









**Partnership for Food Protection
Information Technology Workgroup
(PFP IT WG)**

**Coffee Talk with
*Kevin Kubachka, Ph.D.***






**Chemist
Chromatography and Elemental Section
Inorganic Branch
National Forensic Chemistry Center (NFCC)
U.S. Food and Drug Administration (FDA)**

The [PFP IT WG](#) recently had the pleasure of a Coffee Talk with [Dr. Kevin Kubachka](#). The PFP IT WG's goal is to promote data standards to improve the ability to share food safety regulatory data electronically among strategic partners and support timely and accurate decision making. To achieve this goal, the workgroup has undertaken technical projects that are advancing abilities to harmonize a compatible IT environment among all food safety officials.









	<p>Hello, Kevin Kubachka! Tell us about yourself, and your role and responsibilities as a Chemist at the Chromatography and Elemental Section in the Inorganic Branch of FDA's National Forensic Chemistry Center (NFCC).</p>
	<p>I am a senior chemist at the NFCC and primarily work in the areas of elemental analysis and stable isotope ratio analysis. My primary duties related to these areas include analyzing samples, developing, and validating related methods, training other analysts, and presenting our work at meetings and conferences. Additionally, I work with labs in the FDA, our state partners, and from other agencies by sharing my expertise in these areas. I am also involved in several international working groups, panels, and advisory boards.</p>
	<p>How does the FDA ensure that their labs maintain the highest scientific standards in these areas? Tell us more about the programs in regulatory methods development and technical training the labs maintain.</p>
	<p>In the area of elemental analysis, there are several laboratories that routinely perform this type of work to monitor food and related products for both toxic and nutritional elements. I am the chair of the FDA's Elemental Analysis Steering Committee (EASC) where we work together to harmonize our methods, which are robust and thoroughly tested. While we commonly use these methods for most of our work, some labs have specific areas of expertise that require different or modified methods to address the needs of a given scenario. We offer extensive training courses to our analysts on various topics related to elemental analysis. We completed a training course for 14 analysts on the advanced topic of elemental speciation analysis about a month ago.</p> <p>As for stable isotope ratio analysis, the program is smaller but involves four laboratories that coordinate efforts to develop methods and implement them. Primarily we test for food adulteration in which people add substances to foods for economic gain, for example diluting honey with corn syrup while claiming the product is still pure honey.</p>
	<p>Data exchange and collaboration are crucial for effective food safety regulation. Could you elaborate on the methods and technologies employed by the labs within the FDA Office of the Chief Scientist and the Human and Animal Foods Programs to facilitate data sharing with FDA, states, and other regulatory partners?</p>
	<p>I totally agree with this. For example, through the EASC, we have monthly meetings that involve representatives in the program from across the country – usually about 40 people at a given meeting – to discuss various topics like issues with a difficult sample, troubleshooting instrumentation, or ideas for method development and new research projects, among other topics. Additionally, we work closely with our state partners, specifically those with the Food Emergency Response Network (FERN) program. We recently completed a training for state analysts to learn our primary Elemental Analysis Manual (EAM) method known as EAM 4.7,</p>






	<p>along with other related topics for elemental analysis. We also use collaborative tools such as SharePoint, Teams, and the FERN Portal to share information between multiple parties in real time. In addition to working with state partners, we frequently collaborate with other agencies with similar interests such as the U.S. Department of Agriculture (USDA), U.S. Customs and Border Protection (CBP), and U.S. Environmental Protection Agency (EPA).</p>
	<p>Can you provide a high-level overview of the key responsibilities and objectives of the NFCC to ensure the safety of food and feed products?</p>
	<p>While many of the FDA’s Office of Regulatory Testing and Surveillance labs are geared towards higher throughput and focus on more of the regulatory food and feed products, our lab typically receives more of the “odd” samples. One common scenario for our lab is to receive a sample that has made someone sick, and we try to determine the cause. Elemental analysis is one of the initial analyses we perform to determine if toxic elements could be the cause. Often the samples might not fall into the scope of our routine methods, so our existing methods are modified appropriately to address the specific scenario. While elemental analysis is one piece of the puzzle, it’s great to see all the pieces (LC-MS, GC-MS, and other lab techniques) come together to complete the puzzle.</p>
	<p>Share a bit about the types of testing performed and instrumentation used in the areas of elemental analysis at the FDA. How is the NFCC involved in situations where a contaminant or harmful substance is discovered in a widely distributed product?</p>
	<p>As I previously mentioned, we typically look for toxic elemental contaminants like arsenic, cadmium, lead, and mercury, among others. The primary instrumentation we use for elemental analysis is an inductively coupled plasma mass spectrometer (ICP-MS). We also use a similar instrument – an ICP with atomic emission spectrometer (ICP-AES). Additionally, there are situations in which an energy dispersive X-ray Fluorescence (ED-XRF) device or scanning electron microscopy with energy dispersive X-ray spectroscopy (SEM/EDS) are applicable. Our lab would typically get involved when an appropriate method is not currently developed or validated among our labs. We would develop a method to analyze the sample, ensure its applicability and performance, and help roll it out to other laboratories, and sometimes provide necessary training.</p>
	<p>What are the biggest challenges your lab faces when investigating new contamination cases? How does the lab balance public safety with the interests of manufacturers when dealing with recalls or potential health risks?</p>



	<p>When it's a commodity that we do not typically test or an analyte that we do not typically test for, it can be challenging. In the case of elemental analysis, levels of contamination that cause acute health effects are well above the detection limits of our instrumentation, which are extremely sensitive. However, when considering long-term health effects, especially when exposure occurs in vulnerable populations (for example, infants and pregnant women), lower contaminant levels can be of concern, and we aim our detection limits to be sufficiently sensitive to address those potential concerns. Also, the typical contaminant levels in a specific commodity are not always known, nor is there always a defined target level of concern; both issues can complicate method development. The recently implemented FDA's Closer to Zero action plan hopes to address some of these issues and requires the analysis of lower and lower levels in elemental contaminants in foods consumed by these vulnerable populations.</p>
	<p>Share a successful collaboration between the NFCC and a regulatory partner that led to improved food and feed safety outcomes.</p>
	<p>One recent scenario in which we were involved was the high levels of lead in cinnamon apple sauce fruit pouches. Initial testing by state laboratories found high levels of lead. Additional products were tested by other state and FDA laboratories while the FDA investigated the related supply chain and collected the cinnamon that was the suspected source of the contamination. Another FDA lab determined that lead and chromium levels in the collected cinnamon samples were about 1,000 times higher than normally encountered. The NFCC was able to develop an approach to determine that the lead in cinnamon samples came from lead chromate. Lead chromate has been reported in the scientific literature to be nefariously added to spices to improve the color, thus implying an intentional adulteration. This collaboration consisted of multiple moving parts, and everyone doing their jobs to come together and tackle a large problem ultimately working to ensure these unsafe products do not continue to enter the United States.</p>
	<p>Does the NFCC have an electronic data management system and how does it improve your workflow?</p>
	<p>The NFCC has been using an electronic data management system for over ten years now. We believe it has made our workflow more efficient and has offered several improvements that directly impact the analysts and our management. These include increased data integrity and security, the ability to rapidly search all the metadata associated with our analyses, and locate results for customers quickly, among other advances.</p>
	<p>Share a bit more about the great work of the NFCC lab staff and their responsibilities for lab analysis of domestic and imported products. What new testing methodologies or innovations is the FDA looking to implement?</p>



	<p>In the areas of elemental analysis, we are working across the labs to ensure our methods can meet the potentially low levels of concern related to the FDA’s Closer to Zero action plan. Overall, we are trying to make sure our labs are prepared for the next upcoming area of concern. For example, we received significant interest from various stakeholders for a method to determine the presence of inorganic arsenic in seafood, so we are in the process of a multi-laboratory validation exercise to ensure our proposed method can fill this data gap. For stable isotope ratio analysis, we are continuing to identify areas that this technique can help. One emerging area of consumer fraud is when natural ingredients are being substituted with synthetic versions, typically for the producer’s economic gain.</p>
	<p>Finally, is there something fun and interesting about yourself to share with the readers?</p>
	<p>I’m a big sports person – I love watching sports, especially live, playing sports with my kids, and trying to keep in shape by playing “competitive” basketball. I’m also into fixing things around the house and a DIYer; I hate throwing things away, so if there’s a chance to fix it, I’m going to try. I continue to brainwash my kids to enjoy all things Star Wars and it’s working. Also, for the last six or so years, I have worn a bowtie to work every Friday and have amassed quite a collection.</p>

The PFP IT WG would like to thank Dr. Kubachka for sharing his insights and support of public health and safety, and we look forward to continued collaboration and expanding the PFP IT WG.

The PFP IT WG would like to know what YOU think! Please share your thoughts about the PFP IT WG Coffee Talk, and if there are any areas of interest you’d like to see featured. Please share your thoughts via an email to PFP-IT-WG-Info@fda.hhs.gov.



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