CANADIAN HEALTH FOOD ASSOCIATION
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May 24, 2023

Cannabis Regulations
Controlled Substances and Cannabis Branch
Health Canada
Via email: cannabis.consultation@hc-sc.gc.ca

Re: Feedback for the Consultation on potential amendment to the Cannabis Regulations

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On behalf of the Canadian Health Food Association ("**CHFA**"), we are writing to provide comments on the consultation for Health Canada's potential amendments to the *Cannabis Regulations*. CHFA appreciates the opportunity to provide feedback.

As Canada's largest trade association dedicated to natural health, organic and wellness products, CHFA is committed to representing our members and the industry on proposed regulatory changes that will directly influence their business operations. Our membership base consists of hundreds of businesses across Canada, including manufacturers, retailers, wholesalers, distributors and importers of natural health products and food products. These businesses produce and sell a variety of natural health products and could be significantly impacted by any proposed amendments to the *Cannabis Regulations* that could remove or reclassify phytocannabinoids such as cannabidiol (CBD).

CHFA would like to acknowledge the remarkable advancements the implementation of the *Cannabis Regulations* has provided to date. Through the implementation of the *Cannabis Regulations*, Health Canada has enabled safe access to cannabis and fostered economic opportunity for Canadians. It was an extraordinary federal initiative that garnered widespread attention both domestically and internationally. As the inaugural framework of its kind on a global scale, Canada had limited opportunities to draw insights from international cannabis policy development. Therefore, to maintain our position as a global industry leader and continuously improve, it is imperative that we subject our regulations to rigorous scrutiny during their initial review.

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As part of the development of the *Cannabis Regulations* in 2018, Health Canada established an independent Science Advisory Committee (SAC) on Health Products Containing Cannabis to advise and develop recommendations for a potential approach for non-prescription health products containing CBD. In July 2022, the Committee released its report titled *"Review of Cannabidiol"* [1] and made ten recommendations to Health Canada regarding the safety, efficacy, and post-market considerations for CBD products in Canada.

Drawing from the comprehensive findings of the SAC report, as well as the market experience gained under the *Marihuana for Medical Purposes Regulations (MMPR)*, *Access to Cannabis for Medical Purposes (ACMPR),* and *Cannabis Act*, it has been firmly established that CBD is not habit forming and does not induce the psychoactive effects associated with tetrahydrocannabinol (THC)[2]. In support of the evidence presented in the SAC report, we would like to provide you with a knowledge synthesis commissioned by CHFA which further affirms the safety of CBD within specific dosing ranges and provides insights on adverse events. For detailed information on these aspects, please refer to Appendix A.

While the legalization of cannabis has made progress in reducing the illicit market in Canada, it has fallen short on initial expectations. Several contributing factors include over-regulation restricting product variety and claims, point-of-sale complexities, and unnecessary administrative burden imposed on both the industry and Health Canada. As a result, consumers are turning to illegal markets to access products. The rising popularity of CBD for self-care has led to a proliferation of CBD products being sold through illicit channels[3] or imported for personal use raising concerns about unknown

[1] https://www.canada.ca/content/dam/hc-sc/documents/corporate/about-health-canada/public-engagement/external-advisory-bodies/health-products-containing-cannabis/report-cannabidiol-eng.pdf
[2] https://apps.who.int/iris/bitstream/handle/10665/325073/9789241210270-eng.pdf?sequence=10&isAllowed=y
[3] Illegal, untested CBD products are everywhere and could be putting you at risk | CBC News

manufacturing conditions and potential safety risks. Moreover, these product labels and accompanying material lack important product details and safety information, depriving consumers of the necessary knowledge to make informed choices about their consumption.

Canadians currently face significant limitations in accessing CBD products that are approved for defined therapeutic use. Firstly, outside the scope of the *Cannabis Regulations*, there are only three prescription products containing cannabis that can make health claims, as they were licensed under the *Food and Drugs Act*. Moreover, these products are exclusively available through prescription for very specific indications. Secondly, under part 14 of the current *Cannabis Regulations*, Canadians can access cannabis products for medical purposes with an authorization from their health care practitioner. Unfortunately, since these products do not undergo a pre-market review for safety, efficacy, and quality, they are unable to make health claims for therapeutic use. Lastly, the existing regulatory framework restricts all other CBD sales to provincially regulated recreational cannabis stores, further limiting access. Collectively, these factors severely impede the legal CBD market from realizing its full potential under the current *Cannabis Regulations*. The imposition of restricting access of CBD products not only hampers Canada's economic potential but also lacks solid basis in the most recent safety considerations. As previously mentioned, recent safety data has unequivocally established CBD as non-psychoactive and non-habit-forming. Therefore, continuing to restrict CBD access would be an unnecessary complexity to an already burdened supply chain structure. Expanding point-of-sale access for CBD products is crucial to promote a responsible supply chain and, most importantly, ensures increased accessibility to safe CBD product for Canadians.

In the current context, the benefits of providing easier and safe access to CBD for Canadians far outweigh any advantages that may have previously existed for treating CBD similarly to THC under the initial *Cannabis Regulations*. These past justifications are no longer relevant and should not be used as

[4] https://chfa.ca/Portals/30/RegAffairs/Cannabis/2020/IFSD_CBD_ECON_IMPACT.pdf

a basis for retaining the current regulatory framework for CBD. CHFA strongly advocates for the regulation of products containing CBD as Natural Health Products under the existing *Natural Health Products Regulations*. CHFA firmly believes that CBD can be effectively regulated and managed as an ingredient within Natural Health Products, and enforced under its corresponding framework. It is worth noting that the SAC has endorsed the Natural Health Product regulatory framework as the optimal mechanism for Health Canada to assess and regulate non-prescription health products containing CBD[1].

While the Good Production Practice (GPP) standards of the *Cannabis Regulations* aims to ensure consistent production, the Good Manufacturing Practices (GMP) mandated by the Natural Health Product Regulations represent a distinct and more rigorous set of requirements with international recognition. It is worth emphasizing that GMP is a prerequisite for products used in clinical trials and is also an import requirement for many trading partners. Moving CBD products to a GMP-based framework will not only enable expanded research opportunities but will also facilitate exports.

The opportunity to redefine CBD within the Cannabis Act, enabling the opportunity for CBD to be regulated within the NHP framework would strengthen economic growth. In 2020, the Institute for Fiscal Studies and Democracy (IFSD) released a report [4] estimating the size and benefits of the CBD market if the Government of Canada were to permit CBD as an NHP. The report indicated that a market for CBD health products would be expected to generate $917 million in labour income - $501 million directly and $416 million through induced impacts on the economy and industries along the supply chain. This could generate approximately 9,638 direct full-time equivalent positions (FTEs) and an additional 5,917 FTEs through indirect and induced impacts, totaling 15,550 FTEs. Finally, based on their forecasted size of an easily accessible CBD market, the Institute projected that the CBD market

[1] https://www.canada.ca/content/dam/hc-sc/documents/corporate/about-health-canada/public-engagement/external-advisory-bodies/health-products-containing-cannabis/report-cannabidiol-eng.pdf

could raise real GDP by $2.1 billion and generate 20,255 more FTE jobs in its first five years. Given CBD is derived from cannabis plants, cannabis extractors operating under the *Cannabis Regulations* as Cannabis Processors are included as one of the previously mentioned benefactors, offering a unique revenue stream not previously available for the cannabis industry. Furthermore, this will also create industry incentives to invest in more CBD research.

Now is the opportune time to introduce essential amendments to the *Cannabis Regulations* that would permit the possession and manufacturing of CBD outside of the cannabis framework, enabling the inclusion of CBD as an ingredient in Natural Health Products. Coordinating these changes with the already anticipated revisions to the *Cannabis Act* during its legislative review, along with exempting CBD from the *Prescription Drug List* would support the movement of CBD for use in Natural Health Products (NHPs) and meet the needs of an evolving and modern health care system.

With the appropriate level of regulation, Canada stands to gain from enhanced competitiveness in trade and reap the benefits of a healthier population, all while upholding Health Canada's objectives for ensuring safety, efficacy, and quality. To facilitate a successful transition of CBD for use as an ingredient in Natural Health Products, certain amendments to the cannabis framework are necessary. These amendments encompass the following key changes:

- *Cannabis Act*
    - Add CBD isolate to Schedule 2, separating isolated CBD and in essence exempting it from the same treatment and requirements of 'cannabis' under the *Cannabis Act* and *Cannabis Regulations*.
- *Cannabis Regulations*
    - Part 2 – Licensing - Changes to authorized sale – For example, currently sale to provinces but this would need to be expanded to allow for sale to licensed NHP manufacturers for further processing. (Note: If CBD isolate was added to Schedule 2 of the *Cannabis Act*, this change would be redundant)

- Part 5- GPP – Testing of CBD - to align with what would be required under the NHP Regulations.
- Part 6 – Cannabis Products – adjust reference to CBD
- Part 7 – Packaging and Labelling – to remove the *requirement* to label CBD and CBDA values of a product or amend to align with requirements under proposed NHP regulations.
- Part 10 – Importation and Exportation - With respect to CBD in NHPs, considerations towards import and export requirements. It is recommended that the same import requirements be applied to CBD as other NHP raw materials. I.e. Free trade without permits.
- Part 11 – Retention of Documents and Information – Exemptions for CBD information to reflect changes in other sections.
- Part 12- Reporting and Disclosure – remove CBD isolate as a requirement to report (Note: If CBD isolate was added to Schedule 2 of the Cannabis Act, this change would be redundant)

The changes to the *Cannabis Regulations* that we have proposed carry substantial market benefits, while maintaining a balanced approach that prioritizes regulatory oversight and the safety of Canadian consumers regarding their CBD products. These considerations warrant careful examination to align with the overarching objectives of the regulatory framework, fostering an equitable and competitive economy that promotes inclusive economic growth, entrepreneurship, and innovation to benefit both Canadians and businesses. Furthermore, it is crucial to underscore the pressing significance of these considerations particularly in light of the ongoing post-COVID-19 economic landscape. For a detailed review of the economic impacts of regulating CBD products as health products, please see Appendix B.

Thank you for considering our feedback as part of your review process. We are hopeful that our comments are given due consideration, and a flexible approach is taken when considering regulatory

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changes that can support an agile self-care framework.

Sincerely,

Ashley Cornell
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Canadian Health Food Association