PROGRAM AND ABSTRACTS

Workshop on Measurement of Elemental Contaminants in Cannabis and Hemp Consumer Products

Sponsored by ASTM Committees D37 on Cannabis

June 28-30, 2021
Virtual

PROGRAM

WORKSHOP ON MEASUREMENT OF ELEMENTAL CONTAMINANTS IN CANNABIS AND HEMP CONSUMER PRODUCTS

Sponsored by ASTM Committee D37 on Cannabis

June 28-30, 2021
WebEx

Workshop Chair: Robert Thomas
Scientific Solutions
Gaithersburg, MD, USA

Co-Organizers: Darwin Millard
TSOC, LLC
Evergreen, CO, USA

Cary Black
CK Black Group, Inc.
Chalmette, LA, USA

ABOUT THE WORKSHOP

This workshop will provide a broad perspective and awareness of the current knowledge of elemental contaminants in cannabis/hemp consumer products, communicate their significance, and as a result, educate users, cultivators, processors, testing labs, and regulators within the cannabis/hemp community of their potential risk.

The following topics will be addressed in the workshop:

- The most current research detailing the mechanisms for metal uptake into a cannabis plant-based on growing conditions and soil chemistry.
- Optimization of analytical methodology used to measure heavy metals in cannabis/hemp consumer products.
- Lessons learned from regulating heavy metals in drug products and using a scientifically risk-based approach to predict elemental impurities derived from the manufacturing process.
- Toxicological impact of heavy metals and the industry's responsibility for ensuring consumer health and safety.
- The current state of the art research in phytoremediation and phytoextraction techniques.
- The most recent research in characterizing elemental contaminants in vaping liquids and aerosols produced by electronic nicotine delivery systems (ENDS) and electronic cannabis delivery systems (ECDS).

MONDAY, JUNE 28, 2021
(All times are in U.S. EDT)

9:45 AM	**Welcome** Ralph Paroli, ASTM International
10:00 AM	**Regulating Heavy Metals in Cannabis: What We Can Learn from the Pharmaceutical Industry** Robert Thomas, Scientific Solutions
10:45AM	**Heavy Metals in Hemp Extract Products** Diane Pickett; Dr. Serena Giovinazzi; and, George Kilgore, Florida Department of Agriculture and Consumer Services
11:30 AM	**Validation of an Expanded List of Elements in Cannabis and Hemp Flower by Microwave Digestion and ICP-MS Analysis** Aaron Hineman, PerkinElmer, Inc.
12:15 PM	LUNCH
12:45 PM	**Toxicological Impact of Heavy Metals: The Role of United Natural Hemp Extracts in Ensuring Public Health and Safety** Dr. Joseph Dzisam and Dennis Springs, United Natural Hemp Extracts, LLC
1:30 PM	**Phytoremediation of Radionuclides with Hemp (*Cannabis sativa L.*)** Hanah Rheay, New Mexico State University
2:15 PM	**Essential Practices for Quality Analyses of Metal Concentrations in Hydrophilic and Hydrophobic Vaping Liquids and Aerosols** Dr. R. Steven Pappas; Naudia Gray; and Dr. Nathalie Gonzalez-Jimenez, Centers for Disease Control and Prevention – Mary Halstead, Battelle Analytical Services
3:00 PM	**Examination of Cannabis Hemp Oil Products for Heavy Metal Contamination** Patricia Atkins, Spex Certiprep
3:45 PM	**Open Discussion**
4:30 PM	WORKSHOP ADJOURNS FOR THE DAY

TUESDAY, JUNE 29, 2021
(All times are in U.S. EDT)

9:45 AM	**Recap of Day One** Moderator
10:00 AM	**Beyond the Big Four: Determination of Heavy Metals in a Variety of Cannabis and Cannabis-Derived Products** Jenny Nelson, Craig Jones, Agilent Technologies and Sam Heckle, Leanne Anderson, CEM Corp.
10:45 AM	**Phytoremediation Potential of Hemp (*Cannabis Sativa L.*): Identification of Genetic Modifications Leading to the Development of Hemp Strains for Enhancing its Phytoremediative Properties** Nick Walters and Dr. David Cornett, National Hemp Growers Cooperative; and Cary Black, CK Black Consulting Group LLC
11:30 AM	**Heavy Metals Analysis of Cannabis Related Products by ICP-MS: Optimizing and Troubleshooting a Method for Improved Efficiency and Accuracy** Jonathan Peters, Shimadzu Scientific Instruments
12:15 PM	LUNCH
12:45 PM	**Control of Elemental Impurities in Drug Substances** Dr. Donglei Yu, Office of Pharmaceutical Quality, FDA/CDER
1:30 PM	**Trace Metal Profiling of Commercially Available Hemp Derived CBD Oils** Dr. Tom Gluodenis, Lincoln University, and Robert Thomas, Scientific Solutions
2:15 PM	**Vaping, Metals, and Health Effects: Lessons for Cannabis Products** Dr. Markus Hilpert and Dr. Ana Navas-Acien, Department of Environmental Health Sciences, Columbia University
3:00 PM	**Cadmium Accumulation in Industrial Hemp (*Cannabis sativa L.*)** Amanda Olbrick Marabesi, University of Georgia
3:45 PM	**Elemental Analysis of Tetrahydrocannabinol and Nicotine E-Liquids** Kevin Kubachka and Robert Wilson, US FDA, Forensic Chemistry Center
4:30 PM	WORKSHOP ADJOURNS FOR THE DAY

WEDNESDAY, JUNE 30, 2021
(All times are in U.S. EDT)

9:45 AM	**Recap of Day Two** Moderator
10:00 AM	**Status of ASTM - WK74576 Method: Analyses of Trace Elements in Cannabis and Related Products by Inductively Coupled Plasma-Mass Spectrometry** Dr. William Lipps, Shimadzu Scientific Instruments
10:45 AM	**Cannabis Vaping Aerosols: Non-Polar Methods for Collection and Analysis of Ten Metals** Dr. Amber Wise, Medicine Creek Analytics
11:30 AM	**Effect of the Surrounding Contamination on the Heavy Metals Content of *Cannabis Sativa*** Dr. Murad Ali Khan, Kohat University, Pakistan
12:15 PM	LUNCH
12:45 PM	**Challenges in Development of a Cannabis Reference Material for Trace Elements** Dr. Charles Barber; Dr. Melissa Phillips; Dr. Brent Wilson; and Dr. Laura Wood, Chemical Sciences Division, National Institute of Standards and Technology
1:30 PM	**USP Perspectives on the Limits of Elemental Contaminants in Cannabis/Hemp** Dr. Nandakumara Sarma, United States Pharmacopeia
2:15 PM	**Metals in the Flower, Is It Safe? A Look at Which Metals Cannabis Should be Tested for to Maximize Consumer Safety** Elizabeth Sherburne, All Set Analytical
3:00 PM	**Evaluation of Propensity of the Canadian Hemp Varieties to Accumulation of Elevated Heavy Metal Levels in Grain** Jan J. Slaski and Sharla M. Eldridge - InnoTech Alberta
3:45 PM	WRAP UP & WORKSHOP ADJOURNS

BIOS & ABSTRACTS

Robert J. Thomas, Principal, Scientific Solutions

Robert (Rob) Thomas is the principal of Scientific Solutions, a consulting company that serves the educational needs of the trace element user community. He has worked in the field of atomic and mass spectroscopy for more than 40 years, including 24 years for a manufacturer of atomic spectroscopic instrumentation. He has served on the American Chemical Society (ACS) Committee on Analytical Reagents (CAR) for the past 20 years as leader of the plasma spectrochemistry, heavy metals task force, where he has worked very closely with the United States Pharmacopeia (USP) to align ACS heavy metal testing procedures with pharmaceutical guidelines. Rob has written overt 100 technical publications, including a 15-part tutorial series on ICP-MS. He is also the editor and frequent contributor of the Atomic Perspectives column in Spectroscopy magazine. In addition, he has authored 5 textbooks on the fundamental principles and applications of ICP-MS. His most recent book published in October 2020 focuses on the measurement of heavy metal contaminants in cannabis and hemp. Rob has an advanced degree in analytical chemistry from the University of Wales, UK, and is also a Fellow of the Royal Society of Chemistry (FRSC) and a Chartered Chemist (CChem).

Regulating Heavy Metals in Cannabis and Hemp: What We Can Learn from Pharmaceutical Industry

Author & Affiliation: Robert Thomas, Scientific Solutions, Gaithersburg, MD

Abstract:
The lack of federal oversight with regard to medicinal cannabis and hemp products in the US has meant that it has been left to the individual states to regulate its use. Medical marijuana is legal in 36 states, while 14 states allow its use for adult recreational consumption. The sale of these products is strictly regulated by their THC and CBD content, depending on their use. However, it's also critical to monitor levels of contaminants such heavy metals, as the cannabis plant is known to be a hyper-accumulator of heavy metals in the grow medium and soil. Unfortunately, there are many inconsistencies with heavy metal limits in different states where medical cannabis is legal. Some states define four heavy metals while others specify up to eight. Some are based on limits directly in the cannabis, while others are based on consumption per day. Others take into consideration the body weight of the consumer, while some states do not even have heavy metal limits. So clearly there is a need for consistency across state lines, in order that consumers know they are using products which are safe to use. This presentation will take a closer look at how the pharmaceutical industry changed its 100-year-old sulfide precipitation test for a small group of heavy metals, to finally arrive at a list of 24 elemental impurities using plasma spectrochemical techniques. The cannabis industry can learn a great deal from this process to not only understand the many potential sources of heavy metal contamination, but also how the final cannabis products can be contaminated by the manufacturing equipment, the extraction process and the delivery systems used.

Diane Pickett, Chief of the Laboratory, Division of Food Safety, Florida Department of Agriculture and Consumer Services

Diane Pickett is currently the Chief of the Laboratory within the Division of Food Safety at the Florida Department of Agriculture and Consumer Services. For the past 30 years, she has worked for both State government and the regulated industry creating and implementing guidance, rules, policy, and procedures to ultimately protect human health and the environment from contaminant exposure.

Dr. Serena Giovinazzi, Recall Coordinator, Division of Food Safety, Florida Department of Agriculture

Dr. Giovinazzi is the Recall Coordinator with the Division of Food Safety at the Florida Department of Agriculture with the mission to ensures the safety and wholesomeness of foods here in Florida. Before the Recall Coordinator position, Dr. Giovinazzi worked as a Scientist in the Food Laboratory of the Florida Department of Agriculture, Florida State University, University of Florida and the Italian NIH. She holds a Master's degree in Pharmaceutical Biotechnologies from the University of Bologna, Italy and a Ph.D. in Medical Sciences from University of Florida.

Heavy Metals in Hemp Extract Products

Authors & Affiliations: Diane Pickett, Chief, Food Safety Lab and Dr. Giovinazzi, Recall Coordinator, Division of Food Safety, Florida Department of Agriculture

Abstract:

The Department's mission is to protect consumers from food products that may contain harmful contaminants above the allowable limits established to safeguard human health. To this end, the Division of Food Safety of the Florida Department of Agriculture and Consumer Services has been randomly collecting and analyzing hemp oils from retail establishments for contaminants and cannabinoid content claims since January of 2020. Initial findings indicate that the retail product that reaches customers for consumption may have a different composition than when the product was originally manufactured. This presentation will focus on lead, the most prevalent heavy metal found in the hemp oil products tested. Also, data on the possible sources of contamination, including packaging materials, will be presented.

Aaron Hineman, Inorganic Product Line Leader-Americas, PerkinElmer, Inc.

Aaron Hineman is currently the Inorganic Product Line Leader for PerkinElmer. Prior to this position he was a Senior Field Application Scientist with PerkinElmer. Aaron has a strong background in inorganic analytical chemistry including demonstrated hands-on expertise in state of the art ICP-MS and ICP-OES instrumentation, hyphenated speciation using chromatography coupled to ICP-MS, working in 21 CFR Part 11 compliant laboratories for elemental impurity analysis, and various microwave, acid and fusion sample preparation techniques. Prior to joining PerkinElmer he spent 10 years in environmental and geochemical laboratories developing analytical methodology and laboratory systems.

Validation of an Expanded List of Elements in Cannabis and Hemp Flower by Microwave Digestion and ICP-MS Analysis

Author & Affiliation: Aaron Hineman, PerkinElmer Inc, Shelton, CT

Abstract:
Developing and validating a standardized microwave digestion and ICP-MS method for the determination of an expanded list of metals in flower and oil products down to ppb levels has special considerations associated with it. This talk will present how a single method workflow has been developed and validated per AOAC SMPR® and USP <233> requirements. Recognizing cannabis & hemp is challenging matrix to characterize, data will be presented to show that a single source workflow solution, from digestion to generation of the Certificate of Analysis (COA) is the most ideal. The list of metals selected encompasses target elements of legalized States (California, Colorado, Connecticut, Massachusetts, Michigan, Maryland, and New York) as well as AOAC, NIST, and ASTM and will include Pb, Cd, As, Hg, Cr, Se, Ba, Ag, Cu, Ni, Sb, Zn, Be, Co, Mn, Mo, U, V and Sn. Data will be presented to show the quantitation limits, repeatability, reproducibility, and accuracy. In addition, the influences of rare earth elements in cannabis are investigated and discussed. Taking a holistic vision and adding in bespoke State specific heavy metal protocols and methodology provide higher data accuracy that in turn allows laboratories and regulatory agencies the confidence that a safe cannabis or hemp product is being delivered to the consumer.

Dr. Joseph Dzisam, Vice President of Lab Operations, United Tobacco Company

Dr. Joseph Dzisam is the Vice president of Lab operations at United Tobacco Company with an oversight responsibility in the United Natural Hemp Extracts (UNHE) operations. Dr. Joseph Dzisam holds a Ph.D. in analytical chemistry, specializing in analytical method development and validation using FDA, ICH and USEPA guidelines using LC-MS-MS, and GC-MS. He is skillful and experienced in extraction and separation sciences (7+ years), has published papers in peer-reviewed journals, and showcased his works at many scientific conferences such as the International Symposium on Advances in Extraction Technologies, the American Chemical Society (ACS) meetings, PITTCON, MCF, and the Gordon Research Conference. He has over ten (10) years of experience in Production and Quality Management in a GMP compliant and HACCP regulated food and beverage manufacturing industry. For the past close to 2 years, Dr Joseph has been extensively involved in UNHE's hemp extraction, distillation, crystallization, new product development, and design qualifications. Dr. Joseph is the technical director of all quality and regulatory works at UNHE to ensure excellent application of the track and trace systems, from soil to oil. He is currently finalizing all steps to acquire ISO:9001 certification for UNHE by August 2021.

Toxicological Impact of Heavy Metals: The Role of United Natural Hemp Extracts in Ensuring Public Health and Safety

Authors & Affiliations: Dr. Joseph Dzisam and Dennis Springs, United Natural Hemp Extracts, LLC

Abstract:
Hemp is a widely known phytoremediator, and they tend to accumulate toxicological compounds including heavy metals from the soil, water, manufacturing equipment etc. The presence of heavy metals in hemp and hemp products (flowers, hemp CBD oil, distillates) is a significant threat to human health. Currently, the regulation of heavy metals in hemp is limited, and differs from state to state, and there is the need for more awareness in this direction. To ensure the production of safe hemp products, processors need to follow best practices in the pharmaceutical industry. At United Natural Hemp Extracts (UNHE) in Wilson North Carolina, we employed Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP) in our operations. Before contracts are given to farmers, soil and or water samples were taken from the field(s) where the hemp was to be cultivated and then tested for heavy metals and pesticides. During receiving, several other tests (Heavy metals included) were performed on the biomass. After extracting the biomass at cryogenic conditions (≤ -20 °C) to produce the crude, and further refined by distillation to distillates, heavy metals were again tested to ensure that the levels are quite acceptable, as compared to best practices in other industries. The analysis was done with an ICP-MS in an ISO 17025 accredited lab. Four major heavy metals, namely, Pb, Cd, As, and Hg were monitored in the soil, biomass, crude, and distillates. Preliminary results show that the heavy metals amounts were drastically reduced (max 6.4 ppb) after extraction with cryogenic ethanol, and further reduced during distillation (< 1 ppb).

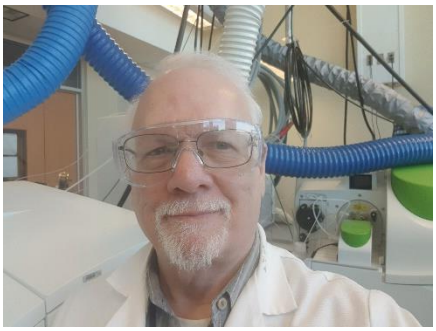
Hanah Rheay, New Mexico State University

Hanah Rheay is pursuing her PhD in Chemical Engineering from New Mexico State University, where she previously received her M.S. in Plant and Environmental Sciences. Her graduate research has centered around the chemistry of native New Mexico hops (*Humulus lupulus neomexicanus*) and whole plant utilization of industrial hemp (*Cannabis sativa*). She is currently working on projects conducting hemp variety trials in New Mexico and investigating the potential of energy production from hemp used for the phytoremediation of uranium.

Industrial Hemp (Cannabis sativa) for Phytoremediation of Contaminated Soil

Authors & Affiliations: Hanah Rheay and Catherine Brewer, New Mexico State University

Abstract:
Interests in the applications of industrial hemp (Cannabis sativa) have been rapidly increasing in the United States over recent years following dissolution of restrictions on production. Cultivation of hemp had been illegal in the United States since 1970 until new regulations were implemented for research and development under the 2014 Farm Bill, followed by federal legalization instituted by the 2018 Farm Bill. Hemp is primarily grown for flower to obtain cannabinoids, seed for oil, and fiber for material processing. In addition to producing hemp for commercial or industrial purposes, hemp can be used as an effective soil phytoremediator of non-arable lands. A large majority of non-arable lands result from mining operations that have ceased. New Mexico is home to many legacy mine sites: former mining sites requiring some level of remediation to reclaim the area's use. There are limited methods available for treatment of non-arable land due to mining contamination, particularly contamination with radionuclides such as uranium. Phytoremediation has been of particular interest as a cost-effective measure for rehabilitation of legacy mine sites. Industrial hemp has been recognized for its ability to uptake heavy metals and other contaminants from soil, and therefore is a suitable candidate for uptake of radionuclides. However, a major economic feasibility issue with phytoremediation is the utilization of the contaminated biomass following harvest. Because contaminants are known to partition into the plant biomass (roots, shoots, and flowers), seeds could be a potential source of economic value from plants otherwise contaminated with low levels of uranium. Industrial hemp seed is a high value product for both its meal and oil: with a protein content of approximately 25% and oil content of approximately 30%. The oil is traditionally used as a nutritional source but is also a suitable feedstock for biofuel processing. Growing a seed-hemp crop on non-arable land could create an economically feasible operation for phytoremediation of uranium contaminated soil.



R. Steven Pappas, Ph.D., Centers for Disease Control and Prevention

Steve Pappas earned his B.S. in Chemistry at Middle Tennessee State University and his Ph.D. in Biochemistry at Vanderbilt University. After faculty positions at Middle Tennessee State University and Georgia State University, he was employed at the Centers for Disease Control and Prevention (CDC) to develop methods for analysis of toxic metals in urine and blood. He later became the Tobacco Inorganics Group Project Lead responsible for development of methods within the ISO 17025 framework for analysis of toxic metals in tobacco, smoke, electronic cigarette liquids, and aerosols. During the 2019-2020 CDC E-Cigarette and Vaping Associated Lung Injury emergency response, he was responsible for method development and analysis of aerosols from nicotine and cannabinoid delivery devices. Steve has earned three National Center for Environmental Health group honor awards for Excellence in Laboratory Research, and a CDC Innovation award for characterization of particles in electronic cigarette aerosols.

In addition to authoring application manuscripts, Steve has written Annex 1, Toxic Metals in tobacco and in Cigarette Smoke in World Health Organization Technical Report Series 967, a Metallomics review, “Toxic elements in tobacco and in cigarette smoke: inflammation and sensitization”, and the metals section in “A Report of the Surgeon General: How Tobacco Smoke Causes Disease (2010).”

Essential Practices for Quality Analyses of Metal Concentrations in Hydrophilic and Hydrophobic Vaping Liquids and Aerosols

Authors & Affiliations: [1]R. Steven Pappas, [1]Naudia Gray, [1]Nathalie González-Jiménez, [2]Mary Halstead, [1]Centers for Disease Control and Prevention, Atlanta, GA, [2]Battelle Analytical Services, Brookhaven, GA

Abstract:
Liquids that are vaporized and aerosolized in electronic nicotine delivery systems (ENDS) and electronic cannabinoid delivery systems (ECDS) contact metal components within the devices. Metal particles are produced in ENDS and ECDS liquids and aerosols as a result of corrosion of internal metal components of the devices. The constituents of the particles that are transported in the aerosol impact the relative health risks to the user and are the bases for choices of analytical targets established by state laws and regulatory agencies. A rationale for elemental choices for analysis (aluminum, chromium, nickel, iron, copper, zinc, cadmium, tin, and lead) is reported based on prevalence in ENDS and ECDS devices, and information regarding arsenic and barium in the aerosols will be provided. ENDS and ECDS liquids that consist of hydrophilic solvents may simply be diluted into aqueous acid solution for analysis by inductively coupled plasma-mass spectrometry. Liquids that consist of hydrophobic solvents may require microwave digestion. In order to provide accurate and valid results of inorganic elemental analyses, sample preparation procedures require high metals purity solvents and trapping materials and the avoidance of glass materials.

To establish standard analytical conditions for liquids, quality control of measurements must be established, calibration must be verified, and valid method detection limits must be determined. In order to establish standard analytical conditions for aerosols, standard puff conditions must be utilized. Aerosol analyte recovery requires special considerations due to inefficient transport of nonvolatile metal oxides in aerosols. This presentation will highlight “best practices” to help other researchers avoid common analytical “pitfalls”.

Patricia Atkins, Senior Applications Scientist, Spex Certiprep

Patricia Atkins is a Senior Applications Scientist. She is a graduate of Rutgers University in NJ and was laboratory supervisor for Ciba Specialty Chemicals in the Water Treatment Division. Patricia later accepted a position conducting research and managing an air pollution research group within Rutgers University's Civil & Environmental Engineering Department. In 2008, Patricia joined Spex as a senior application scientist in our certified reference material's division and spends her time researching industry trends and developing new reference materials. Patricia has been involved with many industry focused advisory & regulatory groups including AOAC, ASTM, ACIL, NACRW and the Emerald Conference. She is a frequent presenter and speaker at numerous conference including NACRW, NEMC, Pittcon and AOAC and published author with her work appearing in various journals and trade publications including Spectroscopy, LCGC and Cannabis Science and Technology where she is a columnist for analytical issues in cannabis testing.

Examination of Cannabis Hemp Oil Products for Heavy Metal Contamination

Author & Affiliation: Patricia Atkins, Spex Certiprep

Abstract:
The cannabis industry has taken the scientific world by storm, flooding the market with new products. Recently, concerns have arisen about safety of this, unregulated market, resulting in many new labs testing for cannabinoid potency, pesticides, bacteria/mold and other potential contaminants. Sadly, a potentially significant group of contaminants has been largely ignored: toxic metals.

Recreational cannabis and hemp are part of the *C.sativa* species, with different cultivars resulting in unique cannabinoid profiles. Federally legal hemp products (hempseed oil, hemp extracts, CBD oil & extracts), those not containing the psychoactive THC, are widely available on the market today. Such products are also used as a base oil for the addition of cannabis & cannabinoid extracts (including medical & recreational cannabis products). However, due to a ban on its cultivation in the US, virtually all the hemp used is imported from China, India, & Eastern Europe. Studies of other consumable commodities exported from these countries have reported widespread heavy metal contamination (i.e. spices, teas, grains etc.).

Cannabis plants (hemp & recreational varieties) are bio-accumulators of heavy metals. In the production of many of the above-mentioned products, a large amount of plant material is processed to extract concentrates and oils, thereby increasing the risk of heavy metal contamination. The scope of this study was twofold; firstly, to analyze various legal hemp products currently on the market and, secondly, to use these as a model for methods development for testing of restricted products. Samples were digested using microwave digestion and analyzed by ICP-OES and ICP-MS to determine the elemental composition of these products and the concentration of potentially toxic heavy metals. A large number of the tested hemp products detected heavy metal contamination.

Jenny Nelson, Application Scientist, Agilent Technologies

Jenny Nelson received her Ph.D. in Analytical Chemistry from the University of Cincinnati in 2007, and her MBA from Saint Mary's College of California in 2011. Currently, Jenny is an Application Scientist for the Life Science and Chemical Analysis team at Agilent Technologies, joining in 2012 (with a step away in 2019). Jenny is also an Adjunct Professor in the Department of Viticulture and Enology at the University of California, Davis, since 2013. Jenny has been very active with AOAC and ASTM over the past eight years, serving on expert review panels, chairing committees, and volunteering to develop new methods needed by the industry.
Jenny has extensive experience in operating and method development for Inductively Coupled Plasma Mass Spectroscopy (ICP-MS), Inductively Coupled Plasma Optical Emission Spectroscopy (ICP-OES), Microwave Plasma Atomic Emission Spectroscopy (MP-AES). Jenny has broad knowledge and experience in different speciation analysis for many sample matrices using GC-ICPMS and LC-ICPMS. As well as vast experience with sp-ICP-MS for many applications.

Beyond the Big 4: Determination of Heavy Metals in a Variety of Cannabis and Cannabis-Derived Products

Authors & Affiliations: Jenny Nelson[1], Craig Jones[1], Sam Heckle[2], Leanne Anderson[2]
[1]Agilent Technologies, Inc., Santa Clara, CA, USA, [2]CEM, Inc., Matthews, NC, USA

Abstract:
Current countries and U.S. states that permit the use of medicinal and recreational marijuana require rigorous testing of cannabis, and the associated products, to ensure safety from inorganic impurities, such as the toxic metals. In this talk we extend the list of elements typically studied and scrutinized and look at the not-as-often reported elements. Regulatory levels for these elements exist for other industries, though they have not been heavily investigated in cannabis production. The method used in our study is applicable for the big four elements; Cadmium, Arsenic, Lead, and Mercury, as well as total recovery of additional elements; Aluminum, Antimony, Barium, Beryllium, Calcium, Chromium, Cobalt, Iron, Magnesium, Manganese, Molybdenum, Nickel, Potassium, Selenium, Silver, Sodium, Thallium, Thorium, Uranium, Vanadium, and Zinc. Many of these elements are crucial to study because they play an important role in growth of the plant and plant byproducts. They can also be an unwanted consequence from the manufacturing and processing of the plants. We looked at this entire suite of elements in a variety of products, covering categories of Inhaled (Plant material, Vape Pen/cartridges, and Shatter), Oral (Pill, Tincture, and Edibles), Topical (Lotions, Oils, and Soaps), and Manufacturing (Biomass, Crude Extract, and Refined Extract).

Dr. J. David Cornett, National Hemp Growers Cooperative

Dr. J. David Cornett is the co-op's agronomist. He will be assisting our grower-members in a variety of ways; among these will be education and support for new hemp producers, defining the best genetics to plant in different geographical areas, and matching genetics to the specific type of harvest desired. David will also work with the co-op's end user customers to ensure the right varieties of hemp are grown to match the needs of our value-added processes, develop collaborations, and oversee research to explore new opportunities for the co-op.

David holds a PhD in Plant Physiology from Colorado State University, an MS in Biology from the University of New Mexico, and a BS in Agronomy from Colorado State University. Additionally, he spent time as a graduate student in Agronomy at Iowa State University. He also has a strong background in plant nutrition and soil chemistry.

His research has ranged from plant experiments aboard the Space Shuttle, to the biochemistry of seed germination, plant cell tissue culture and enzyme kinetics and, most recently, evaluating the agronomic performance of hemp varieties in climatic zones other than those for which they have been developed.

Nick Walters, National Hemp Growers Cooperative

Nick has spent time in economic development and public policy. He was appointed by President George W. Bush as the State Director of the United States Department of Agriculture's Office of Rural Development in Mississippi. While State Director, Nick received special recognition for his role in the rebuild of his home state after Hurricane Katrina.

He currently owns Easy Grants, a non-profit grant writing firm, and Hetman Consulting Services – a nation-wide sales and marketing firm. Nick also serves on the adjunct faculty of Belhaven University as a professor of history.

Cary Black, CK Black Consulting Group LLC.

Mr. Black is an accomplished and results-driven analytical chemist, ASQ certified quality engineer (CQE), QMS Auditor, Preventive Control Qualified Individual (PCQI), and GMP consultant with multiple skill sets and 30+ years' experience in project management, developer of training and QMS programs, lead auditor, quality control and assurance, consulting, technical writing, risk analyses, process engineering/process improvement, continuous improvement champion and trainer, polymeric chemistry, lean manufacturing, research and development, EU GMP, and US FDA regulations, author of 8 ASTM standards and Chairman of D37.06 Personnel Training, Assessment, Credentialing.

Phytoremediation Potential of Hemp (Cannabis sativa L.): Identification of Genetic Modifications Leading to the Development of Hemp Strains for Enhancing its Phytoremediative Properties

Authors & Affiliations: Dr. David Cornett and Nick Waters, National Hemp Growers Cooperative; and Cary Black, CK Black Consulting Group LLC.

Abstract:
Pollution to soils caused by fertilizers' long-term use may result in toxins being introduced to the soils, specifically Cadmium (Cd) (often associated with phosphate-based fertilizers). These can create long-term environmental and health problems. Soil toxicity has emerged as a significant problem throughout the world. There is a pressing need to maintain a safe and healthy environment for human beings; thus, there is a need to identify the underlying genetics of hemp (Cannabis sativa L.) to evaluate cannabis genetic variables for an increased understanding of their mechanisms. From this knowledge, we can develop strains that exhibit accelerated phytoaccumulative properties. Current research, theories, and discoveries in the context of phytoremediative property enhancement of hemp will be discussed.

Jonathan Peters, Elemental Spectroscopy Product Manager, Shimadzu Scientific Instruments

Jon Peters is Elemental Spectroscopy Product Manager at Shimadzu Scientific Instruments in Columbia, Maryland. He has fifteen years of experience with marketing and analytical instrumentation, and has worked extensively with ICP, ICPMS, AA, TOC, and X-Ray analytical instrumentation. Jon has worked in several industries including sample introduction for spectroscopy and pharmaceutical manufacturing.

Heavy Metals Analysis of Cannabis Related Products by ICP-MS: Optimizing and Troubleshooting a Method for Improved Efficiency and Accuracy

Author & Affiliation: Jon Peters, Shimadzu Scientific Instruments, Columbia, MD

Abstract:
Heavy metals analysis in cannabis and related product is important for both regulatory and safety concerns. In this talk, we will discuss various tips and tricks to optimize sample preparation and analysis parameters—including selection of internal standards, selection of isotopes to avoid common isobaric interferences, avoidance of polyatomic interferences, sample introduction hardware tricks, and various software parameters to achieve optimum efficiency and accuracy.

Donglei Yu, Ph.D., Office of Pharmaceutical Quality, FDA/CDER

Donglei Yu joined FDA in 2008 as a Commissioner's Fellow. In 2010, she joined the Center for Veterinary Medicine (CVM) of FDA as a Chemist doing method development of veterinary medicine including Speciation of Arsenic Residues in Chicken Liver. She joined the Division of Life Cycle API, Office of New Drug Product, Office of Pharmaceutical Quality in 2013, and currently serves as a Senior Pharmaceutical Quality Assessor.

Before joining FDA, she was a Research Assistant Professor in Eshelmen School of Pharmacy in the University of North Carolina at Chapel Hill. She received her Ph.D. in Pharmaceutical Sciences from UNC-Chapel Hill. She also holds MS degree in Natural Product Chemistry (Phytochemistry) and BS degree in Medicinal Chemistry.

Control of Elemental Impurities in Drug Substances

Authors & Affiliations: Donglei Yu, Wei Liu, Mst Hasina Akter and Ramnarayan Randad
Division of Lifecyle API/ONDP/OPQ, Center for Drug Evaluation and Research, Food and Drug Administration

Abstract:
Elemental impurities in drug products may arise from several sources; they may be residual catalysts that were added intentionally in synthesis or may be present as impurities (e.g., through interactions with processing equipment or container/closure systems or by being present in components of the drug product). Because elemental impurities do not provide any therapeutic benefit to the patient, moreover, they pose toxicological concerns, their levels in the drug product should be controlled within acceptable limits.

ICH Q3D is the guideline for elemental impurities. This guideline presents a process to assess and control elemental impurities in the drug product using the principles of risk management. This process provides a platform for developing a risk-based control strategy to limit elemental impurities in the drug product. As an active ingredient in a drug product, the drug substance should also be evaluated for the elemental impurities.

In this presentation, we will discuss the sources of elemental impurities, principles of the safety assessment of elemental impurities for oral, parenteral and inhalation routes of administration. Several examples will be provided to the audience for better understanding the control strategy. We hope by explaining the basic principles and control strategy of elemental impurities used by the pharmaceutical industry, the cannabis industry could consider using these principles for the metal / elemental impurity controls.

Dr. Tom Gluodenis, Associate Professor, Lincoln University

Dr. Tom Gluodenis earned a PMFS from Florida International University, an EMBA from St. Joseph University in Philadelphia and his MSc. and Ph.D.in analytical chemistry from the University of Massachusetts, Amherst. He spent 23 years with Hewlett-Packard/Agilent Technologies and retired in 2019 from his role as Global Marketing Manager for Forensics & Forensic Toxicology. In that role, Dr. Gluodenis was an expert resource on forensic trends, regulations, technologies, and testing protocols while coordinating countless partnerships & collaborations with practitioners and researchers around the globe. Currently,

Dr. Gluodenis is an Associate Professor at Lincoln University in Pennsylvania and founder of the highly acclaimed online symposium series, *Current Trends in Forensics & Forensic Toxicology* which has provided continuing education to over 6000 students, educators, and practitioners in over 73 counties. He is a past member of the Seized Drug subcommittee of the NIST OSAC and currently serves on several standard consensus bodies including ASTM E.30 and the Toxicology section of the American Standards Board. He is a member of several national and international forensic organizations including the Society of Forensic Toxicologists, the American Academy of Forensic Sciences, the International Association of Forensic Toxicologists, and the Forensic & Clinical Toxicology Association of Australasia.

Trace Metal Profiling of Commercially Available Hemp Derived CBD Oils

Authors & Affiliations: Tom Gluodenis, Ph.D, Associate Professor, Lincoln University, Lincoln University, PA; and, Robert Thomas, CSci, CChem, FRSC, Principal Consultant, Scientific Solutions, Gaithersburg, MD

Abstract:
In an era when CBD is being touted as a panacea for many afflictions and a component of preventative medicine, the objective of this project is to validate the safety of CBD based consumer products relative to elemental contamination. A broad sampling of CBD oils procured over the internet and from local smoke shops will undergo comprehensive (i.e. entire periodic table) elemental profiling. The source of the CBD oils will represent both producers that are members of industry-based certification programs and those that are not. Multiple samples from each source will be obtained to assess lot to lot variability. Any metals found at toxicologically significant concentrations will be quantitated and the following three questions answered:

1) Does the sample population studied support or call into suspect truth in labelling relative to the metals content reported in commercially available CBD oils?
2) Does the sample population studied suggest a quality difference between producers who are members of industry-based certification programs and those that are not?
3) Do current state regulations go far enough to protect public health and safety or does the empirical data support expanding the panel of elemental contaminants that should be routinely monitored?

Dr. Markus Hilpert, Associate Professor, Columbia University

Dr. Markus Hilpert is an associate professor of environmental health sciences at Columbia University. He is expert in pollutant transport working at the interface between environmental engineering, hydrology and environmental health. His research agenda includes multiphase flow and emergent contaminant transport in subsurface environments, volatile organic compound (VOC) releases at gas stations, traffic-related air pollution, and electronic cigarettes (e-cigarette). His e-cigarette research particularly focuses on metal emissions from e-cigarettes, aerosol collection from e-cigarettes, low-cost systems for whole-body exposure of rodents to e-cigarette aerosol, and metal uptake of e-cigarette aerosol exposed mice.

Vaping, Metals, and Health Effects: Lessons for Cannabis Products

Authors & Affiliations: Markus Hilpert and Ana Navas-Acien, Department of Environmental Health Sciences, Columbia University

Abstract:
Tobacco products are a well-established source of metals. Combustible cigarettes are particularly high in cadmium because the tobacco plant avidly absorbs cadmium from the soil. Lead is another metal commonly found in tobacco smoke. Recent studies have found that e-cigarettes are also a relevant source of toxic and carcinogenic metals including nickel, chromium, lead, and manganese among others. The source of the metals could be the heating coil or other parts of the device as most metals are generally low in the e-cigarette e-liquid solution and metal concentrations increase markedly once this solution has entered in contact with the device. Studies on metal biomarkers following chronic vaping are generally lacking. This research is needed to confirm that metal biomarkers increase with vaping and to study the health effects of e-cigarettes and the role of metals in e-cigarettes in explaining those effects. The VapeScan study is currently ongoing, with the goal to study the long-term subclinical cardiovascular and lung effects of vaping. Additional research is needed to study the relevance of these findings for chronic use of cannabis products.

Amanda Olbrick Marabesi, University of Georgia

Amanda Olbrick Marabesi is a second-year Ph.D. student in Horticultural Sciences at the University of Georgia (UGA). She got a bachelor's degree in Agronomic Engineering from the University of Sao Paulo, Brazil, and a master's degree in Agricultural and Environmental Education at UGA. Her research interests are in plant physiology and sustainable agrifood systems. Amanda's Ph.D. dissertation is focused on evaluating heavy metal accumulation in hemp flower material, aiming to improve quality and safety of hemp derived products.

Cadmium Accumulation in Industrial Hemp (*Cannabis sativa* L.)

Authors & Affiliations: Amanda Olbrick Marabesi and Dr. Timothy W. Coolong, University of Georgia

Abstract:
There is a dearth of research on heavy metal accumulation in industrial hemp grown for the medicinal market. In the present research, we evaluated the accumulation of cadmium (Cd) by the industrial hemp (*Cannabis sativa* L.) variety "Southern Tiger", grown for cannabinoid production.

The plants were greenhouse-grown in deep water culture systems containing a nutrient solution and a known concentration of Cd. Cadmium treatments were as follows: 0, 2.5, 10, and 25 ppm Cd. Nutrient solutions were replaced completely every 14 days. Photosynthetic yield was assessed after 15, 45, and 60 days from exposure to treatments. Growth parameters such as plant height, root length, and plant biomass were measured at harvest. Root, stem, leaf, and flower material were collected at harvest for elemental analysis. Flower material will be further subjected to cannabinoid analysis. Further, genes such as the ATPases HMA2, HMA3, and HMA4 were evaluated to determine the impact of Cd on expression of heavy metal transporter genes which are involved in root-to-shoot translocation, accumulation in vacuoles, and xylem loading of heavy metals.

Although this research is ongoing, we hypothesize that industrial hemp will accumulate quantities of Cd in excess of accepted thresholds in root and stem tissue. We expect accumulation of high levels of Cd in the floral material when exposed to high levels (>10 ppm Cd) in the nutrient solution. We also hypothesize that Cd may affect the accumulation of cannabinoids and up regulate gene expression related to heavy metal uptake and translocation in the plant.

Kevin Kubachka, Ph.D., US FDA, Forensic Chemistry Center

In 2003, Dr. Kevin Kubachka, received his B.S. degree in forensic chemistry from the Eastern Kentucky University. He then continued his education at the University of Cincinnati where he received his Ph.D. in chemistry (area of analytical chemistry) in 2007. Following graduate school, he was a federal post-doctoral researcher at the USEPA. After 16 months at the USEPA, he joined FCC as a chemist, where he has worked since September of 2008.

At the FCC, Dr. Kubachka has focused his efforts on elemental speciation and isotope ratio mass spectrometry (IRMS). His primary area of expertise is elemental analysis, with emphasis on elemental speciation of arsenic using liquid chromatography interfaced with inductively coupled plasma mass spectrometry (LC-ICP-MS). Additionally, he has been responsible for developing and implementing the FCC's IRMS capabilities to detect adulteration of foods with low-cost sweeteners. He has published several peer-reviewed journal articles and has given numerous invited presentations on these topics. Dr. Kubachka has been an instructor and course organizer for several ORA and training courses.

Elemental Analysis of Tetrahydrocannabinol and Nicotine E-Liquids

Authors & Affiliations: Kevin Kubachka and Robert Wilson, US FDA, Forensic Chemistry Center, Cincinnati, OH

Abstract:
During the e-cigarette, or vaping, product use-associated lung injury (EVALI) investigation the US FDA's Forensic Chemistry Center (FCC) received numerous sample submissions from various states and other sources. Many of these products were linked directly to patients while others were not; both categories included used and unused product.

Elemental analysis using inductively coupled plasma mass spectrometry (ICP-MS) preceded by microwave assisted decomposition was carried out on the cartridge contents of 65 of these submitted samples. Challenges encountered included limited sample, high sample viscosity, and adhesion which necessitated sample preparation techniques not commonly used by the elemental analysis community. The elemental concentration of contaminants including Pb, As, Cd, Cr, Ni, Cu, and Sn in THC e-liquids associated with EVALI were determined. Nicotine e-liquid samples collected alongside the THC e-liquid samples were analyzed in tandem during method development.

Several samples contained concentrations for Ni, Cu, and Pb at part per million levels. This presents the first report of elemental concentrations in multiple THC e-liquid samples and also delves into the method considerations needed for testing a difficult sample matrix in limited quantity.

Dr. William Lipps, General Manager, Shimadzu Scientific Instruments

William is currently the general manager of government and regulatory business development at Shimadzu Scientific Instruments in Columbia, Maryland. William is the ASTM D19 committee on water Chair, an Editor for Standard Methods for the Examination of Water and Wastewater and acting Part 4000 coordinator, and an ISO TC 147 (water) SC2 (chemistry methods) delegate and expert. William has been a member of ASTM since 1987 and is a participating member of multiple ASTM Committees including D34, D22, E50, E01, and of course D37 on Cannabis. Prior to joining Shimadzu, William developed a new commercially available on-line cyanide analyzer for determination of cyanide in gold process solutions, it's sample filtration module, redesigned existing continuous flow and discrete analyzers, designed a new Flow Injection Analyzer, and has developed and validated numerous analytical methods. William's work on sampling, preservation, and minimization of interferences in cyanide analysis led to the development of six new or modified ASTM standards, five of which are EPA approved at 40 CFR Part 136.3. William also authored, or co-authored methods for nitrate, ammonia, TOC, and TKN that are also approved at 40 CFR Part 136.3 and collaborated with EPA in defining method flexibility at 40 CFR Part 136.6. William wrote an ASTM guide to the International Cyanide Management Code, and was a contributing author to the SME "Management Technologies for Metal Mining Influenced Water, Volume 6: Sampling and Monitoring for the Mine Life Cycle". At Shimadzu, William is working on new methods intended for EPA approval, including Total and ammonia Nitrogen, pesticides and PCBs, Perfluorinated compounds, and nitrosamines, William has also worked at several commercial testing laboratories in multiple capacities including owner, Chief Science Officer, Chief Chemist, lab manager, bench chemist, and environmental consultant.

In addition to work at consensus organizations, William has given hundreds of podium and poster presentations at national and local environmental laboratory and mining association conferences. He has given numerous webinars and has taught several short courses including topics such as "cyanide analysis", "wet chemistry analysis" and "how to select laboratory instruments". In addition, William has authored numerous technical guides and application notes, and is a contributing author to various trade journals.

Status of ASTM - WK74576 Method: Analyses of Trace Elements in Cannabis and Related Products by Inductively Coupled Plasma-Mass Spectrometry

Author & Affiliation: William Lipps, Shimadzu Scientific Instruments

Abstract:
This proposed new ASTM method standardizes the digestion and analysis of metals in cannabis products. The method, as currently written, uses microwave digestion followed by ICP-MS of arsenic, cadmium, mercury, and lead. These metals, called the big four, are minimum required in most (or all) states. Other states have added additional metals that can be included at a later revision. At this time the method has undergone sub-committee level balloting. Content of the method, and subcommittee results will be discussed.

Dr. Amber Wise, Science Director, Medicine Creek Analytics

Amber Wise earned her PhD in Chemistry from UC-Berkeley and was a Postdoctoral Fellow at UC-San Francisco. Before transitioning to the cannabis industry, she was an undergraduate chemistry lecturer and research professor for 7 years at universities in San Francisco, Bangladesh and Chicago.

After transitioning out of academia in 2016, she was the Scientific Director at Avitas Agriculture in Washington and Oregon for two years, overseeing the cannabis extraction and refinement facilities and handling the data analysis, new product development and scientific growth of the company.

She currently leads Medicine Creek Analytics, an ISO-17025 accredited cannabis testing lab outside Seattle, WA as their Science Director. She is the programming chair for the American Chemical Society's Cannabis subdivision, and also serves on Washington State's Cannabis Science Task Force Steering Committee

Cannabis Vaping Aerosols: Non-Polar Methods for Collection and Analysis of Ten Metals

Author & Affiliation: Amber R. Wise, PhD, Medicine Creek Analytics-Fife, WA

Abstract:
Cannabis vaporizer cartridges have increased in popularity and availability, and there are concerns regarding exposure to heavy metal compounds from their use. The hardware components of the cartridge devices themselves have been implicated as a potential source of metals exposure, but it is not known if these metals migrate into the inhalable vapor. This study has two parts; the first is optimizing the sample collection, preparation, and analysis of the nonpolar cannabis aerosol mixtures and the second part analyzes the hardware components and aerosol mixtures of vaporizer cartridges for 10 different metals (As, Cd, Co, Cr, Cu, Hg, Mn, Ni, Pb and Sn) using ICP-MS. We investigate both a model system as well as 6 randomly purchased commercially available cannabis cartridges to compare the elemental profiles. Results indicate Chromium, Copper, Nickel, and Lead migrate both into the cannabis oil and the inhaled vapor phase. Non-cartridge heating methods of cannabis flower and concentrate were compared, and results indicate the heating device hardware is a source of metals contamination. As safety and compliance testing regulations evolve, it will be important to update analytical methods as well as include more than the standard As, Cd, Hg, and Pb elements to the list of regulated metals.

Prof. Dr. Murad Ali Khan, Department of Chemistry, Kohat University of Science & Technology, Kohat, Pakistan

Dr. Murad Ali Khan is a tenured Professor and Dean of Social Sciences at the Kohat University of Science & Technology in Kohat, Pakistan. He received his Ph.D. in Chemistry in 1999 from the HEJ Research Institute of Chemistry, University of Karachu, Pakistan. In 1991, Dr. Khan received his M.Sc. Chemistry at the Gomal University Dera Ismail Khan, Pakistan. From 1994-1996 he served as DAAD Fellow at the University of Tübingen, Germany and then a Postdoctoral Fellowship from 2001-2003 at the Mayo Clinic in Jacksonville, FL, USA.

Other positions held and awards received include:

- Tamgha- i- Imtiaz from the government of Pakistan 2012
- Chairman Department of Chemistry KUST, Feb. 2009- Feb. 2015
- Director QEC KUST, Oct. 2015- Feb. 2017
- Member American Chemical Society
- Fellow Chemical Society of Pakistan
- University Best Teacher Award 2011 by HEC
- Member Royal Society of Chemistry
- Research Productivity Award in 2007, 2011, 2012, 2015

Effect of the Surrounding Contamination on the Heavy Metals Content of *Cannabis Sativa*

Authors & Affiliations: Prof. Murad Ali Khan, Ph.D., Department of Chemistry, Kohat University of Science & Technology, Kohat, Pakistan

Abstract:
Cannabis is used as recreational and medicinal drug all over the world. The end products of cannabis come from the flowering tops, leaves, stems, and seeds of the plant. In Pakistan it is mostly used in smoking and as topical treatment for pain relieving. Apart from these it is also used as an extract (decoction) in juices with different dry fruits which vary its effect and is locally termed as warm or cold depending on the dry fruits used. It is also added in feed to chicken for laying eggs and to pigeon for long flying. Cannabis is mostly wildly grown plant in the uncultivated lands. This makes it more prone to the accumulation of toxic metals from the surrounding. Heavy metals were investigated in the Cannabis sativa and the soil of the area from where the plant was collected using atomic absorption spectrophotometer. The plant samples were collected from five different locations of Khyber Pakhtunkhwa Pakistan. The plant parts including roots, stem and leaves were found to have the quantity of heavy metals corresponding to their contents in the soil. The purpose of the study is to make awareness among the people about the proper use and collection of medicinal plants, containing high level of heavy metals and their adverse health effects.

Dr. Charles Barber, Research Chemist, National Institute of Standards and Technology

Charles A. Barber is a research chemist in the Inorganic Chemical Metrology Group at the National Institute of Standards and Technology (NIST). Currently Charles serves as one of the program coordinators for the Cannabis Quality Assurance Program (CannaQAP). In conjunction with the CannaQAP, he is working on measurements for development of toxic elements in hemp and cannabis reference materials. Much of his other work involves analysis of nutritional and toxic element measurements for the development and certification of food and dietary supplement reference materials. Prior to working for NIST, he worked as a Forensic Scientist at the Alabama Department of Forensic Sciences in the Implied Consent Laboratory's Breath Alcohol Testing Program. He received his B.S. in Chemistry and Biochemistry from Florida State University.

Challenges in Development of a Cannabis Reference Material for Trace Elements

Authors & Affiliations: Barber, C.A., Phillips, M.M, Wilson, W.B., and Wood, L.J., Chemical Sciences Division, Material Measurement Laboratory, National Institute of Standards and Technology, Gaithersburg, MD

Abstract:
Cannabis is increasingly being used for recreational or medicinal purposes. Increasing sales of cannabis both domestically and internationally as well as regulatory requirements for contaminants in the raw plant materials are drivers for the National Institute of Standards and Technology (NIST) to develop reference materials (RMs) to support the cannabis community. Analytical and sample preparation procedures used for other agricultural SRMs are not necessarily suitable for the evaluation of cannabis. Preliminary evaluation of various over-the-counter CBD materials derived from Cannabis sativa found measurable levels of potentially toxic elements, including As, Cd, Pb, Co, Cr, Mn, Mo, Se, Be, Ni, and U in many products. Measuring and establishing baseline values for toxic elements will assist the cannabis industry in establishing regulatory guidelines on contaminants in cannabis products. Toxic elements are one of the most highly targeted contaminant groups, with a key focus on cadmium, arsenic, lead, and mercury. Currently, NIST is screening numerous plant materials for potential use as RMs to assist the cannabis community, including regulators, product developers, contract testing laboratories, and forensic laboratories. These samples will also be included in the second exercise of the Cannabis Quality Assurance Program at NIST. A summary of results and methods used to determine elements of interest in ground Cannabis sativa materials will be presented along with methods used for quantification.

Dr. Nandakumara Sarma, Director, Dietary Supplements and Herbal Medicines Program, United States Pharmacopeia

Dr. Nandakumara (Nandu) Sarma is the Director for the Dietary Supplements and Herbal Medicines program at US Pharmacopeia (USP) responsible for strategy and external stakeholder engagement for new and innovative projects, working with global stakeholders and expert volunteers in the development of quality standards (monographs and general chapters) for dietary supplements and herbal medicines that are published in the USP *Dietary Supplements Compendium* and the *Herbal Medicine Compendium*.

Before joining USP 2006, he was a post-doctoral fellow at National Cancer Institute, Bethesda, and Thomas Jefferson University, Philadelphia and was a Senior Scientific Officer at The Himalaya Drug Company, India. His research experience includes isolation and analysis of active components of botanicals and their biologic activity. He published more than 25 scientific articles in peer-reviewed journals. Dr. Sarma holds a Pharmacist degree and a Ph.D. in pharmaceutical sciences (pharmacognosy) from Banaras Hindu University, India.

USP Perspectives on the Limits of Elemental Contaminants in Cannabis/Hemp

Author & Affiliation: Nandakumara Sarma, Ph.D., United States Pharmacopeial Convention, Rockville, MD.

Abstract:
Interest in cannabis and hemp-derived products is active and growing. Consumers and patients expect quality to be inherent in the products they use for good reason; poor quality products can lead to acute adverse events and long-term health risks as well as lack of the expected benefits. Also, ensuring quality is important for conducting clinical research related to the development of drugs containing cannabis and cannabis-derived compounds. Appropriate quality specifications, including analytical methods and acceptance criteria, help ensure identity, composition, and minimal exposure to contaminants. Controlling toxic elemental contaminants is critical for cannabis and hemp, since these plants are known to readily absorb inorganic elements, including heavy metals, that may be introduced from soils, water, and other inputs.

The United States Pharmacopeia (USP) Cannabis Expert Panel recently published cannabis-specific quality considerations, which can be a helpful resource to control the quality of cannabis and related products. Considering the potential inhalation use of cannabis inflorescence, the panel has suggested adoption of stringent acceptance criteria from the USP General Chapter <232> Elemental Impurities−Limits for inhalation products for arsenic NMT 0.2 μg/g, cadmium NMT 0.2 μg/g, lead NMT 0.5 μg/g, and mercury NMT 0.1 μg/g due to the ubiquitous nature of these elements and to reduce the risk of harm. Analytical methodologies were referenced from the USP General Chapter <233> Elemental Impurities−Procedures. In addition to the above specifications, the panel noted that other elemental impurities may need to be controlled based on a risk analysis to determine whether other contaminants may be present (e.g., due to past or nearby industrial activities, or if an element is inherent in a plant material sourced from a geographical area). USP General Chapter <232> states that “when additional elemental impurities are known to be present, have been added, or have the potential for introduction, assurance with the specified levels is required.” USP general chapters could be used as a resource for toxicologically-based limits for elemental contaminants in addition to the four identified above to control quality.

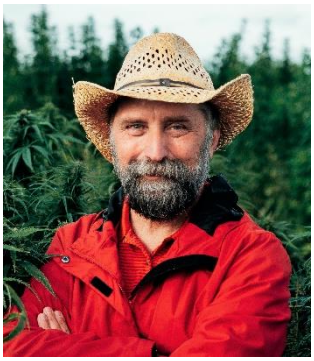
Elizabeth Sherburne, All Set Analytical, LLC

Elizabeth (Liz) Sherburne earned her B.S. in Biochemistry in 2002 from the University of Vermont and her M.S. in Healthcare Administration in 2011 from New England College. She has over 20 years of laboratory experience in a variety of industries including healthcare, environmental, food & beverage, and cannabis. Quality control, ISO 17025 guidance/implementation, and inorganic chemistry are her areas of expertise. Liz and her husband, Jim, are the sole proprietors of All Set Analytical, a laboratory consulting company based in New Hampshire. All Set Analytical specializes in providing laboratory solutions internationally to the cannabis and hemp industry through quality management system development/implementation and the design, implementation, and validation of cannabis test methods associated with the following technologies: ICP-MS, GC/MS, GC-FID, LC/MS/MS, HPLC, and qPCR.

Metals in the Flower, Is It Safe? A Look at Which Metals Cannabis Should be Tested for to Maximize Consumer Safety

Author & Affiliation: Elizabeth Sherburne, All Set Analytical

Abstract:
Consumer safety has spent an increasing amount of time in the public spotlight. People are becoming more cognizant of what they put in or on their bodies. This is also true in the cannabis industry; however, is faced with a lack of federal oversight and regulations that vary state by state. Most states only test for four metals (arsenic, cadmium, mercury and lead) in cannabis. The consumer safety related to metals has been well established in many other industries including pharmaceuticals, food and beverage, plastics, cosmetics, and drinking water to name a few. This paper will evaluate and compare the varying analyte lists and limits for metals across multiple products and industries to consolidate existing knowledge regarding metals to make a recommended list of metals that should be tested in the cannabis industry to ensure consumer safety.



Jan J. Slaski Ph.D., P.Ag. (Dist.), InnoTech Alberta

Jan J. Slaski is a Principal Researcher with the Bio-Industrial Services Division of InnoTech Alberta, Vegreville, Alberta. He obtained a M.Sc. in agronomy from the Warsaw Agricultural University and Ph.D. from the Plant Breeding and Acclimatization Institute, Poland. During the last 19 years he has been leading research aimed at introduction and breeding of hemp varieties that suit the needs of industries utilizing fibre, grain and cannabinoids-laden crop parts. Jan has been also conducting extensive studies focused on the development of best management practices permitting sustainable hemp and cannabis production under changing environmental conditions. To fully realize the potential residing within these crops and to assure whole crop utilization, Jan has assembled at InnoTech Alberta a program offering solutions from “Seed to Final Product“ that includes three domains: breeding/agronomy, analyses/processing and product development. Since 2012, Jan has been serving the hemp industry as a director of the Canadian Hemp Trade Alliance.

Evaluation of Propensity of the Canadian Hemp Varieties to Accumulation of Elevated Heavy Metal Levels in Grain

Authors & Affiliations: Jan J. Slaski, Sharla M. Eldridge - InnoTech Alberta, Vegreville, AB, Canada

Abstract:
The study aimed to identify edaphic factors that affect uptake and distribution of cadmium in hemp cultivars grown in Canada. Greenhouse experiments focused on evaluation of the accumulation potential of hemp and identification of soil conditions conducive to cadmium uptake were performed in a pot experiment. Two batches of farm topsoil containing 0.32 mg/kg Cd that significantly differed in pH were used in the experiment including acidic soil of pH 5.8 and neutral soil of pH 6.8. Soil in the pots was spiked with increasing levels of cadmium: 3, 12 and 48 mg/kg supplied in the form of aqueous solution of CdSO4. After harvest, the stems, leaves, seed heads, the roots were collected and subjected to cadmium analyses. The study revealed that low soil pH significantly enhanced Cd uptake by the hemp plants. Uptake of Cd was strongly correlated with Cd concentrations in soil. Depending on variety, roots were the primary organ accumulating approximately 50 to 70% Cd taken up be the plants. Concentration of Cd in the seeds of all tested varieties grown under conditions of non-contaminated Prairie soils (0.32 mg/kg Cd) did not exceed the proposed maximum acceptable contamination limit (0.1 µg/g seeds) for international trade.