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HUMAN FOODS PROGRAM

CENTERS OF EXCELLENCE ANNUAL REPORT

WCFS UC DAVIS

JOINT INSTITUTE for FOOD SAFETY AND APPLIED NUTRITION — UNIVERSITY of MARYLAND

THE UNIVERSITY OF MISSISSIPPI
National Center for Natural Products Research

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH

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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 Centers of Excellence (COE) program is one of several approaches HFP uses to collaborate with external partners to fulfill its public health mission. The 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. 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 COEs; 1) the Western Center for Food Safety (WCFS) at the University of California, Davis, 2) the Institute for Food Safety and Health (IFSH)/National Center for Food Safety and Technology (NCFST) at the Illinois Institute of Technology (Illinois Tech), 3) the National Center for Natural Products Research (NCNPR) at the University of Mississippi, Oxford, and 4) the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) at the University of Maryland, College Park.

This report highlights selected research and capacity building efforts conducted by the COEs during the 2023-2024 Cooperative Agreement budget period.

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 address the development of approaches and data that are critical to understanding the risks associated with the interface between production agriculture and food protection. This information is used to develop scientifically validated "best practices" for mitigating risks at the production, harvest and postharvest (versus processing) level. In addition to research, the Center provides education, outreach, and technical assistance to food safety stakeholders. The WCFS' research portfolio includes projects related to exploring the sources of microbial contamination on fresh produce and nuts, including agricultural water and soil, as well as collaborations with other academic institutions to increase our understanding of best agricultural practices across varying agro-ecological landscapes. The WCFS' research and outreach efforts assist 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
WCFS Program Manager – Dr. Michele Jay-Russell
HFP Project Officers - Dr. Samir Assar and Heather Brown, Project Manager, GWCPM

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 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 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, 1) to better understand the key sources of *E. coli* O157:H7 and STEC for produce contamination in the greater Salinas Valley region, 2) how these bacterial pathogens persist and are transmitted between key pathogen sources and produce commodities, and 3) to use this new knowledge to begin developing recommendations for

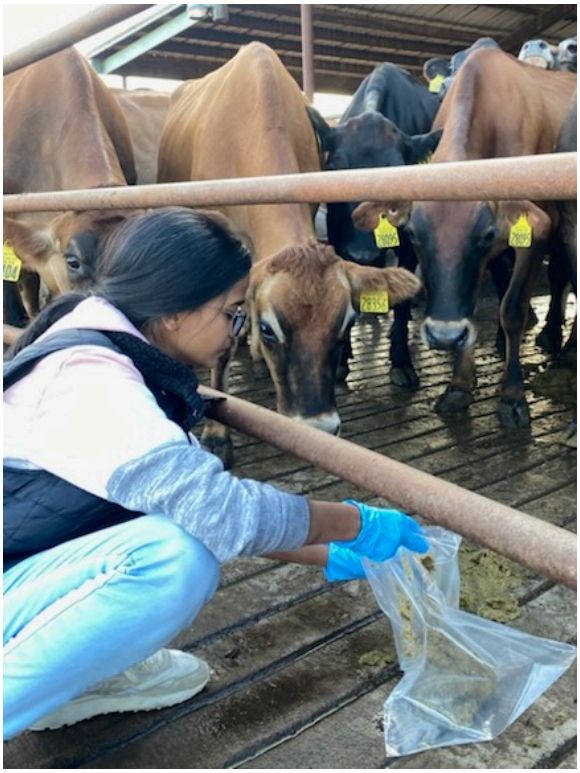
intervention strategies and good agricultural practices that can reduce *E. coli* O157:H7 and STEC contamination of produce throughout this critical agricultural region. To accomplish these goals during the fourth year of the study (fiscal year 2023-24), scientists and staff from three laboratories at the Western Center for Produce Safety continued extensive longitudinal sampling throughout the Salinas Valley region at a diverse portfolio of private property agricultural operations (e.g., commercial produce farms, vineyards, composting facility, livestock ranches) and publicly accessible sites. This sampling effort was developed in close collaboration and input from multiple HFP scientists who are partners on this CALS project. This extensive network of sampling sites is allowing the CALS project to better characterize how the risk of bacterial contamination of produce is associated with proximity to land-use practices and potential pathogen sources such as ranches and riparian corridors, how proximity to the Salinas River may influence food safety risks, and relative occurrence of *E. coli* O157:H7 and STEC in matrices such as airborne fugitive dust, irrigation tail-water, manure-based composts, livestock feces, river sediment, and wildlife scat.

A large diversity of field samples was collected during fiscal year 2023-24, from which a rich bank of *E. coli* O157:H7 and STEC isolates have been cultured and are in the process of being whole genome sequenced by HFP scientists. In addition, the microbiome of targeted sample matrices is being 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, abiotic and biotic 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 whole 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 impacts the microbiomes and potentially STEC presence or persistence. This research was funded through HFP's Cooperative Agreement with the WCFS.

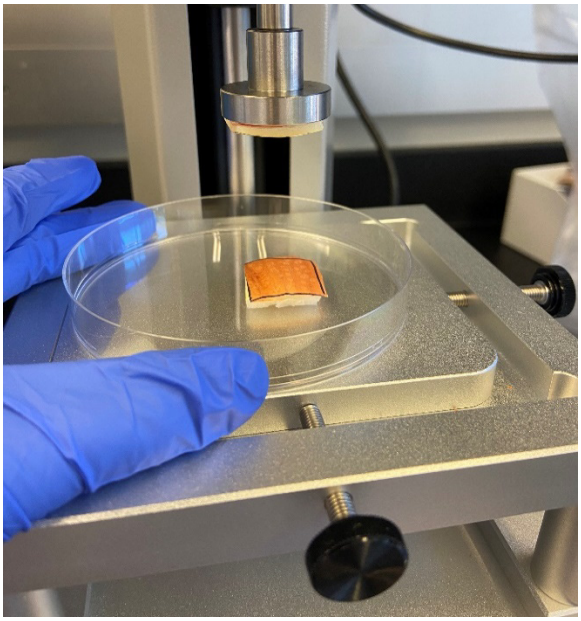
San Joaquin Dairy STEC

Based on estimates from 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* (STECs) have been readily documented in dairy manure and this STEC reservoir could contribute to food, waterborne, and environmental contamination. The major goals of the Dairy STEC project were to protect food safety and public health through generating clearer insights into the STEC reservoir and genomic diversity of dairy-origin STEC in the nation's primary dairy production region. The specific objectives are to, 1) assess the occurrence of *E. coli* O157 and STEC in dairy manure and 2) characterize genomics structure and diversity of *E. coli* O157 and non-157 STEC in the nation's primary production region.



To achieve these objectives, during the 2023-2024 fiscal year, the team reached out to the California dairy industries and advocated the significance of the dairy STEC research. Subsequently, 14 dairy farms in the San Joaquin Valley were successfully enrolled based on the farm owners/managers willingness to participate in the study. Ten fresh manure samples (composites of five individual samples) were collected from each enrolled farm, in total 140 composite (700 individual) manure samples. Per suggestions from HFP, each composite sample was split between the WCFS lab and a commercial lab (IEH) to evaluate and improve the efficacy of recovering O157 and STEC from samples in both labs. Based on the preliminary results at the WCFS lab, the occurrence of O157 and STEC differed among enrolled farms with an average prevalence of approximately 38% of O157 and 44% of STEC. Given the unique capacities and resources of enrolling dairy farms and collecting manure samples in this primary dairy production region, FDA and IEH requested that WCFS collect extra manure samples to support the FDA's contract with IEH on foodborne pathogens research. To satisfy this request, approximately 130 additional individual manure samples were collected and shipped to IEH for testing for the presence of *Salmonella* and *E. coli.* This research was funded through HFP's Cooperative Agreement with the WCFS.

Cross-Contamination Risks in Dry Environments



Cross-contamination during the handling and processing of fresh produce is one of the key factors that can lead to an outbreak of foodborne illness. Despite significant progress in understanding cross-contamination risk factors during wet handing and processing of fresh produce, there remains gaps in knowledge regarding cross-contamination risk factors in dry environments. The survival of *Salmonella enterica* and *Enterococcus faecium* on food contact surfaces under dry environmental conditions was evaluated. The results showed that the presence of produce residues, such as onion juice extract, prolonged bacterial survival on food contact surfaces. Transfer rates of bacteria during simulated dry handling of model fresh produce (e.g.,

onions and stone fruits) were also quantified. These results showed that transfer rates significantly increased in the presence of onion or peach juices or fruit waxes. However, transfer rates from conveyor to onion, nectarine, or peaches did not differ significantly. Other factors such as bacterial species, food contact material, direction of transfer, and inoculation levels had varying influence on transfer rates. Subsequently, a risk model was developed incorporating laboratory-generated data to assess cross-contamination in dry environments.

The outcomes of this project address critical gaps in knowledge by providing information on identification of bacterial survival on food contact surfaces and characterization of risk factors of bacterial transfer to address food safety challenges in dry handling and processing of fresh produce. The results of this project also highlight the needs of development cleaning and sanitation strategies for dry handling and processing of fresh produce to ensure the food safety. This research was funded by the Center for Produce Safety.

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

Work continued in the fourth year of this five-year project with two separate research thrusts. There have been three reported salmonellosis outbreaks in North America linked to consumption of cashew cheese analogs that were prepared from soaked and fermented cashews. To better understand the risks, the behavior of *Salmonella* was evaluated during fermentation of cashews. Rifampin-resistant *Salmonella*-inoculated cashews (1 to 2 log CFU/g) were soaked in water at 4°C for 24 ± 1 h, drained, and then blended with additional water. *Salmonella*-inoculated or uninoculated cashews with or without added commercial *Lactococcus lactis* starter culture (LAB), and with LAB and NaCl (0.8% and 1.6% w/w), citric acid (0.4% w/w), or a combination of NaCl and citric acid, were held at 24 ± 1 °C for up to 72 h. When LAB was present, aerobic plate counts increased from ~8 log CFU/g to ~9 log CFU/g after 24 h. The pH decreased from an initial pH ~6 to pH 4.5–5.0 at 24 h in the presence of LAB or at 48 h in the absence of LAB. The presence of LAB significantly impacted populations of *Salmonella*. After 24 h, populations of *Salmonella* increased by ~5 log in the absence of LAB and by <2 log in the presence of LAB, with or without added NaCl. There was no significant difference in *Salmonella* populations between the treatments with LAB alone and the treatments with LAB in combination with added NaCl or citric acid. These data provide information to support guidance for commercial preparation of these products and emphasize the need to consider a range of control measures for their preparation.

In collaboration with the Almond Board of California technical staff, revisions to their validation guidance documents were advanced over the past year. A major focus was on 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 were reviewed and reassessed under laboratory conditions for their impact on levels of *E. faecium* and on inoculated almond drying times. Addition of yeast extract (YE) to tryptic soy agar (TSA) or broth (TSB), incubation times, volume for seeding agar lawns, or inoculum volume per 400 g of almonds were assessed. Compared to the SM, *E. faecium* populations in the inoculum suspension were not significantly

($P \geq 0.05$) impacted by addition of YE to either broth or agar or by the amount of culture used to seed bacterial lawns but were significantly ($P < 0.05$) larger when the incubation time was increased to 24 h. Populations of *E. faecium* on dried inoculated almonds were significantly lower at 4 and 10 but not at 15 mL of added inoculum and a significant 24-h reduction in drying time was achieved. Small modifications in the SM lead to increased final populations of *E. faecium* on almonds with a corresponding decreased drying time and will be incorporated into the revised guidance document. This research was funded by the U.S. Department of Agriculture – NIFA AFRI SAS.

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 2024 at two different orchards in the San Joaquin Valley, California, two of the 150 soil samples collected for this project were positive for STEC and one soil sample tested positive for *E. coli* O157:H7. All soil samples positive for these bacterial pathogens were from grazed sections of the orchards and no positives were from the ungrazed control sections of the orchards. A second year of soil sampling will occur during 2025, which will allow the project to further assess the association between sheep grazing within almond orchards and the occurrence of these bacterial pathogens on the surface of soil. This research was funded through a 2023 Western SARE Professional and Producer Grant.

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

The National Center for Food Safety and Technology (NCFST) was established in 1988 at the Illinois Institute of Technology's (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, and the Center for Specialty Programs. IFSH also coordinates 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 (FSVP), Intentional Adulteration, and Sprout Safety. The FSPCA also provides a Technical Assistance Network (TAN) 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

Factors Affecting *Salmonella* Inactivation on Apples During Hot Air Drying

Drying fruits has long been employed as a method to prolong their shelf life by reducing water activity (a_w), which inhibits the growth of microorganisms. While some drying methods prioritize expediting moisture removal from the fruit, the microbiological food safety requirements mandated by the Food Safety and Modernization Act were not always given top priority during the design phase. Research has indicated that a low moisture environment leads to increased thermal resistance in pathogens. This highlights the potential risks of foodborne illnesses associated with the drying process, as it involves the creation of a low-moisture environment through thermal treatment. The objective of this study is to examine the reduction in *Salmonella* spp. during hot air apple drying under various temperatures, air velocities, and drying bed depths. Additionally, we aim to explore the correlation between apple a_w and *Salmonella* spp. inactivation.

A six-strain *Salmonella* cocktail (Agona 447967, Tennessee K4643, Montevideo 488275, Mbandaka 698538, Enteritidis PT30 ATCC BAA-1045, Reading Moff180418) was harvested from lawns cultured on tryptic soy agar with 0.6% yeast extract (TSAYE) and inoculated onto Gala apple cubes (6.40 mm) at 9.41±0.21 log CFU/4 cubes. Inoculated apple cubes were dried at

low (L), medium (M), and high (H) conditions for temperature (T; 88, 104, 120°C), bed depth (B; 5.1, 8.9, 12.7 cm), and air velocity (A; 25, 37.5, 50.0%) respectively utilizing a Box Behnken Design. A total of 13 drying conditions were assessed. *Salmonella*-inoculated apple cubes were collected at various time points (n=6), measured for water activity, and *Salmonella* counts enumerated on modified TSAYE.

This study showed that the water activity of the apple cubes during drying could be used as a predictor for *Salmonella* inactivation under tested drying conditions. A 5-log *Salmonella* reduction was not achieved in any tested conditions on intermediate moisture (0.6 a_w) apple cubes. Drying apples with higher temperatures, higher airflow, and lower bed depth could lead to higher *Salmonella* inactivation under the conditions tested. A beneficial effect of decreasing bed depth on microbial inactivation is more pronounced at certain airflow rates. Optimizing these two factors together could improve *Salmonella* inactivation efficiency.

This work was supported by the Agriculture and Food Research Initiative, Sustainable Agricultural Systems Program Grant from the USDA National Institute of Food and Agriculture and in part through HFP's Cooperative Agreement with IFSH and the DFPST operating budget.

Efficacy of Dry-heat Treatment in Reducing *Salmonella* and *E. coli* O157:H7 Populations on Sprout Seeds

The Produce Safety Rule requires that seeds used to grow sprouts be treated to reduce pathogens. Treatments may be applied at sprout operations or by seed suppliers. Numerous studies have been performed in search of effective seed treatments. Most of these studies focused on treatments applicable to sprout growers. Very few have examined treatments that may be applied by seed suppliers. Although chemical treatments are the most studied, their industrial use are limited due to the lack of EPA approved chemicals. Physical methods, such as dry heat, have

increasingly been evaluated. Dry-heat treatments have the added advantages in that they are scalable and can avoid the need for a post-treatment drying step typically required for chemical treatments. These advantages make dry heat treatment a potential option for seed suppliers. The efficacy of dry heat for decontamination of seeds differed among published studies. For dry heat to be recommended as a seed treatment option, research is needed to better understand factors that may affect treatment efficacy and to identify conditions that can effectively decontaminate seeds while preserving their germination capability.

The efficacy of dry heat treatment in reducing *Salmonella* on alfalfa seeds as affected by treatment time (6, 16, 24 h), temperature (60, 70, 80°C), relative humidity (20-80%) was examined. The impact of treatment on seed germination and sprout yield was also examined. Ten g of seeds inoculated with ~4 log CFU/g of *Salmonella* were subjected to dry heat treatment in a humidity-controlled chamber. Treated seeds were analyzed for *Salmonella* by plate count and culture enrichment. One hundred treated or control seeds were germinated in a petri dish and percent germination was recorded for 5 d. Sprout yields were determined after 7 d. A greater log kill was observed when treatment was conducted at higher temperatures, under higher relative humidities (RH), or for longer time. Heat treatment can negatively affect germination and sprout yield. Optimal treatment conditions that reduced *Salmonella* by > 3 logs or to below detection (< -0.3 log CFU/g) while maintaining germination at > 90% and sprout yield at > 85% were identified (60°C/80%RH/6h, 60°C/60%RH/24h or 70°C/40%RH/16h).

Findings from this research will provide the sprout industry and FDA with needed knowledge regarding the effectiveness of dry heat for seed decontamination as well as the factors to be considered when conducting seed treatment validation studies. An understanding of pathogen proliferation during sprouting will inform sprout production testing programs. This research was funded through HFP's Cooperative Agreement with IFSH and the DFPST operating budget.

Examination of *Listeria monocytogenes* Survival in Refrigerated Hard-Boiled Egg-Based Deli Salads Depending on Egg Treatment and Ingredients

Deli salads with chopped hard-boiled eggs are commonly purchased from retail stores, prepared by restaurants, or prepared by consumers. Pre-packaged hard-boiled eggs have been a source of foodborne illness due to contamination with *Listeria monocytogenes.* Due to outbreaks and recalls associated with hard-boiled eggs and previous research suggesting that citric acid at pH 2.5 may not be effective at reducing *L. monocytogenes* on hard-boiled eggs, it is important to understand how the addition of treated or untreated contaminated hard-boiled eggs into deli salads affects the survival and/or growth of *L. monocytogenes*.

Hard-boiled eggs (HBEs) were submerged in 2% citric acid or water at 5°C for 24 h as a pre-treatment. The HBEs were then inoculated with a high inoculation level of *L. monocytogenes* for modeling studies (4 log CFU/HBE) or at a low level for survival studies (1 log CFU/HBE). The inoculum was allowed to dry and the eggs were chopped. Chopped HBEs were stored at 5, 10 or 25ºC for up to 14 days. It was determined that there was no significant difference between the growth rates of *L. monocytogenes* on citric acid treated and untreated chopped HBEs when stored at 5ºC. However, there was a significant difference between growth rates at 10 and 25ºC between the HBE treatments; longer lag phases were observed in the citric acid treated HBEs, along with lower growth rates. Inoculated, chopped HBEs were then incorporated into commercial deli salad recipes including potato, chicken, macaroni, tuna and egg salad. Deli salads were then stored for up to 1 month at 5, 10, or 15ºC. Minimal differences in survival in deli salads was observed at 5 and 10°C regardless if the salads were made with treated or untreated HBEs. At 15ºC storage, potato salad had the highest population after storage.

The results indicated that lower temperature storage greatly impacts the effectiveness of the citric acid treatment of the HBEs, resulting in increased lag phases and lower *L. monocytogenes* populations. Refrigerated storage of HBEs and deli salads is essential to mitigate microbial growth in post-process contaminated deli salads. The information from this study could be used to inform guidance on the safe storage of chopped HBEs and deli salads containing chopped HBEs. This research was funded through HFP's Cooperative Agreement with IFSH and the DFPST operating budget.

Evaluation of Wiping and Washing Treatments for Removal of Allergens and Gluten from Food-Contact Surfaces

The Food Code represents FDA's best advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service. Provisions in the Food Code (in Chapters 3 & 4) pertain to washing, rinsing and sanitization of equipment, food contact surfaces and utensils as well as the use limitations for wiping cloths. These provisions were developed to reduce microbiological risks associated with food. Until recently, little was known about the effectiveness of these provisions in preventing allergen cross-contact.

Over the past year, two separate studies were completed. The first study evaluated the use of wet and dry wipes on their ability to remove allergens from food-contact surface, while the study determined the effectiveness of manual and mechanical washing methods at removing allergen-containing foods from food-contact surfaces. For the wiping study, three stainless steel (SS) and three textured white polyethylene (PE) coupons were contaminated with 0.5 g or 1 g of egg-based (powdered whole egg; reconstituted whole egg powder), gluten-containing (wheat flour; wheat-containing batter), or sesame-based (sesame flour; tahini) foods. After drying for 30 min at ambient temperatures (23 ± 2°C), coupons were wiped with either a dry paper wipe, a dry terry cloth, a wet terry cloth soaked in 200 ppm quat solution, or one, two, or three sanitizing wipes for 5 sec. A second type of sanitizing wipe was also evaluated for tahini-contaminated surfaces. After wiping treatments, coupons were tested for residual allergens with lateral flow devices (LFDs). Three independent trials were conducted for each experimental variable. For the washing study, coupons made of PE (n=3), SS (n=3), and ceramic (CE, n=3) were contaminated with 0.5 g or 1 g of egg-based (egg powder; reconstituted egg powder), gluten-containing (wheat

flour; batter), or sesame-based (sesame flour; tahini) foods. After drying for 30 min at 23±2°C, coupons were subjected to a manual or mechanical washing treatment. The manual treatment used three, 18.9 L buckets containing wash solutions at 43°C. Coupons were washed (10 sec), rinsed (10 sec), and then sanitized (60 sec), in neutral detergent solution, water, and 200 ppm quat solution, respectively. Mechanical treatments involved washing contaminated coupons in commercial warewashing machines. Residual allergens on coupons were detected with LFDs. Washing trials were done in triplicate.

Results from the wiping study indicate that dry wiping methods were not effective at removing allergen-containing foods from the SS and PE coupons. The wet terry cloth was effective, and the sanitizing wipes were effective when more than one wipe was used. PE was more difficult to clean than SS, and foods in paste form were more difficult to remove than powdered forms. There were no observable differences in the ability to remove 0.5 g than 1.0 g of food soils. LFDs were able to detect allergens on some surfaces that were visually clean. The manual washing treatment removed gluten-containing foods on SS, but mixed results were seen for PE and CE. Egg-based foods were removed from all surfaces during manual washing. Mixed results were found when the manual method was used to remove sesame flour from SS and CE coupons, while complete removal was found for PE. Tahini was detected on all three surfaces after manual washing. Mechanical washing treatments were effective at removing gluten-containing foods, egg powder and sesame powder from all surfaces while reconstituted egg and tahini were challenging to remove.

Overall, the results indicate that wet wipes are more effective for removal of allergens than dry wipes. Using multiple wet wipes facilitates removal of allergenic foods. The results from the washing study indicate that the nature of the food soil and surface impacted the effectiveness of washing treatments. More extensive washing treatments were needed for difficult-to-clean soils such as food pastes. This research was funded through HFP's Cooperative Agreement with IFSH and the DFPST operating budget.

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
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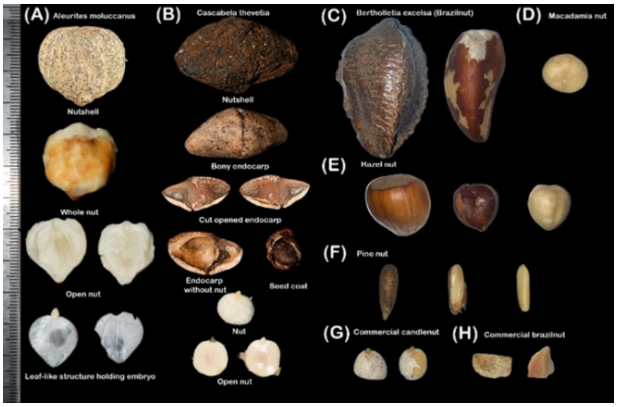
Analytical Investigations to Assure the Overall Quality of Botanical-Based Dietary Supplements (BDS)

The extraction, purification, and characterization of standard compounds from authentic botanical extracts play a crucial role in developing analytical methods, quantifying individual components within those extracts, and establishing unique analytical fingerprints to ensure the authenticity, quality, and safety of various dietary supplements. The availability of authenticated reference materials for botanicals is the first step in developing analytical methodologies for identifying and quantitatively analyzing botanical products. The NCNPR has successfully placed formal agreements with several international academic and governmental institutions from Southeast Asia, China, Europe, South Africa, and Central and South America. Moreover, NCNPR has cultivated a productive relationship with potential partners to obtain relevant authenticated herbs and spices for the COE's botanical research needs. For example, formal agreements exist to exchange and implement collaborative phytochemical research with the University of Naples Federico II, Italy, and the Korean Society of Ginseng, South Korea.

The NCNPR continues its focus on developing analytical techniques to both corroborate reported botanical materials and to identify unknown botanical materials. For example, the COE team investigated *Eriodictyon* species, commonly known as yerba santa, a plant native to the Southwestern United States and northern Mexico. Even with a long history of medicinal use

among indigenous communities, many species remain chemically uncharacterized, and their constituent profiles have not been fully documented. To address this gap, an extensive set of *Eriodictyon* samples, *E. californicum* (n = 85), *E. angustifolium* (n = 8), *E. trichocalyx* (n = 5), *E. crassifolium* (n = 9), *E. tomentosum* (n = 2), *E. traskiae* (n = 1), and *E. capitatum* (n = 1), were investigated. Using the Ultra-High Performance Liquid Chromatography-Diode Array (UHPLC/DAD) method, the team quantified 14 compounds, including flavonoids and phenolic acids. Method validation revealed excellent linearity ($R^2 > 0.99$), impressive sensitivity (LOD: 0.01–0.1 µg/mL, LOQ: 0.05–0.2 µg/mL), and precision (RSD < 2.78%) with recoveries ranging from 88.9 to 103.2%. Moreover, employing Ultra-High-Performance Liquid Chromatography Coupled with Electrospray Ionization Quadrupole Time-of-Flight (UHPLC/ESI/QToF) data and analyzing protonated and deprotonated adducts and fragment ions in both positive and negative ion modes, the research team identified 53 compounds within yerba santa plant samples. This comprehensive dataset represents a significant advancement in understanding the chemical constituents of *Eriodictyon* species. Additionally, the developed method could serve as an important analytical tool to ensure the quality of raw materials and commercial herbal products containing various *Eriodictyon* species.

In another analytical project, the NCNPR successfully employed Ultra-High Performance Liquid Chromatography-Quadrupole Time of Flight-Tandem Mass Spectrometry (UHPLC-QToF-MS/MS) combined with molecular networking to rapidly dereplicate 40 unique steroidal saponins in the aerial parts and rhizomes of botanically verified *Smilax sieboldii*. These saponins include 3-oxy-, 3, 6-dioxy-, and 3, 6, 27-trioxy-steroidal variants. Tandem mass diagnostic fragmentation patterns of aglycons such as diosgenin, sarsasapogenin/tigogenin, and laxogenin were crucial for identifying the distinct nodes associated with six groups of nineteen unknown steroidal saponins in *S. sieboldii*. Additionally, mass fragmentation analysis revealed 6-hydroxy sapogenins as well as other saponins within *S. sieboldii*. These 6-hydoxy sapogenins are believed to be pivotal precursors in the biosynthesis of characteristic smilaxins and sieboldins. By analyzing the leaf, stem, and root/rhizome of *S. sieboldii*, researchers established the relative biodistribution and characteristic molecular network profiles of these analytes. This work is expected to enhance the overall quality control of botanical dietary supplements, streamline investigations, and facilitate the identification of exogenous components in the final products.

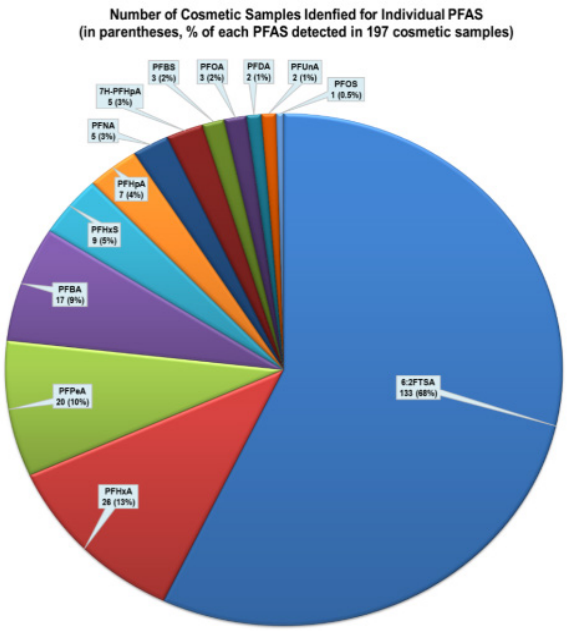


Several dietary supplements based on *Aleurites moluccanus* (candlenut) and *Bertholletia excelsa* (Brazil nut) are commonly marketed for weight loss purposes. However, these products have

occasionally been adulterated with toxic nuts or seeds from yellow oleander (*Cascabela thevetia*). A recent study highlighted crucial identification parameters to distinguish between genuine and adulterated nuts. The NCNPR collected, macroscopically investigated, and established characteristic features for both voucher and commercial samples. Interestingly, all eight commercial candlenut samples and two of six Brazil nut samples were identified to be adulterated with yellow oleander. Histochemical analysis with Raymond reagent and further validation with LC-DAD-QToF for the presence of several cardenolides (viz., Thevetin A) indicated that these samples are indeed substituted or adulterated with yellow oleander. In any case, the current study employs simple key identification features, including micro-morphology, histochemical localization of cardiac glycosides, HPTLC fingerprints, and LC-DAD-QToF analytical parameters, to detect and identify adulteration in commercial products. This research was funded through HFP's Cooperative Agreement with the NCNPR.

Safety of Botanical Ingredients in Cosmetics and Other Personal Care Products

The growing utilization of botanical extracts and compounds in cosmetics underscores the importance of safety assessment. With the enactment of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), the FDA now wields expanded authority to regulate cosmetics, ensuring the well-being of millions of daily users. In addition to botanicals, our research mission has expanded to analytical investigations of per- and polyfluoroalkyl substances (PFAS) and acetyl hexapeptides in various cosmetic products to ensure overall quality and safety.



To assess PFAS contamination in cosmetics, the developed an UHPLC-MS/MS method to analyze 16 PFAS in makeup products. The method was validated and demonstrated high sensitivity (LOD: 0.4 ng/g, LOQ: 0.9 ng/g), accuracy (40-120% recovery), and precision (RSD ≤

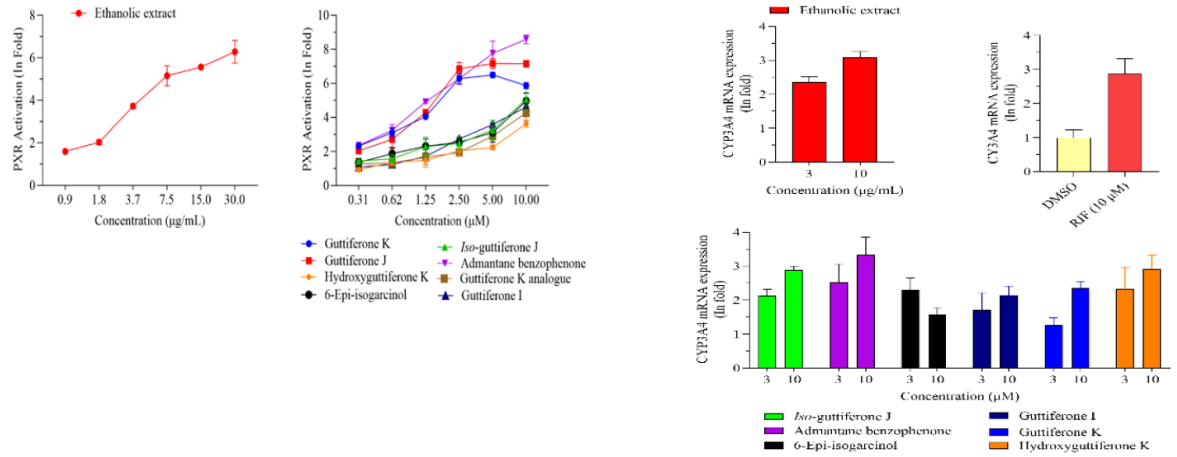
20%). Analysis of 197 cosmetic samples revealed the presence of 13 PFAS in various products. 6:2 FTSA was the most prevalent, detected in 70% of samples. Overall, 80% of samples contained at least one PFAS, with some containing up to 10 different PFAS. Our findings, including detailed methodology and results, have been shared with HFP. These results underscore the need for increased consumer awareness and regulatory oversight regarding PFAS exposure through cosmetics.

To assess the presence of anti-aging peptides in cosmetics, we developed an LC-MS/MS method to analyze six peptides commonly used in these products. The method was validated and demonstrated high sensitivity (LOD: 0.2 ng/mL, LOQ: 0.5 ng/mL), accuracy (40-115% recovery), and precision (RSD ≤ 15%). Analysis of 77 cosmetic products revealed that 54.5% contained at least one of the targeted peptides. However, despite claims of acetyl hexapeptide-8 (AHP-8) inclusion, only 33% of products actually contained detectable levels of this peptide. These findings underscore the need for improved quality control in hexa-peptide-based cosmetics and emphasize the importance of effective implementation of MoCRA regulations. This research was funded through HFP's Cooperative Agreement with the NCNPR.

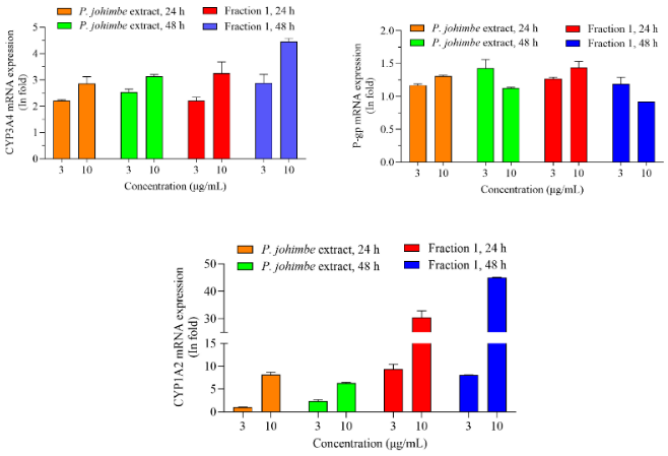
Adverse Effects of BDS – Modulation of Drug-Metabolizing Enzymes and Transporters (DMET) and Implications to Herb-Drug Interactions

The widespread use of herbal products has increased significantly in recent decades. However, excessive consumption can alter protein functions and lead to herb-drug interactions (HDIs), posing serious health risks, especially when consumed alongside conventional pharmaceutical drugs. This study focuses on the two primary mechanisms driving pharmacokinetic HDIs: inhibition or induction of xenobiotic-metabolizing enzymes and transporters by botanical ingredients. During this reporting period, we evaluated various botanical extracts, fractions, and key components for their HDI potential to ensure product safety.

Herb-drug interactions (HDI): *Garcinia gummi-gutta*, also known as *G. cambogia*, a tree native to Indian which produces sour, pumpkin-like fruits with culinary and medicinal uses. While its supplements gained popularity for weight control, they were linked to health issues like hepatotoxicity. Guttiferones, compounds found in *G. gummi-gutta*, resemble the antidepressant hyperforin. We hypothesized that they may interact with the pregnane X receptor (hPXR), a key regulator of drug metabolism. Our team investigated the impact of *Garcinia gummi-gutta* fruit extract and its isolated phytochemicals on PXR activity in HepG2 cells.



Results showed that the extract and three guttiferones (K, J and adamantane-type benzophenone) significantly enhanced PXR activity in dose-dependent manner, comparable to rifampicin, a known PXR activator. To validate the inductive effects of PXR, we assessed the extract's effect on expression of its downstream gene, CYP3A4 in HepG2 cells. Incubation with *Garcinia gummi-gutta* extract at 3 and 10 µg/mL significantly increased CYP3A4 gene expression by approximately 2.36 - and 3.09-fold, respectively. Additionally, six pure phytochemicals from *G. gummi-gutta* fruit enhanced CYP3A4 expression in dose-dependent manner, except for 6-epi-isogarcinol. These findings highlight the potential interactions between the extract and its phytochemicals with the xenobiotic receptor PXR, suggesting a significant role in HDIs.



Similar to the HDI potential of *Garcinia gummi-gutta*, the NCNPR team investigated herb-drug interactions related to yohimbine-based supplements. Drawing from the historical use of *Pausinystalia johimbe* (which contains yohimbine), these products target a specialized audience, aiming to enhance sexual performance, aid in weight loss, and improve athletic abilities. Our study assessed *P. johimbe* extract, ten fractions, and nine pure phytochemicals for PXR and AhR activities. The findings revealed significant dose-dependent activation of both PXR and AhR by the *P. johimbe* extract and one fraction. Additionally, we examined their impact on CYP3A4, P-gp, and CYP1A2 gene transcription in HepG2 cells. While the extract and fraction 1 had a mild

effect on CYP3A4 transcription, they substantially increased CYP1A2 gene expression after 24 and 48 hours of incubation, aligning with the PXR and AhR data. This research was funded through HFP's Cooperative Agreement with the NCNPR.

Capacity Building and Leveraging Research Efforts

Since its inception, the NCNPR has unlocked numerous opportunities by leveraging our existing cooperative agreement. These efforts transcend the boundaries of our program, encompassing a wide array of initiatives. Notably, we have consistently secured funding from the Consortium for Health and Military Performance in collaboration with the Department of Military and Emergency Medicine at the Uniformed Services University of the Health Sciences. Additionally, our ongoing partnership with the Duke Clinical Research Institute serves as a data coordinating center for a five-year Drug Induced Liver Injury Network (DILIN) grant from the NIH/National Institute of Diabetes and Digestive and Kidney Diseases. Furthermore, we've actively engaged in a collaborative research contract with the FDA/CDER Botanical Review Team (BRT), focusing on botanical drugs. Our affiliation with the University of Mississippi Medical Center as a clinical center facilitated a five-year grant from the NIH/Office of Dietary Supplements (ODS), which centers around evaluating the efficacy of Spirulina-derived oral supplementation in enhancing resilience against viral infections. Looking ahead, we plan to seek continued support from the same sponsors for an additional five years, proposing novel botanical candidate(s) for the next funding cycle. Lastly, we've successfully secured a research grant from the USDA/Agricultural Research Service to explore and develop natural product-based insect management compounds.

Public Awareness of Emerging Problems with Botanicals via Education and Stewardship

Training: The NCNPR, in collaboration with the FDA, has been instrumental in enhancing FDA inspector training on cGMP compliance for botanical ingredients. Following two training sessions conducted in 2023-2024, we have successfully trained over 1,165 FDA inspectors, equipping them with the necessary technical, educational, and hands-on experience. These collaborative efforts have also enabled the HFP/Office of Dietary Supplement Programs (ODSP) delegates to visit the NCNPR and stay updated on our ongoing botanical research. Researchers at the NCNPR remain open to research areas identified by the FDA. The training to FDA inspectors was funded through HFP's Cooperative Agreement with NCNPR.

ICSB Conference: The 22nd International Conference on the Science of Botanicals (ICSB) held in conjunction with the 7th World Congress of Medicinal Aromatic Plants (WOCMAP) focused on critical aspects of dietary supplement safety and quality. Discussions covered FDA insights on investigational new drugs and new dietary ingredients, updates from the botanical safety consortium, and emerging trends in botanicals like cannabis and mushrooms. The conference featured 79 presentations and over 128 scientific posters, attracting 333 participants from 16 countries. This event provided a valuable platform for industry, government, and academia to engage in discussions and share knowledge on the latest advancements in botanical science. The

ICSB is made possible through the support of our sponsors, including HFP, the involvement of national and international colleagues, and the dedication of our volunteers.

Stewardship: The NCNPR introduced the "Quality by Design" framework to safeguard the safety and integrity of botanical dietary supplements. Ashwagandha, a commonly employed botanical, has encountered recent criticism due to documented adverse effects. Our extensive research on botanical dietary supplements has led the COE's leadership to identify several concerns within the existing scientific literature on ashwagandha. These concerns, including insufficient raw material verification, the use of incorrect plant components, inconsistent extraction solvents, and a neglect of extract chemical composition in clinical trials, were summarized in an opinion article published in the Journal of Ethnopharmacology. This work was funded through HFP's Cooperative Agreement with the NCNPR.

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 (FSPCA) and Produce Safety Alliance (PSA) training. It also provides training on Good Agricultural Practices (GAP), Good Aquacultural Practices (GAqP), Good Fishery Vessel Practices (GFvP), Commercially Sterile Packaged Food (CSPF), Food Inspector Training Course (FIT), 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

Shrimp Mandate International Training Programs

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 2023-24, JIFSAN provided and supported 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.

Indonesia Good Aquaculture Practices (GAqP) Training: JIFSAN collaborated with the Marine and Fisheries Quality Assurance Agency (MFQAA) and the Directorate General of Aquaculture (DGA) in Surabaya, Indonesia to present a 4.5-day GAqP training from July 31 to August 4, 2023. The training consisted of 3 days of lectures and group exercises, a visit to a local working shrimp farm, and a local in-country guest speaker. The training provided participants with a technical approach to Good Aquaculture Practices to improve safety and prevent and minimize the impact of diseases on aquaculture seafood. Approximately 43 participants attended the course from academia, government, and industry sectors. Members from the FDA and USDA were also in attendance throughout the training.

Indonesia and India Sensory Decomposition Trainings: The Sensory Decomposition training in Indonesia was led by JIFSAN in collaboration with the Marine and Fisheries Quality Assurance Agency (MFQAA) and Bumi Menara Internusa (BMI) to present two, 2-day Seafood Sensory Decompensation trainings in Surabaya, Indonesia on November 6-7 and November 9-10, 2023. A total of 48 participants attended the course from academia, government, and industry sectors. The Sensory Decomposition training in India was led by JIFSAN along with The Central Institute of Fisheries Technology (ICAR-CIFT) to present two, 2-day Seafood Sensory Decomposition trainings in Kochi, India January 29-30 and February 1-2, 2024. JIFSAN, partnering with FDA, provided on-site support and assistance. Over 40 participants attended the course from the academia, government, and industry sectors.

In both trainings, participants were able to perceive and distinguish through sensory analysis basic quality odor attributes when evaluating seafood products and were able to identify different odors of spoilage and the degree of spoilage that defines the accept/reject level for the product examined. Their work will help to prevent exposure to food safety hazards and the resulting trade concerns with seafood products by achieving compliance with U.S. government regulations.

Each of these training courses was conducted to comply with the Congressional Mandate on Imported Shrimp. The outcomes of these workshops are multifaceted with the overall desired outcome that the Indian, Indonesian, and Ecuadorian seafood industries will produce seafood safe for consumers, both domestic and exported seafood; will be in compliance with the FDA and other governmental regulations; and will have a lower risk of rejection at the border. Seafood processors are expected to develop or modify their respective seafood safety plans or programs based on the knowledge gained during each workshop, which is expected to reduce the risk of food safety hazards associated with their products. Government inspectors or auditors are expected to integrate the information and knowledge gained during these workshops into their regulatory scheme, including program, policy, or implementation changes. The overall goal of this program is to work jointly with the FDA to establish best practices that help to ensure the safety of imported foods regulated by the FDA. Importantly, these trainings and adoption of their principles and practices facilitate food exports to the U.S. market, thus benefiting producers. This program was funded through HFP's Cooperative Agreement with JIFSAN.

Risk Analysis Program

The increasing emphasis on risk-based decision-making and the increasingly global nature of the food supply has resulted in the use of risk analysis to systematically address food safety issues worldwide. This has created a need to educate food safety and other public health professionals about the principles of food safety risk analysis and the tools and techniques required to apply this approach. JIFSAN through the years has developed training courses on risk assessment, risk management, and risk communication. This program intends to meet the needs of food safety risk analysis training of federal agencies, ministries, state and provincial governments, academics, industry, trade and consumer groups, and economic, legislative, and legal professionals. In a classroom face-to-face setting, the Summer Integrated Program (SIP) is offered once a year. This consists of a set of six courses, four Core courses including Overview of Risk Analysis, Food Safety Risk Management, Food Safety Risk Assessment, and Food Safety Risk Communication; and two advanced courses in Quantitative Risk Assessment and Epidemiology for Risk Analysis. The SIP in 2024 was held from July to August 16. A total of 21 professionals from the US, Korea, Suriname and Ghana participated in the program.

A program in Regulatory Economics for Risk Management was also piloted and co-taught in November 2023 with the George Washington University Regulatory Studies Center, USDA Office of Risk Assessment and Cost-Benefit Analysis, and the Society for Benefit-Cost Analysis. The course was held via Zoom with attendees representing U.S. government agencies, industry, and foreign agencies. In addition, we held a course on Risk Management for Hong Kong Polytechnic University in Hong Kong in September 2023 (25 participants) and Vietnam's National Institute for Food Control in Vietnam in December 2023 (28 participants). The SIP program is tuition-based and fully funded by tuition. The other programs were funded by the sponsoring organizations.

USDA Food Safety Inspection Service (FSIS) Data Sharing Initiative

JIFSAN led a data sharing initiative for USDA Food Safety Inspection Service (FSIS) to develop trust amongst the private sector to share *Salmonella* enumeration data that would aid in the development of a dose-response model using *Salmonella* subtypes. The UMD-JIFSAN, in collaboration with Structured Partnerships and the Institute for the Advancement of Food and Nutrition Sciences (IFSANS), held over 70 meetings with poultry industry organizations, FSIS, and other interested stakeholders from July 2022 through September 2023. The UMD-JIFSAN team established working groups with industry and FSIS, including scientists and lawyers, to clarify data criteria and establish mechanisms to securely provide anonymized industry data.

This dialogue resulted in signed data transfer agreements between industry and UMD-JIFSAN and UMD-JIFSAN sharing available industry data on *Salmonella* levels in ground turkey with FSIS. A final report "Facilitate dialogue and engagement on industry data-sharing to inform USDA FSIS's quantitative risk assessments for *Salmonella* in poultry" was submitted to the USDA Food Safety Inspection Service. This work was funded by USDA/FSIS.

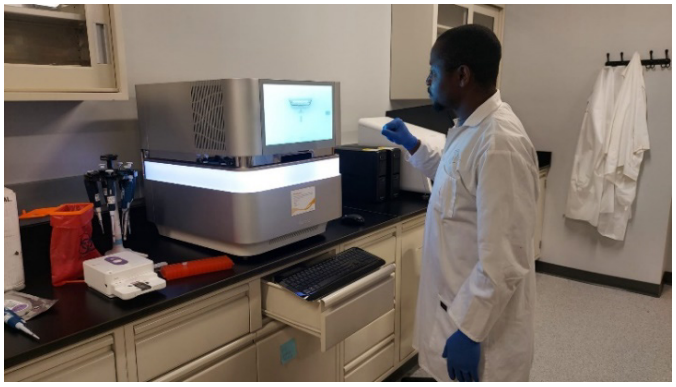
Undergraduate Student Internship Program

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 HFP's research and science program. The 2023-24 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 2023-24 cohort was comprised of 20 undergraduate students that collectively contributed ~11,000 hours of time and effort across the program for the academic year. In addition to FDA funding, JIFSAN benefited from a scholarship account established by a private donor with the University of Maryland College Park Foundation (UMCPF). This scholarship supported two

internships for the 2023-24 year, allowing two continuing interns to participate in their projects for a second year.

Notable intern accomplishments included but were not limited to: Poster presentation and awarded Travel Scholarship to the 2023 International Association for Food Protection (IAFP) conference in Toronto, Ontario, Canada; Poster presentation at the 2024 Integrated Foodborne Outbreak Response and Management (InFORM) conference in Washington, D.C.; Poster presentations by multiple interns at the joint National Capital Area Regional Chapter of the Society of Toxicology (NCAC-SOT) and CFSAN 2023 Fall Symposium; Project presentations by multiple interns at the 2023 FDA Annual Student Scientific Research Day (ASSRD) at the White Oak Campus; Publication of a factsheet based on a new defined term featured in the FDA Food Code for "In-shell Product" molluscan shellfish and other publications. This program was funded through HFP's Cooperative Agreement with JIFSAN.

The JIFSAN Food Safety Microbiology Lab



The Food Safety Microbiology Lab at JIFSAN fosters dynamic research collaborations, bringing together UMD faculty, students, postdoctoral researchers, FDA scientists, and international visiting scholars. It serves as a premier hub for training in cutting-edge technologies like Whole Genome Sequencing (WGS), playing a critical role in numerous high-impact research initiatives.

The lab's state-of-the-art facilities support key projects, such as the *Salmonella* in Surface Water study, while also serving as a central platform for WGS-related research collaborations. UMD researchers have utilized the lab to investigate a wide range of topics, including the intricate ecological factors contributing to grapevine diseases and the complex interactions between fungicide-resistant and wild-type *Colletotrichum* strains in berries. Additionally, the lab has provided WGS training for the GenomeTrakr network and international collaborators engaged in research requiring advanced genomic technologies. It has also played a significant role in supporting HFP's WGS training and capacity-building programs in India, Indonesia, and Mexico. The laboratory was funded through HFP's Cooperative Agreement with JIFSAN.

National Milk Drug Residue Database (NMDRD)

The National Milk Drug Residue Database (NMDRD) 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. In 2023, JIFSAN assumed responsibility for support of the database including the maintenance, quality and accuracy of the existing database that consists of the results of testing milk samples for drug residues by the industry and state agencies. This service provides the regulators, U.S. dairy industry and consumers a report of trends and prevalence of animal drug residue in our nation's milk supply.

The database recorded 3,694,059 samples of cow's milk and pasteurized milk products that were reported. The dairy industry continued the downward trend of positive test results in the 2023 period. JIFSAN's successful administration of the project motivated Massachusetts and Washington to resume reporting results to the database. This was accomplished through educating and explaining the importance of the NMDRD to the dairy program personnel. We also updated the NMDRD website and produced the final annual report on December 15, 2023, for the FDA and are providing quarterly updates on delinquent reporting. This work was funded through HFP's Cooperative Agreement with JIFSAN.

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