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RE: Canada Gazette, Part I, Volume 155, Number 25: Regulations Amending the Cannabis Regulations (Flavours in Cannabis Extracts), June 19, 2021

As the national representative of cannabis producer and processor license holders, the Cannabis Council of Canada "C3", offers the following commentary on the proposed Regulations Amending the Cannabis Regulations (Flavours in Cannabis Extracts), June 19, 2021. Our response consists of three parts:

- 1. Industry position on youth cannabis vaping.
- 2. Commentary on the Regulatory Impact Assessment Statement (RIAS).
- 3. Recommendation on the Proposed Regulatory Text.

1. Industry Position on Cannabis Youth Vaping

We share and support Health Canada's efforts to limit non-medical youth access to cannabis products – in all forms, not just vaping. Statistics point to our collective success in restricting non-medical youth access to cannabis products, making this the major public policy accomplishment of cannabis legalization.

We are cognizant of the public health crisis in youth nicotine vaping, which leading authorities have attributed to the consumption of legal products acquired from legal retail outlets. We support all government efforts to restrict youth nicotine vaping and the marketing and sale of these products to youth.

When it comes to youth cannabis vaping, the evidence suggests that the situation is markedly different than youth nicotine vaping. With youth cannabis vaping, the situation is



one of youth acquiring illicit market vaping products from criminal in-person or online dealers. Research from the US-based Centers for Disease Control (CDC) indicates that illicit market cannabis vapes were the cause of the EVALI health crisis. Where there is youth access to cannabis vapes, the source is from sophisticated criminal enterprises capable of manufacturing a complex product.

We submit that Canada's regulatory approach to youth cannabis vaping must be based on the unique situation facing cannabis vapes, not on the experience of nicotine vapes. We wish to reiterate that this perspective was shared with Health Canada at the recent C3 - Health Canada bilateral meeting. We implore regulators to cease the regulation of cannabis as if it were tobacco or nicotine and to end the deliberate conflation of cannabis with tobacco.

As an industry concerned about non-medical youth use of our products, we are frustrated in seeing Canada's success in restricting youth access to cannabis and protecting public health being undermined by the prevalence of the criminal illicit cannabis industry in Canada. Efforts to deter youth cannabis by means of restrictions on flavoured vaping products pale in terms of their impact when compared to efforts focused on combating the unrestrained ubiquity of the illicit market and the criminal cannabis industry.

In support of efforts to restrict youth access to all cannabis products for non-medical purposes, Canada's cannabis License Holders call on the Government of Canada to:

- 1. Enforce existing criminal laws and enact new laws to deter illicit activities in relation to cannabis.
- 2. Work with provincial governments, stakeholders and the technology industry to stop criminals from using the Internet to promote, sell and deliver illicit cannabis products to youth and to all Canadians.
- 3. Review the performance of current approaches to deterring youth access to legal cannabis (age-gating of websites, in-person retail) and update those that are missing the mark.
- 4. Increase criminal and administrative penalties for providing cannabis products to youth.
- 5. Deploy an educational campaign on the personal health (unsafe and untested products) and the societal consequences (supporting criminal activity and organizations) of consuming illicit cannabis vapes and edibles.
- 6. Conduct research into the composition of illicit market vaping products and use the results to support educational campaigns.



7. Stop the abuse of Health Canada permits for the personal production of cannabis (Access to Cannabis for Medical Purposes) by illicit market operators and enterprises.

2. Commentary on the Regulatory Impact Assessment Statement (RIAS)

According to the Government of Canada's Policy on Regulatory Development, a RIAS is:

an evidence-based, non-technical synthesis of expected impacts, positive and negative, of a proposed regulation.

We respectfully submit that the RIAS produced in support of the Regulations Amending the Cannabis Regulations (Flavours in Cannabis Extracts), fails to make the case for the proposed regulation of cannabis vaping flavours:

- There is no evidence of a "rapid rise in youth cannabis vaping in Canada" as a result of consumption of legal vaping products.
- The evidence suggests that increases in cannabis youth vaping are a function of accessing cannabis vaping products from the illicit market.
- The rationale for the regulation of flavours in cannabis vaping products is not supported by the evidence cited.
- The RIAS mistakenly applies nicotine vaping evidence to cannabis vaping.
- The RIAS fails to appropriately address the negative public health and safety consequences of the regulation related to increasing the use of illicit market cannabis vaping products.

1. There is no evidence of a "rapid rise in youth cannabis vaping in Canada" as a result of consumption of legal vaping products.

The evidence presented in the regulatory proposal fails to make the case that there has been a "rapid" rise in youth cannabis (persons under the age of 18) vaping in Canada as a result of any activity related to the licensed producers, processors or legal retailers. If anything, the evidence cited points to the ease with which underage persons access of cannabis vape products from the illicit market.

According to the Canadian Cannabis survey 2020 found:

1. The rates of past-year cannabis vape pen/cartridge users in the 20–24 age bracket did not change significantly in 2018 (33%), 2019 (32%) and 2020 (31%).



2. There was a 6% change in past-year cannabis vape pen/cartridge users in the 16–19 age bracket increased from 2018 (27%) to 2019 (33%).

According to the most recent CSTADS survey cycles:

- 1. Among all students surveyed in Grades 7–12, no change in overall cannabis use was observed between 2018–19 (18%) and 2016–17 (17%).
- 2. Among students in Grades 7–12 (i.e., those aged 13 to 17) who used cannabis, rates of cannabis consumption via vaporizing/vaping increased from 30% in 2016–17 to 42% in 2018–19.

Based on the aforementioned data, we submit:

- a. If anything, there has been a slight decline in young persons' cannabis vaping, not a "rapid rise".
- b. Increases in youth vape pen usage in the years cited 2016 to 2019 must be a function of the illicit market given that cannabis vaping products where illegal during the study period.
- c. Without evidence to the contrary, any increases in youth cannabis vaping are the product of the illicit market (students in grades 7-12).

Additionally, we submit that the purpose of the Cannabis Act (s. 7) is to restrict youth access to cannabis, not to govern legal consumers choices around legal cannabis product forms. Given that there has been no overall increase in youth use of cannabis and there has not been a "rapid rise" in legal cannabis vaping by young persons, we question the effectiveness of the proposed regulations in light of the objectives of the Cannabis Act and the success of Canada's regulated approach to legal cannabis access. In fact, restricting access to flavoured vapes for young persons and other adult consumers may have the unintended consequence of driving them to the illicit market.

2. Increases in cannabis youth vaping are a function of accessing cannabis vaping products from the illicit market

The increase in youth cannabis vaping cited in support of the regulatory proposal has occurred in the youth population sub-group — students in grades 7 to 12 - that is unable to purchase legal cannabis and at a time when legal vapes were not on the market. Given the evidence that these students are not procuring cannabis from legal sources, one must conclude that any increase in youth cannabis vaping is a function of the availability of these products on the illicit market. This conclusion is supported by the latest research conducted by Health Canada



(Understanding Youth and Young Adults Interest in, and Usage of, Flavoured Cannabis Vaping Products, Strategic Counsel, March 2021) which found that:

- The majority of respondents (76%) first began vaping cannabis before the age of 19. The majority of youth (aged 15-17) started vaping cannabis between 13-18 years old (79%). Another one in-five (21%) began when they were less than 13 years of age.
- "9 out of 10 in the younger are group (88%) [aged 15-17] say that these products [flavoured cannabis vapes] are somewhat or very easy to obtain" (p.10).
- there were no significant variations in responses to the question about "obtaining flavoured cannabis products" by respondents who live in provinces where cannabis vapes are not legally available (p.30).

It is important to note that since some respondents who would not be able to legally purchase cannabis vape products (i.e., those aged 15-17 and those living in provinces that do not permit the legal sale of cannabis vape products) did report obtaining them from legal sources.

We submit that the results of the *Understanding Youth and Young Adults Interest in, and Usage of, Flavoured Cannabis Vaping Products* survey are unable to demonstrate that flavoured legal cannabis vaping products are the cause of youth use of cannabis vaping products.

3. The rationale for the regulation of flavours in cannabis vaping products is not supported by the evidence cited.

The RIAS in question states:

Public opinion research commissioned by Health Canada indicates that flavours are a significant factor that attract youth and young adults to use cannabis vaping products.

Understanding Youth and Young Adults Interest in, and Usage of, Flavoured Cannabis Vaping Products, Strategic Counsel, March 2021 is the public opinion research commissioned by Health Canada to connect flavours to young person's use of vaping products. The methodology used to conduct this research indicates that: <t>he data was collected using a non-probability sampling method, targeting youth and young adults aged 15-24 years old (p.54).

The research results are not based on a representative probability sampling method. The survey is reflective of the research panel participants and not representative of young Canadians or young persons who vape cannabis products. While informative, the research is not a substitute for statistically reliable research on youth and young persons' experiences with cannabis



vaping, gathered over a longitudinal time-frame. Accordingly, we submit that the research used to support the regulations on cannabis vaping flavours does not support the regulatory proposal

4. The RIAS mistakenly applies nicotine vaping evidence to cannabis vaping

We are not contesting that there has been a rapid rise in nicotine vaping by Canadian youth or that this situation requires action. This is evidenced by the data presented in the tobacco vaping flavours regulatory proposal which demonstrates that there has been a 100% increase in the incidence of high school student tobacco vaping (Canada Gazette, Part I, Volume 155, Number 25: Order Amending Schedules 2 and 3 to the Tobacco and Vaping Products Act (Flavours):

Data from the 2018–2019 CSTADS indicates the prevalence (past 30 days) of vaping doubled among students compared to the previous survey in 2016–2017.

We are contesting the RIAS' use of nicotine vaping evidence to make the case for a "rapid rise" in youth cannabis vaping and to support the position that flavoured cannabis vaping products induce young persons to vape cannabis. We note the following references in the RIAS to nicotine vaping and flavours:

- There is also strong evidence to suggest that flavours can affect youth nicotine vaping behaviours. The 2017 Canadian Tobacco, Alcohol and Drugs Survey (CTADS) demonstrates that flavours are a more commonly reported reason for using e-cigarettes among 16–19 (56%) and 20–24 year-olds (70%), compared to adults aged 25 and older (43%).
- In the vaping context, flavoured vaping products are widely appealing to youth. Flavours
 influence both product perceptions and usage behaviours among youth. According to
 research from the United States and the United Kingdom, adolescents consider flavoured
 vaping products (e.g. fruit, candy, menthol flavours) to be less harmful than tobaccoflavoured vaping products. footnote11

A recent publication in the New England Journal of Medicine outlined the differences between the youth nicotine vaping epidemic and the youth cannabis vaping EVALI epidemic in the United States:

However, the epidemics (EVALI and youth nicotine vaping) also differ in some key ways. The EVALI epidemic primarily affects young adults 18 to 34 years of age, which is the population with the highest rates of marijuana use in the United



States. It is driven by the use of THC-containing products from informal and illicit sources and is linked to thickening agents or diluents in product formulations.⁴

The youth vaping epidemic, for its part, primarily affects adolescents younger than 18 years old, is driven by the use of nicotine-containing products obtained mostly from formal sources such as authorized retailers, and has been driven by multiple factors, including those that enhance the appeal and availability of these products to young people. 1,2

- The EVALI and Youth Vaping Epidemics — Implications for Public Health, <u>Brian A. King</u>, Ph.D., <u>Christopher M. Jones</u>, Dr.P.H., <u>Grant T. Baldwin</u>, Ph.D., and <u>Peter A. Briss</u>, M.D., New England Journal of Medicine, January 17, 2020

The youth nicotine vaping crisis is different from the youth cannabis vaping situation. The rapid rise in youth nicotine vaping was a function of legal market access to these products, via a distributed network of convenience stores and gas stations, and an environment where these products where widely marketed to people, including youth.

The increase in cannabis vaping is a function of access to illicit market products. This fact was acknowledged by the US Centers for Disease Control in January 2020:

National and state data from patient reports and product sample testing show tetrahydrocannabinol (THC)-containing e-cigarette, or vaping, products, particularly from informal sources like friends, family, or in-person or online dealers, are linked to most EVALI cases and play a major role in the outbreak.

- Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products, Centre for Disease Control, January 29, 2020.

Cannabis is not nicotine or tobacco, yet cannabis is consistently treated as the same by Health Canada regulators. According to federal government's "Cannabis in Canada" web page, the adverse consequences from cannabis consumption are related to mental health, brain development, addiction, "hurt your lungs and make it harder to breathe" and poisonings. Almost 50,000 Canadians die each year from tobacco smoking. It should also be noted that cannabis is used as a medicine by 400,000+ Canadians. These products are different.

We share Health Canada's concerns about youth cannabis vaping, and we support efforts to address this situation, as previously noted. However; we must object to the use of nicotine vaping data to make the case for regulating cannabis vaping. Concerns about youth cannabis vaping are being driven by concerns about increases in youth nicotine vaping and the public



health crisis resulting from access to legal nicotine products and illegal cannabis vaping products.

Finally, we submit the following in support of our concerns about the conflation of the youth nicotine vaping crisis with youth cannabis vaping:

In cooperation with other orders of government and key stakeholders, address the rapid rise in youth vaping. This should start with regulations to reduce the promotion and appeal of vaping products to young people and public education to create awareness of health risks. You are encouraged to explore additional measures.

- Minister of Health Mandate Letter, Rt. Hon. Justin Trudeau ,December 13, 2019.

5. The RIAS fails to appropriately address the negative consequences of increasing the use of illicit market cannabis vaping products

The RIAS states that: "there is a risk that some consumers may turn to the illicit cannabis market to purchase flavoured inhaled cannabis extracts" (p.13) but fails to adequately consider this risk or the consequences of this risk. This is problematic given the evidence cited throughout the RIAS points to the fact that youth vaping of cannabis flavoured products is a function of the illicit market. It is worth noting that the only measure proposed to reduce this risk is a public awareness campaign by the Public Health Agency of Canada.

The objective of the regulatory proposal is "to protect young persons and others from inducements to use cannabis by further limiting the appeal of inhaled cannabis extracts in order to discourage youth and young adult uptake." A basic online search for cannabis vaping products will reveal an abundance of inducements for illicit flavoured vaping products and none for age-gated cannabis Licence Holder websites. Given the prevalence of these inducements and the evidence of youth use of illicit vaping products, one questions why the regulation of flavours was selected as the sole regulatory instrument for dealing with youth use of flavoured vaping products and why a public awareness campaign is the only measure focused on reducing the risks of consumers consuming unsafe products from the illicit market.

Section 7 (d) of the Cannabis Act states:

"The purpose of this Act is to protect public health and public safety and, in particular, to deter illicit activities in relation to cannabis through appropriate sanctions and enforcement measures."



We submit that the proposed regulatory approach of regulating flavours in cannabis products will drive consumers to the illicit market and further impede the ability of the legal industry to support the public policy objectives of cannabis legalization. The evidence cited in the RIAS demonstrates that flavoured cannabis vapes from the legal cannabis industry are not the cause of any increase in youth consumption of cannabis. This objective would have been better served by a regulation that also includes efforts to deter access to illicit cannabis vaping products.

3. Commentary on Proposed Regulatory Text

We offer the following comments on the proposed regulatory text.

2.1 Recommendations on regulating taste that is "typical for cannabis"

The regulations are seeking to "prohibit inhaled cannabis extracts or their emissions from imparting a smell, taste or chemesthetic sensation other than one that is typical for cannabis."

Terpenes, aldehydes, and ketones — molecules that are responsible for the characteristic flavours of cannabis plants — are examples of flavouring substances that can be derived from the cannabis plant or from other plant sources. These molecules are naturally occurring in cannabis plants and other plant sources and can individually or collectively impart a range of flavours (e.g., pine, diesel, skunk, cheese, and fruit). Leafly contains an extensive strain database for cannabis and uses 47 different cannabis flavour and aroma descriptors.

Flavours and aromas		
Ammonia	Grapefruit	Pungent
Apple	Honey	Rose
Apricot	Lavender	Sage
Berry	Lemon	Skunk
Blueberry	Lime	Spicy/Herbal
Blue Cheese	Mango	Strawberry
Butter	Menthol	Sweet
Cheese	Mint	Tar
Chemical	Nutty	Tea
Chestnut	Orange	Tobacco
Citrus	Peach	Tree fruit
Coffee	Pear	Tropical
Diesel	Pepper	Vanilla
Earthy	Pine	Violet
Flowery	Pineapple	Woody
Grape	Plum	



It is unclear what flavour or sensory experiences the regulator will ultimately deem "typical for cannabis". Lack of clarity on "sensory perception other than one that is typical for cannabis" will place all cannabis vapes at risk on non-compliance. Determination of whether or not the flavour is typical of cannabis is subjective in nature and the decision will focus on perception of the degree of flavour. The perception of the degree of flavour in cannabis vapes will rest with three different parties – the producer, the consumer and the regulator.

The absence of a definition of "typical for cannabis" phrase to qualify flavour will pose challenges for adherence to the regulation. Accordingly, we recommend that the following amendments to the regulatory proposal:

Current proposal:

101.51 (1) A cannabis extract that is intended to be consumed by means of inhalation and that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — or the emissions of such an extract must not have sensory attributes that result in a sensory perception other than one that is typical for cannabis that is referred to in item 1 of Schedule 1 to the Act.

C3 Recommended Proposal:

We note that the promotion of cannabis vapes with certain sensory attributes (confectionary, dessert, soft drink, or energy drink) is prohibited by the proposed regulation. Based on this prohibition and the unworkability of regulating vapes based on a "flavour typical for cannabis", we recommended revising section 101.51 (1) to:

101.51 (1) A cannabis extract that is intended to be consumed by means of inhalation and that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — or the emissions of such an extract must not have sensory attributes that result in a sensory perception that is of a confectionary, non-fruit dessert, soft drink or energy drink nature

2.2 Recommendations on the promotional prohibitions

Many desserts have fruit flavours. Many cannabis cultivars contain terpenes, aldehydes, and ketones — molecules that are responsible for the characteristic flavours of cannabis plants — that produce a fruit flavour that is typical of cannabis. Additionally, there are many strain names that contain a fruit name — lemon haze for example. For the promotion regulation to be workable and align with the allowance of cannabis vapes containing terpenes, aldehydes, and ketones natural to cannabis, we recommend that the table in section 104.11 of the proposed



regulatory text be amended by replacing "dessert" with "non-fruit dessert" and by referring to the definition of "typical of cannabis" in the C3 Recommended section 101.51.

Current Proposal

- **104.11** It is prohibited to promote a cannabis extract or a cannabis accessory that contains a cannabis extract under subsections 17(2) to (6) of the Act, in a manner that could cause a person to believe that the cannabis extract or the cannabis accessory has
 - (a) a flavour set out in the table to this section or any other flavour, except one that is typical for cannabis referred to in item 1 of Schedule 1 to the Act, in the case of a cannabis extract that is intended to be consumed by means of inhalation; or
 - **(b)** a flavour set out in the table to this section, in the case of a cannabis extract that is not intended to be consumed by means of inhalation.

C3 Recommended Proposal

- **104.11** It is prohibited to promote a cannabis extract or a cannabis accessory that contains a cannabis extract under subsections 17(2) to (6) of the Act, in a manner that could cause a person to believe that the cannabis extract or the cannabis accessory has
 - (a) a flavour set out in the table to this section or any other flavour, except one that is typical for cannabis <u>as defined in section 101.51</u> and referred to in item 1 of Schedule 1 to the Act, in the case of a cannabis extract that is intended to be consumed by means of inhalation; or
 - **(b)** a flavour set out in the table to this section, in the case of a cannabis extract that is not intended to be consumed by means of inhalation.

2.3 Recommendation on Display Regulation

In order to align the proposed display regulation with the regulation for "typical of cannabis" and the promotion of cannabis vaping products, we propose that section 132.13 be amended by adding "as defined in section 101.51" to subsection 123.13(1) (a).

Current Proposal

132.13 (1) It is prohibited to display on a cannabis extract that is a cannabis product or on a cannabis accessory that contains a cannabis extract and that is a cannabis product, or on the



package of such a cannabis product or on the label or panel of a container in which such a cannabis product is packaged, an indication or illustration, including a brand element, that could cause a person to believe that the cannabis product has

- (a) a flavour set out in the table to section 104.11 or any other flavour, except one that is typical for cannabis referred to in item 1 of Schedule 1 to the Act, in the case of a cannabis extract that is intended to be consumed by means of inhalation; or
- **(b)** a flavour set out in the table to section 104.11, in the case of a cannabis extract that is not intended to be consumed by means of inhalation.

C3 Recommended Proposal

132.13 (1) It is prohibited to display on a cannabis extract that is a cannabis product or on a cannabis accessory that contains a cannabis extract and that is a cannabis product, or on the package of such a cannabis product or on the label or panel of a container in which such a cannabis product is packaged, an indication or illustration, including a brand element, that could cause a person to believe that the cannabis product has

- (a) a flavour set out in the table to section 104.11 or any other flavour, except one that is typical for cannabis <u>as defined in section 101.51 and referred to in item 1 of Schedule 1 to the Act, in the case of a cannabis extract that is intended to be consumed by means of inhalation; or</u>
- **(b)** a flavour set out in the table to section 104.11, in the case of a cannabis extract that is not intended to be consumed by means of inhalation.

Conclusion

As the license holders that adhere to strict standards, quality controls, rigorous product testing and operate in accordance with the objectives of the Cannabis Act, we are concerned about the public health and safety implications of youth cannabis vaping. We support all efforts to educate youth about the consequences of cannabis vaping and of informing all Canadians of the personal health dangers of consuming illicit cannabis vaping products.

The proposed regulations on restricting cannabis vaping flavours are but one part of a response to a complex public policy issue – cannabis vaping by underage youth. While we are concerned about the application of a regulation based on a subjective measure of taste or smell like "typical for cannabis", we are prepared to do our part to ensure the success of the proposed regulation, whether or not our recommendations are incorporated into the final regulation.



Cannabis legalization has been a public health success. Reported youth cannabis consumption rates have not increased. Legal retail cannabis environments have dutifully restricted youth access to legal cannabis products. Yet there are some risks on the public health and safety fronts – such as youth cannabis vaping and the youth edibles poisonings - that are a clear function of the prominence and ease of access of the illicit cannabis market. To date, the bulk of the fight against the illicit market has fallen to license holders in the form of price competition with the illicit market.

Criminal cannabis markets and sells toxic products to our youth and to all Canadians and uses the proceeds to spread violence and despair in our communities. Legal cannabis does not sell or market to youth. Legal cannabis employs tens of thousands of Canadians and generates hundreds of millions of dollars in tax revenues to governments. Legal cannabis invests in R&D, developing safe medical and adult-use cannabis products focused on harm reduction principles.

Three years after the Cannabis Act, the time has come for governments, both federal and provincial, to enforce existing laws designed to deter criminal participation in cannabis or to develop new ones that build on the lessons learned of cannabis legalization. Failing this, governments must provide license holders with the capabilities needed to accomplish the public health and safety objectives of the Cannabis Act.