbon (AhR) and pregnane X (PXR) receptors, leading to increased mRNA expression of CYP1A2 and CYP3A4, respectively. However, while elevated CYP1A2 mRNA correlated with increased enzyme activity, CYP3A4 enzyme activity was paradoxically inhibited. Given that CYP3A4 is responsible for metabolizing over 50% of prescription drugs, this dual effect of gene induction and enzyme inhibition suggests that *P. amarus* consumption could significantly alter the pharmacokinetics of co-administered medications. These preclinical findings underscore the critical need for further clinical investigation to establish the real-world relevance of these potential HDIs and inform safe usage guidelines for consumers. This research was funded through HFP's Cooperative Agreement with the NCNPR.

Collaborating with FDA Scientists in Research Areas of Mutual Interest

Emerging Cannabinoids in various consumer products: The 2018 Farm Bill's legalization of hemp has led to a chaotic and risky market. Driven by economic pressure, manufacturers are creating a flood of mislabeled and unregulated cannabis products, including synthetic cannabinoids and high potency vapes with unknown safety profiles. This unchecked innovation involving emerging cannabinoids poses a growing public health risk. To address the chemical composition of some cannabis products, the NCNPR, in collaboration with FDA's Center for Drug Evaluation and Research (CDER), has conducted a large-scale market analysis, acquiring and analyzing over 250 cannabis products using an ultra-high performance liquid chromatography with ultraviolet-visible detector mass spectrometry (UHPLC-UV-MS) analytical method. Our initial findings reveal that many vapes are already laced with unlisted

compounds such as cannabinol (CBN), synthetic hexahydrocannabinols (HHCs), and delta-8 tetrahydrocannabinol (THC). This survey is the first critical step toward understanding what is truly in these products and ensuring consumer safety. After further validation and cross-confirmation testing, these results will be disseminated through scientific channels.

Dissolution and disintegration of supplement products: Disintegration and dissolution of BDS are often overlooked in clinical studies, risking study failure and wasted resources. To address this, our team, in collaboration with FDA's CDER Botanical Review Team, evaluated four turmeric supplements in lab settings that mimic the human digestive system. We found that even products that passed standard quality tests showed significant differences in how their active compounds dissolved, with dissolution being significantly higher when a "meal" was simulated. This suggests that consuming turmeric supplements with fatty foods may significantly enhance their absorption. Nevertheless, our research highlights the importance of these cost-effective, preclinical tests. By incorporating simple, proactive disintegration and dissolution profiles of supplements, better-designed clinical studies can be conducted to predict the behavior of supplements, ultimately ensuring the safety and effectiveness of botanical products. This research was funded through HFP's Cooperative Agreement with the NCNPR.



International Conference on the Science of Botanicals (ICSB)

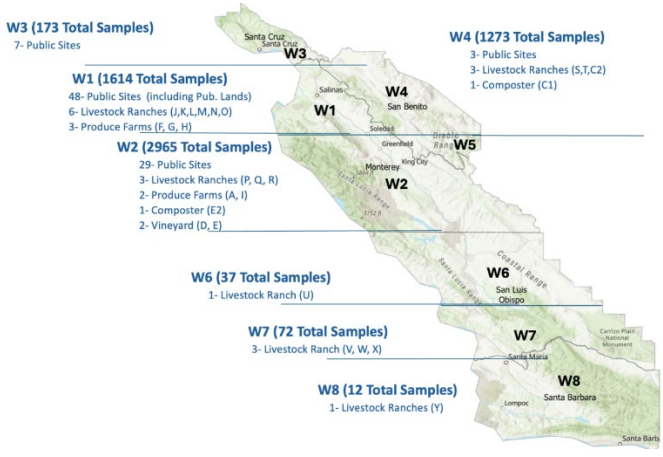
From April 7 to 10, 2025, the 23rd ICSB was held jointly with the 24th International Congress of the International Society for Ethnopharmacology in Oxford, Mississippi. This landmark event convened a global audience from industry, academia, and regulatory agencies to explore the multifaceted world of medicinal and aromatic plants. The comprehensive program covered a range of critical topics, including market trends, quality control, regulatory perspectives from the FDA, and the latest research on traditional medicine and its pharmacological effects. Co-sponsored by leading international institutions from Europe and Asia, the conference highlighted the NCNPR's long-standing history of fostering strategic global partnerships, which have led to the establishment of key research centers and continue to advance the scientific study of botanicals.

Western Center for Food Safety (WCFS) - University of California, Davis

The Western Center for Food Safety (WCFS) was established in 2008 at the University of California, Davis, to improve food safety and reduce microbial risk associated with production agriculture. Activities conducted by the WCFS support the development of scientifically validated good agricultural practices (GAPs) for mitigating food safety risks at the production, harvest and postharvest (versus processing) level. In addition to research leading to actionable GAPs, the Center provides education, outreach, and technical assistance to a broad array of food safety stakeholders (state and federal regulators, industry, agricultural consultants, etc.). WCFS' research portfolio has included projects related to identifying the source(s) of microbial contamination of food commodities such as leafy greens, tree nuts, fruit, and foods of animal origin. In addition, our projects have focused on development of GAPs to prevent intrusion of microbial pathogens into the agricultural production environment through contaminated air, water, soil, including wildlife intrusion. WCFS collaborates extensively with other academic institutions to increase understanding of GAPs across varying agro-ecological landscapes. WCFS' research and outreach efforts assist the FDA HFP and the food safety community in the implementation of FSMA provisions and regulations.

WCFS Principal Investigators – Dr. Robert Atwill and Dr. Linda J. Harris
HFP Project Officers - Dr. Samir Assar

Longitudinal Study to Investigate the Ecology and Epidemiology of Human Foodborne Pathogens in the California Central Coast Production Region (California Longitudinal Study [CALS])



Between 2009 and 2018, FDA and the Centers for Disease Control and Prevention (CDC) identified 40 foodborne outbreaks of Shiga toxin-producing *Escherichia coli* (STEC) infections in the U.S. with a confirmed or suspected link to leafy greens. In the winter of 2019, there were three *E. coli* O157:H7 foodborne illness outbreaks with 167, 11, and 10 cases associated with consumption of leafy greens from the Salinas Valley region of California. The California Longitudinal Study (CALS) was initiated in 2020, following publication of the FDA Leafy Greens STEC Action Plan. The longitudinal study is a multi-year, "shoulder-to-shoulder" partnership between FDA HFP, WCFS, the California Department of Food and Agriculture (CDFA), and numerous California agriculture industry partners. CALS is an environmental microbiology study that applies adaptive research strategies

to address the outbreaks of *E. coli* O157:H7 and other STEC associated with romaine lettuce and other leafy green crops grown along the central California coast. This approach serves as a model to perform research in a large geographic area to better understand underlying causes of contamination in the production environment. The major goals of the CALS project are to better understand the key sources of *E. coli* O157:H7 and other STEC for produce contamination in the greater Salinas Valley region, how these bacterial pathogens persist and are transmitted between key pathogen sources and produce commodities, and to use this new knowledge to develop recommendations for intervention strategies that can reduce *E. coli* O157:H7 and other STEC contamination of produce throughout this critical agricultural region.

To accomplish these goals, scientists and staff from the WCFS conducted several years of extensive longitudinal sampling throughout the Salinas Valley region at numerous private property agricultural operations (e.g., commercial produce farms, vineyards, composting facilities, livestock ranches) and publicly accessible sites. This sampling effort was developed in close collaboration with HFP scientists who are partners on this CALS project, with online meetings occurring approximately every two weeks to optimize the sampling effort. This network of surveillance locations is located throughout the Salinas Valley region, extending East and West to both sides of the Valley, and North to South of the Valley to capture the wide range of farming activities and management practices common to this area. The data generated from this network of sites will help characterize how the risk of bacterial contamination of produce is associated with proximity to adjacent land-use practices and potential pathogen sources such as livestock ranches and wildlife corridors. In addition, data will be generated to quantify the occurrence of *E. coli* O157:H7 and other STEC in matrices such as airborne fugitive dust, irrigation tail-water, manure-based composts, livestock feces, river sediment, and wildlife scat. Field samples that were collected from July 2020 to May 2025, from which a bank of *E. coli* O157:H7 (270 isolates), STEC (1,200 isolates), and *Salmonella* (642 isolates) have been cultured by WCFS and subsequently the whole genomes were sequenced by HFP scientists. In addition, the microbiome of targeted sample matrices was characterized by HFP scientists to better understand how matrix composition, environmental factors, climate, sample location within the valley, and other multi-scale factors collectively influence the likelihood and composition of *E. coli* O157:H7 and STEC isolates found in these agricultural samples. These metagenomic analyses are a key tool being used in CALS. Unlike traditional bacterial culture methodology that detects one target, metagenomics involves broad analysis of DNA from a sample to detect membership in a microbial community. This technology may provide a more informed understanding of the water, sediment, soil, and air microbiomes, including how the microbiomes and *E. coli* populations compare across the region and temporally. The data may also provide clues to how factors like adjacent land use impact microbiomes and potentially STEC presence or persistence. In preparation for statistical analysis, data from three WCFS laboratories were combined, reviewed, and cross-checked for errors. Information gaps were filled, where possible, including additional onsite measurements obtained from May through August 2025. A meeting that brought together CALS scientists from WCFS and HFP was held in College Park, MD in June 2025. In the meeting, strategies and framework for data analysis and project communication rollout were agreed upon. This research was funded through HFP's Cooperative Agreement with the WCFS.

San Joaquin Dairy STEC

Based on estimates from the U.S. Environmental Protection Agency (EPA), over 50 billion pounds of dairy manure are produced by California's dairy industry each year, with much of this organic waste material used in crop agriculture and livestock forages. The presence of Shiga toxin-producing *E. coli* (STEC) has been readily documented in dairy manure, with this STEC reservoir possibly contributing to food, water, and environmental contamination. The major goals of the Dairy STEC project are to protect food safety and public health through generating clearer insights into the STEC reservoir, genomic diversity and similarity of dairy-origin STEC in the nation's primary dairy production region. The specific objectives were to 1) assess the occurrence of *E. coli* O157 and STEC in dairy manure and 2) characterize genomic diversity of *E. coli* O157 and non-157 STEC in the nation's primary production region.

To achieve these objectives, WCFS reached out to the California dairy industry to allow fecal sampling on a range of commercial dairy farms. Despite the challenge of gaining access onto dairies due to an outbreak of highly pathogenic avian influenza, we successfully enrolled 12 new dairy farms and collected 160 composite (800 individual) fresh manure samples from throughout the San Joaquin Valley. Each composite sample was split and evaluated for the presence of *E. coli* O157 and STEC by the WCFS and a commercial lab, the Institute for Environmental Health (IEH). Based on results from the WCFS lab, the occurrence of *E. coli* O157 and STEC varied widely between farms, with an average prevalence of 69.9% for *E. coli* O157 and 42.6% for STEC. These WCFS isolates of *E. coli* O157 (n=262 isolates) and other STECs (n=115 isolates) were shipped to the IEH lab for whole-genome sequencing (WGS) to characterize the genomics of *E. coli* O157 and STEC. When the IEH lab completes the WGS and shares results, the outcome of the project will improve our understanding of the broad spatial distribution and with-dairy genomic characteristics of *E. coli* O157 and STEC in this large dairy production region. This research was funded through HFP's Cooperative Agreement with the WCFS.

Sustainable, Systems-Based Solutions for Ensuring Low-Moisture Food Safety

Work continued in the 5th year of this 5-year project. In collaboration with the Almond Board of California (ABC) technical staff, revisions to their validation guidance documents were advanced over the past year. A major focus was the *Enterococcus* guidance document which was last revised in 2014. *Enterococcus faecium* NRRL B-2354-inoculated almond kernels, prepared with a standard method (SM), are used to validate reduction of *Salmonella* during thermal

treatments. The current methods used to inoculate almonds for validation studies were reviewed and reassessed under laboratory conditions for their impact on levels of *E. faecium* and on inoculated almond drying times. Small modifications in the SM led to increased final populations of *E. faecium* on almonds with a corresponding decreased drying time and were incorporated into the revised guidance document. A meeting with ABC-recognized process authorities was held to discuss the revisions and to solicit feedback on changes to other guidance documents. In addition, a study that focused on co-inoculation of almonds was completed. Traditional laboratory-based pathogen-surrogate comparison studies often involve inoculating each organism into separate samples, which can subsequently introduce variability due to differences in food microenvironments and processing conditions. Co-inoculating pathogens and surrogates onto the same sample minimizes this variability by subjecting both microorganisms to identical conditions. This study evaluated a co-inoculation method for comparing the thermal resistance of *Salmonella enterica* and *Enterococcus faecium* on almonds. Selective media were validated for accurate differentiation and enumeration of co-inoculated wild-type or rifampin-resistant *Salmonella* and *E. faecium* on almonds. The media reliably distinguished and quantified each organism, with no cross-recovery observed. Reductions in *Salmonella* were not significantly different between wild-type and rifampin-resistant strains, nor between CHROMagar *Salmonella* and tryptic soy agar supplemented with rifampin at 50 µg/mL ($P > 0.05$). *E. faecium* demonstrated similar or greater thermal resistance compared to co-inoculated *Salmonella*, supporting its use as a surrogate during dry heat treatment of almonds. The findings support the utility of co-inoculation for laboratory-based pathogen-surrogate comparison studies. This research was funded by a grant from the USDA National Institute of Food and Agriculture, Agriculture and Food Research Initiative, Sustainable Agricultural Systems.

Integrating Cover Crops and Sheep Grazing in Almond Orchards

Integrated crop-livestock systems (ICLS), such as grazing sheep in orchards, present multifaceted opportunities to enhance the sustainability of agriculture. Integrated systems increase land use efficiency, producing multiple outputs (e.g. wool, lamb, and almonds) on land that might otherwise produce a single agricultural product. Ruminants can enhance nutrient cycling efficiency by transforming vegetation into nutrient-rich manure, which may reduce fertilizer needs. Strategic grazing can manage weeds, reducing the need for chemical herbicides, and grazing can replace some mowing practices, reducing gasoline- and diesel-powered equipment use. These characteristics of ICLS align with growing interest in regenerative agricultural systems and may present solutions to almond growers, who seek innovative ways to reduce rising input costs. However, there are many perceived limitations to adoption of integrated systems, including the risk of introducing enteric foodborne pathogens, damaging trees and irrigation lines, and adapting important orchard management practices. Livestock can be sources of pathogens associated with food safety outbreaks in various agricultural commodities.

In almond orchards, there is no data on fecal pathogen prevalence in the soil post-grazing from sheep, which if occurring would off-set the benefits of using sheep as an alternative to chemical herbicides. With respect to field sampling during the 2 years at two different orchards in the San

Joaquin Valley, California, four of the 300 soil samples collected for this project were positive for STEC and three soil sample tested positive for *E. coli* O157:H7. This research was funded by a 2023 Western SARE Professional and Producer Grant.

Democratizing Data: A Low-Cost, Real-Time Monitoring Network for Alabama

This newly funded project will dramatically increase the collection and availability of water quality data —biological and physical/chemical—within currently impaired waterways of coastal Alabama. We will develop an adaptable, low-cost, real-time monitoring network that can be easily adopted and expanded upon by multiple stakeholder groups. The proposed network will be public-facing and will be paired with water sampling efforts for indicator bacteria analysis at multiple locations throughout the Mobile Bay watershed in locations where data are currently lacking, and where coastal communities have identified a need for improved monitoring. This research is funded by a grant from the EPA Gulf of Mexico Division (GMD).

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