HARNESSING MEASUREMENT SCIENCE TO ADVANCE FOOD SAFETY

FINAL REPORT APRIL 2020

> findings from the FOOD SAFETY WORKSHOP

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Harnessing Measurement Science to Advance Food Safety

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April 2020



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EXECUTIVE SUMMARY

The National Institute of Standards and Technology (NIST) has leveraged its expertise in food nutrition measurement services as well as its strong relationships with stakeholders to host 170 U.S. and international experts from the food industry, government, academia, and support organizations (e.g.,

trade and standards organizations, instrument manufacturers) for a three-day Food Safety Workshop in October 2019. The main output of the workshop is this report summarizing needs and possible measurement science solutions and technology transfer opportunities in major areas of food safety, which includes documentation of stakeholder needs, key insights from workshop discussions, and a clear plan for advancing the field.

This report summarizes **measurement challenges** identified in four main pillars of global food safety (microbiological contaminants, chemical contaminants, allergens, and authenticity and adulteration) as described by the experts assembled at the workshop and explores **potential future actions** needed to improve food safety measurement **Date:** October 28–30; a fourth day, October 31, was designated for reference material producers

Location: NIST Campus, 100 Bureau Drive, Gaithersburg, MD 20899

Participants: 170 experts from industry, regulatory bodies, RM producers, national metrology institutes, and academia from across the global food safety community; 75 NIST staff

Website: www.nist.gov/foodsafety

science. This paper is accompanied by a second, complementary report on the international capabilities across national metrology institutes (NMIs) and other reference material producers present at the workshop and prospective actions to ensure global food safety (<u>https://doi.org/10.6028/NIST.SP.1252</u>).



Measurement Challenges and Potential Solutions

Throughout the workshop, speakers identified measurement challenges and potential solutions related to each of the four main pillars of food safety. Numerous common needs were identified, including reference materials, education and training, updated analytical

methods, greater global collaboration and harmonization, and assurances of laboratory quality. Unique challenges were also identified under each pillar as summarized in the table below.

Needs Identified			
Microbiological Contaminants	Chemical Contaminants	Allergens ଷ୍ଟର୍ଷ ଷ୍ଟର	Authenticity & P
 Repositories for validation data RMs for method verification studies New approaches that reduce analysis time and cost 	 Incurred matrix RMs and PTs Calibration materials (metabolites, isotopically labeled) RMs for metal species 	 Understanding what tests are measuring, testing limitations Support for a suite of complementary approaches Commodity and finished product RMs 	 Authentic materials Isotope ratio CRMs Controls for rapid and handheld monitoring Data repositories and analysis tools

Suggested solutions for implementation in the **short-term** (1-5 years) include increasing the variety of reference materials with respect to incurred analyte/matrix combinations, creating data interpretation tools, developing a resource repository, improving test kit training, designing fit-for-purpose methods vetted through a stakeholder process, creating a food safety taskforce, and developing international documentary standards. Potential activities for the **long-term** (6+ years) include developing RMs for non-targeted methods and non-chemical food testing, providing guidance for the use of alternative or in-house methods that have not been vetted through a standardization body, improving robustness and efficiency of analytical methods, and establishing additional documentary standards, frameworks, and databases. By collaborating with regulatory agencies, private laboratories, universities, metrology institutes, reference material producers, proficiency testing providers, and technology developers, the NIST intends to directly provide or oversee the progress toward solutions for many of the challenges identified at the workshop.



NIST Food Safety Program

NIST aims to develop an integrated Food Safety Program that will provide cutting-edge measurement science and world-class standards for ensuring food quality and safety, while building partnerships with food industry and product manufacturers to ensure consumer protection and securing reliable U.S. agricultural and food manufacturing supply chains. Short term activities identified for the NIST Food Safety Program include new measurement services, such as reference materials and interlaboratory studies for pesticides in various cereal crops and allergens in milk products, and new reference material and data suites for confident seafood and natural product authenticity determination and adulteration detection. As the Food Safety Program grows, long term activities will leverage other NIST centers and programs, in partnership with food industry and product manufacturers, to further develop innovative diagnostic technologies and next-generation measurement capabilities. NIST is also poised to serve as a trusted broker for universally translatable data and knowledge exchange for the U.S. and global food supplies while providing continuous standards and services that promote global trade and commerce.

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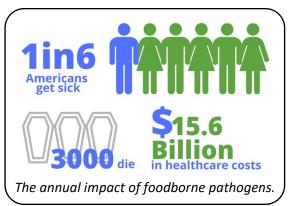
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LIST O	FACRONYMS
BPA	Bisphenol A
CEN	European Committee for Standardization
CFSAN	Center for Food Safety and Applied Nutrition
CRM	Certified Reference Material
DI	Designated institute
EGCG	Epigallocatechin gallate
ELISA	Enzyme-linked immunosorbent assay
FCM	Food contact material
FDA	U.S. Food and Drug Administration
GC	Gas chromatography
GDP	Gross Domestic Product
HRAM	High resolution accurate mass
ICP-MS	Inductively coupled plasma mass spectrometry
ILAC	International Laboratory Accreditation Cooperation
IRM	Industry Reference Materials
ISO	International Organization for Standardization
JRC	Joint Research Centre (European Commission)
KCDB	Key Comparison Database
LC	Liquid chromatography
LOD	Limit of detection
MALDI	Matrix-assisted laser desorption/ionization
MCPD	Monochloropropanediol
MML	Material Measurement Laboratory
MS	Mass spectrometry
nDATA	Non-target data acquisition for target analysis
NGS	Next-generation sequencing
NIST NMI	National Institute of Standards and Technology
NMR	National Metrology Institute Nuclear magnetic resonance
NT	Non-targeted
PCR	Polymerase chain reaction
PFAS	Per- and polyfluoroalkyl substances
PT	Proficiency testing
QA	Quality assurance
QAP	Quality Assurance Program
QC	Quality control
RASFF	Rapid Alert System for Food and Feed
RM	Reference Material
SI	International System of Units
SIS	Small intestinal submucosa
SITE	Stable isotope and trace element
SRM	Standard Reference Material
UK	United Kingdom
USP	U.S. Pharmacopeia
VITAL	Voluntary Incidental Trace Allergen Labelling
WGS	Whole genome sequencing

WORKSHOP RATIONALE

The food industry, comprising all aspects of production and distribution, is a complex, global enterprise reliant on all entities across the supply chain to ensure the safety and quality of the world's food supply. In the U.S. alone, agriculture, food, and related industries contributed \$1.053 trillion to the gross domestic product (GDP) in 2017,¹ indicating that the U.S. food supply represents a crucial economic asset that must be protected. Despite diligent efforts of food producers to ensure food safety and prevent foodborne illness, the U.S. Food and Drug Administration (FDA) reported 763 food recalls from January 2017 through

December, 2019.² Of those, 51% of recalls were due to the known or potential presence of undeclared allergens and 40% were based on known or potential microbial contamination. A 2011 joint report by the Grocery Manufacturers Association and the Food Marketing Institute estimated that direct costs of a food recall average \$10 million to the food manufacturer responsible for the recall, not including indirect costs associated with litigation, government fines, lost sales, and damage to brand and reputation.³ Additional health care costs are incurred upon consumption of contaminated or mislabeled food products. The Centers



for Disease Control and Prevention estimates that each year, 1 in 6 Americans get sick and 3,000 die from consumption of contaminated foods and beverages.⁴ The U.S. Department of Agriculture estimates the annual cost of foodborne illnesses tops \$15.6 billion.⁵

With today's expansive global supply chains, protecting human health and the safety of food has become extraordinarily complex. Global sourcing of raw materials and ingredients poses challenges regarding food manufacturing practices and potential product adulteration. Moreover, in the last few decades, increasing numbers of joint ventures have formed between food producers and international suppliers, processors, and manufacturers, resulting in branched and fragmented supply chains and making monitoring and regulation more difficult. Laboratories also face challenges with testing food ingredients and production lots due to a lack of suitable reference materials, surrogate microbial organisms, and accessible data repositories, which result in siloed work within each company or organization and increases the resources required for adequate testing. Consumers rely on food manufacturers and testing laboratories to ensure a diverse, abundant, and stable food supply, and the availability and accessibility of information has encouraged point-of-consumption testing with smartphone integration and crowdsourcing of data,

¹ United States Department of Agriculture, Economic Research Service, Ag and Food Sectors and the Economy, retrieved from <u>https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/ag-and-food-sectors-and-the-economy.aspx</u> (September 2019)

² United States Food and Drug Administration, Recalls, Market Withdrawals, & Safety Alerts, retrieved from <u>https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts</u> (January 2020)

³ Grocery Manufacturers Association and Food Marketing Institute, Capturing Recall Costs: Measuring and Recovering the Losses. GMA, Covington & Burling LLP, and Ernst & Young (2011)

⁴ United States Centers for Disease Control and Prevention, Food Safety, retrieved from <u>https://www.cdc.gov/foodsafety/cdc-and-food-safety.html</u> (January 2020)

⁵ United States Department of Agriculture, Economic Research Service, Cost Estimates of Foodborne Illnesses, retrieved from <u>https://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses.aspx#48446</u> (September 2019)

creating citizen scientists that are ever more aware of the source, quality, and safety of the foods they consume.

To meet the needs of food producers, testing laboratories, and ultimately consumers, **critical food safety challenges must be addressed**. NIST has extensive experience in preparation and characterization of reference materials and providing measurement support through quality assurance programs for food nutrition to support U.S. industry in meeting labeling requirements. Leveraging this expertise as well as strong relationships with stakeholders in the food industry, **NIST is poised to be a leader in providing metrology solutions to address food safety challenges**.

Food safety is a broad topic, ranging from heavy metals, toxins, and residue contamination resulting from growth conditions to allergens and bacteria arising from cross-contact during processing and/or packaging. Food safety can also extend to authenticity, fraud, and adulteration, or even to potential spoilage. To better understand the needs of this stakeholder group, NIST organized the Food Safety Workshop to bring experts from the food industry, government, academia, and support organizations (e.g., trade and standards organizations, instrument and test kit manufacturers) together with international metrology experts to discuss measurement challenges and possible solutions facing

laboratories charged with ensuring the safety of the U.S. and global food supply.

The challenges and activities included in this paper center around **four main pillars of global food safety** identified by NIST through extensive stakeholder engagement prior to the NIST Food Safety Workshop. Other food safety topics were considered outside of scope for this workshop and may be addressed in future events.

Four Food Safety Pillars



FOOD SAFETY MEASUREMENT CHALLENGES

During the workshop, invited speakers were asked to share regulatory, industry, and laboratory perspectives on food safety, specifically related to the following challenges:

- Assurance that levels of microorganisms in foods are below risk-assessed thresholds via analytical testing
- Identification and quantification of chemical contaminants and residues in raw materials, ingredients, and finished products
- Identification and quantification of protein food allergens in raw materials, ingredients, and finished products
- Assertion of authenticity (e.g., species, source, provenance) and purity of raw materials or ingredients via analytical testing
- Lack of existing global food safety measurement solutions

Summaries of each of the workshop speaker presentations can be found in *Appendix A: Summary of Presentations*.



Workshop Opening and Keynote Addresses

The workshop began with a welcome to NIST and **Keynote Addresses** covering regulatory, industry, and laboratory perspectives on food safety challenges. The presentations touched on topics including the changing role of testing in food safety regulatory

programs, balancing testing with risk assessment and other control mechanisms, challenges with raw material supply and addressing adulteration risks, the robust test methods required at laboratories testing large numbers of samples, and the lack of appropriate reference materials. Before turning to the major food safety pillars, NIST staff framed the overall focus and goals of the workshop. Highlighting the history of the NIST Food and Nutrition program demonstrated past success in utilizing stakeholder feedback to develop measurement capabilities and produce reference materials, quality assurance programs, and other measurement services. Leveraging those skills and building upon relationships with food industry stakeholders will lead to future success of the NIST Food Safety Program. The four main pillars of global food safety were chosen for the workshop based on NIST interactions with stakeholders and requests for new solutions.

Experts

James Olthoff, NIST

Robert Buchanan, University of Maryland Department of Food Science

Roger Lawrence, Lawrence & Associates, LLC (formerly McCormick & Company)

Darryl Sullivan, Eurofins Scientific

Melissa Phillips, NIST



Microbiological Contaminants

The session on microbiological contaminants highlighted the challenges that the industry faces in understanding and controlling exposure of consumers to pathogens in foods. Disease outbreaks related to microbes in food are commonplace, most recently resulting

from *E. coli* in romaine lettuce and *Salmonella* in produce, and can be severely damaging to an industry. To prevent these events, manufacturers rely on a combination of process controls, risk assessments, and testing schemes to evaluate safety of food products prior to release. With respect to testing, **pathogens may**



In 2019, 167 people in 27 states were sickened by romaine lettuce contaminated with E. coli. More than 75,000 pounds of salad products were recalled. Source: FDA not be homogeneously dispersed throughout a product, requiring fit-forpurpose sampling plans to represent the original material. Laboratories must also balance their measurement approaches

Experts

International

Pamela Wilger, Cargill

Thomas Hammack, U.S. Food and Drug Administration Wendy McMahon, Silliker Food Science Center Mike Clark, Bio-Rad Jesse Miller, NSF

between classical reference methods, which are often labor and time intensive, and more rapid technologies that may require validation and/or verification. **Current testing approaches have drawbacks**, in that while methods can be broadly applicable, no one method can be validated for all food matrices. Test methods can also be complex and difficult to perform correctly, and private laboratories may lack access to sufficient information for proper method selection, validation, and verification for different matrices. In most cases, reference materials are not available for use in method validation and verification studies, resulting in increased time and costs required to complete such studies. Similarly, sharing of validation data is limited within the industry and results in duplication of efforts and siloed method development. No publicly accessible repositories have been developed for validation data; thus, laboratories lack a mechanism for sharing best practices and conducting cross-laboratory comparisons of validation and verification approaches.



Chemical Contaminants and Residues

The session on chemical contaminants and residues explored the wide variety of potentially harmful compounds that may be present in our food, including toxic elements, natural toxins, pesticide and veterinary drug residues, environmental and processing

contaminants, unapproved additives and adulterants, and migrants from packaging materials. Most analytical testing strategies include mass spectrometry (MS)-based methods to identify and quantify these contaminants in food ingredients and finished products. In an industry testing environment, testing for elemental contamination is focused on the "big four" elements (arsenic, cadmium, lead, mercury) as well as second tier elements such as aluminum, chromium, selenium, silver, and beryllium. Such contamination may occur naturally in the environment or result from processing of raw ingredients into finished products. For nearly all countries, determination of natural toxins, such as mycotoxins and phycotoxins in crops and seafood, respectively, pesticide and veterinary drug residues, and environmental and processing contaminants in foods is critical for establishing relevance and public health impact of various contaminants as well as ensuring safety of food commodities. To ensure that foods and beverages are available for safe consumption, millions of

Experts

Katerina Mastovska, Eurofins Food Integrity and Innovation

Christopher Smith, Coca-Cola Company

Pearse McCarron, National **Research Council Canada**

Jon Wong, U.S. Food and Drug Administration

Joe Boison, Canadian Food Inspection Agency (retired)



Algal blooms like this 2016 instance in Florida increase the amount of phycotoxins in the water, making fish unsafe to eat.

Source: phys.org

analytical tests are performed annually worldwide and require proper use of matrix-based reference materials for quality assurance. In all classes of chemical contaminants and residues. measurements are challenged by the limited number of incurred matrix reference materials and proficiency testing schemes available to support routine testing as well as advancements toward multi-analyte and multi-class methods. The global market requires laboratories to support testing under the regulations of numerous countries and regions, demanding the highest level of international accreditation and resulting in a strong dependence on availability of these tools for method validation and verification. Additionally, as analytical methods advance, lack of calibration materials for new, unique, or locally unregistered

compounds, metabolites, and isotopically labeled analogues limits the ability to perform accurate quantitation of chemical contaminants and residues in food samples. Availability of both calibration and matrix-based reference materials for chemical contaminants and residues will also support improvements

to **field-testing options that are currently not robust**. In addition to improved technologies and tools for method validation and verification, **improper training and lack of fundamental understanding of principles, interpretations, and limitations of food testing** leads to an inability to identify sources of, and mechanisms to avoid, these types of contaminants.



Allergens

The session on allergens revealed numerous disconnects in the allergen testing community, from clinicians working with patients to diagnose symptoms, to regulators protecting those patients, food companies working to ensure the safety of the products

they make, and through researchers looking to advance technology in all of these areas. Allergic reactions tend to be self-reported rather than clinically diagnosed, leading to a misrepresentation of the number and severity of allergies within the population. Once reported, clinicians may perform challenge studies with a patient to determine an eliciting dose, above which the patient will observe symptoms of the allergy. Unfortunately, the foods used to perform these tests are not sufficiently characterized or standardized with respect to the allergenic proteins prior to the study. Thus, the measurement community suffers from a lack of robust data on the population statistics of allergen-eliciting doses to help inform product testing. Additionally, allergen regulations and thresholds are established with respect to the pure commodity (e.g., milk, peanut), and do not directly translate to the amount of allergenic protein in a processed food. As a result, testing methods are challenged by both product heterogeneity and transformation of allergenic proteins during traditional food processing. Numerous test kits are available



Allergic reactions can be lifethreatening, and uncertainty in product testing and labeling lead to higher likelihood of unintended allergens present in food products. Presence of undeclared allergens is the leading cause of U.S. food recalls. Source: FDA

for testing foods for the

presence of allergenic proteins, but face challenges in that each has individual advantages and limitations and different methods for testing the same allergens may produce different results. Improper use and implementation of test kits may lead to confusion in interpretation of results and subsequently impact the product consumer. In addition, test kits are generally developed and calibrated using the best available pure commodity material. Because of the lack of standard commodity materials, manufacturers may utilize different materials from one another and therefore modify the relative specificity of their assay with respect to the target proteins. Additionally, these differences in specificity are often not disclosed by manufacturers, further complicating efforts toward standardization. The allergens community also faces challenges due to the lack of finished product reference materials with

assigned values for allergenic proteins, which, if available, would serve as testing controls and increase confidence in measurement of allergen content in finished products. To further complicate the allergen

Experts

Eric Garber, U.S. Food and Drug Administration

Stefano Luccioli, U.S. Food and Drug Administration

Bert Pöpping, FOCOS GbR

Melanie Downs, University of Nebraska-Lincoln

Jupiter Yeung, Nestle Nutrition

Todd DeKryger, Nestle Nutrition

Scott Hegenbart, Conagra Foods testing landscape, the **allergy statements on food labels are not standardized** and the language used on the label may be confusing, may not include all allergens present in the product, or may be overly cautious by naming allergens not present in the product, all of which may make consumers unsure about whether the product is safe to eat.



Authenticity and Adulteration

The session on authenticity and adulteration highlighted challenges in ensuring thorough testing that an ingredient or food is being accurately represented. The scope of the authenticity and adulteration problem ranges from an accidental substitution of one

product for another (e.g., two crops physically resemble one another and are mislabeled during or after harvest) to fraud through intentional substitution of one lower-cost commodity for another to downright threats to public health involving addition of components to boost certain attributes of the product (e.g., melamine in milk to increase the measured results of a non-specific protein determination). Therefore, **unpredictability in the type and manner of adulteration** is a major challenge in confirming the authenticity of a product, and regardless of the intent or approach, ingredient suppliers and food manufacturers need solutions for identifying authentic products in order to meet consumer expectations and demonstrate compliance. Unfortunately, the **limited availability of test materials of known origin and growth conditions** for many commodities has limited the collection of data and development of data repositories for evaluation of authenticity. Such test materials



In 2019, the government of New Zealand prosecuted a manuka honey producer accused of adding nonapproved substances to their products.

Source: The Guardian

are required to capture the natural variation in the composition of plants and animals as related to the

Experts

Spencer Carter, Dyad Labs

Simon Kelly, International Atomic Energy Agency

Julian Braybrook, UK National Measurement Laboratory at LGC

Stefan Gafner, American Botanical Council

SeonBeom Kim, University of Illinois at Chicago College of Pharmacy

John Szpylka, Mérieux NutriSciences

growth environment, nutrient consumption, and time of sample collection, which is critical to future determinations of compliance against an established specification. However, even in a case when numerous verified samples are available for testing, many laboratories suffer from a **lack of access to appropriate tools for testing product authenticity**. For example, border inspection agents who are responsible for testing imported products for authenticity and safety often lack a background in chemistry and therefore require tools that provide rapid, easy-to-interpret results. Tests being used on imports may be simple but incorrectly applied, or more complex than

necessary and the results incorrectly interpreted.



Global Food Safety

In a concluding session on global food safety, representatives from four international institutes and reference laboratories shared the challenges faced when ensuring food safety in their regions (Africa, the Americas, Europe, and Asia/Pacific). With the

globalization of the supply chains, food safety can no longer be considered a local, national, or even regional challenge, and the speakers reflected on numerous common observations and needs. A primary challenge described by the global panel was a **lack of adequate reference materials** to validate testing methods, especially for new markets such as alternate protein sources (e.g., insects) and food trends (e.g., *Cannabis* products). The **effects of climate change** will alter the ability to grow common crops and therefore could potentially shift trends in food import and export needs, which will in turn require new methods of testing to ensure safety. Chemical contaminants such as mycotoxins that proliferate based on environmental conditions will also be affected by climate change and will require modifications to testing protocols. Without remedy, these impacts may translate to fewer available commodities that are known to be safe and of high quality, reducing access to

Experts

Maria Fernandes-Whaley, National Metrology Institute of South Africa (NMISA)

Valnei Cunha, INMETRO, Brazil

Hongmei Li, National Institute of Metrology (NIM), China

Piotr Robouch, Joint Research Centre of the European Commission

proper nutrition in some regions. As the climate changes, regulatory bodies and NMIs should rely on one another for capacity building, as **capacity gaps in some countries** (i.e., in metrology institutes or other laboratories) can hinder the development and implementation of valid testing methods. Laboratories with underdeveloped capacity rely on more advanced counterparts for knowledge sharing and access to technology, which may delay overall progress with limited resources. Similarly, unintentional **lack of collaboration and data sharing** has led to duplication of effort and work siloes, delays in reaching consensus that impacts material development and cross-laboratory studies, and ultimately reaching



The global food supply chain encompasses many growing operations, shipping companies, processors, and retailers. Major issues at any point in the chain can lead to millions in lost revenues.

consensus on paths forward. As each country or regional economy works to meet local challenges, the ability to collaborate or assist in other parts of the world may not be the highest priority. Lastly, the nature of the global supply chain and differences in regulatory practices around the world pose a major challenge to ensuring global food safety. For example, guaranteeing the authenticity of globally sourced materials and ingredients depends significantly on the regulations and their implementation in the country of origin. In addition, local regulations, such as those in the U.S. for Cannabis, may complicate the development and validation of testing methods by complicating the ability to obtain testing samples and to share results with other laboratories or companies. International regulations are also not necessarily harmonized, delaying the ability to reach consensus among countries even within the same global region.

POTENTIAL SOLUTIONS

In addition to providing insight into the biggest measurement challenges in food safety, each speaker at the NIST Food Safety Workshop was charged with recommending solutions to those challenges. Following each session, panel discussions were held in which speakers addressed attendee questions related to the challenges and solutions presented. Though the challenges faced by the food industry are significant, due in part to the global nature of the food supply chain, ample opportunities were presented to address these challenges.

ACTIVITIES FOR THE NEAR TERM (1-5 YEARS)

Reference Materials

To improve quality assurance through method validation and verification, numerous needs for CRMs and RMs were identified. Requests for greater variety in **incurred matrix CRMs and RMs** were requested in all areas of food safety testing. For microbiological testing, the

greatest need for reference materials lies in more matrix diversity. Currently, commercial materials available for microbiological testing are limited to proficiency testing remainder samples, which are typically a high carbohydrate matrix such as mashed potatoes. For determination of chemical contaminants and residues, a similar need was expressed for an increased number of incurred analyte/matrix combinations, specifically including speciation of metals in various food matrices; cadmium in cocoa; acidic herbicides in vegetation; monochloropropanediol (MCPD) and glycidyl esters in infant formula; marine toxins in seafood, dietary supplements, and water; and veterinary drug residues and metabolites in animal tissue and feed. Allergen experts expressed a need for additional food commodity RMs (e.g., tree nuts) and more incurred matrix RMs for finished product foods. Reference materials for the allergens community should be prepared using whole commodities of the allergenic food to support evaluation of sample preparation and extraction approaches and to ensure the utility for a variety of analytical techniques and targets. For authenticity testing, a wide array of materials of verified origin is needed to improve machine-learning algorithms for evaluating incoming ingredients or products across many popular food and natural product commodities. To complement these matrix-based materials, calibration CRMs are also needed for chemical contaminants including pesticides that are not registered in the United States, for metabolites of veterinary drugs, and for stable isotopes of pesticides and veterinary drugs to facilitate quantitation using MS-based analytical approaches. Better pure-protein calibrators and appropriate internal standards are also needed for new MS-based technologies for allergen measurements.



Education and Training

In addition to production of new RMs, workshop participants agreed that many food safety challenges could be addressed through education and training. While global harmonization of vocabulary and best practices across geographical and scientific

communities would be ideal, creating a resource repository for such information would assist the food

safety community in identifying the best approach in each situation. The types of resources that could be made available in this repository include:

- General best practices for specific food safety issues
- Common vocabulary for reporting scientific results
- Videos outlining basic analytical techniques
- Guidance for understanding method scope and limitations, proper implementation through validation and verification, and determination of uncertainty, including for non-targeted methods
- Guidance for selection and use of proficiency and stability testing
- Simple instructions on trending and use of data, including multivariate statistics for food authentication and origin determination

Test kits are commonly used in the determination of microbiological contaminants and allergens in food products or on environmental surfaces used to produce and package food products. Attendees suggested that manufacturers **improve existing training opportunities for test kits** as well as offer training opportunities continually. Under each of the four pillars, **more diverse proficiency testing options** were also requested, to include a wider variety of sample matrices and analytes for demonstrating laboratory and/or analyst competency. In addition, better guidance on the various benefits of participation in proficiency testing (see **resource repository** above) or other interlaboratory comparisons were suggested to increase the number of participating laboratories and therefore the amount and quality of resulting data.



New and Updated Analytical Methods

Needs for new and updated analytical methods were also discussed during the workshop, many of which can be addressed in the near term. A resounding concern was that methods must be fit-for-purpose and vetted through a stakeholder process (e.g., AOAC

INTERNATIONAL, ISO, ASTM) whenever possible. Although higher order methods are driving instrumental trends, more basic fit-for-purpose methods are needed globally. Workshop participants mentioned wanting best practices, methods, and metrics for determining **antimicrobial resistance**. Additionally, the need for **more accurate and higher throughput field-testing approaches** with thorough validation in all technical areas, as well as standardization of test kits for more reliable analysis were also highlighted. More specific method needs were expressed to support new, advanced approaches for the determination of chemical contaminants and residues as well as for isotope-ratio determinations for food authenticity. For example, screening approaches are trending toward determination of **multiple classes of pesticide residues** in a single method and stakeholder consensus around the best approach is needed. Similarly, as more sophisticated studies reveal the toxicological differences between metal species, analytical methods are needed to measure **species of multiple elements** simultaneously. Lastly, more definitive authenticity testing methods are also needed, and workshop participants expressed interest in methods for **isotope and isotope ratio determination in food matrices** as a routine approach for the future.



Collaboration and Harmonization

In many instances, increased collaboration between stakeholders in the food industry and better regulatory harmonization could help address significant challenges faced by the industry. For example, a **food safety task force** would help to unite national metrology institutes (NMIs), designated institutes (DIs), and other stakeholders interested in analytical method development and dissemination as well as RM development and production. In addition, future meetings and workshops can provide a platform for scientists from public/private, government, and academic sectors to congregate, network, and share new ideas and are designed to encourage participants to think of solutions and paths forward for challenges they face as an industry. These types of meetings bring together stakeholders who may otherwise never meet face-to-face, let alone collaborate on potential projects, and may lead to public/private partnerships. Such partnerships between stakeholders in the food industry can reduce the impact of fraud by addressing the problem quickly, help improve and maintain food quality, increase understanding of parameters such as process variability that may impact future food testing, and encourage data sharing. Fruitful partnerships reduce work siloes and duplication of effort and help to build capacity, which helps reduce strain on laboratories that may have limited time or effort to spend on testing requests. Lastly, harmonization between various global regulatory bodies and validation bodies can lead to the development of globally accepted international standards (e.g., for methodology, food-borne pathogens) and increased recognition of validation certificates. Availability of additional standards helps companies and private laboratories better demonstrate compliance to recognized methods, materials, and processes, and encourage technological innovation.



Laboratory Quality

Participants at the workshop also identified gaps in laboratory quality and potential ways that quality could be further supported for laboratories performing food safety testing. Participants were seeking assurances that testing laboratories were **operating under strict**

ISO guidelines, such as those addressing good laboratory practice (GLP) and standard operating procedures for cleaning. These guidelines help laboratories prove their regulatory compliance and give companies a mechanism to quickly determine whether a third-party testing laboratory is a contractual fit. Similarly, participants requested better **record keeping for annual training, official manufacturing audits, and factory assessments** for demonstration of compliance and laboratory quality. The overall sentiment was a fear that laboratories could falsely claim ISO compliance and produce low-quality data at a lower cost, and potentially take business away from more qualitied laboratories. Additionally, a standardized system for **demonstrating rigorous supplier vetting and auditing procedures**, traceability through the entire supply chain (i.e., upstream and downstream), and label verification would help avoid potential contamination occurring at various risk points. Support should be provided for producers who are developing new cleaning products or materials and designing equipment for easier breakdown for cleaning and inspection.

ACTIVITIES FOR THE LONG TERM (6+ YEARS)

Once significant progress has been made in development of new reference materials and methods, education and training outreach, collaboration and harmonization, and laboratory quality, food safety stakeholders will face new challenges. Stakeholders projected out to the long-term (6+ years) to identify solutions that may be needed as technology evolves.



Reference Materials

As methodology moves toward non-targeted screening approaches for many food safety issues, reference materials will be needed to evaluate the quality, repeatability, and reproducibility of **non-targeted methods**. Greater confidence in screening methodology

will lead to the identification of new contaminants to be evaluated for potential human health concerns and monitored in the food supply, requiring new targeted reference materials and standards for calibration, validation, and verification of analytical methods. Additionally, participants were forecasting needs related to **non-chemical food testing applications**, which may include sequenced or live specimens in the areas of microbiological testing, natural toxins, or authenticity. If future testing needs move in this direction, new reference materials will be needed to support accurate measurements. Also, as techniques and approaches for determination of product authenticity mature, additional RMs to validate testing approaches for f**ood certification** will be needed (e.g., halal, organic, vegan). Lastly, participants anticipated future needs for RMs to evaluate the **impact of recycled ocean plastic** on the food supply, including foreign matter contamination and chemical leaching from the plastic material into water and seafood.



Education and Training

Several long-term education and training needs were identified during the workshop. One request focused on guidance for **use of alternative or in-house methods** that have not been vetted through a standardization body. As new areas of food safety emerge, the

standard setting process can be slow to respond and may result in adoption of lower quality methods. Participants expressed a desire for guidance on appropriate use cases for alternatives to common methods to ensure that laboratory staff are familiar with proper testing procedures and can recognize fitness-for-purpose of an alternative method. Also, additional guidance on key components influencing **target organism detection** (e.g., contamination risks) would lead to development of better microbial testing procedures and assist laboratory staff with performing this type of test.

Allergen stakeholders recognized knowledge gaps between food scientists, clinicians, and the general public about **determination and interpretation of clinical thresholds** for allergenic foods. To provide perspective on test results, clinical thresholds for different allergens need to be added into targeted testing. In turn, improved allergy management practices would be encouraged, and clinicians would gain a better overall understanding of food allergies and the variability in reaction inducing allergen consumption levels among the population.



New and Updated Analytical Methods

Long-term needs for methods and method development involve improvements to testing approaches to make them more robust and efficient. Overall, workshop participants stressed the need for **more effective sample preparation/clean-up** methods to reduce

interferences and extend instrument lifetime. Additionally, all laboratories seek novel approaches to **increase sample throughput** without a significant reduction in data quality. For allergens research, achieving long-term goals will require **improved diagnostic procedures and tests** and standardized implementation to understand true clinical thresholds and stratify patients according to allergen dose

reactivity risk. Once identified, these protein allergen thresholds should be used directly in development of **informed targeted testing approaches** to give perspective on the meaning of the test results and for better allergy management practices. Lastly, developing economies need **low-cost options for authenticity testing**. Reducing costs of these authentication approaches would allow more laboratories in more parts of the world to develop methods, increasing their exposure to authentication testing and building their capacity in this area.



Collaboration and Harmonization

Long-term actions and goals for collaboration and harmonization were also discussed at the workshop and were based on observations and prediction of trends in testing and regulation for food safety. Participants described the need for **risk- and science-based**

allergen thresholds (e.g., based on established approaches such as from the VITAL program in Australia and New Zealand), noting that most countries lack regulatory thresholds and therefore also lack common targeted testing levels. With the current development of numerous point-of-consumption technologies that enable consumers to evaluate food safety, a harmonized regulatory framework for consumer devices (e.g., gluten detection devices) would address the disparity among the devices available on the market. As technology develops for point-of-consumption testing of foods for pathogens, chemical contaminants, or even authenticity, additional regulations and policy will be required. Lastly, access to data and proper data curation was one of the most expressed needs at the workshop. Developing databases and curating their content based on existing databases would help address many issues with collaboration, regulation, capacity building, test method development, and other areas relevant to the food industry.

ACTIVITIES FOR THE NIST FOOD SAFETY PROGRAM

By collaborating with regulatory agencies, private laboratories, universities, metrology institutes, reference material producers, proficiency testing providers, and technology developers, the NIST Food Safety Program will act as a conduit to solve many of the challenges identified at the workshop. This program will support reference material development, stakeholder education and training, the development and transfer of testing methods and new technologies, data and information brokering, and collaboration among food industry experts.

NIST plays a key role in harnessing measurement science to advance food safety, in line with its mission, capabilities, and interests. NIST will maximize its impact and mission fulfillment by positioning itself to anticipate future food safety technology trends that are aligned with industry and federal agency needs. As a non-regulatory agency of the U.S. Department of Commerce, **NIST is well positioned to address measurement challenges in the food industry and contribute to efforts to bolster food safety**.

The Material Measurement Laboratory (MML) is one of two metrology laboratories within NIST and provides critical measurement services and standards in the chemical, biological, and material sciences. MML provides the majority of the NIST's Reference Materials (RMs), Standard Reference Materials[®] (SRMs) and Quality Assurance Programs (QAPs) as measurement services directly to its stakeholders. In addition to these services, the measurement science, higher-order methods, and

reference data from MML provide confidence in measurements and technologies used in a wide range of applications, including clinical and health assessments, food nutrition and labeling, and most recently, food safety.



Near-Term Activities

In the near term (1-5 years), NIST will **develop a series of food-based RMs** (and SRMs when appropriate) for protein food allergens, inorganic and organic contaminants, and various indicators of product quality that can be used in analytical method development and

validation and to provide QA/QC for various food testing laboratories. Some examples currently in development include:

- A ground oats material suite with high and low levels of glyphosate and aminomethylphosphonic acid (AMPA)
- Naturally incurred pesticide residues in a mixed vegetable and fruit matrix
- Two single-source tree nut allergen materials

NIST aims to obtain a series of candidate product materials from sources across the agricultural and product manufacturing communities and then conduct a measurement screening effort (either internally or directly with stakeholders) to determine the range of contaminants or other product quality indicators observed. NIST may facilitate the development of candidate RMs through partnerships with agricultural producers, food manufacturers, or other stakeholders to lessen the demand for NIST to manage the material processing step of RM production.

In addition to RM production and characterization, MML has a three-decade long history of **conducting QAPs and interlaboratory studies** to demonstrate the performance of laboratories for a range of specific measurement challenges. At present, NIST is conducting a milk allergen protein interlaboratory study to assess measurement equivalence across multiple analytical platforms. Additional studies are being planned for chemical and microbiological contaminants for a range of candidate food reference materials. Outcomes from such interlaboratory programs are expected to lead to the development of fit-forpurpose, community-evaluated RMs and SRMs. NIST stakeholders also benefit directly from participation in these interlaboratory studies as an opportunity to assess in-house measurements, obtain feedback about performance from NIST experts, and ultimately improve their measurement capability.

MML is also developing **new measurement approaches, reference data collections, and data evaluation tools** for the confident determination of authenticity in seafood, natural products, and routinely adulterated food items, such as honey. A newly acquired seafood suite containing farm-raised and wildcaught salmon and shrimp is being developed for use in confident differentiation of seafood sources by a targeted analysis of fatty acids and toxic elements in addition to DNA analysis for species identification. Non-targeted analysis protocols are also being applied to a wide variety of authentic ginseng samples and other botanical natural products over a range of growing seasons and regions of geographic origin. The short-term goal is to develop reference material and data suites for stakeholder use and determine what unique data sets are needed to further aid the determination of authenticity.

NIST has recently established a program in microbial metrology to address critical national needs. RMs including enumerated cellular mixtures and genomic DNA mixtures are under development to **enable the adoption of advanced culture-independent, molecular technologies** that have emerged as a platform for

modern microbial detection and identification with broad applicability. Moving forward, NIST intends to expand past efforts focused on fundamental microbial measurement challenges to address challenges that are unique to the food safety community.

Finally, NIST will lay framework for a **Food Safety Measurements Consortium (FSMC)** to engage stakeholders for communication and promotion of the development, dissemination, and harmonization of measurement services, reference data and standards, and quality assurance and quality control practices in the safety testing of food products. The FSMC will support prioritization and development of collaborative research efforts to further measurement services and measurement science for advancement of food safety testing through engagement of global stakeholders representing food industry, testing laboratories, academia, and government perspectives. NIST will provide infrastructure, guidance, and leadership to the FSMC with the intention of developing capabilities of other stakeholders and empowering truly global collaborative solutions.



Long-Term Activities

In the long term (6+ years), NIST is on course to become one of the primary stakeholders in global food safety efforts with contributions from our renowned measurement services, reference data, and standards. As the program grows, other NIST centers and programs

beyond MML will be leveraged, and private-public partnerships with food industry and product manufacturers will improve block chain management and advance food packaging technologies. NIST has also earned international trust and is uniquely poised to become a leader in the development of innovative diagnostic technologies and next-generation measurement capabilities such as point-ofconsumption sensors for rapid and reliable detection and identification of pathogens, adulterants, and chemical contaminants to protect consumers. NIST is also poised to serve as a trusted broker for universally translatable data and knowledge exchange for the U.S. and global food supplies while providing continuous standards and services that promote global trade and commerce. **Our aim is to combine innovative measurement science with world-class chemical and biological metrology and standards to provide U.S. food industry and manufacturers with an industrial competitiveness advantage for a global impact. This integrated NIST program will utilize cutting-edge measurement science, standards, and measurement services coordination, and advanced communications to detect food safety hazards and prevent the spread of illness and injury while securing reliable U.S. agricultural and food manufacturing supply chains.**

LOOKING FORWARD

NIST leveraged strong relationships with food industry stakeholders to convene the NIST Food Safety Workshop. NIST is poised to be a leader in providing metrology solutions to address food safety challenges, built through extensive experience in preparation and characterization of reference materials and providing measurement support through quality assurance programs. The stakeholder input gathered at the workshop, as well as the networks strengthened through a common goal, will be invaluable in the development and success of the NIST Food Safety Program. The invited speakers expressed that key challenges in the food safety industry involve a lack of information and data sharing; time-consuming and

costly testing methods; a lack of suitable reference materials for method development, validation, and verification; limited collaboration between institutions; ensuring ingredient and product authenticity; and non-standardized product labeling. In addition, the lack of harmonized international standards may cause unnecessary hurdles in improving food safety, such as requiring redundant testing. The NIST Food Safety Program will focus on addressing these challenges through development of reference materials; quality assurance programs; mechanisms for data collection, sharing, and evaluation; and other innovative tools. A driving principal of the NIST Food Safety Program will be ongoing conversations with and continuous feedback from stakeholders in the food industry to ensure that the developed solutions are fit-for-purpose and meet the needs of this global community.

APPENDIX A: SUMMARY OF PRESENTATIONS

OCTOBER 28, 2019 – WELCOME AND KEYNOTE ADDRESSES

Welcome to NIST — James Olthoff, Associate Director for Laboratory Programs, NIST introduced the workshop participants to NIST and its purpose in using measurements to advance fields such as food safety. He discussed the work that NIST does that is applicable to food safety, including reference material and other standards development efforts, as well as what NIST hopes to accomplish through this workshop.

Regulatory Perspective on Food Safety — *Robert Buchanan, Professor, Department of Food Science and Nutrition, University of Maryland* spoke about the changing role of testing in food safety regulatory programs as a result of the "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" Rule of the Foods Safety Modernization Act of 2011. He explained the implications of this regulation and what is required of food manufacturers to comply with it; he also introduced key concepts on microbiological testing with hypothetical examples of when and how to use various testing methods.

Industry Perspective on Food Safety — *Roger Lawrence, Lawrence & Associates, LLC (Formerly of McCormick and Company)* outlined the challenges that the food safety faces regarding raw material acquisition, using the spice trade to outline examples of adulteration risks and the importance of a strong supply chain.

Laboratory Perspective on Food Safety — Darryl Sullivan, Chief Science Officer, Eurofins Scientific, Inc. presented the challenges with food safety faced by laboratories, including challenges with the amount of testing requested, determining the level of validation required, developing robust test methods for large sample volumes, and having access to reference materials.

Keynote Summary and Workshop Focus — *Melissa Phillips, Research Chemist, Chemical Sciences Division, NIST* spoke about the overall focus of the workshop, including the goals, the schedule, the spread of participants (i.e., industry, laboratories, governmental organizations), and the work that NIST has been involved in to promote food safety efforts.

OCTOBER 28, 2019 – MICROBIAL CONTAMINATION

Microbial Contamination: An Industry Perspective on Risk Management — Pamela Wilger, Applied Microbiologist and Food Safety Senior Global Expert, Cargill spoke about microbial contamination risk identification and assessment, sharing best practices for defining preventive controls, process validation, preventing recontamination after validation, and conducting tests in a finished product. She discussed common challenges with microbial contamination and potential solutions.

Regulatory Perspective on the Adoption and Implementation of Microbiological Methods — *Thomas Hammack, U.S. Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSAN)* spoke about the factors that affect the FDA's adoption and implementation of microbiological methods, including the qualities that FDA looks for in methods. He also outlined the FDA's guidelines for method validation and guidelines for accepting data from tests conducted by private, non-governmental laboratories.

Approaches to the Validation of New and Emerging Microbiological Technologies: A Micro Challenge in Private Laboratories — Wendy McMahon, General Manager, Silliker Food Science Center spoke about method validation for microbial testing, including advantages and disadvantages of different methods. She discussed challenges and potential solutions related to complex food matrices and the ability of validated methods to detect a target organism. She also presented case studies where validated alternative methods could be used across different foods not included in a validation study.

Challenges of Method Development in a Diverse Testing Environment — *Mike Clark, Global Marketing Manager, Bio-Rad* spoke about method development and the various aspects that inform the process, including customer requirements, validations, regulations, matrix complexity, and performance. He also spoke on several challenges developing methods for more challenging food matrices (e.g., spices, dairy powders), noting that some of the challenges could be addressed through international regulatory harmonization and standard development.

Genomic Methods: Benefits and Challenges for Industry Adoption — Jesse Miller, Director of Applied Research and Innovation, National Science Foundation spoke about types of genomic test methods, including the Sanger Sequencing process, next-generation sequencing (NGS), whole genome sequencing (WGS), and 16S rRNA sequencing. He outlined different equipment and platforms for NGS and WGS and how industry uses these test/platforms to sequence various matrices (e.g., botanicals, seafood). He also noted the challenges with these methods and offered potential solutions.

OCTOBER 29, 2019 - CHEMICAL CONTAMINANTS & RESIDUES

Chemical Contaminants and Residues in Food — *Katerina Mastovska, Eurofins Food Integrity and Innovation* spoke about the variety of chemical contaminants and residues in food: pesticide and veterinary drug residues, toxic elements, natural toxins, environmental and processing contaminants, migrants from packaging materials, and unapproved additives and adulterants. Modern analytical strategies include mass spectrometry (MS) based methods for targeted or non-targeted analyses. She discussed the primary uses of reference materials as well as some alternative options.

Analysis of Toxic Elements in Foods — *Christopher Smith, Coca-Cola Company* spoke about food safety from an industry perspective. Its mission is to ensure that all food and beverages are available for safe consumption, with a focus on the "big four" metals as well as second tier metals. Because of all the ingredients and outputs, millions of performance tests are performed. Auditors help ensure that prevention and good manufacturing processes are in place.

Analysis of Natural Toxins in Foods — *Pearse McCarron, National Research Council Canada* provided insights and analysis of natural toxins in food. Of the two major classes—mycotoxins and phycotoxins— McCarron focused on phycotoxins and seafood safety. To ensure public health, good measurements are needed to establish relevance of the toxins. Recommendations and needs included improved field-testing options, comprehensive multiclass toxin monitoring, improved reference materials, proficiency testing, training and collaboration.

Analysis of Pesticide and Herbicide Residues in Foods — Jon Wong, US FDA CFSAN spoke about how he and his colleagues have been developing screening procedures. He highlighted the emerging need for pesticide analysis and standards—pesticides not registered in the U.S. that lack standards are difficult to screen for. While accredited labs require proficiency testing for multiresidue procedures, there are a wide

variety of pesticides, a great number of matrices, and different testing procedures. Several possible remedies were suggested.

Analysis of Veterinary Drug Residues in Foods — Joe Boison, Canadian Food Inspection Agency (retired) spoke about the public health concern of veterinary drugs, which may remain unmetabolized in the animal if food producers do not follow the rules; this residue can be toxic to humans. Labs play a role in monitoring the use of drugs in domestic and foreign product: labs should be accredited by international requirements. Boison stressed the need for materials for veterinary drugs—SISs, CRMs, and IRMs.

OCTOBER 29, 2019 – FOOD ALLERGENS

Protein Allergens in Food; Overview of Commodities, Chemistries, and Matrices — Eric Garber, US FDA Center for Food Safety and Applied Nutrition provided an overview of protein allergens and addressed a number of questions about food allergens, such as What does it mean to be allergic to 'soy'? and Are there meaningful Standards of Identity and can these be used to quantify 'soy'? He gave an overview of "allergenic proteins," highlighting peanuts, milk, and the Brazil nut. He also discussed various needs, such as determining levels of safety and acceptable levels of variance.

The Clinical Perspective of Food Allergens — *Stefano Luccioli, US FDA CFSAN* spoke about the burden on public health (including psycho-social impact) and discussed various labeling issues, such as ambiguity of terms, and treatments. Allergy prevalence rates, which are self-reported rather than clinically diagnosed, are not well determined, and may be more widespread than previously thought. Future goals include educating the public and physicians and improving diagnostic and epidemiological tools.

Overview of International Regulations of Protein Allergens in Food — *Bert Pöpping, FOCOS GbR* gave a top-level overview of food regulations for various countries and regions. He spotlighted the approach used in Japan of authorizing particular test kits to inform food allergens, as well as the process of setting rules for food labeling across Europe. German authorities implemented action levels based on VITAL 2.0 while the scientific committees concerned with food allergens of Belgium and The Netherlands set levels which, for some priority allergens like egg and milk, differed no less than 100 times. At present, there are no threshold levels set by the European Commission. He emphasized the need for more reference materials for allergens and the hope for harmonization.

Measurement of Protein Allergens in Food: Immunoassay, Mass Spectrometry, and DNA — Melanie Downs, University of Nebraska-Lincoln, Food Allergy & Resource Program spoke about various methods (immunoassays, polymerase chain reaction [PCR], mass spectrometry [MS], and consumer devices) to measure protein allergens in food. Each method has particular uses, shortcomings, and challenges (an ideal method would be able to detect all forms of allergen-derived ingredients). Recommendations include risk-based sampling plans, quantitative results for risk-assessment and action level enforcement, and method comparability.

Supply Chain Management for Protein Allergens in Food — Jupiter Yeung, Todd DeKryger, Nestle Nutrition spoke about allergen challenges to the food industry; the impact of global trade; AOAC Official Methods of Analysis, many of which have been adopted as harmonized international reference methods; and controlling allergens in the supply chain (e.g. Gerber's traceability systems). They spotlighted comingling opportunities from farm to table against a backdrop of global trade, and emphasized the need to control allergen presence through education and proper practices.

Protein Allergen Management in Food Production — *Scott Hegenbart, Conagra Foods* spoke about how allergen management has evolved food production practices, particularly sanitation and changeover; how allergen thresholds have the potential to enhance allergen management; and how risk calculations show that label verification is a vital aspect of allergen management. All components of food production have evolved for improved allergy management. In addition to sanitation, proper labeling is an essential component which needs more work.

OCTOBER 30, 2019 – AUTHENTICITY, FRAUD, & ADULTERATION

"Nitrogen Spiking" of Protein-Based Nutritional Products — Spencer Carter, Senior Vice President, Dyad Labs spoke about the issue of nitrogen spiking in products such as whey protein powder and discussed the reasons why it occurs. He discussed a qualitative method for protein analysis that Dyad labs is developing and leading a reproducibility study for and talked about the formation of a USP Dietary Protein Expert Panel to support development of new reference materials, monographs, standards, tests, and assays.

The Application of Multi-Element and Multi-Isotope Analysis; A Potential Tool to Detect Food Fraud — *Simon Kelly, Food Safety Specialist (Traceability), International Atomic Energy Agency* spoke about using stable isotope and trace element (SITE) analyses for food authentication, which maps a food to the environment where it was produced and the agricultural methods used in its production. He illustrated the precision of SITE analyses via an example using beef products from the United Kingdom, which showed that these methods could determine in which region the cows were raised. He also highlighted issues with these methods and potential ways to address them.

UK Government Chemist – Statutory Case Analysis – Julian Braybrook, Director of Measurement Science, UK National Measurement Laboratory spoke about the roles and responsibilities of the UK's Government Chemist and case studies of various issues with food authenticity, explaining the National Measurement Laboratory's methodology for assessing various allergens, toxins, and other substances in foods.

Preventing Adulteration in Botanical Dietary Supplements — *Stefan Gafner, Chief Scientific Officer, American Botanical Council* spoke about detecting adulterated dietary supplements, focusing specifically on turmeric—one of the most adulterated spices. He described different types of tests used to determine turmeric adulteration, including high-performance thin-layer chromatography and carbon isotope measurement, and discussed common risk points to keep in mind for botanical supplements.

New Technologies in Botanical Authenticity Analysis — SeonBeom Kim, University of Illinois at Chicago College of Pharmacy spoke about analytical methods and instruments used by his team for botanical material authentication, including DNA barcoding analysis, nuclear magnetic resonance (NMR) spectroscopy, chemometrics/Principal Component Analysis, and benchtop NMR. He included examples of these analyses used to authenticate dietary supplements including various licorice species as well as curcumin, discussing the results gathered using different methods.

Food Fraud and Economically-Motivated Adulteration — John Szpylka, Director of Scientific Affairs, Merieux NutriSciences spoke about the various types of food adulteration (e.g., substitution, dilution, concealment, mislabeling, grey market production, unapproved enhancements, counterfeiting) and the challenges and capabilities of using non-targeted testing methods to detect fraud. He also discussed reference materials for non-targeted methods, listing the challenges/questions associated with their development.

OCTOBER 30, 2019 – GLOBAL FOOD SAFETY

Global Food Safety: An African Perspective — Maria Fernandes-Whaley, National Metrology Institute of South Africa, Pretoria shared information on agricultural production in Africa and the challenges the continent faces with food safety, particularly aflatoxin testing and regulatory capacity building. She spoke on the work that the National Metrology Institute of South Africa is doing to develop proficiency testing schemes and certified reference materials for various food matrices as well as its future plans for population growth, alternative protein sources, and climate change.

Global Food Safety: An American Perspective — *Valnei Cunha, Inmetro Brazil* spoke about the agricultural markets in American countries and the challenge that countries face when their main source of GDP (i.e., agricultural products) is affected by food safety issues. He also shared the work that INMETRO has done to bring together experts from various regional metrology institutes to share information and build measurement capacity, as well as a new project to develop a suite of plant-based protein reference materials with NIST and the National Research Council of Canada.

Global Food Safety: An Asia/Pacific Perspective—Hongmei Li, National institute of Metrology, China highlighted major trends of food safety in the Asia/Pacific region, the regulation system for food safety in a number of Asian countries, activities focused on measurement standards and CRMs, and needs and challenges in food safety analysis along with possible solutions.

Global Food Safety: A European Perspective—Piotr Robouch, European Commission Joint Research Centre highlighted the challenges in global food safety from a European perspective and the necessity of collaboration to reach a consensus. He spoke about the Official Control Regulation, which addresses the application of food and feed laws, rules on animal health and welfare, and plant health and protection products; EU Reference Laboratories at the JRC; the Rapid Alert System for Food and Feed (RASFF); Horizon Europe (a research and innovation program), and spotlighted RM demands by application and region.

APPENDIX B: POSTERS

Submitted posters were displayed in the NIST Poster Hallway throughout the Workshop. Posters presented by NIST authors were available virtually and are available on the <u>NIST Food Safety Workshop</u> <u>Webpage</u>. Poster authors discussed their research with viewers during the poster reception session on October 29, 2019.



Chemical Contaminants and Residues

Optimizing a 190+ Pesticides Multi-Residue Screening Workflow for the Preparation and Analysis of Produce by LC-MS/MS — Joseph Konschnik, RESTEK Corporation; Landon A Wiest, RESTEK Corporation; Dan Li, RESTEK Corporation; Alexacndria M Pavkovich, RESTEK

Corporation; Sue Steinike, RESTEK Corporation; and Justin Steimling, RESTEK Corporation.

Developing a robust LC-MS/MS method for the determination of anionic polar pesticides in a range of foodstuffs without derivatization — *Emily Britton, Waters; Joe Romano, Waters; Dimple Shah, Waters; Benjamin Wuyts, Waters; and Euan Ross, Waters.*

Detection of Pesticides and Herbicides in Craft Beer Using DART-MS — *Frederick Liu, Ionsense, Inc.; Brittany Laramee, Ionsense, Inc.; Taylor Feraco, NeXeP LLC.; Paul Liang, Ionsense, Inc.; and Brian Musselman, Ionsense, Inc.*

The analysis of polar anionic pesticides and contaminants by a new single, multi-analyte, robust and sensitive 'sample-to result' IC-MS/MS workflow — Dan Quinn, Thermo Fisher Scientific; Fausto Pigozzo, Thermo Fisher Scientific; Richard Fussell, Thermo Fisher Scientific; and Qilei Guo, Thermo Fisher Scientific.

A Multiresidue Method for Pesticide Analysis Using an Orbitrap Tribrid Mass Spectrometer and Automatic Background Exclusion — Dan Quinn, Thermo Fisher Scientific; Dipankar Ghosh, Thermo Fisher Scientific; Anastasia Kalli, Thermo Fisher Scientific; and Seema Sharma, Thermo Fisher Scientific.

Trace concentration determination of phthalates in non-PVC food packaging — *Katherine Carlos, FDA CFSAN; Lowri de Jager, FDA CFSAN; and Timothy Begley, FDA CFSAN.*

Non-Targeted Investigation of Extracted and Leached Chemicals from Packaging Materials by GC-MS and HR GC-MS — Brad Barrett, LECO Corporation; Elizabeth Humston-Fulmer, LECO Corporation; and Joe Binkley, LECO Corporation.

Direct Mass Spectrometric Identification of E-Waste in Polymeric Food Contact Materials — *Luke K. Ackerman, US-FDA Center for Food Safety & Applied Nutrition; and Franky Puype, ITC-Zlin.*

Determination of Free Bisphenol A in Commercially Packaged Ready to Consume Carbonated/Noncarbonated and Non-alcoholic Beverages with Immunoaffinity Column Purification and UPLC Fluorescence Detector — Jianmin Liu, Waters Corp.; Danrey Toth, Waters Corp.; Justine Yu, Waters Corp.; and Lingyun Chen, Waters Corp.

Determination of Multi-Mycotoxins in Astragalus Root by Imunoaffinity Purification and LC-MS/MS — *Jianmin Liu, Waters Corp.; Elise Palmer, Waters Corp.; Dan Mao, Waters Corp.; and Lingyun Chen, Waters Corp.*

Application of an Automated Sample Preparation System for Mycotoxin Analysis in Foods — *Kai Zhang, FDA/CFSAN.*

Preparation and characterization of an aflatoxin B1 calibration solution in the framework of a capacity building program for mycotoxin metrology — Gustavo Martos, Bureau International des Poids et Mesures (BIPM); Steven Westwood, BIPM; Lucía Casas, Laboratorio Tecnológico del Uruguay (LATU); Laura Vanessa Morales, Instituto Nacional de Metrología de Colombia (INM); Rachel Torkhani, Institut National de Recherche et d'Analyse Physico-Chimique (INRAP); Magali Bedu, BIPM; Xiang Jiang Li, National Institute of Metrology (NIM), China; Ralf Josephs, BIPM; and Robert Wielgosz, BIPM.

The Impact of Polarity Switching in LC-MS/MS for Analyzing Large Panels of Mycotoxins and Metabolites in Agricultural Samples — Oscar G. Cabrices, SCIEX; Jianru Stahl-Zheng, SCIEX; and Daniel McMillan, SCIEX.

A Year-to-Year Comparison of the Occurrence of 3-Monochloro-1,2-Propanediol (3-MCPD) Esters and Glycidyl Esters in Infant Formulas Purchased in the U.S. and Germany — Jessica Beekman, U.S. Food and Drug Administration; Linda Kanz, University of Hohenheim; Michael Granvogl, University of Hohenheim; and Shaun MacMahon, U.S. Food and Drug Administration.

Examination of Heavy Metal Contamination found in Raisins, Sultanas & Currants by ICP-MS — *Patricia Atkins,* SPEX CertiPrep; *Robert Lockerman,* CEM Corporation; *Tina Restivo,* CEM Corporation; and *Carlye McConnell,* SPEX CertiPrep.

Examination of Elemental Composition & Toxic Metals in Bread Spreads — *Patricia Atkins, SPEX CertiPrep; Robert Lockerman, CEM Corporation; Tina Restivo, CEM Corporation; and Carlye McConnell, SPEX CertiPrep.*

Arsenic species in edible seaweeds commercialized in the United States — *Sean D. Conklin,* Food and Drug Administration, Center for Food Safety and Applied Nutrition; **Mesay Mulugeta Wolle**, Food and Drug Administration, Center for Food Safety and Applied Nutrition; **Sara Handy**, Food and Drug Administration, Center for Food Safety and Applied Nutrition; and **Todor Todorov**, Food and Drug Administration, Center for Food Safety and Applied Nutrition;

Non-Targeted and Suspect Screening using LC/HR-MS to Identify Unknowns: Quality Controls and Retention Time Prediction — *Christine M. Fisher*, Food and Drug Administration, Center for Food Safety and Applied Nutrition; Jacob H. Premo, Food and Drug Administration, Center for Food Safety and Applied Nutrition; and Ann M. Knolhoff, Food and Drug Administration, Center for Food Safety and Applied Nutrition.

Miniature Mass Spectrometers for Field Detection of Food Chemical Contaminants and Residues — Christina Ferreira, Department of Chemistry and Bindley Bioscience Center, Purdue University; Zhuoer Xie, Department of Chemistry, Purdue University; and R. Graham Cooks, Department of Chemistry, Purdue University.

Certification of Marine Toxins by Quantitative NMR (qNMR) and Isotope Dilution MS (IDMS) — *Matthias Nold, MilliporeSigma; Markus Obkircher, MilliporeSigma; Alexander Rueck, MilliporeSigma; Christine Hellriegel, MilliporeSigma; Rudolf Koehling, MilliporeSigma.*

Perfluoroalkyl Substance (PFAS) Analysis in Drinking Water, Sediments and Food Samples by QuEChERS, SPE, and LC-MS/MS — Scott Krepich, Phenomenex; Nick Mitchell, Phenomenex.



Allergens

Detection of peanut in legume containing food products — *Chung Cho*, *Office of Regulatory Science, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration; Rakhi Panda, FDA; Katherine Ivens, FDA; Anne C. Eischeid, FDA; Shaun*

MacMahon, FDA; Gregory O. Noonan, FDA; and Eric A.E. Garber, FDA.

Development and Validation of a Multiplex Real-time PCR Assay to Detect Allergenic Peanut in Complex Food Matrices — Anne Eischeid, U.S. Food and Drug Administration; and **Caroline Puente-Lelievre**, U.S. Food and Drug Administration.

The curation of transcriptomic data for use as a proxy protein database for unsequenced tree nuts — *Cary Prione-Davies,* The U.S. Food and Drug Administration; *Melinda A. McFarland,* The U.S. Food and Drug Administration; *Christine H. Parker,* The U.S. Food and Drug Administration; and *Timothy R. Croley* The U.S. Food and Drug Administration.

The Selection of Tree Nut Peptide Markers: A Need for Improved Protein Sequences Databases — *Weili Xiong, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition; Melinda A. McFarland, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition; Cary Pirone, <i>U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition; and Christine H. Parker, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition; and Christine H. Parker, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition;*

Western Blot Analysis of Fermented-hydrolyzed Gluten Utilizing Antibodies Employed in a Novel Multiplex-Competitive ELISA — Rakhi Panda, FDA; and Eric A.E. Garber, FDA.

Measurements of Specific Milk Allergens in Baked Food Challenge Materials — *Stephanie Filep, Indoor Biotechnologies, Inc.; Bryan Smith, Indoor Biotechnologies, Inc.; Sabina Wuenschmann, Indoor Biotechnologies, Inc.; and Martin Chapman, Indoor Biotechnologies, Inc.*

Simultaneous Quantification of Major Food Allergens Using a Multiplex Immunoassay — Stephanie Filep, Indoor Biotechnologies, Inc.; Bryan Smith, Indoor Biotechnologies, Inc.; Kristina Reid Black, Indoor Biotechnologies, Inc.; and Jessica Lee, Indoor Biotechnologies, Inc.

xMAP FADA: A multiplex method for simultaneous detection of 15 food allergens plus gluten — *Katherine Ivens, FDA; Chung Y. Cho, FDA; and Eric Garber, FDA.*

Optimization of a targeted, multi-allergen LC-MS/MS method for the quantification of egg, milk, and peanut in food — *Katherine L. Fiedler*, U.S. Food and Drug Administration; *Weili Xiong*, U.S. Food and Drug Administration; and *Christine H. Parker*, U.S. Food and Drug Administration.

Development of an in vitro Bio-assay using Human Intestinal and Immune Cell-lines to Measure the Immuno-pathogenicity of Food Allergens — **Prasad Rallabhandi**, Food & Drug Administration; **Chung Y. Cho**, FDA/CFSAN; **Shaun MacMahon**, FDA/CFSAN; and **Eric A.E. Garber**, FDA/CFSAN. **Characterization and Certification of Milk Proteins as Certified Reference Materials** — *Derrell Johnson, MilliporeSigma; Kevin Ray, MilliporeSigma; Andria Widaman, MilliporeSigma; Uma Sreenivasan, MilliporeSigma; and Norman Hardt, MilliporeSigma.*

Food allergen reference materials - addressing an unmet need — Gill Holcombe, LGC; Clare Mills, The University of Manchester; Malcolm Burns, LGC; Chiara Nitride, The University of Manchester; Adrian Rogers, Romer Labs UK Ltd; Malvinder Singh, LGC; Victoria Lee, The University of Manchester; Anuradha Balasundaram, The University of Manchester; Stephen Ellison, LGC; Kirstin Gray, LGC; Julian Braybrook, LGC; and Michael Walker, LGC.

Reference materials for food allergen analysis — *Bert Popping, FOCOS* - *Food Consulting Strategically; and Roland Poms, MoniQA Association.*



Authenticity and Adulteration

International Standards for Food Authenticity and Allergen Detection from ISO TC 34/SC 16 Horizontal Methods for Molecular Biomarker Analysis — *Michael Sussman*, USDA.

Food safety and food authenticity by peptide mass spectrometry – Constitution of new § 64 LFGB working groups for method validation and standardization — Manfred Stoyke, Federal Office of Consumer Protection and Food Safety; and **Rene Becker**, Federal Office of Consumer Protection and Food Safety.

A traceable two-dimensional image analysis method for the characterizing quality parameters in ricebased candidate reference material — Bryan Calderón-Jiménez, Chemical Metrology Division, Costa Rican Metrology Laboratory (LACOMET); Dionisio Gutiérrez-Fallas, Molecular, Image and Color Spectroscopy Laboratory, Physics School, Costa Rica Institute of Technology; Ernesto Montero-Zeledon, Molecular, Image and Color Spectroscopy Laboratory, Physics School, Costa Rica Institute of Technology; Gabriel Molina-Castro, Chemical Metrology Division, LACOMET; and Katia Rosales-Ovares, Chemical Metrology Division, LACOMET.

Meat Authenticity: Does more frequent PT participation improve PT performance? — *Heather Jordan, LGC Group; and Dr. Matthew Whetton, LGC Group.*

A Rapid, Univariate FT-NIR Procedure to Determine Moisture Concentration, a Quality Parameter, in Olive Oil — Magdi Mossoba, FDA; Ali Reza Fardin-Kia, FDA; Sanjeewa R. Karunathilaka, FDA; Betsy Jean Yakes, FDA; and Zachary Ellsworth, University of Maryland, Joint Institute for Food Safety and Applied Nutrition.

Analysis of Acylglycerols in Edible Oils by Gas Chromatography Using a Unique Stationary Phase — Joseph Konschnik, RESTEK Corporation; Colton Myers, RESTEK Corporation; Kristi Sellers, RESTEK Corporation; Jana Rousova, RESTEK Corporation; Shawn Reese, RESTEK Corporation; Jaap de Zeeuw, RESTEK Corporation; and Chris Rattray, RESTEK Corporation.

Real-Time Authentication of Whiskeys Using DART-QDa Analysis — *Emily Britton, Waters; Sara Stead, Waters; and Renata Jandovia, Waters.*



Other

Advanced Oxidation Process (Clean Flow) as a Risk Prevention Control Step for Microbiological and Chemical Hazards Encountered on Fresh Produce and Food Contact

Surfaces — Peter E. Gordon, International Ultra Violet Association, Food and Beverage Safety Initiative Co-Chair; Keith Warriner, University of Guelph; and Mahdiyeh Hassani, University of Guelph.



NIST Virtual Posters

Screening for Ten Phthalates in Four Food Standard Reference Materials (SRMs) by Gas Chromatography/Tandem Mass Spectrometry (GC/MS/MS) — Bruce A. Benner, Jr., NIST Chemical Sciences Division.

Addressing Current Measurement Challenges with the Health Assessment Measurements Quality Assurance Program (HAMQAP) — Charles A. Barber, NIST Chemical Sciences Division; Bruce A. Benner, Jr., NIST Chemical Sciences Division; Jeanice M. Brown Thomas, NIST Chemical Sciences Division; Carolyn Q. Burdette, NIST Chemical Sciences Division; Johanna Camara, NIST Chemical Sciences Division; Katrice A. Lippa, NIST Chemical Sciences Division; Stephen E. Long, NIST Chemical Sciences Division; Jacolin A. Murray, NIST Chemical Sciences Division; Melissa M. Phillips, NIST Chemical Sciences Division; Benjamin J. Place, NIST Chemical Sciences Division; Catherine A. Rimmer, NIST Chemical Sciences Division; Michael R. Winchester, NIST Chemical Sciences Division; Laura J. Wood, NIST Chemical Sciences Division; and Lee L. Yu, NIST Chemical Sciences Division.

Human Exposure to Arsenicals in Seafood — *Caleb Luvonga*, NIST Chemical Sciences Division and Department of Chemistry and Biochemistry, University of Maryland; *Lee L. Yu*, NIST Chemical Sciences Division; *Catherine A. Rimmer*, NIST Chemical Sciences Division; and *Sang Bok Lee*, Department of Chemistry and Biochemistry, University of Maryland.

An Interlaboratory Study to Evaluate the Equivalence of Milk Protein Allergen Measurement — Winnie Tran, Biochemistry Department, University of Maryland; Marie-Alexandre Adom, Chemistry Department, University of Virginia; Melissa M. Phillips, NIST Chemical Sciences Division; Ashley Beasley Green, NIST Biomolecular Measurement Division; and David Bunk, NIST Biomolecular Measurement Division.

A Reference Material Suite for Evaluating Seafood Authenticity and Safety — Debra L. Ellisor, NIST Chemical Sciences Division; Melissa M. Phillips, NIST Chemical Sciences Division; Benjamin Place, NIST Chemical Sciences Division; Catherine Rimmer, NIST Chemical Sciences Division; and Laura Wood, NIST Chemical Sciences Division.

Screening Glyphosate and AMPA in Oat Cereals for the Selection of Candidate Reference Materials — Justine M. Cruz, NIST Chemical Sciences Division; Jacolin A. Murray, NIST Chemical Sciences Division; and Katrice A. Lippa, NIST Chemical Sciences Division.

Assessing Performance of Metagenomic Profiling Using Microbial Genomic DNA Reference Material Mixtures — Jason G. Kralj, NIST Biosystems and Biomaterials Division; Dieter M. Tourlousse, NIST Biosystems and Biomaterials Division; Stephanie L. Servetas, NIST Biosystems and Biomaterials Division; Samuel P. Forry, NIST Biosystems and Biomaterials Division; and Scott Jackson, NIST Biosystems and Biomaterials Division. Characterization of Silicon Dioxide Food Additives by Single Particle Inductively Coupled Plasma Mass Spectrometry — Monique E. Johnson, NIST Chemical Sciences Division; Sadia Afrin Khan, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition (CSFAN); Timothy R. Croley, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition (CSFAN); Antonio R. Montoro Bustos, NIST Chemical Sciences Division; Ingo H. Strenge, NIST Chemical Sciences Division; and Karen Murphy, NIST Chemical Sciences Division.

Development and Value Assignment of an Incurred Multi-Mycotoxin Reference Material — Melissa M. *Phillips,* NIST Chemical Sciences Division; Jennifer Ness, NIST Chemical Sciences Division; Tomás López *Seal,* Instituto Nacional de Tecnología Industrial (INTI); Carolyn Q. Burdette, NIST Chemical Sciences Division; and Kai Zhang, US Food and Drug Administration (FDA).

Chemical Sciences Division: Cryogenic Reference Material Production Facility — *Rebecca Pugh*, *NIST Chemical Sciences Division*.

Determination of Benzo[a]pyrene at low-levels in Olive Oil — *Walter B. Wilson, NIST Chemical Sciences Division; Jacolin A. Murray, NIST Chemical Sciences Division; Blaza Toman, NIST Statistical Engineering Division.*

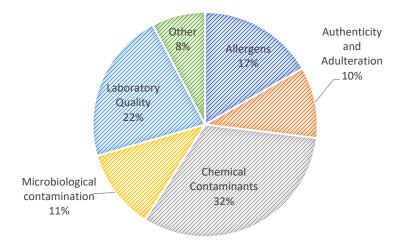
Future Plans at the National Institute of Standards and Technology for Hemp Quality Assurance Program and Reference Materials — *Walter B. Wilson*, *NIST Chemical Sciences Division; Charles A. Barber*, *NIST Chemical Sciences Division; Melissa M. Phillips*, *NIST Chemical Sciences Division; Catherine A. Rimmer*, *NIST Chemical Sciences Division; Laura J. Wood*, *NIST Chemical Sciences Division.*

APPENDIX C: SLIDO QUESTIONS AND POLLS

The following questions posed by workshop participants were generated via Slido⁶, a polling platform tool implemented during the workshop. During the speaker presentations, participants asked questions to be answered during the discussion portions of the workshop. Participants could upvote questions to indicate additional interest in that question. Slido was also used to poll the audience, and open-ended questions with participant responses are provided below.



At the opening of the workshop, attendees were asked to describe the one food safety measurement challenge that keeps them up at night. The results of that poll are summarized in the word cloud above, and further distilled into the pie chart below.



Questions are organized by the session in which they were asked, and questions in each section are organized by the number of upvotes, with questions receiving more upvotes listed first. Some participant questions and responses have been modified for archival clarity, and duplicate or repetitive questions or comments have been removed. In addition, relevant polls results are summarized under the sessions to which they correspond.

⁶ <u>https://www.sli.do/</u>

Keynotes

Could the role of pesticides in food safety be viewed more as an acute versus chronic problem?

Which class of safety issues concerns you the most and why?

Are contract testing laboratories generally accredited and to what standard? Are uncertainties assigned to their measurements?

How much does method validation cost vs a recall and/or lawsuit?

Do contract testing laboratories normally report results at or below LOD from a quantitative method, like ICP-MS for heavy metals in foods?

How does test method validation change with "smarter" instrumentation or less informed analysts considering the complexity of analytes and matrices for food?

Could you comment a bit more on your opinion of the importance of screening and semi quantitative methods, and what their role should be in the lab?

How important is supplier accreditation in assuring quality in the supply chain?

Microbiological Contaminants

How confident are we in linking illnesses to food?

How NIST could partner with companies to determine process variability?

What is the metric for "quantitative" microbiological evaluations?

Are microbial regulations quantitative or qualitative?

What would you recommend as the first target microbiological contaminant to focus on for a food or cannabis reference material?

Should not FDA collaborate with other government and non-government organizations globally to create a database of historical data from challenge studies?

Is MALDI technology the best platform for microbiology testing?

Do most companies/laboratories go through the validation rigor that you describe?

Could you describe how a surrogate microorganism is used? Is it spiked into product that is then sold to the public?

Where can data from challenge studies and historical testing be accessed? Is there a database disseminating new info as food products undergo challenge studies?

What is the metrological traceability (SI?) for microbiological quantifications?

Is the lack of sharing at the scientist level or the company management level?

If DNA measurements are not quantitative, what do I do if multiple species are reported?

Would accreditation help solve some of the issues that were presented today regarding method validations, increased industry responsibility, etc.?

Microbiological Contaminants

Could ISO standards or other international organizations such as Codex be the best mode for method harmonization? What are the alternatives?

Does a kit manufacturer or a food company pay for the fit for purpose studies?

Are there any 'quick tests' for toxins produced by microbes that you would trust?

Would microbiological reference materials benefit from being incurred instead of spiked?

Does the necessary sample size change from sample to sample different foods or cannabis?

For MALDI, how can an analyst determine a mass spectrum is good?

Could a central repository host data from challenge studies (and others) without curation, or would curation be needed?

Would it be useful and feasible for accreditation bodies to standardize measurement capacity declarations into a single database?

Chemical Contaminants

Are CRMs mostly needed for understanding method uncertainty? Or is metrological traceability necessary to meet regulations in some cases? Will non-certified materials work?

For pesticides, what sample matrix has the highest priority for CRM development?

Can industry and government partner to make relevant reference materials?

Should CRM producers increase outreach efforts on how to use uncertainty values?

Does the food industry not find the ISO guides on reference materials useful? Why develop your own terminology and practice guides?

Are nanomaterials known to be a health hazard in any food, or is it just a question to be answered?

Do you have a "CRM wish list" for the drugs and metabolites which have the most pressing need?

What is the most commonly adulterated food or supplement? What are some example methods to detect food adulterants?

If saxitoxin is considered a chemical weapon, how does NRC sell a reference material with this analyte?

Several speakers have mentioned the difficulty developing good methods. Is there an organization that accepts and evaluates methods, making them available?

Which type of HRAM instrumentation is best for nDATA workflow?

What are the priority matrices for metals?

Can you perform targeted analysis on high resolution instrumentation?

Chemical Contaminants

What is the time frame of complete drug residue removal from an animal's body? Because it would differ from drug to drug, is there any accepted average time frame?

If quantitative methods are used for veterinary drug metabolite residues, wouldn't metabolite concentration depend on each animal's consumption & metabolic efficiency?

How can accreditation be useful for international trade if measurement capabilities are neither standardized reported nor uncertainties declared?

How challenging should it be to reach the CRM assigned value? Most of our contract labs have a really hard time getting acceptable results on CRMs.

Will CRM match equivalently to the targeted bulk ingredients/materials in the food matrices?

Should measurement uncertainty be used in evaluation of results from a proficiency test?

Is there any effort to develop an official method for glyphosate?

Is there a standard method for chlorate (AOAC, CEN)?

75% of recent chemical contamination media scares are food packaging/material (PFAS/BPA/photoinitiators/methylnapthalene/phthalates). Shouldn't we have some FCM RMs?

Are any shellfish toxins and shellfish allergies at all related from a perspective of how the body responds?

Can fieldable methods be confidently employed for seafood toxin screening?

Does USP offer Reference Standards for most vet drugs? Is there value in commercial Reference Materials providing traceability to USP (or other pharmacopeia)?

How do you regulate and prevent contamination of plants from heavy metals in countries that use fly ash as fertilizer?

How well do your Cr methods work? Could you be converting to hexavalent Cr during sample prep?

How easy is it to collaborate with other pesticide library generators and compare results for equivalence/harmonization?

With the non-target analysis, did you highlight new compound of interest (such as a metabolite) which is usually non targeted in food?

To avoid problems with MS ionization suppression/enhancement, why not try LCxLC, GCxGC, or ion mobility?

How is a spectral library developed for LC-MS?

Do you have a recommended internal standard for Domoic Acid?

How do you screen for protein toxins? Using databases? How can you make sure that you have eliminated all risks?

Chemical Contaminants

What is needed in terms of methods, repositories where new data is being deposited, etc., for novel toxins identification?

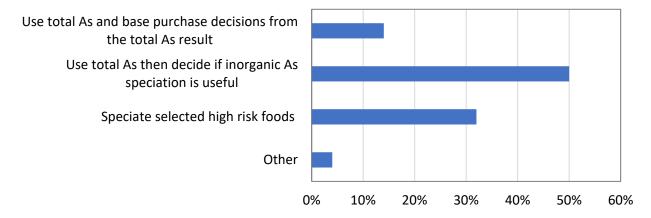
Can the same nDATA workflow described for pesticide residues be used for veterinary drug multi residues analysis?

Is there a HRAM method that works for toxins, vet drugs, and pesticides in a single untargeted or targeted analytical run?

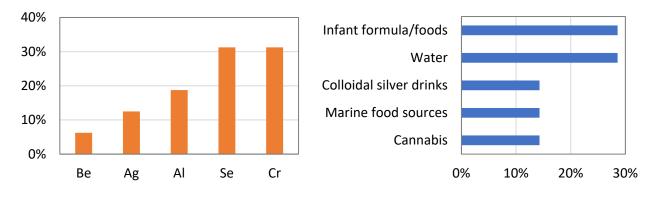
Which kind of chemical contaminant is of most concern for a beverage company: heavy metals, food contact materials, or pesticides?

Which are the priority pesticides needed as Matrix CRMs? Do you think we need CRMs for qualitative analysis or screening methods?

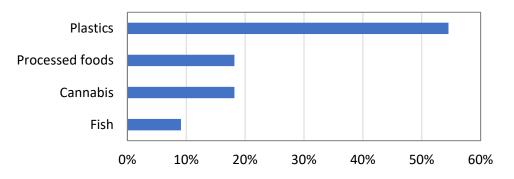
Poll question 1. For Arsenic speciation, how does your organization prefer to manage sample evaluations? (28 total responses)



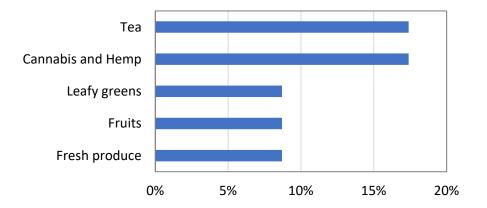
Poll question 2. Of the metals Al, Cr, Se, Ag, and Be, which would be a priority for your organization? Please share the matrix and whether speciation is critical. (16 responses about metals, 7 responses about matrices)



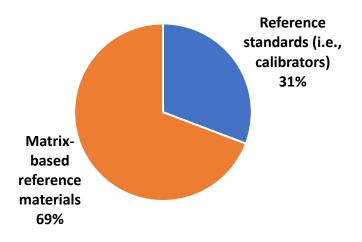
Poll question 3. What food matrix and target analyte would have wide interest for new CRM development in the metals community? Note: The only specific target analytes mentioned were Hg (2) and "big four" (2). (11 total responses)



Poll question 4. For pesticides, what sample matrix would you recommend as the highest priority for CRM development? (15 total responses; other matrices receiving one vote included wine, soybean, rice, plant-based dietary supplements, infant formula, human milk, honey, fruit juices, and coca)



Poll question 5. Which is more pressing, reference standards (i.e., calibrators) or matrix-based reference materials? (39 total responses)



Food Allergens

Can protein CRMs help to calibrate allergens ELISA kits to align the values and make ELISA results more reliable and comparable?

Does MS testing have the potential to replace immunoassays as the most widely used technique for allergens detection and if yes how fast this will happen?

Is there a general trend towards global standardization of food allergen labelling regulations similar to those in Japan, where thresholds define the need to label?

Does the measurement of a single allergenic protein from an allergen commodity in food provide sufficient protection for those with food allergies?

Why aren't the allergen thresholds based on certain allergenic proteins as opposed to whole commodities, such as "milk" or "wheat"?

Has anyone tried methods using metal tagging for food allergen protein measurements?

Are there clinical reference materials that could provide better understanding of food allergies?

Is sulphite an allergen in the true sense?

If allergenic foods differ based on variety, environment, etc., how useful are allergen methods that detect in concentration of allergenic food?

How are the materials used in oral food challenge studies characterized for allergen content?

What prevents more allergen thresholds from being enacted into legislation?

Is there any consideration for NMR for detection of food allergens?

Would FDA accept VITAL reference doses if food industry uses it for risk assessment / management or compliance?

How critical are proteoforms and posttranslational modifications to elicit an allergic response?

What are the advantages/disadvantages of polyclonal vs. monoclonal antibodies in immunoassays?

How should you consider the measurement uncertainty of the CRM for an allergen protein to meet the test requirements?

Is allergen prevalence in children due to changes in genetics or environmental factors, or is it possible to "grow out" of allergens in adulthood?

Is lactose intolerance considered an allergy, insensitivity, neither?

How is a 2 milk differentiated from the heterozygous?

Would allergen CRMs be needed to establish reliable eliciting dose levels?

What additional considerations does your company have in terms of safety for your infant food and formula products?

I've heard of children "growing out" of food allergies. What is the cause/reason for this? Is this something that can be predicted?

Food Allergens

What's the difference between allergenicity and antigenicity?

Are people undergoing gene therapy to become non-allergic?

Can someone become allergic to milk in adulthood?

Is there a correlation between light chain rearrangement or immune self-recognition development and food allergies?

Do you expect Germany/Belgium/The Netherlands to update proposed action levels given release of VITAL 3.0?

How is isothermal nucleic acid amplification affecting allergen detection if at all?

Is there any effort to define the target allergenic proteins and use them to set regulatory thresholds? At this point, is not clear what the "analytes" are.

What should a Foreign Supplier Verification Program look like for allergens due to the differences in thresholds for different countries?

For MS-based allergen measurements, what improvements are needed in DNA data sets?

Are personal consumer devices helpful? Should they be regulated?

Poll question 6. Do you or a member of your immediate family (parent, sibling, or child) have a food allergy? (31 total responses)



Authenticity, Fraud, and Adulteration

Which isotopes and which food matrices should be developed as new reference materials?

Has anyone started a database for food chemical/compound fingerprints to use for food province or region of origin? If not, would this be of interest and benefit?

If someone wanted to get many (100+) samples of authentic botanical or food materials from difference sources, what are the ways for them to get them?

Can isotope ratio analysis be used in the average food laboratory?

How would customs and border control sample to adequately determine the authenticity of a material?

Authenticity, Fraud, and Adulteration

What is the prevalence of lab shopping to get desired results? How could reference materials prevent this practice?

How compatible are "fingerprints" or "profiles" across laboratories?

Is the uncertainty of the nitrogen-to-total protein conversion factors included in the uncertainty of total protein determinations?

Why might one choose to use stable isotope techniques over MS techniques?

Do CRM providers need a "chain of custody" to ensure authentic material from source to obtain reference material (i.e., literally send staff to the source)?

Would stable isotope analysis be able to differentiate between natural and synthetic actives in botanicals? For example, EGCG in green tea?

How does authenticity play a role in food safety?

Can isotope ratio methods be fooled by incorporating locally produced "adulterants," e.g., grinding horse meat from the farm next door into your beef?

Have legal actions been taken about adulterants like melamine being added, or only about protein content mislabelling?

How many samples do you need to define the variety in authentic materials?

Regarding protein analysis, can anyone comment on the potential cost difference between an LC-MS/MS method vs something like the Kjeldahl method?

Would the C13 and N15 analysis be able to differentiate between different species of botanicals? For example, different species of turmeric?

What are the most at-risk botanicals this year?

How do you define authentic honey?

Is there a standard method used to test dietary supplements or botanicals for homogeneity throughout a batch/lot?

How viable will non-targeted testing be for a large industry, given 97% confidence vs. 1000's of samples? Can't afford chasing ghosts from even 3% uncertainty?

Won't analytes important for authentication immediately be added to inauthentic product to fool the test?

Given all the efforts currently in place, what percentage of food fraud would speakers estimate is being discovered?

To what extent does UK referee process default to Codex Type II methods for dispute resolution? What does process look like? Metrics on frequency used?

How can accreditation be useful if accreditation scopes of testing labs do not state measurement ranges and uncertainties in a standardized way (like the key comparison database)?

Authenticity, Fraud, and Adulteration

Why does 30/30 correct results in a non-targeted test not give 100% confidence? What would be necessary to achieve greater than 97% confidence?

Are there ways around unintentional adulteration due to sourcing raw materials from overseas in areas where good manufacturing practices essentially do not exist?

To better detect the fraud, what analytical characteristics will be the best to help the development of detection methods? Like response factor, LC column, sample preparation, etc.?

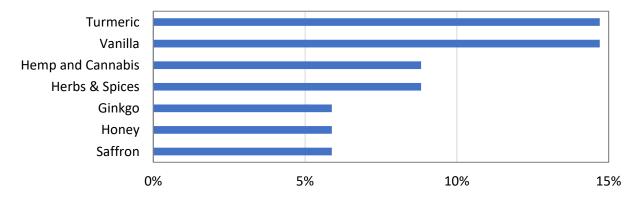
In a global market where food is harvested in one region and then processed in another, how can you trace authenticity?

What is the practicality of different techniques for large scale screening?

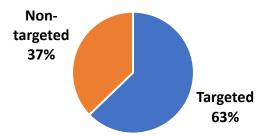
Could you couple a non-protein-nitrogen analysis with a standard nitrogen/protein analysis to get a more accurate result of true protein in a product?

Authentic sample database creation and curation requires lots of time and money. Who and how should manage it (mostly in US)?

Poll question 7. What do you consider to be the most frequently adulterated botanical ingredient? (34 total responses; other ingredients receiving one vote included Cordyceps, olive oil, kava, pomegranate, paprika, aloe, fruit juice, plant protein, berries, black pepper, caffeine supplements, and spelt)



Poll question 8. Which type of methods do you prefer for authenticity testing? (43 total responses)



Global Food Safety

Is there a need for animal feed RMs?

Is the pesticides in soy RM "naturally" incurred or spiked?

Is there any project for kava CRM in the South Pacific region?

Can the NMIs from América participate in the NMISA comparison for zearalenone in maize in 2020?

Cadmium in cocoa tend to be lower in beans from Africa, should you consider having RM for Asia and South America and represent all cocoa?

Wrap Up

Where do nano food additives fit under the food safety umbrella?

What is the best way to fund the need for new standards?

What databases are an urgent need for both regulatory agency and industry? RMs, authentic materials, supply chain traceability?

How can accreditation be useful for choosing services if testing accreditation do not state measurement ranges and uncertainties like the KCDB? Is ILAC working?

Volunteers in the supply chain are needed to provide those authentic materials...anyone?

Many commercial and government entities are working on the development of standards. Are there efforts to collaborate to make standards more widely available?

For NMIs who have already developed CRM of mycotoxins in matrix, what is the biggest difficulty that have faced?

Are there any expectations from the group for the third-party testing labs for all these concerns we covered?

Are there any CRMs for pyrrolizidine alkaloids?

Should everyone be publishing their data in a findable accessible interoperable retrievable way?

What other kind of activities could NIST plan to do (as a regular service) for food safety, besides CRMs?

Is applying measurement uncertainty really its role for comparability? Shouldn't it be used for example also for evaluation of results in proficiency testing?

Would it be possible for NIST and other NMIs to offer a guidance document to labs on how to apply measurement uncertainty for a CRM to their results?

What is your opinion about CRMs for pesticides? Is it better to deal with the problem through proficiency testing?

Is this community ready for a semantic web approach to metrological ontologies and controlled vocabularies?

Poll question 9. What are some unexpected learnings that the attendees can share?

Food contact materials are a pending issue, as we take on recycling

The huge problem in allergen analysis

An approach to NT and Targeted testing for authenticity

Pesticide community seems more interested in very specific pesticides (even banned ones) in very specific matrices rather than pesticides more frequently quantified in more common food

Lots of standard providers competing to sell standards

Food fraud is a much bigger/widespread concern than I originally anticipated (are there any nonadulterated foods in the stores?)

I'm not alone on the path to find an allergen method that works.

Disconnect between countries/regulations in regards to thresholds

Large allergen databases being built and shared for identification of unknowns

Prioritization of all the RM 'asks'

Poll question 10. Are you still kept up at night by the same things as when this workshop began?

Now, more

Yes... HONEY but at least someone else is also doing something

The same things and more...

The assurance of metrological traceability for measurement standards

Add cannabis quality

Unfortunately, yes

Got my questions answered by the presenters at the workshop. Great job!

No. I'm more concerned with lack of standards and authenticity.

APPENDIX D: LIST OF PARTICIPANTS

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