SYNTHETIC CANNABINOID ADVISORY COUNCIL REPORT

House Bill 948

AUGUST 2024

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Advisory Council Members

Members	Organization
Jona Verreth	Department of Agriculture
Steve Crawford	Department of Justice
Isaac Coy	Department of Health and Human Services
Kathy Wiegand-Palmer (presiding officer)	Department of Revenue
Shane Bancroft	Department of Revenue
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House Bill 948 Introduction

House Bill 948 (HB948) was passed during the 2023 legislative session and became effective May 22nd, 2023. The purpose of HB948 was to prohibit the manufacture and distribution of synthetic marijuana products by providing for enforcement by departments and law enforcement, restrictions by local governments, clarifying unlawful transactions to children, clarifying the offense of altering a label on dangerous drugs, requiring public reporting of violations, and creating a temporary advisory council.

Background of Intoxicating Hemp-derived Cannabinoids

Following the federal legalization of hemp with the passage of the 2018 Farm Bill, the prevalence of hemp-derived cannabinoids (intoxicating and non-intoxicating), or what the state of Montana through HB948 has defined as "synthetic cannabinoids", has drastically increased. This is due to the 2018 Farm Bill's broad definition of hemp as seen below.

> ***7 USC § 1639o (1) HEMP***
> *The term "hemp" means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.*

As the federal definition of hemp includes the language, "all derivatives", synthetic cannabinoid manufacturers argue for the legality of these products as they are typically manufactured from hemp sourced CBD and thus are derivatives of hemp. However, many of these products are intoxicating and produce the same or similar effect of natural delta-9 THC upon which state legalized programs are built. Additionally, the lack of federal regulation or enforcement of these substances has implications for public health, safety, and consumer awareness.

Synthesizing cannabinoids typically requires CBD isolate sourced from hemp, organic solvents, strong acids, metal catalysts, and energy in some form. This process has the potential to create unintended and unknown by-products the majority of which have not been identified or studied for their effects on the human body. Additionally, these products may also contain unconsumed synthesis reagents and unknown contaminants. With no regulatory or enforcement framework in place to oversee this synthetic process, intoxicating products likely containing an array of unknown compounds and contaminants are entering the consumer space under the guise of hemp.

The implications of this seemingly benign federal definition of hemp have allowed an unregulated national marketplace to rapidly emerge. These products can be found in retail brick and mortar stores and online businesses. They are not taxed nor are there any federal regulations for minimum safety testing and manufacturing standards. Additionally, these substances do not have standardized packaging and labeling requirements. Often, synthetic cannabinoid products are sold in containers that would be considered appealing to children in legal state marijuana programs and commonly contain labels with misleading or incorrect information. Copycat products imitating consumer goods such as brand name cookies, cereals, or snacks are prevalent as well. Standardized dosing requirements are non-existent and often these products can be purchased with levels of intoxicating cannabinoids that are orders of magnitude higher than what is allowed in legal state marijuana programs. Lastly, these products do not have age restrictions thereby increasing the chances for youth access and use. All of these issues have led to a sharp increase in adverse events reporting nationwide as the ability for consumers to make informed decisions about the products they consume is undermined.

Common synthetic cannabinoids include delta-8 THC, delta-10 THC, HHC, THCP, THC-O-Acetate, HHCP, and many others. Many synthetic cannabinoids are entirely novel and not found anywhere in nature. Some synthetic cannabinoids are purported to be substantially more intoxicating than the naturally occurring delta-9 THC found in the legal Montana market. Other synthetic cannabinoids, such as delta-8 THC, may have a natural equivalent or analog. However, these are typically found only in trace amounts in the biomass. Due to the miniscule amount found naturally in the plant, these cannabinoids are economically and financially inviable for natural production. The sheer volume of biomass required to extract and concentrate commercial amounts of these target cannabinoids would result in unsustainable production costs along with exorbitant retail value.

In Montana, with the passage of HB948, synthetic cannabinoids and products that contain them, including those produced using a chemical synthesis or biological synthesis, are prohibited from sale and manufacture in Montana.

> ***16-12-117. Synthetic marijuana products prohibited -- restriction on sale of marijuana products.*** *(1) A person may not manufacture, process, or offer for sale a synthetic marijuana product.*

The intent of HB948 was to close the loophole created by the 2018 Farm Bill's definition of hemp. In doing so it defined the terms synthetic cannabinoid and synthetic marijuana product in 16-12-102 MCA.

Additionally, HB948 adopted the federal definition of hemp into 80-18-101 MCA with two notable amendments. The first, specifying that not more than 0.3% total delta-9 tetrahydrocannabinol (THC), not simply delta-9 THC, is the threshold for distinguishing between hemp and marijuana. Second, clarifying that synthetic cannabinoids are not considered hemp.

> ***16-12-102. Definitions.***
> *(40) "Synthetic cannabinoids" has the meaning provided in 50-32-222 and includes any cannabinoids produced artificially, whether from chemical synthesis or biosynthesis using recombinant biological agents, including but not limited to yeast and algae.*
> *(41) "Synthetic marijuana product" means marijuana or marijuana products that contain synthetic cannabinoids*

> ***18-18-101. Definitions.***
> *(1) (a) "Hemp" means all parts and varieties of the plant Cannabis consistent with the United States department of agriculture's definition of hemp and rules established by the department the plant species Cannabis sativa L. and any part of that plant, including the seeds and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a total delta-9 tetrahydrocannabinol concentration of not more than 0.3% on a dry weight basis.*
> *(b) The term does not include synthetic cannabinoids.*

The addition of the word 'total' in Montana's statutory definition of hemp is more consequential than it may initially appear. Total delta-9 THC is a simple calculation that includes both the acidic and neutral forms of the compound. Delta-9 THC is the neutral and psychoactive component of marijuana. However, delta-9 THCA, or the acidic and non-psychoactive form of the compound, is easily converted to delta-9 THC with the application of heat through actions such as smoking. Marijuana biomass contains larger amounts of delta-9 THCA than its neutral psychoactive form, delta-9 THC. Many hemp products on the market exploit this total delta-9 THC versus delta-9 THC relationship by marketing products with less than 0.3% delta-9 THC while containing large amounts of delta-9 THCA. In practice, this means the product is psychoactive when smoked, vaped, or otherwise heated. Requiring the "total delta-9 tetrahydrocannabinol concentration" to be 0.3% or less eliminates this deceptive practice for certain product types. The calculation for total delta-9 THC in percent by weight is provided below.

$$\% \text{ Total delta-9 THC} = (\% \text{ delta-9 THCA} \times 0.877) + \% \text{ delta-9 THC}$$

HB948 also created a temporary advisory council tasked with various work items pertaining to synthetic cannabinoids and the products that contain them. The following is a summary of the advisory council's work pertaining to the synthetic cannabinoid space.

Synthetic Cannabinoid Products in Montana

The following are examples of synthetic cannabinoid products identified in non-dispensary retail businesses by the Cannabis Control Division's Synthetic Cannabinoid Inspector.

	A gummy product that contains 7000mg/container (70x the legal limit) and 350mg/serving (35 times the legal limit) of synthetic cannabinoids THCP and HHCP. The proportion of which is unknown. THCP and HHCP are purported to be 30 times more psychoactive than delta-9 THC.
	Copycat products of everyday consumer cereals marketed directly toward children and contain intoxicating synthetic cannabinoid, delta-8 THC.
	Hemp flower containing THC-O and delta-8 THC.

Guiding Principles

The advisory council convened on a monthly cadence and met six times starting in November of 2023 and concluding in May of 2024. Discussion was grounded in the following agreed upon guiding principles.

1. Ensure consumer protection and safety.
2. Base recommendations on data and science.
3. Develop clear recommendations and guidance that considers alignment with other state, federal, and/or international standards when possible and appropriate.
4. Avoid adverse effects on the existing legal Montana marijuana program.
5. Support education and research opportunities.

Advisory Council Tasks

The advisory council was charged with the following three tasks per HB948 as seen below:

> *NEW SECTION.* ***Section 3. Synthetic marijuana products advisory council.***
> *(4) The advisory council shall review available research, data, and regulations of other jurisdictions related to synthetic marijuana products, including but not limited to:*
> *(a) definitions of the term "impairing" in relation to cannabinoids, as well as definitions of the terms "artificial cannabinoids" and "synthetically derived cannabinoids"; and*
> *(b) recommendations on potential guidelines for safe methods of manufacturing, extracting, and synthesizing cannabinoids, including the sale of synthetic marijuana products.*
> *(5) The advisory committee shall compile findings and make recommendations in a report to the economic affairs interim committee, in accordance with 5-11-210, regarding regulating synthetic marijuana products in the adult-use marijuana market by September 15, 2024.*

The first task from New Section 4(a), will be addressed in the “Terms & Definitions”, “Proposed Amended Terms & Definitions”, and “Proposed New Terms & Definitions” sections below. The second task from New Section 4(b), will be addressed in the “Potential Guidelines for Safe Manufacturing” section below. The third task from New Section 5, is satisfied with the completion of this report.

Terms & Definitions

In researching potential definitions for the terms specified in New Section 4(a), it became apparent additional terms and definitions may become relevant and necessary for the effective regulation and enforcement of synthetic cannabinoids. The advisory council took advantage of the bill language allowing for expanding the scope of the terms and definitions reviewed and evaluated.

HB948 specifically tasked the advisory council with defining the term “impairing” in relation to cannabinoids. The scientific literature has identified approximately 150 natural cannabinoids. The number of existing synthetic cannabinoids is ever growing and novel cannabinoids are continually

created as this market space charges forward nationally. Further complicating matters, each cannabinoid has a different binding affinity with receptors found within the human body and every person has a different tolerance to cannabinoids and their potential effects. At this juncture, the wide array of cannabinoids, their potential for impairment, and the lack of testing standards and impairment thresholds has been studied only minimally. The advisory council discussed possible definitions for "impairing" and concluded that given the immense scope of the subject, potential law enforcement implications, and lack of research, a definition could not be adequately and reliably achieved at this time.

HB948 specifically tasked the advisory council with defining the terms "artificial cannabinoids" and "synthetically derived cannabinoids". The advisory council determined these terms, along with the term "synthetic cannabinoid", are synonymous. The advisory council agreed upon maintaining the nomenclature, "synthetic cannabinoid", as the term already exists in the Montana Controlled Substances Act in 50-32-222 MCA and is a nationally recognized term.

Proposed Amended Terms & Definitions

The advisory council agreed upon the following proposed amendments to the existing statutory term and definition below. Provided is an explanation of why the amendment is necessary and specific comments of interest.

- The advisory council recommends amending the statutory term "synthetic marijuana product" as seen in the interlined and underlined language below. As the current definition stands, a product in question must first be marijuana and then a synthetic product. The advisory council determined the use of the word "marijuana" in both the term and definition to be an inaccurate assessment of the origin of these products because they are in fact sourced from hemp. Therefore, a more accurate and nationally recognized term would be "synthetic hemp product" instead of "synthetic marijuana product". However, the advisory council proposes the term "synthetic cannabinoid product", thereby removing any negative or positive connotation that may be associated with hemp or marijuana and identifying the product more specifically. The definition was similarly updated to allow for a more accurate assessment of the product origin and to avoid confusion.

  16-12-102 Definitions
  (41) "Synthetic ~~marijuana~~ <u>cannabinoid</u> product" means ~~marijuana or marijuana~~ consumer products that contain synthetic cannabinoids.

Proposed New Terms & Definitions

The advisory council agreed upon the following proposed new terms and definitions. Provided is an explanation of why these terms are necessary, a recommendation concerning the Montana Code

Annotated (MCA) or Administrative Rules of Montana (ARM) designation, and other specific comments of interest.

- The advisory council recommends including the proposed term "synthetic cannabinoids" to ARM to continue to build upon the existing statutory definitions found in 16-12-102 MCA and 50-32-222 MCA. This definition further clarifies what cannabinoids are included within the term, excluded from the term, and may be included in the term. These qualifying elements are based on the processes by which the cannabinoids in question are manufactured and function in partnership with the proposed definitions to follow in this section of the report.

  "synthetic cannabinoids" *means the same as the term provided in 16-12-102, MCA.*
  (a) The term does not include:
  (i) natural cannabinoids; and
  (ii) cannabinoids produced by the decarboxylation of natural acidic cannabinoids without the use of a chemical catalyst.
  (b) The term does include:
  (i) cannabinoids produced by the decarboxylation of synthetic acidic cannabinoids with or without the use of a chemical catalyst; and
  (ii) cannabinoids produced by the decarboxylation of natural acidic cannabinoids with the use of a chemical catalyst.
  (c) The term may include;
  (i) intoxicating or non-intoxicating cannabinoids; and
  (ii) cannabinoids with a naturally occurring equivalent.

- The advisory council recommends adding the proposed term "chemical synthesis" to ARM to clarify what that process entails. This term is necessary as it further clarifies and complements the statutory definition of synthetic cannabinoid found in 16-12-102 MCA.

  "chemical synthesis" *means a process to create a chemical substance through a chemical reaction or conversion by human agency, which changes the molecular structure of any chemical substance, including but not limited to those substances derived from the plant Cannabis family Cannabaceae, that involves the use of chemicals and reagents, as opposed to those of natural origin.*
  (a) The term does not include:
  (i) the decarboxylation of acidic natural cannabinoids without the use of a chemical catalyst.
  (b) The term does include:
  (i) the decarboxylation of synthetic acidic cannabinoids with or without the use of a chemical catalyst.
  (ii) the decarboxylation of natural acidic cannabinoids with the use of chemical catalyst.

- The advisory council recommends including the proposed term "natural cannabinoids" to ARM as it further clarifies what cannabinoids fall within this term while mirroring the language and format proposed for the counterpart of this term. *i.e.* synthetic cannabinoids. Including

language describing these compounds provides needed clarity ensuring these substances can be adequately differentiated by the process by which they were manufactured. This is particularly important given that some cannabinoids may fall into both a synthetic and natural status, based solely on the process by which it was attained.

"natural cannabinoids" *or "phytocannabinoids" means a cannabinoid present or occurring naturally in the biomass of the plant Cannabis family Cannabaceae. These may be separated and further purified by chemical or mechanical manufacturing, as defined in ARM 42.39.102, directly from the biomass.*
(a) The term does not include:
(i) synthetic cannabinoids or synthetically derived cannabinoids; and
(ii) cannabinoids produced by the decarboxylation of synthetic acidic cannabinoids with or without the use of a chemical catalyst; and
(iii) cannabinoids produced by the decarboxylation of natural acidic cannabinoids with the use of a chemical catalyst.
(b) The term does include:
(i) cannabinoids produced by the decarboxylation of natural acidic cannabinoids without the use of a chemical catalyst.
(c) The term may include;
(i) intoxicating or non-intoxicating cannabinoids; and
(ii) cannabinoids with a synthetic equivalent.

- The advisory council recommends including the proposed term "natural cannabinoid product" to ARM to further clarify what consumer products fall within this term and to mirror the language and format proposed for the counterpart of this term. *i.e.* synthetic cannabinoid products.

  "natural cannabinoid product" *means consumer products that contain natural cannabinoids and does not include synthetic cannabinoids.*

- The advisory council recommends including the proposed term "decarboxylation" to ARM to further clarify the proposed terms synthetic cannabinoid, natural cannabinoid, and chemical synthesis.

  "decarboxylation" *means the conversion of an acidic cannabinoid into its neutral form typically with the use of thermal energy such as the conversion of delta-9-THCA into delta-9-THC with heat.*

Note that all the terms included in this section, "Proposed New Terms & Definitions", are recommended to be included in ARM. This is quite intentional and was discussed at length by the advisory council. These terms are technical in nature and the synthetic cannabinoid space is novel and innovative. The recommended inclusion of these terms in ARM provides the applicable departments much needed flexibility to amend regulations as the cannabinoid space continues to evolve at speeds that far exceed the pace of statutory regulation.

Potential Guidelines for Safe Manufacturing

The advisory council was tasked with reviewing the available research, data, and regulations of other jurisdictions related to synthetic marijuana products, including but not limited to recommendations on potential guidelines for safe methods of manufacturing, extracting, and synthesizing cannabinoids, including the sale of synthetic marijuana products. In discussing this topic, two prominent paths forward presented themselves and were discussed at length by the advisory council. The advisory council ultimately agreed upon what was coined, "the FDA route".

When discussing the overall safety of consumer products that contain synthetic cannabinoids, a thorough and well-rounded approach is paramount. One that focuses both on the manufacturing process and the final product. The process and product must meet or exceed minimum safety standards to ensure employee and consumer safety. It is important to recognize that HB948 asks the advisory council to "recommend potential guidelines for safe methods of manufacturing, extracting, and synthesizing cannabinoids, including the sale of synthetic marijuana products". Yet, it does not specifically ask the advisory council to also investigate or evaluate the safety of the final product. The advisory council has chosen to provide information regarding not only potential safe methods of synthesizing cannabinoids, but also and just as importantly, an evaluation on the safety of synthetic cannabinoids in consumer products.

It is critical to recognize that the mere existence of a safe method of manufacturing, for any given compound, does not inherently mean that the compound itself is safe for human consumption. Consider methamphetamine. This compound can be manufactured or synthesized in a safe manner from readily available and legal starting materials. However, the end product is not safe for use in the general consumer space and has resulted in considerable harm to public health. Therefore, allowing for the production and sale of any compound, including synthetic cannabinoids, based solely on if the manufacturing method is safe, is an extremely poor determining factor to use when considering if these products are safe for Montana consumers. The latest available research indicates that synthetic cannabinoids, many of which are nascent and unstudied, have high potential to harm public health. This is evident by the increase in synthetic cannabinoid adverse event reporting, since 2018, as seen in the FDA's Adverse Events Reporting System (FAERS).

Given the isomeric chemistry of cannabinoids, they can easily be manipulated and modified into an almost unlimited number of analogs, which have the potential to interact with the human body in ways that are unstudied and unknown. The scientific literature in this regard is sorely inadequate and will likely remain so as new synthetic cannabinoids are being created at a pace faster than researchers can study. What literature is available on the more established synthetic cannabinoids clearly indicates that some are over 30 times more pharmacologically active than naturally occurring delta-9 THC. Additionally, the synthetic manufacturing process uses toxic chemicals and reagents which can remain in the final product. Finally, as no chemical synthesis is 100% efficient, the process also creates unintended by-products which may include non-target novel synthetic cannabinoids along with a host of other unidentified compounds. All of which have unknown human health effects. Even if regulations existed to ensure the synthetic manufacturing process was safe, including the removal of by-products and reagents, the scientific literature does not support safe human consumption of these compounds at this time.

Should legislators wish to entertain the idea of allowing for the manufacture and sale of synthetic cannabinoids, a logical approach would be to utilize the long-standing FDA pathways to ensure that both the process, and just as importantly, the product is safe. These pathways include the drug development pathway, along with the Generally Recognized as Safe (GRAS) and the New Dietary Ingredient (NDI) pathways. The drug development pathway involves a review process ensuring the drug is safe and effective for its intended use, the benefits outweigh the risks, and a risk management strategy is in place. A few natural and synthetically derived prescription cannabinoid drugs have been approved through this process and are available through the prescriptive power of a licensed physician. The FDA's GRAS and NDI programs ensure that the ingredients to be included in food or dietary supplements must meet certain assumed minimum safety thresholds for the conditions of its intended use prior to formulation in food or dietary supplements. This recognition of safety through scientific procedures is based upon generally available, accepted, and published scientific data. Currently, a successful application for a synthetic cannabinoid has yet to achieve a GRAS or NDI designation.

Final Advisory Council Recommendations

The advisory council discussed contradictory language identified in HB948 concerning 80-18-101(1) MCA, 16-12-117(2) MCA, and 16-12-117(3) MCA. 16-12-117(2) MCA and 16-12-117(3) MCA inadvertently used the 0.3% delta-9 THC threshold found in the federal definition of hemp. However, HB948 intentionally amended and adopted a definition of hemp that uses a 0.3% total delta-9 THC threshold. This small change in language has large consequences. To correct the contradictory language identified between 80-18-101(1) MCA and 16-12-117(2) and (3) MCA, it is highly recommended the following amendments be adopted to 16-12-117(2) and (3) MCA to maintain the current statutory definition of hemp in Montana.

> *16-12-117(2) ~~Products containing or consisting of cannabinoids produced and processed for any type of consumption into a human body, whether marketed as containing or consisting of cannabinoids or not, that exceed a THC concentration of 0.3%~~ Marijuana and marijuana products may only be sold by a manufacturer licensed under 16-12-222 or a dispensary licensed under 16-12-224 unless the products are authorized as a drug by the United States food and drug administration. Products under this section may not exceed the potency levels established in 16-12-224.*

Adopting the amendments above simplifies the statutory language, removes the need to update the language should the definition of marijuana change in the future, and infers the correct numerical threshold for distinguishing between hemp and marijuana.

> *16-12-117(3) ~~Products containing a THC concentration of 0.3% or less~~ Hemp and hemp products sold by any person other than a licensed manufacturer under 16-12-222 or a licensed dispensary under 16-12-224 may not exceed 0.5 milligrams of total delta-9 THC for each serving and may not exceed 2.0 milligrams of total delta-9 THC per package.*

Adopting the amendments above simplifies the statutory language, removes the need to update the language should the definition of hemp change in the future, and infers the correct numerical threshold for distinguishing between hemp and marijuana.

Conclusion

The advisory council believes we have addressed the tasks put forth in HB948 and that the provided recommendations will aid Montana to better regulate cannabis and ensure consumer safety. The advisory council recognizes that the cannabis industry is nascent and that state law will no doubt require future amendments and updates as the space continues to mature and federal laws change. Specifically, changes to the "Farm, Food, and National Security Act of 2024", or Farm Bill, are expected to alter the federal hemp landscape including how hemp derived synthetic cannabinoids are regulated. The advisory council does not make any recommendations based on the current draft language or potential outcome of this important bill, but rather simply acknowledges that it may have a future impact and brings it to the Montana Legislature's attention. We acknowledge the extremely valuable input and expertise from all the representatives who participated in the proceedings. The advisory council would like to take this opportunity to thank the legislators who developed this legislation so these important conversations could be held in a public and transparent manner.