



Considerations for a Framework to Regulate the Possession and Transportation of Delta-9 Tetrahydrocannabinol Extracted from Hemp in Minnesota



Anthony Cortilet

625 Robert Street North, Saint Paul, MN 55155

www.mda.state.mn.us

1/24/2020

In accordance with the Americans with Disabilities Act, this information is available in alternative forms of communication upon request by calling 651-201-6000. TTY users can call the Minnesota Relay Service at 711. The MDA is an equal opportunity employer and provider.

Table of Contents

EXECUTIVE SUMMARY	3
INTRODUCTION	4
Hemp Production Issues with Cannabinoid Extraction and Products	4
Legislation Creating the Report	5
Hemp Cannabinoid Workgroup Members	6
HEMP CANNABINOID WORKGROUP FINDINGS	6
A) Primary Issues for Developing an Effective Framework	6
1) CONFLICTING AND UNCLEAR STATE AND FEDERAL LAWS	6
2) LIMITED RESOURCES FOR REGULATION	7
3) NEED FOR A SINGLE ENTITY TO COORDINATE STATEWIDE CANNABIS REGULATION	7
B) HCW Suggestions for a Regulatory Framework.....	9
1) COMPONENTS TO CONSIDER FOR A STATE REGULATORY FRAMEWORK.....	9
a) <u>Transportation</u>	9
b) <u>Processors</u>	11
c) <u>Facilities and Processing Equipment</u>	12
d) <u>Inventory Management and Disposal</u>	13
e) <u>Record Keeping</u>	14
2) USE EXISTING FEDERAL FRAMEWORK	14
a) Drug Enforcement Administration Registration	14
CONCLUSION	15

Pursuant to Minn. Stat. § 3.197, the cost of preparing this report was approximately \$9,000. Cost estimate based on committee member time to discuss, draft, edit and review report - twelve members (\$40/hour) by 15 hours. Costs were paid for by the representative agencies participating in the development of the report.

Executive Summary

In 2019, the Minnesota Legislature directed the Minnesota Department of Agriculture (MDA) to meet with the Departments of Health (MDH) and Public Safety (DPS) to develop a framework for regulating the possession and use of tetrahydrocannabinol (THC) resulting from the extraction of cannabinoids from hemp plants. After passage of the 2018 Farm Bill, *Cannabis sativa* L. with a concentration of total delta-9 THC (total THC) at or below 0.3% on a dry weight basis, is considered hemp and can be commercially grown as a legal agricultural commodity in the United States. Minnesota's hemp industry began primarily for both grain and fiber production through its federally approved pilot program following the passage of the Industrial Hemp Development Act in 2015. Since then world-wide consumer demand for non-psychoactive products containing cannabinoids extracted from the hemp plant has increased dramatically. In order to supply the sudden and large demand for hemp flower extracts like cannabidiol (CBD), the hemp industry developed more complicated extraction methodologies that remove and isolate a variety of cannabinoids from harvested flower materials. These processes and technologies were developed within the recreational marijuana industries in states like Colorado and California. However, when these approaches are applied to hemp, it creates a problem because the extraction process concentrates THC above the 0.3% threshold, thus producing a controlled substance. Eventually, processors will refine the initially extracted materials to be diluted below the 0.3% THC level for hemp or remove THC from the final product altogether.

The MDA licenses growers and processors of raw hemp materials under its Hemp Program. Unfortunately, there are no current state laws regulating the processing of hemp or cannabinoid products. The MDA initially met with DPS and MDH to discuss the idea of developing a framework for the processing of hemp when THC is concentrated. After an initial meeting and discussion regarding other Minnesota laws that govern similar industries and processes, a Hemp Cannabinoid Workgroup was formed that contained representatives of MDA, MDH, DPS and local law enforcement. The workgroup held four meetings in 2019 to discuss the issue of hemp processing and concentration of THC and developed recommendations outlined in this report for the Minnesota Legislature to consider for a possible regulatory framework.

Cannabis regulation poses many challenges in the state. The workgroup has identified that there are conflicting federal and state laws and limited resources for the various agencies and law enforcement to coordinate and communicate effectively. The workgroup suggests that an Office of Cannabis Management be created in order to review and examine existing state and federal laws, identify the agencies best suited for particular regulatory oversight of the various industries and develop systems using available technologies to effectively coordinate efforts and utilize existing resources among regulatory agencies and federal, state, and local law enforcement. The workgroup also suggests that two options exist for a framework: 1) A state-developed management framework that adopts policies for transportation, processors, facilities, equipment, inventory, disposal and record keeping or 2) mandatory federal Drug Enforcement Administration (DEA) registration for any hemp processor creating a controlled substance (i.e., THC above the accepted 0.3% threshold for hemp). This report discusses the various options and highlights existing state statutes that could be utilized to address concentration of THC as a result of the cannabinoid extraction process for hemp flowers.

Introduction

Hemp Production Issues with Cannabinoid Extraction and Products

In 2016, the MDA began licensing the first hemp producers since cannabis prohibition in the late 1940s, under a pilot program established through the passing of the 2014 Farm Bill and the 2015 Minnesota Industrial Hemp Development Act. Since then, Minnesota farmers and businesses have created a strong foundation for an emerging hemp industry that is poised to continue developing and expanding into the future. Hemp is grown in the state for three primary uses: fiber, grain and flower. Fiber and grain hemp products contain little to no THC and are fairly easy for law enforcement to distinguish from marijuana. Hemp flower production is distinct from grain and fiber because it focuses on production of female-only plants (similar to the marijuana industry) and the floral material is harvested, dried and sold by the pound. The resultant floral derived products can look identical to illegal marijuana.

Prior to the passage of the 2018 Farm Bill, *Cannabis sativa* L. containing 0.3% or less delta-9 THC was defined as “industrial” hemp and the primary end products for hemp production in states adopting pilot programs in 2015 – 2017 were for food (grain) and industrial uses (fiber). Around the end of 2017, a large percentage of licensed hemp growers throughout the U.S. were drawn to take advantage of high market prices for hemp flower that is sold for extraction of non-psychoactive cannabinoids like CBD and turned into a variety of oral and topical products. Hemp flowers can also be sold today at a premium for the smokable market where the perceived beneficial complex of cannabinoids produced by the hemp plant can be delivered into the body through inhalation. These products are often sold as an alternative to vaping and cigarette smoking. Products can range from pre-rolled joints, ground hemp flower or dried hemp flower buds.

Although flower production has the potential to bring hemp producers their largest return on investment when compared with fiber and grain, it comes with several side-effects. Hemp flower that is sold for the smokable market and the plethora of extracted cannabinoid products made from the flower are often difficult for law enforcement to discern from marijuana. Even if the products are legal hemp, law enforcement do not have a field test that can determine if the total THC concentration is at or below the allowable 0.3% level. Furthermore, the Bureau of Criminal Apprehension Laboratory (BCA) does not have the staff and financial resources to test THC concentrations for the myriad of products derived from cannabis that law enforcement encounters daily. This leads to confusion among both law enforcement and prosecuting attorneys who are mandated to protect public safety from Schedule 1 Narcotics like marijuana.

Currently, there is little to no regulation of the cannabinoid extract industry. Federal and Minnesota hemp laws only give the MDA authority to regulate the production of hemp, not hemp processing, products or their sale. The U.S. Food and Drug Administration (FDA) has recently approved the first CBD based drug Epidiolex® for treatment of seizures. Therefore, the FDA considers cannabinoids like CBD to be medicinal in structure and function and illegal additives to food and dietary supplements. In 2019, the Minnesota Legislature passed Minnesota Statute 151.72 which created testing, labeling and sale requirements of certain cannabinoid products like CBD. This statute also provides a legal way forward for ingestible CBD products to be sold in the state; although, they remain prohibited as

additives to food and dietary supplements under federal law. A significant issue that remains is the lack of infrastructure and financial resources for the Board of Pharmacy (BOP), MDA or the MDH to provide oversight and regulation for the immense number of products being manufactured and sold throughout Minnesota.

Extraction of cannabinoids derived from legally harvested hemp crops is also an issue. Although the plants being processed are legal hemp as determined through MDA field sampling (or another states' equivalent testing processes), the extraction process can concentrate total THC from those plants up to 10 times above the allowable 0.3% level that defines hemp. Until the THC is either further removed by additional processes or the final products diluted to be at or below the acceptable 0.3% THC level, the extractor is technically in possession of marijuana. This can be challenging because in order for the extract to be brought to a legal level, they may have to transport the material to another destination for final processing. The hemp industry throughout the United States is aware of this issue and looking for federal guidance to find a solution to this necessary facet of the cannabinoid extraction process that will protect public safety from potential diversion of THC to an illicit use, and at the same time, allow for a safe cannabinoid processing industry to develop. Without cannabinoid extraction from hemp, the public consumer demand for CBD and other cannabinoids could not be met and Minnesota farmers would miss out on a potentially rewarding financial opportunity.

The purpose of this report is to discuss potential solutions as outlined in conversations with experts in the state who deal with criminal law enforcement, medical cannabis, the cannabinoid extraction process and hemp production in order to propose a regulatory framework for the processing of hemp where total THC is concentrated above the acceptable 0.3% threshold. Grain and fiber processors that produce or purchase hemp with an MDA issued Fit for Commerce Certificate and are not processing to extract cannabinoids, are not the intended target of this report.

Legislation Creating the Report

In 2019, the Minnesota Legislature directed the commissioner of agriculture to consult with the commissioners of public safety and health to develop a framework for regulating the possession and use of tetrahydrocannabinol (THC) resulting from processing of hemp. The Laws of Minnesota 2019, 1st Spec. Sess. chapter 1, article 2, section 20(b), allowed the MDA to form a workgroup with members of the DPS and MDH to discuss the issues surrounding the extraction of cannabinoids from hemp and the potential for concentrated THC to be regulated in a manner that prevents the diversion and misuse of a controlled substance. The goal of the workgroup was to consider a framework that would create a consistent process for tracking processed hemp materials above the legal limit and records for their transportation, remediation and disposal. The members of this workgroup helped to provide the suggestive actions and considerations outlined in this report.

Sec. 20(b). (b) The commissioner of agriculture, in consultation with the commissioners of public safety and health, must develop a framework for regulating the possession and use of tetrahydrocannabinol resulting from industrial hemp processing, including but not limited to the extraction of cannabidiol or other components. No later than February 15, 2020, the commissioner of agriculture must submit the proposed framework to the chairs and ranking minority members of the legislative committees and divisions with jurisdiction over agriculture, public safety, and health.

Hemp Cannabinoid Workgroup Members

The Hemp Cannabinoid Workgroup (HCW) was formed by MDA to assist with the development of this report. The workgroup was comprised of the following representatives from the Minnesota Departments of Agriculture, Public Safety and Health and county and municipal law enforcement:

Anthony Cortilet, Supervisor, Noxious Weed and Industrial Hemp Programs - Minnesota Department of Agriculture
Margaret Wiatrowski, Industrial Hemp Program Coordinator – Minnesota Department of Agriculture
Kathryn Mutschler, Industrial Hemp Regulatory Specialist – Minnesota Department of Agriculture
Denise Thiede, Section Manager, Seed, Weed, Hemp and Biotech Section, Plant Protection Division – Minnesota Department of Agriculture
Douglas Spanier, Department Legal Counsel – Minnesota Department of Agriculture
Chris McNulty, Data Practices Attorney – Minnesota Department of Agriculture
Brian Marquart, Statewide Gang and Drug Coordinator – Minnesota Department of Public Safety
Carla Cincotta, Director, Alcohol and Gambling Enforcement – Minnesota Department of Public Safety
Captain Jon Olsen, State Patrol Commercial Vehicle Commander - Minnesota Department of Public Safety
Jesse Grabau, Narcotics Investigator - Fillmore County Sheriff's Office and Statewide Drug Task Force
Clayton Barg, Patrol Officer – City of Baxter Police Department
Chris Tholkes, Acting Director, Office of Medical Cannabis – Minnesota Department of Health
Megan Thompson, Planning Program Supervisor – Office of Medical Cannabis – Minnesota Department of Health

Hemp Cannabinoid Workgroup Findings

A) Primary Issues for Developing an Effective Framework

1) CONFLICTING AND UNCLEAR STATE AND FEDERAL LAWS

Similar to the findings of the Sale of Certain Cannabinoid Products Workgroup (SCCPW) established by the MDH in 2019 as a result of the Laws of Minnesota 2019, 1st Spec. Sess. Chapter 9, Article 11, section 110, the HCW discussed the need for better regulatory oversight regarding the myriad of state and federal laws concerning regulation of cannabis. The legislative report developed by the SCCPW outlined eleven individual components of federal and Minnesota laws that regulate cannabis. Many of these regulations unintentionally put federal and state agencies in conflict with one another. There needs to be better uniformity between state and federal cannabis laws to reduce confusion among law enforcement, agency regulators, farmers, industry and the public. Currently, marijuana production and product development are illegal under federal law. For the time being, federal law enforcement has chosen not to enforce violations of the Controlled Substances Act (CSA) in states where laws have been developed to regulate recreational and medicinal uses of marijuana. This has been true for Minnesota's medical cannabis program. Hemp is currently the only federally legal form of cannabis

that can be produced in the country. Until federal laws are also developed for the processing, manufacturing and retail of hemp and hemp cannabinoid products, states will be required to intervene with their own laws to help guide and develop this new industry.

2) LIMITED RESOURCES FOR REGULATION

Cannabis production, distribution and sale, through both hemp and medical cannabis state laws, currently place a burden on the MDA, MDH and BOP. These agencies have been provided with the authority to collect fees to offset some financial needs, but there have been significant costs associated with the expectations to oversee production, manufacturing and sale of both types of cannabis that would require fee increases well above an acceptable level to support and develop viable industries in the state. This does not account for the untold hours and costs incurred by state and local law enforcement officers trying to differentiate between illegal marijuana, legal hemp and legal medical cannabis during their normal duties. Law enforcement are faced with serious issues regarding methamphetamine distribution and use within the state, an opioid crisis and violent crime related to illegal drugs. Although illegal activity related to marijuana has become a lower priority for law enforcement and criminal prosecutors over the past decade, it can still consume a significant amount of time if appropriate resources and partnerships among all relevant regulatory agencies are not established. It is important that law enforcement have the appropriate tools to quickly recognize legal activities related to hemp production, processing and manufacturing, in order to focus their time on priority issues.

If it is determined that agencies and law enforcement should provide robust regulation over all forms of legal and illegal cannabis in Minnesota, a true cost analysis should be conducted in order to determine the funds needed and the appropriate way to collect via fees, taxes, etc. It may be prudent to review other state laws and regulations where multiple legal uses of cannabis have already been established in order to determine the best course of action.

The HCW also recommends that the Legislature consider the cost, development and implementation of a cannabis data system that can be shared by all agencies and law enforcement statewide. Other states have successfully integrated 3rd party software, specific to the medical, recreational and hemp industries, that allows agency regulators and law enforcement to successfully communicate with one another regarding cannabis activities and products. The HCW feels that any framework for regulation of cannabis and its derivatives in Minnesota must include a well-developed data system that is accessible 24 hours/7 days a week and can easily identify producers, processors, manufacturers, laboratories, sellers and products for agencies and law enforcement throughout the state.

3) NEED FOR A SINGLE ENTITY TO COORDINATE STATEWIDE CANNABIS REGULATION

Currently, Minnesota has laws for hemp (M.S. 18K) and medical cannabis (M.S. 152.21 – 37) that are overseen by separate agencies, MDA and MDH respectively. Additionally, sales of cannabinoid products derived from hemp are regulated by the BOP under M.S. 151.72. State and local law enforcement oversee the controlled substances laws which address any non-hemp cannabis. While hemp is legal under federal and state law, medical cannabis is only legal under Minnesota law. This

creates difficulty with state and local police who are partnering with federal law enforcement on issues within the state.

Differences in agency oversight also creates significant problems for uniform enforcement of cannabis laws. The lack of a universal data sharing system for cannabis activities among regulatory entities creates confusion, especially when law enforcement encounters cannabis. Because each agency currently operates independently from one another under specific statute authorities, it is suggested that the Legislature consider forming a single entity that oversees the primary decisions for regulation of cannabis in its different forms.

The Legislature should review and consider the best use of agency resources and personnel within state government and assign regulatory responsibilities accordingly. Although MDA, MDH, and BOP are the primary agencies currently providing oversight of regulations established for hemp production, medical cannabis and labeling of cannabinoid products in Minnesota respectively, there are other agencies with expertise in areas that could also greatly benefit the oversight of cannabis regulation in the state. For example, Department of Commerce (DOC) Weights and Measures; DPS Alcohol and Gambling Enforcement; Department of Revenue (DOR) Property Assessments, Taxes and Banking; Pollution Control Agency (PCA); etc. Development of an Office of Cannabis Management could be one way for the Legislature to begin organizing all agency expertise and resources in state government to efficiently regulate and support the emerging legal cannabis industries in Minnesota. This would make better use of already existing infrastructure and prevent costly efforts to recreate what may already exist in other sectors of state government.

The creation of an **Office of Cannabis Management** was recommended for consideration by the SCCPW report submitted to the Legislature on January 15, 2020. States like Colorado, Oregon, and California that have laws for recreational marijuana, medical cannabis and hemp, have developed similar oversight entities to improve regulation in their jurisdictions. In each case, agencies and law enforcement still retain their specific inspection, investigation and regulatory duties for specific aspects of cannabis, but the office or board creates consistency, efficient real-time data sharing, and enhanced communication among the regulatory entities. The board or office also serves as a conduit between regulators/law enforcement, the state legislature and the governor's office to determine if new laws are needed or if existing laws need to be revised. This interaction is both beneficial to the cannabis industry as well as those charged with regulating it.

Therefore, the HCW recommends that the Legislature create an Office of Cannabis Management that would oversee hemp, medical cannabis and cannabinoid products. The HCW feels that this office would be able to review and develop the recommendations for consideration within this report and create a more encompassing framework for all cannabis regulation in Minnesota. The office should be led by individuals who have experience and knowledge of the issues impacting government regulators, law enforcement, the cannabis industries and the general public.

B) HCW Suggestions for a Regulatory Framework

1) COMPONENTS TO CONSIDER FOR A STATE REGULATORY FRAMEWORK

The HCW held several meetings in 2019 and the beginning of 2020 to discuss the Legislature's directive to develop a regulatory framework for resultant THC above the acceptable 0.3% threshold produced through the extraction of cannabinoids from hemp. The HCW discussed in-depth the need for such a framework and that there is no national standard that currently exists. Discussions also reflected on the multitude of existing federal and state laws, contradictions among regulations, differing mandates among regulatory agencies and law enforcement, the current uncertainty of the United States Department of Agriculture's (USDA) recently posted Interim Federal Rules for hemp and media reports regarding the possibility of adult recreational marijuana laws being developed in Minnesota. The workgroup was able to determine that there are already federal and Minnesota laws in place that could be mirrored or modified to address this issue.

Therefore, this report recommends that the legislature review existing statutes that cover multiple agency responsibilities and consider building a regulatory framework that includes (but may not be limited to) the following components with shared agency responsibilities: Transportation, Processors, Facilities, Storage, Disposal and Record Keeping. Another idea that should also be considered (discussed at the end of this report) and would require the approval of the United States Department of Justice, would be mandatory DEA Registration of all hemp processing operations creating a controlled substance (i.e., concentrating THC above the acceptable 0.3% threshold for hemp).

The HCW also believes that the legislature should consider establishing the Office of Cannabis Management to build, oversee and coordinate this regulatory framework to be used among state agencies and law enforcement.

a) Transportation

The HCW recommends that the legislature consider regulations for transportation of cannabis products (not just those above the 0.3% total THC threshold) in addition to the possession of THC resulting from the processing of hemp. This is important because total THC is not something that can be observed in cannabis plant materials or products. THC concentration must be measured through laboratory sample analysis that can take several days to perform.

As part of the process for development for cannabinoid products, transportation of the initial crude extract may be required because extractors and final processors of products may be separate businesses, especially if the initial extraction facility does not further refine the material into a hemp product at or below the legal total THC threshold. Although it would be preferred that a single entity performs all cannabinoid processing in the same facility, this is not always a reality for the complex processes and specialization required for cannabinoid extraction and refinement (similar to alcohol and pharmaceutical manufacturing). Therefore, it is essential that transportation be regulated so that law enforcement officers encountering vehicles containing cannabis materials can quickly determine what the materials are, if they originated from licensed operations, what THC concentrations are present, and where the final destination is. This is also necessary for hemp flowers which are the main material

harvested for cannabis extraction and need to be transported from the farm to an extraction facility. The flowers of hemp are virtually identical to illegal marijuana, drug-sniffing dogs are not able to tell the difference between hemp and marijuana and there is currently no roadside or field test for determining total THC concentration. Therefore, requiring transportation manifests will be useful in ensuring that only legal cannabis materials are being transported on public roadways and that law enforcement are able to check the manifest and quickly determine if the shipment is legal.

➤ **Several key requirements for transportation were discussed by the HCW**

- Determine regulations for hemp flower and other plant parts verses hemp-derived liquids and powders

Raw hemp plant materials must be accompanied by a Minnesota Department of Agriculture Fit for Commerce Certificate showing that the MDA sampled the pre-harvested material and that it is at or below the legal total THC threshold.

Processed materials in oil or solid form must contain a Certificate of Analysis (COA) from an accredited laboratory clearly stating the concentration of total THC by volume or weight for all containers. The manifest must also indicate the presence of any processed materials exceeding the 0.3% total THC threshold and report the weight/volume of the container and what the final product being produced will be and where it will be produced.

- Commercial verses non-commercial transport

It will be important to distinguish regulations for both commercial and non-commercial transport of hemp and processed hemp materials. Commercial laws would apply to anyone transporting hemp flower or processed materials for commerce. The development of a statewide (or federal) law enforcement shipping database should be a priority so that transporters can log-in and report routes, dates and materials being shipped. Shipping data could be entered for the transportation of materials prior to any shipment leaving the facility of origin. This would allow commercial vehicle enforcement personnel, county sheriffs and local police departments to receive warnings for their jurisdictions ahead of time, which would significantly lower the confusion for determining legal cannabis during traffic stops or at weigh stations.

Another consideration would be to require tracking devices for vehicles that commercially transport cannabis so that the routes vehicles have taken during transport can be reviewed by law enforcement. This would be more useful for shipments where extracted materials have not yet been refined at or below the legal total THC threshold and are being transported to another facility for final remediation into hemp products.

Drivers in Minnesota who transport commercial cannabis shipments should be registered with the state. This should also be required of any vehicle used to transport cannabis materials. Drivers and vehicles must also be properly insured. Anyone shipping cannabis materials should be required to immediately inform law enforcement during traffic stops or routine inspections. Shipments must be

accompanied by a bill of lading or manifest showing where the shipment originated and its destination, a COA and a log of weights, volumes, container types and description for all materials being shipped. Shipping manifest should be standardized so that all state law enforcement can easily examine.

All loads should be secured with security ties from the shipping origin. After inspection by law enforcement, a load must have a new security tag affixed. This process will continue until the shipment reaches its final destination.

Non-commercial transport would apply to farmers and local processors who are moving harvested non-processed hemp materials from production locations to storage, drying and non-cannabinoid processing facilities (i.e., grain and fiber). For this type of shipment, the grower or processor should have a valid Minnesota Hemp Grower or Processor License and a Fit-For-Commerce Certificate (or equivalent document from the state of origin or the USDA).

➤ **Review of Existing Minnesota transportation statutes and state agency oversight that could be considered applicable for hemp products and extracted materials containing THC**

The HCW reviewed existing state statutes and determined that transportation requirements for Medical Cannabis (Chapter 152 and Administrative Rules 4770) and Liquor (Chapter 340A and Administrative Rules 7515) could either be applied to cannabis and cannabis products or be used to draft specific statutes and rules.

- **Therapeutic Research Act; Medical Cannabis – M.S. 152.29 – Manufacturer of Medical Cannabis Duties**
 - Minnesota Rule 4770.1100 - Transportation of Medical Cannabis
 - This rule has guidelines for when and where medical cannabis can be transported, outlines for a manifest system and chain of custody, vehicle requirements, driver requirements, etc.
- **Minnesota Liquor Laws - Chapter 340A**
 - Minnesota Statute 340A.306 – Fraudulent Shipments
 - Minnesota Statute 340A.407 – Common Carriers
 - Minnesota Statute 340A.701(2) – Unlawful Acts
- **Minnesota Liquor Administrative Rules – Chapter 7515**
 - Minnesota Rule 7515.0940 – Transportation
 - Minnesota Rule 7515.1110 – Alcoholic Contents to be Indicated on Containers

b) Processors

Currently there are no specific laws or rules established for the regulation of hemp processing, product manufacturing or retail. Although hemp is processed similarly to other agricultural commodities that do not require licensing, the legislature should consider establishing licensing for any person or entity that is processing hemp for cannabinoid extraction, manufacturing products from cannabinoid extract,

and selling products containing cannabinoid extracts. The HCW also recommends that the legislature consider what agency (or agencies) will be best suited to provide proper oversight and ensure that those agencies are funded accordingly to provide efficient regulation of this industry.

The process of extracting cannabinoids, concentrating THC and then manufacturing products that have removed or diluted the THC concentrate at or below the legal threshold for hemp and hemp products has similarities to the manufacturing of medical cannabis and alcohol products regulated by Minnesota Law, Chapters 152 and 340A. The HCW recommends that both the medical cannabis and liquor laws be reviewed to determine if they can be mirrored or adopted for hemp cannabinoid processing.

- **Minnesota Liquor Laws - Chapter 340A**
 - Minnesota Statute 340A.301 - Manufacturers, Brewers, and Wholesalers Licenses
 - Minnesota Statute 340A.701(1) – Unlawful Acts
 - Minnesota Statute 340A.907 – Inspection

- **Minnesota Liquor Administrative Rules – Chapter 7515**
 - Minnesota Rule 7515.0210 – Regulatory Permits and Fees
 - Minnesota Rule 7515.1400 – Ethyl Alcohol Permit Required
 - ***This rule is important as it applies to hemp processors who use ethyl alcohol as part of their cannabinoid extraction process***

- **Therapeutic Research Act; Medical Cannabis – M.S. 152.29 – Manufacturer of Medical Cannabis Duties**
 - Minnesota Rule 4770.0400 – Medical Manufacturer; Operations
 - Minnesota Rule 4770.0500 – Medical Cannabis Manufacturer; Quality Control; Assurance Program

c) Facilities and Processing Equipment

Facilities should be required to be licensed with the state if they process hemp products where THC levels are concentrated above the 0.3% total THC threshold. Additionally, the equipment used for extracting cannabinoids should also be tested and inspected at least once annually by the appropriate agency to ensure that it is operating correctly. It is also fundamentally important that regulations are determined for where a processing facility can operate and what type of processing is allowed based on the location, the facility, safety and security provisions, etc. Cannabinoid extraction can be done in various ways, and in some cases, using high pressured equipment, dangerous chemicals and explosive gases that can be hazardous to workers, neighbors and the general public near and around the facility. The HCW recommends that the legislature consider establishing regulations that require any facility involved in the processing of hemp for extraction of cannabinoids to meet specific requirements, adhere to all local zoning laws and be inspected regularly by the local fire department to ensure that proper safety measures are in place.

Because there are no specific statutes or rules governing hemp processing facilities or processing equipment, the HCW recommends that the legislature review the Minnesota Liquor Laws (Chapter

340A and Administrative Rules - 7515) pertaining to manufacturers and Gambling Laws (Chapter 299L) that apply to licensing of gambling devices.

The HCW also reviewed Minnesota medical cannabis statutes (Chapter 152) and determined that administrative rules require medical cannabis facilities to provide adequate monitoring and surveillance, alarm systems and personal identification systems. These rules are intended to ensure that medical cannabis is not being diverted from the facilities for illegal activities. Currently, there are no such requirements for hemp processing facilities that are in possession of illegal THC materials during the extraction and product formulation process. The HCW recommends that the following administrative rules for medical cannabis facility security also be considered for hemp processing facilities extracting or processing cannabinoids where total THC is concentrated above the legal threshold for hemp.

- **Therapeutic Research Act; Medical Cannabis – M.S. 152.21 – 152.37**
 - Minnesota Rule 4770.0900 - Monitoring and Surveillance Requirements
 - Minnesota Rule 4770.1000 Alarm System Requirements.
 - Minnesota Rule 4770.1400 - Personnel Identification System

- **Minnesota Liquor Laws - Chapter 340A**
 - Minnesota Statute 340A.301 - Manufacturers, Brewers, And Wholesalers Licenses
 - Minnesota Statute 340A.907 – Inspection

- **Minnesota Liquor Administrative Rules – Chapter 7515**
 - Minnesota Rule 7515.0210 – Regulatory Permits and Fees

- **Minnesota Gambling Enforcement - Chapter 299L**
 - Minnesota Statute 299L.07 – Gambling Devices

- **Minnesota Gambling Devices Administrative Rules – Chapter 7570**
 - Minnesota Rule 7515.0030 – Records Requirements
 - Some aspects of this rule for gambling devices may be important to consider for hemp cannabinoid processing equipment because some of the equipment used by processors can be dangerous and may need to be licensed in the state so that EMS and fire departments are aware of such equipment in their jurisdictions.

d) Inventory Management and Disposal

Storage of material from the processing of cannabinoids that exceeds the total THC threshold for hemp should also be regulated. The medical cannabis statutes have established rules for inventory management of cannabis materials that could also be adapted to a framework for hemp processing of cannabinoids.

- **Therapeutic Research Act; Medical Cannabis – M.S. 152.21 – 152.37**
 - Minnesota Rules 4770.1800 – Inventory

Disposal of concentrated THC will also be another issue facing hemp cannabinoid processors. The following administrative rule for medical cannabis could be adopted into a framework for hemp processing as well.

- **Therapeutic Research Act; Medical Cannabis – M.S. 152.21 – 152.37**
 - Minnesota Rule 4770.1200 - Disposal of Medical Cannabis and Plant Material

e) Record Keeping

In order to accurately track the processing of hemp from raw harvested material to final product, it should be required of hemp processors extracting cannabinoids to keep accurate records and retain them for a specified amount of time so that regulators can review if issues arise. It will also be important for the MDA to have an all-in-one digital data management system that can track licenses, growing and processing locations, planting dates, harvest dates, field THC tests, and storage/inventory of harvested material. This system should also be accessible to law enforcement 24 hours a day so that identification of legal growers, processors and materials can be determined quickly. Currently, there is not system that provides this type of efficient data and record keeping and MDA's Hemp Program will need funding to hire a 3rd party software developer to ensure that a system is built, supported and properly serves the needs of agencies, growers, processors and law enforcement. The HCW feels that this could be another responsibility for an Office of Cannabis Management to oversee, since it could benefit all state agencies and law enforcement involved in cannabis regulation.

The following administrative rules for medical cannabis could provide a potential framework for record keeping and product recall procedures for hemp processing of cannabinoids and manufactured products.

- **Therapeutic Research Act; Medical Cannabis – M.S. 152.21 – 152.37**
 - Minnesota Rule 4770.1600 – Record Keeping; Requirements

2) USE EXISTING FEDERAL FRAMEWORK

a) Drug Enforcement Administration Registration

Anyone planning to manufacture, distribute, research, analyze, import or export a controlled substance in the United States is required to be registered with the DEA. This requires submitting an application (DEA Form 225) and being inspected by DEA in order to be approved for a registration. The DEA registration process already has an intricate framework developed for regulation of those handling controlled substances like THC. The registration process also subjects manufacturers to stringent rules and audits by DEA in order to prevent the misuse or diversion of controlled substances. DEA can impose penalties or criminal charges for any registrant that does not comply with the laws and regulations pertaining to their specific registration.

Requiring DEA registration of all hemp processors in the state who are concentrating THC above the 0.3% threshold may be a potential solution to this issue. It would eliminate the need to create new state laws and would allow Minnesota processors to be held to a national standard. This would be

beneficial because anyone with a DEA registration would be following federal manufacturing and safety requirements allowing them to do business anywhere in the United States and within most countries. Since hemp is now a federally approved agricultural commodity and the issue of concentrating THC is consistent among a majority of cannabinoid processors in every state, DEA registration may be the best available framework to utilize.

However, before requiring DEA registration, the HCW has determined that the legislature should consult with DEA and Minnesota hemp processors to determine if this would be a workable situation. The DEA typically deals with pharmaceutical manufacturers and larger entities that are accustomed to these types of federal regulations and standards. Federal hemp laws are new and still being developed and the DEA does not have a lot of experience working directly with agricultural processors. Additionally, hemp processors range in size from small to medium-sized businesses that are not typically subjected to the strict type of regulations that a Schedule 1 Registration requires. Before any requirement of DEA registration is approved in Minnesota, the legislature should consider if 1) DEA is open to the idea of working with hemp processors and manufacturers and allowing them to apply for a Schedule 1 Registration to remediate levels of THC produced above the acceptable 0.3% limit during cannabinoid extraction, 2) Minnesota hemp processors are willing to meet the requirements of DEA, and 3) DEA would either create a new category specific to hemp production or be flexible to meet the needs of agricultural processing and the hemp industry so that Schedule 1 Registration is fair to both small and large processing operations.

- **21 U.S.C. Controlled Substances Act; Part C** <https://www.dea diversion.usdoj.gov/21cfr/21usc/>

Conclusion

Hemp production has seen an exponential growth in Minnesota and throughout the U.S. over the past two years. In a single year alone (2018 to 2019), national data has shown a 650% increase in acres dedicated for hemp production. Most of the acres were dedicated to hemp grown for cannabinoid extraction to meet the public demand for products containing CBD. Even with the prices for cannabinoid extracted crude declining over the past six months, Minnesota continues to see increased interest in hemp production and the MDA has been accepting applications for the 2020 growing season at a rate that is similar to 2019.

Cannabinoid products continue to evolve, and new cannabinoids are being extracted and marketed in addition to CBD. Cannabinol (CBN), Cannabigerol (CBG) and Cannabichromene (CBC) are all non-psychoactive cannabinoids produced in the hemp plant that are finding their way into new products and markets. As consumer demand for these cannabinoids continues, processing for extraction will also be a necessary part of the developing hemp industry. Because THC concentration is a byproduct of hemp cannabinoid processing, there needs to be a regulatory process established that can aid the developing hemp industry in Minnesota while also preventing the illegal use and distribution of THC. A thoughtful regulatory framework that considers the complexity of state and federal laws in addition to the overlapping regulatory authorities of multiple agencies and law enforcement jurisdictions, should be developed to strengthen the hemp industry by deterring illegal activities and providing legitimacy to

growers and businesses that follow the rules and regulations to produce high-quality products in a safe and consistent manner.