# State of California

# Department of Cannabis Control

# California Code of Regulations, Title 4, Division 19

# Initial Statement of Reasons:

# Animal Cannabis Product Standards

## INTRODUCTION

The Department of Cannabis Control ("Department") is responsible for administering and enforcing the provisions of the Medicinal and Adult-Use Cannabis Regulation and Safety Act ("MAUCRSA," Bus. & Prof. Code §26000 et seq.). MAUCRSA establishes a comprehensive regulatory structure governing the cultivation, distribution, transport, storage, manufacturing, processing, testing, and sale of medicinal and adult-use cannabis, including cannabis products intended for use on, or consumption by, animals.

## PROBLEM STATEMENT

Assembly Bill (AB) 1885 (Chapter 389, Statutes of 2022) requires the Department to promulgate regulations for cannabis products intended for use on, or consumption by, animals no later than July 1, 2025. Under BPC section 26130(e)(1), if a cannabis product is intended for therapeutic effect or health supplementation use on, or for consumption by, an animal, the cannabis product must conform with any additional relevant standards, including, but not limited to, an alternative standardized concentration, established by the Department through regulations. Under BPC section 26130(e)(2), cannabis products may not be marketed or sold for use on, or consumption by, animals before these regulations for animal standards take effect.

## ANTICIPATED BENEFITS

The proposed regulations will protect the health and safety of animals by establishing clear standards specifically tailored to govern manufacture, distribution, and sale of animal cannabis products. In general, animal cannabis products must meet the same standards as cannabis products intended for human consumption currently on the market. These standards include strict compliance with manufacturing quality control programs, and packaging, labeling, and testing requirements that will ensure animal products are not adulterated or misbranded. Restricting manufacture to edible products, orally consumed concentrates, and topical products will allow for and encourage the development of a robust and varied market for animal cannabis products while ensuring that animals are not exposed to potentially harmful forms of cannabis, such as combustible and inhalable products. Restricting animal cannabis products to not more than one milligram of total THC per package will reduce the risk of toxicosis and death from exposure to unsafe levels of THC.

## SPECIFIC PURPOSE OF, AND RATIONALE FOR, EACH PROPOSED CHANGE

### Chapter 1. All Licensees

### Article 1. Division Definitions and General Requirements

Amend §15000. Definitions.

Existing subsection (w) is amended to state that "edible cannabis product" has the same meaning stated in BPC section 26001(y). BPC section 26001(y) was amended by AB 1885 (Chapter 389, Statutes of 2022), which rendered the definition of "edible cannabis product" in section 15000(w) inconsistent because it does not account for animal consumption. Existing language regarding oral consumption is non-substantively relocated to the second sentence of the definition. These changes are necessary to harmonize the regulatory and statutory definitions of this term.

### Chapter 10. Cannabis and Cannabis Products

### Adopt Article 4. Animal Cannabis Products

Adopt §17350. Animal Cannabis Product Standards.

New subsection (a) defines the term "animal cannabis product." BPC section 26001(k) defines "cannabis products" to include "cannabis products intended for use on, or consumption by, an animal," yet while all animal cannabis products are cannabis products, not all cannabis products are animal cannabis products. Accordingly, this definition is necessary to clearly distinguish animal cannabis products from other cannabis products.

New subsection (b) states that except for the animal-specific conditions established in subsections (c) and (d), described below, animal cannabis products are subject to the same statutory and regulatory requirements that apply to adult-use cannabis products. As mentioned above, BPC section 26130(e)(1) requires animal cannabis products to conform with any "additional relevant standards, including, but not limited to, an alternative standardized concentration" established by the Department via regulations. This statute merely implies that animal cannabis products must also conform to all other relevant standards. Proposed subsection (b) is necessary to clearly and expressly declare that the only animal-specific product standards and alternative concentrations are those established in this section, and that all other existing standards and requirements imposed by MAUCRSA and this division still apply.

New subsection (c) identifies the three types of products that may be manufactured, distributed, or sold as animal cannabis products: edible cannabis products, orally consumed concentrates, and topical cannabis products. Some manufactured products that fall under the category of "cannabis products," including suppositories and inhalable and combustible products, such as vapes, dabs, shatter, and wax, may be harmful to animals. Whether these products can be safely administered to animals is largely unknown and not sufficiently studied. After an extensive review of available scientific literature and consultation with leading veterinary scientists and researchers, the Department determined that prohibiting the manufacture and sale of these products is necessary to ensure the safety and wellbeing of animals. Limiting animal cannabis

products to edible products, orally consumed concentrates, and topical products still provides owners and handlers with sufficient flexibility to administer cannabis in a form best suited to their animal's needs.

New subsection (d) establishes a limit of no more than one milligram of total THC per package for animal cannabis products. Though BPC section 26130(e) does not require the Department to establish a standardized THC concentration limit for animal products that differs from the limits established for human products, the Department believes that adult-use product THC concentrations (e.g., for edible products, ≤10 mg THC per serving) are inappropriate and may be dangerous for many animals.

Due to cannabis' federal classification as a Schedule I controlled substance, it is difficult, burdensome, and expensive to perform research on the effects of THC on animals. Still, available scientific research overwhelmingly indicates that animal consumption or use of THC may result in acute toxic harm, adverse effects, and death.[1, 2, 3, 4, 5, 6, 7] There are a few studies showing that THC appears to be well-tolerated in healthy dogs. However, these studies tend to have very small sample sizes, including only a specific weight and breed of dog.[8, 9] Based on the latest research, it is apparent that the effects of THC on animals are highly dependent on the species and weight of the animal, which makes safe THC dosing in animals across the board incredibly difficult.

Animal cannabis products will be available for many different types of animals, not just dogs. Though some animals, including dogs, may tolerate THC, there is still a lack of research proving the safety of THC in all animals at higher doses across the board.

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[1] Thompson, G. R., Rosenkrantz, H., Schaeppi, U. H., & Braude, M. C. (1973). Comparison of acute oral toxicity of cannabinoids in rats, dogs and Monkeys. *Toxicology and Applied Pharmacology*, *25*(3), 363–372. https://doi.org/10.1016/0041-008x(73)90310-4.

[2] Fitzgerald, K. T., Bronstein, A. C., & Newquist, K. L. (2013). Marijuana poisoning. *Topics in Companion Animal Medicine*, *28*(1), 8–12. https://doi.org/10.1053/j.tcam.2013.03.004.

[3] Amissah, R. Q., Vogt, N. A., Chen, C., Urban, K., & Khokhar, J. (2022). Prevalence and characteristics of cannabis-induced toxicoses in pets: Results from a survey of veterinarians in North America. *PLOS ONE*, *17*(4). https://doi.org/10.1371/journal.pone.0261909.

[4] Brutlag, A., & Hommerding, H. (2018). Toxicology of marijuana, synthetic cannabinoids, and cannabidiol in dogs and cats. *Veterinary Clinics of North America: Small Animal Practice*, *48*(6), 1087–1102. https://doi.org/10.1016/j.cvsm.2018.07.008.

[5] Chicoine, A., Illing, K., Vuong, S., Pinto, K. R., Alcorn, J., & Cosford, K. (2020). Pharmacokinetic and Safety Evaluation of Various Oral Doses of a Novel 1:20 THC:CBD *Cannabis* Herbal Extract in Dogs. *Frontiers in veterinary science*, *7*, 583404. https://doi.org/10.3389/fvets.2020.583404.

[6] Vaughn, D., Kulpa, J., & Paulionis, L. (2020). Preliminary investigation of the safety of escalating cannabinoid doses in Healthy Dogs. *Frontiers in Veterinary Science*, *7*. https://doi.org/10.3389/fvets.2020.00051.

[7] Kulpa, J. E., Paulionis, L. J., Eglit, G. M., & Vaughn, D. M. (2021). Safety and tolerability of escalating cannabinoid doses in Healthy Cats. *Journal of Feline Medicine and Surgery*, *23*(12), 1162–1175. https://doi.org/10.1177/1098612x211004215.

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[9] Chicoine, A., Illing, K., Vuong, S., Pinto, K. R., Alcorn, J., & Cosford, K. (2020). Pharmacokinetic and Safety Evaluation of Various Oral Doses of a Novel 1:20 THC:CBD *Cannabis* Herbal Extract in Dogs. *Frontiers in veterinary science*, *7*, 583404. https://doi.org/10.3389/fvets.2020.583404.

While most animals that experience cannabis toxicosis recover completely (suggesting that most cannabis toxicoses do not result in long-term negative effects), animals may still experience acute harm and negative effects from THC consumption. Further, the Department expects many animal cannabis product purchasers to seek out products for therapeutic use on unhealthy animals, for whom the safety and efficacy of THC are largely unknown.

Animals cannot clearly communicate to their owners or handlers that they are experiencing negative effects from consumption of THC, nor can animals choose to reduce their THC consumption if they experience negative effects. Among all other factors considered, these are perhaps the most persuasive. The Department is committed to making decisions regarding cannabinoid concentration and product safety based on scientific evidence, and at this time, there is insufficient scientific evidence demonstrating the safety of high-THC products for animals. The Department believes that animal cannabis products manufactured in accordance with the proposed THC concentration limit, and used or administered responsibly, have low potential to cause animal suffering or harm from acute THC intoxication.

Additionally, the alternative standardized concentration proposed in subsection (d) is limited to total THC, which means that manufacturers are permitted to include other cannabinoids (e.g., cannabidiol (CBD)) as desired in animal cannabis products. There are a multitude of studies showing the tolerability and efficacy of CBD in a wide range of

animals.[10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20] These studies typically do not show the same negative adverse events seen in some animal THC exposure studies, especially those with elevated doses of THC.

## TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDIES, REPORTS OR DOCUMENTS


1. Amissah, R. Q., Vogt, N. A., Chen, C., Urban, K., & Khokhar, J. (2022). Prevalence and characteristics of cannabis-induced toxicoses in pets: Results from a survey of veterinarians in North America. *PLOS ONE, 17*(4). https://doi.org/10.1371/journal.pone.0261909.
2. Bradley, S., Young, S., Bakke, A. M., Holcombe, L., Waller, D., Hunt, A., Pinfold, K., Watson, P., & Logan, D. W. (2022). Long-term daily feeding of cannabidiol is well-tolerated by Healthy Dogs. *Frontiers in Veterinary Science, 9*. https://doi.org/10.3389/fvets.2022.977457.


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11. *Guidelines for veterinarian recommendation of cannabis*. Department of Consumer Affairs, Veterinary Medical Board. (2023, April 19). https://www.vmb.ca.gov/forms_pubs/cannabis_guidelines.pdf.
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## ECONOMIC IMPACT ASSESSMENT

The Economic Impact Assessment for this proposed action was performed by ERA Economics, LLC and is included as Attachment 1 to this statement of reasons.

## CONSIDERATION OF ALTERNATIVES

Alternative 1: Allow the manufacture, distribution, and sale of animal cannabis products with the same level of THC currently allowed in products for human consumption.

This alternative was rejected for the reasons discussed above in consideration of all available veterinary science regarding the dangers of THC toxicosis in animals. It would be irresponsible to adopt regulations permitting, with implicit claims of safety and harmlessness, animal owners or handlers to administer or feed products with adult-use levels of THC to small dogs, cats, rabbits, and the like.

Alternative 2: Prohibit the manufacture, distribution, or sale of animal cannabis products at this time.

This approach is well within the Department's rulemaking authority and would have been consistent and in compliance with BPC section 26130. This would also have been the most conservative approach to animal cannabis products, considering the dearth of formal scientific research in this area. However, the Department rejected this option because evidence suggests that while THC is potentially dangerous for animals, other cannabinoids are not. Adopting regulations that restrict total THC content to a safe, minimal level but do not restrict the levels of other cannabinoids is a reasonable balance that protects animals while allowing therapeutic and otherwise beneficial products to be made available to animal owners and handlers.