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TOWARDS SAFER CANNABIS AND HEMP CONSUMER PRODUCTS: THE IMPORTANCE OF TESTING FOR HEAVY METALS

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INTRODUCTION

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The toxicity effects of heavy metals have been well documented in the public domain because they have a serious impact on human health, particularly for people with compromised immune systems. For that reason, the testing of heavy metals in cannabis and hemp and their many consumer products is critically important.

This article explores the importance of measuring elemental contaminants (heavy metals) in cannabis and hemp consumer and medicinal products, common challenges encountered within the industry and ways in which they may be better regulated to mitigate some of these issues.

WHERE ARE THE LIKELY SOURCES OF HEAVY METALS?

Cannabis and hemp plants are natural accumulators of contaminants and are often used for phytoremediation purposes, to clean up contaminated soils [1-5]. Therefore, it is important to understand the chemistry of the soil where cannabis is being planted, because if not grown in clean uncontaminated soil, there's a very good chance that the plants are going to absorb heavy metals [6,7].

However, elemental contaminants will not be the same in all soil. For example, if a hemp farmer is planting under consistent growing conditions, the lot to lot and batch to batch is going to be very similar with regard to heavy metals. There may be some rarer examples too, such as when hemp or cannabis are being planted in a contaminated area near an old Department of Defense/Department of Energy site. In this case the area is probably going to contain radionuclides such as uranium in the soil and the likelihood is high that it will be taken up by the plant [5].

Other sources of contamination include fertilizers, nutrients and growth enhancers, particularly ones made from mineral phosphates, as they may contain high levels of transition elements and other heavy metals [8]. Awareness of pollutants in the water supply is also crucial. While it's assumed drinking water is clean and pure, there are often cases where it can be polluted, particularly if the potable water flows through contaminated soil or through lead pipes [9].

It is also important to look at the solvent extraction process, which is necessary to purify and concentrate the essential cannabinoid compounds from the plant while also removing the undesired contaminants. These compounds are mainly found in the female flower's glandular trichomes, which contain most of the cannabinoids of interest. When the optimum extraction temperature and pressure are employed, it can either result in pure, isolated compounds or more natural, full-spectrum extracts containing a wide array of the cannabinoids found in the plant material. However, if heavy metals are absorbed by the plant, they will likely find their way into the trichomes and as a result end up in the extracted cannabinoid, and can then become concentrated further down the purification processing line [7, 10].

> "If heavy metals are absorbed by the plant, they will find their way into the trichomes and end up in the extracted cannabinoid."

Metallic cutting and blending equipment could also be a source of contamination. For example, if tools are made from stainless steel there's a good chance that metals such as iron (Fe), chromium (Cr) and nickel (Ni) could be leached into the product. Finally, when the liquid extracts are packaged into plastic/glass bottles or used in common delivery devices, such as vape cartridges, there's a strong likelihood that the products will absorb metals from the containers and even from the ink used in graduated droppers [11].

To summarise, there are many opportunities throughout the cannabinoid manufacturing process for heavy metal contamination to occur.

WHY ARE HEAVY METALS SO HARMFUL FOR THE CONSUMER?

Depending upon the concentration of the heavy metals and the method of cannabis consumption, they can have a wide range of effects on the human body. Symptoms can range from something as benign as a headache or nausea, all the way to organ failure, and even cancer in cases of prolonged or extreme exposure. Because cannabis is often combusted or inhaled, there can be an increased respiratory risk as well.

Smoking is an efficient way to get heavy metals into the body, since it bypasses a lot of the other fail-safes in our body, such as the liver or the digestive process. Once inside the body, heavy metals can mimic other essential elements and actually replace them in bones or in other cellular processes. This can then result in the malfunctioning of cells and ultimately toxicity. Furthermore, elements such as lead (Pb) and mercury (Hg) are neurotoxins, which break through the blood-brain barrier, causing cognitive impairment and learning disabilities [10,12,13].

Heavy metals can also create an oxidative stress, which greatly increases free radicals in the body and can cause further damage. For example, chromium is a lung carcinogen and when inhaled can be highly toxic, depending on the valency state of that chromium. Hexavalent chromium (Cr+6) is highly toxic and is attributable to lung cancer, while trivalent chromium (Cr+3) is an essential element [11].

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HOW MANY HEAVY METALS SHOULD BE MONITORED AND HOW OFTEN?

In the United States of America, cannabis is regulated by individual states. The consensus of the vast majority of the 37 states where cannabis is legal is to test for the "big four" heavy metals, lead (Pb), cadmium (Cd), arsenic (As) and mercury (Hg), with some states adding chromium and others including copper, nickel, zinc and antimony. There is evidence to support the expansion of the panel of elemental contaminants measured, particularly as hemp is predominantly grown outdoors where soil quality could be impacted by anthropogenic activities such as mining or metal refining [7]. If hemp is planted in a soil which contains a wide range of heavy metals, transition elements or radionuclides, they will be taken up by the plant and transported to the flower. It is therefore imperative to be aware of the multitude of potential sources of elements that could find their way into cannabis consumer products [5].

The challenge is to balance testing, real-world evidence, and the possibility of people getting sick, versus the impact of the increased cost of testing. The more heavy metals that are monitored, the more expensive the analyses will become and this burden will most likely be passed on to the consumer. Should products become cost-prohibitive, patients and consumers may refuse to buy them and instead resort to the illicit market for supply. This sets a dangerous precedent, as the illicit market is unregulated and therefore does not uphold the same rigorous safety and quality levels as the legal market. Should cannabis patients and consumers move to that illicit market, the industry would likely see an increase in instances such as the EVALI (E-cigarette or Vaping Use-Associated Lung Injury) vaping crisis in 2019, when around 3000 people got pneumonia-type symptoms, resulting in 68 deaths, mainly from illicit THC vaping devices containing vitamin E acetate [14].

Unfortunately, the importance of testing is not always recognised by consumers. It can be misconceived, given that cannabis is considered safe and legal to use in the majority of US states, there is no difference in quality regardless of the source from which it is purchased. Because it is not fully understood that testing is for their safety, consumers may not be willing to pay for it.

Additionally, there is no overarching uniformity in testing. A product can be over the regulated limit in one state and below the maximum limit in another state [7]. Oversight on a federal level is required for unification of testing methodology, and to make prices consistent and reasonable so that patients don't end up being forced into an illicit market.

Guidance can be taken from the pharmaceutical industry, where manufacturers of drug products look at different batches of the drug product over time to identify which elemental contaminants do and do not occur, so that the method can be adapted to focus on only those contaminants observed. Provided there are no significant process changes, it can be reasonably assured that the elemental impurities that need to be monitored as a QC function - batch to batch, lot to lot - can be minimized. Therefore, it is essential to stress that not every element necessarily needs to be tested on every batch or in every lot [15].

> "Guidance can be taken from the pharmaceutical industry, where the method can be adapted to focus on the elemental contaminants observed."

The National Institute of Standards and Technology (NIST) is releasing a hemp certified reference material (CRM) in 2022, containing a 13-element panel, including uranium. It is important to be aware that as the heavy metal panel is likely to be expanded the chances of finding obscure elemental contaminants increases. Geographical location should be a factor and taken into consideration when assessing the risks. It is safe to assume that the panel will be expanded in future to reflect real-world cultivation and manufacturing situations.

TOWARDS SENSIBLE REGULATIONS

Regulations developed out of the 2014 American Herbal Pharmacopeia (AHP) monograph for heavy metals, the big four (Pb, Cd, As and Hg) were suggested. This monograph was never meant to be a regulator's guide, but quickly became one, as it was the only point of reference the cannabis industry could look towards. Washington State was the first to pick this up, and as other states simply followed suit, the big four became the regulated list by default. Maryland first broke the mould by adding four more contaminants, selenium, barium, silver and chromium, making a total of eight. However, the current commission has since backed down to five, keeping chromium in addition to Pb, Cd, As, Hg [7].

Guidance for the cannabis industry comes predominantly from the food and pharmaceutical industries. It took the pharmaceutical industry 20 years to establish comprehensive regulations for 24 elemental impurities in drug products. This was achieved by conducting a risk assessment strategy to understand the toxicity of the heavy metals and the likelihood of where they might occur in the drug manufacturing process. Therefore, the pharmaceutical industry has an effective model that the cannabis industries could follow [15].

US states are not equipped to do this kind of risk assessment work individually and independent testing laboratories cannot do it themselves, therefore an alternative organization without a financial stake in the outcome should be responsible for conducting the assessment. There are appropriate national organizations like AOAC, ASTM and NIST, but this work would need to be a collaborative effort, because there is currently no federal oversight of the industry.

Summary of state-based regulations

Figure 1 represents an overview of state-based regulations for heavy metal contaminants in cannabis consumer products compared to federal regulations for drug products and the NIST panel for toxic metals in hemp.

Majority of 37 states that allow medicinal and recreational cannabis	Maryland, Missouri (amongst others)	Michigan	New York	NIST Panel for toxic metals in hemp	USP Chapter <232>/ICH Q3D Guidelines for Elemental Impurities in Drug Formulations
					Cr
					Sn
					Cu
					Mo
					Ba
					Sb
					Li
					Pt
					Ag
					Se
					Ru
				V	Rh
				U	Os
				Se	Ir
				Ni	Pd
			Zn	Mo	Au
			Sb	Mn	Tl
		Cu	Cu	Cr	Ni
		Ni	Ni	Co	V
	Cr	Cr	Cr	Be	Co
Pb	Pb	Hg	Pb	Pb	Pb
Cd	Cd	Inorganic As	Cd	Cd	Cd
As	As	Cd	As	As	As
Hg	Hg	Pb	Hg	Hg	Hg

State Regulations | Federal Regulations / NIST

Elements Required

WHAT HAPPENS IF HEAVY METALS EXCEED THE REGULATED LIMITS?

Many states allow for remediation, while others do not. Remediation of heavy metals is not easy and is also very expensive, compared to a microbial or a moisture content remediation. Emphasis should be on minimizing the risk and making sure plants are grown in clean, uncontaminated soil, because it's going to cost a significant amount of money to remediate. Unfortunately, over the past two years, there have been many reports of product recalls for heavy metals exceeding regulated limits, or having a suspicious Certificate of Analysis (COA). When this happens, many states do not even allow the product to be released, with the supplier often not getting a COA to enable them to release it to the public for purchase, so they have to absorb the cost or consider remediation or disposal. Remediation would include conducting their own root cause analysis and looking at all the inputs, before investing in the cultivation, curing and drying processes and finally testing. A high number of manufacturers and producers have learned the hard way that these factors, which were not even a consideration when they applied to the states to become a producer, are vitally important. Unfortunately, few manufacturers are focused on solving the source of these issues, as opposed to taking pre-emptive actions [7].

> "Emphasis should be on making sure cannabis is grown in uncontaminated soil, because it's going to cost a significant amount of money to remediate."

THE ROLE OF THE INDUSTRY IN MINIMIZING HEAVY METAL CONTAMINATION

The cannabis industry grew from an illicit market that suddenly realized that there was a need for regulation. As there is no federal body overseeing this in the US, there are clearly still many challenges to overcome.

Product packaging, such as the plastic containers or bottles containing the liquid extracts, oils or tinctures, have to be critically examined. Presentations at the ASTM International D-37 heavy metal in cannabis workshop demonstrated elevated levels of heavy metals in some off-the-shelf CBD extracts [16]. One research group at the Florida Department of Agriculture specifically found lead in extracts in dropper bottles, but what was unusual was that the lead levels increased over time. On further investigation they discovered that the graduated marks of the droppers were likely made from lead-based ink, which was being leached into the extract during the time the study was being conducted. In one case, they found the lead content had increased from below the regulated limit of 0.5 ppm up to almost 20 ppm [17].

> "One research group found lead (Pb) in extracts in dropper bottles that was increasing over time."

Packaging selection falls under the responsibility of product development. With Food and Drug Administration (FDA) involvement in the regulatory process, it would be a requirement to demonstrate that there is no interaction between the container, closure system and the product. This would be done during the development phase – selecting the container closure system and doing accelerated stability studies to exaggerate environmental conditions to see if anything leaches out or there is any kind of interaction with the container [18]. However, this is currently not a regulatory requirement in the industry today.

MONITORING HEAVY METALS IN CANNABIS VAPING DEVICES?

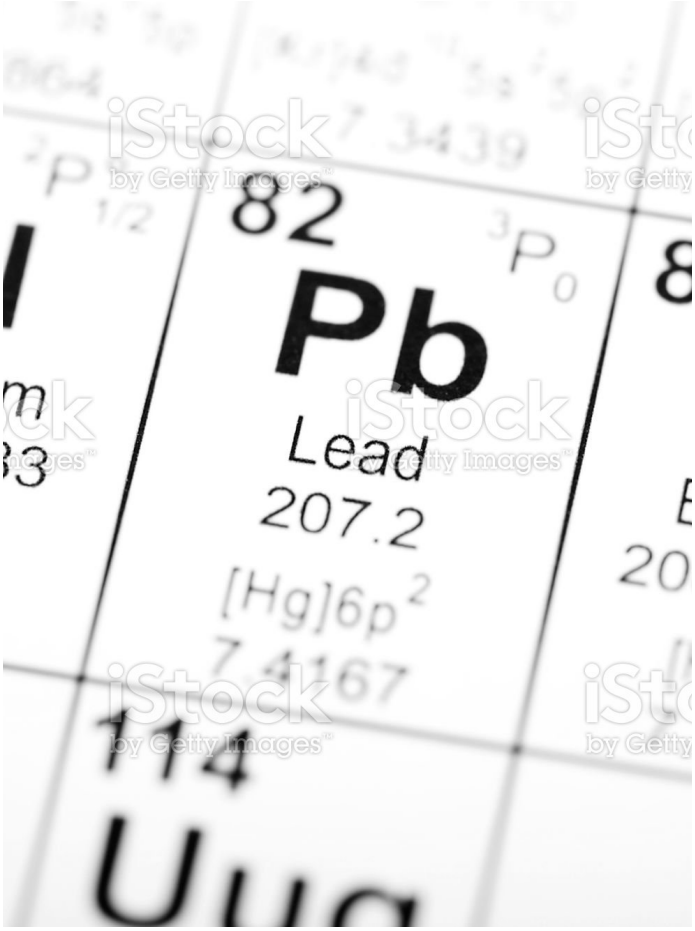
The FDA Forensic Chemistry Centre carried out a comprehensive study of elemental contaminants in vaping devices as a result of the EVALI crisis [19]. It confirmed some of the early work with nicotine vaping systems, that at elevated vaping temperatures, the extracts are corroding the internal metallic components [20]. For example, nickel, chromium and iron were coming from the stainless steel tank, while zinc and copper were detected as a result of the brass heating coil. However, the FDA investigation only characterized the liquids in the tank and not what was being transported in the aerosol. This is far more complex because the aerosol condensate, which could be a mixture of polar and non-polar compounds, has to be trapped, collected, dissolved and diluted before it is introduced into the Inductively Coupled Plasma Mass Spectrometry (ICP-MS) system for analysis.

> "Some research has shown that these metals are in particulate form, meaning users (of vaping devices) could inhale nanoparticles into their lungs."

This requires significantly more work to develop a standardized method and at present there is a limited amount of research in the public domain on characterizing aerosols [21]. Some research has shown that these metals are in particulate form as well as dissolved ions in solution, meaning a user could inhale nanoparticles of chromium, nickel, iron, aluminium, copper and lead into their lungs. The Centre for Disease Control and Prevention (CDC) has just published a paper on the topic demonstrating that alloys like nichrome, kanthal, stainless steel, brass and solder used in many vaping devices are being corroded by the liquids at elevated temperatures and transported via the aerosol to the consumer [22].

Under normal circumstances, this testing protocol directive would come from the FDA. A drug-device combination needs to be studied and monitored just like the drug does. US states could set up specifications for the device or component and the testing burden should then be on the device manufacturer, not on the cannabis processor or cultivator. By using this approach, substandard and potentially dangerous devices can be stopped from entering the marketplace from other countries (with less strict standards) and kept away from patients and consumers [15].

Vaping is increasingly popular with cannabis consumers. Therefore, unless some action is taken to minimize or reduce the likelihood of toxic heavy metals being transported into someone's lungs [7], there is the potential for the EVALI crisis to happen again. The cost of just one product recall would be an incentive enough for manufacturers to use higher quality materials.



> "Unless some action is taken to minimize or reduce heavy metals in vaping aerosols, there is the potential for the EVALI crisis to happen again."

WHAT IS THE BEST WAY TO TEST FOR HEAVY METALS?

ICP-MS is the preferred technique for this type of analysis, not only because it is a rapid multi-element technique, but many of the regulated limits that are being proposed by the states are using extremely low inhalation PDE limits from pharmaceutical regulations. For solid cannabis matrices there also has to be some type of dissolution procedure. For that reason, ICP-MS coupled with microwave sample digestion is the most suitable methodology to use. This approach has been supported by standards organizations such as AOAC and ASTM, as both have standardized ICP-MS methods for testing cannabis for a panel of elemental contaminants. However, the biggest problem area for testing laboratories is contamination control. There are environmental metallic contaminants in every lab no matter how many precautions are taken, so controlling the method blanks is a major issue [15].

Typical cannabis testing laboratories do not have a great deal of experience of working in the ultra-trace environment; an ICP-MS cannot be installed in a warehouse and expect to get good data. The entire analytical process from grinding the sample, weighing it into a microwave vessel, using a suitable digestion method at the optimum temperature and pressure to make sure it is completely dissolved, and then diluting the sample into a clean, uncontaminated vessel and analysing it by ICP-MS with good accuracy and precision, is not a trivial task. The testing lab must be able to implement a validation procedure to show the regulatory authority that they can absolutely guarantee the results being generated by the instrument are correct within the limitations of the procedure [7].

There is a void in validation in the cannabis industry, however it should be recognised that there are some states who are allocating funds to set up their own testing laboratories, with their own equipment and staff. California is almost ready to launch their state laboratory. Maryland is actively looking for space to do the same thing. The top priority for these laboratories is to look in depth at method validation for all the testing methods. Unfortunately, this is work that the private sector really cannot undertake, just by virtue of the time involved, their business models and trying to deliver a profit for the investors.

FINAL THOUGHTS

As scientists and medical professionals, we should continue to raise awareness and educate the cannabis industry on the sources of heavy metal contamination and, most importantly, the risks it poses to consumer safety. It would be wise to follow the pharmaceutical regulators and carry out a comprehensive risk assessment study. However, this is unlikely to happen unless it is made a legal requirement. The pharmaceutical industry was mandated by the FDA over 20 years ago to update its testing protocols from monitoring one heavy metal (lead), using a 100-year-old semi-quantitative colorimetric method, to measuring up to 24 elemental impurities by plasma spectrochemistry. Today, all pharmaceutical manufacturers must demonstrate to the FDA that they are fully conversant with all these manufacturing touch points and, if requested, must show evidence that there are no areas of concern regarding elemental impurities. Given the time it can take to implement such a process, the cannabis industry, regulatory bodies and governments need to start this sooner rather than later if they are to ensure the safety of cannabis patients and consumers and prevent health crises that could otherwise be avoidable.

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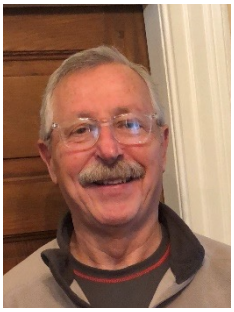

Robert (Rob) Thomas is the principal of Scientific Solutions, a consulting company that serves the educational and writing needs of the trace element user community. He has worked in the field of atomic and mass spectroscopy for more than 45 years, including 24 years for a manufacturer of atomic spectroscopic 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, in which role he has worked very closely with the United States Pharmacopeia (USP) to align ACS heavy metal testing procedures with the new pharmaceutical guidelines. Rob has written over 100 technical publications, including a 15-part tutorial series on ICP-MS. He is also the editor of and a frequent contributor to the Atomic Perspectives column in Spectroscopy magazine, as well as being on the editorial advisory board of Analytical Cannabis. In addition, he has authored five textbooks on the fundamental principles and applications of ICP-MS. His most recent book, published in December 2021, is a new paperback edition of *Measuring 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).

Heavy Metals in Cannabis and Hemp Education

Dr. Kelly Cheshire holds a PhD in Forensic Science from University College London, where she specialized in the chemical analysis of forensic evidence. Her doctorate research on elemental analyses of soil for forensic investigation has been published in the Australian Journal of Forensic Sciences. She is also an Associate Member of the Chartered Society of Forensic Sciences. As Global Product Manager at LGC. Kelly manages the organic and inorganic reference material portfolios for the Cannabis, Environmental, Food and Forensics markets. In her role she is integral to collaborating with thought leaders in industry in an effort to share and build knowledge with the scientific community. During her career she has presented at conferences globally, including EAFS, ANZFSS and CFSRE, as well as taking part in a number of LGC webinars and panels on topics including cannabis regulation, cannabis heavy metals, counterfeit agrochemical detection, and the impact and regulation of pharmaceutical and veterinary contaminants in food and the environment. Most recently she released a podcast with Spectroscopy on the topic of heavy metals testing in hemp and cannabis for consumer safety.

Dr. Kelly Cheshire

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