



AUMA Responses to Federal Consultation on the Proposed Regulations for Cannabis Edibles, Extracts, and Topicals

1. What do you think about the proposed THC limits for the new classes of cannabis products?

For edible cannabis: adequate. The proposed THC limit per discrete unit is aligned with the limits adopted by Colorado and Washington states, and the limit per package is considerably lower (5 to 10 times) than the ones in Alaska, Colorado, Oregon, and Washington. Moreover, using the amount of THC to establish the limit, instead of its concentration in the products, helps minimize the risks of accidental consumption and overconsumption.

For cannabis extracts: may need some adjustment. The limit of 1,000mg of THC per product package and per vape pen may increase the risks of accidental consumption and overconsumption. A recent study found that the “inhalation of a 25mg dose of THC was associated with pronounced drug effects, increased incidence of adverse effects, and significant impairment of cognitive and psychomotor ability” in infrequent cannabis users.

For cannabis topicals: may need monitoring. The limited availability of studies on the pharmacokinetics and use of topical cannabis products makes it challenging to define an optimum THC limit for this class yet. The drug-abuse potential of cannabinoid transdermal patches is expected to be low because of slow delivery of THC to the brain. However, extraction of cannabinoids from the patch for administration by a more-rapid method has not been evaluated.

2. Do you think the proposed new rules addressing the types of ingredients and additives that could be used in edible cannabis, cannabis extracts, and cannabis topicals appropriately address public health and safety risks while enabling sufficient product diversity?

For edible cannabis: yes. Limiting edible cannabis products to those that do not need refrigeration or freezing aligns with the regulations in the U.S. state of Washington and avoid issues related to the cannabinoids’ degradation due to storage conditions.

For cannabis extracts: may need some adjustment. Early findings show that “Canadian teenage vaping rates have increased substantially, similar to the dramatic increase in the U.S. where rates shot up by 80 per cent in one year, a trend the FDA called “epidemic.”” In face of this scenario, Canadian pediatricians are calling for a ban on flavoured vaping products, which the government did not signalize that is going to happen anytime soon. Permitting flavouring agents in cannabis extracts, which can be used for vaping, does not



appropriately address this public health issue identified by the medical and research communities and contributes to increase the appeal of such products to youth.

For cannabis topicals: may need monitoring. The limited availability of studies on the pharmacokinetics and use of topical cannabis products makes it challenging to establish rules concerning allowed ingredients and additives for this class yet.

3. Do you think that the proposed rules for other classes of cannabis will accommodate a variety of oil-based products for various intended uses, even though cannabis oil would no longer be a distinct class of cannabis?

Yes. Cannabis extracts and cannabis topicals include oil-based products that are currently under the cannabis oil class, making the latter no longer necessary under the regulations.

4. What do you think about the proposed six-month transition period for cannabis oil? Is a six-month transition period sufficient?

Considering the amendments proposed are not more restrictive than the regulations currently in place, but instead permit a broader diversity of products to be produced and sold, a six-month transition period seems reasonable.

5. What do you think about the proposed new rules for the packaging and labelling of the new classes of cannabis products?

They are adequate overall but may need some adjustment. Given the frequency of cannabis overdoses associated with the consumption of edibles that was observed in the U.S. states where cannabis was legalized, edible labels in Colorado and Oregon also "must state that their intoxicating effects may not be felt for up to 2 hours after consumption". A warning statement that highlights the delayed onset of cannabis effects when ingested (as opposed to inhaled) could contribute to reduce the risk of overconsumption associated with edible cannabis in Canada.

Furthermore, marking edibles with the standardized cannabis symbol would help users to differentiate cannabis products that are no longer in their package from regular edibles and avoid accidental consumption. Such a regulation was adopted by Colorado, where "every single standardized serving (a serving consists of 10 mg of THC) of an edible retail marijuana product must be individually marked, stamped or imprinted with the new universal symbol. When impractical to mark an edible retail marijuana product with the universal symbol, as in the case of bulk goods and powders, these products must be packaged in a single serving, child-resistant container."

6. With respect to edible cannabis, what do you think about the requirement for all products to be labelled with a cannabis-specific nutrition facts table?



It seems adequate that the cannabis-specific nutrition facts table is consistent with the requirements that apply to food under the food and drugs regulations.

7. What do you think about the proposal for the labelling of small containers and the option to display certain information on a peel-back or accordion panel?

It seems adequate. It is of note that if any other warning message is to be added to the regulations, such as the one suggested in the answer to question 5, it would be expected that this message is also required to be displayed on the exterior surface, rather than as part of an expanded panel.

8. What do you think about the proposal that the standardized cannabis symbol would be required on vaping devices, vaping cartridges, and wrappers?

It is consistent with the current regulations and it seems adequate to clearly and prominently display the standardized cannabis symbol on the exterior surface of any accessory or wrapper that is in direct contact with a cannabis product.

9. Do you think that the proposed new good production practices, such as the requirement to have a Preventive Control Plan, appropriately address the risks associated with the production of cannabis, including the risk of product contamination and cross-contamination?

Yes. The new good production practices are consistent with the Safe Food for Canadians regulations and it is reasonable to expect that licensed facilities have some measures already in place for safety and quality control reasons.

10. What do you think about the requirement that the production of edible cannabis could not occur in a building where conventional food is produced?

It is an appropriate requirement to ensure the safety and integrity of Canada's food system, which provides the domestic market and international partners with assurance that there can be absolutely no cross-contamination of Canadian food products with cannabis.

11. What do you think about the overall regulatory proposal?

Overall, the proposed changes and amendments to the cannabis regulations are consistent with the *Cannabis Act's* objective to provide for the legal production of cannabis to reduce illegal activities in relation to cannabis, and with the experience of U.S. jurisdictions that have legalized and regulated access to cannabis, including edibles, extracts, and topicals. It



is important, though, that concerns such as delayed effect warnings and the potential harms of flavoured vaping products are considered when revising the regulations.

Even with the current strict regulations over quality control, there have been several recalls of cannabis products throughout 2017 and 2018. In addition to the Health Canada random testing of cannabis products produced by licensed producers, we believe that a requirement of disclosure of the laboratory analysis results performed for each batch of products available for sale should be added to the regulations. This would increase transparency and accountability to the costumers and contribute to reassure Canadians that they are consuming safe, quality-controlled product.

12. Are there any additional comments you would like to share on the proposed regulations for the new classes of cannabis?

Yes. The topic of teenage vaping is of extreme concern from a public health perspective. The *Tobacco and Vaping Products Act* in its current form may not provide the most appropriate rules to mirror in cannabis regulations concerning cannabis extracts.

The mere prohibition of the representation of certain flavours that are appealing to youth, while permitting the addition of flavours to cannabis extracts (and by extent to the cannabis-infused products intended to be used for vaping) may not be restrictive enough to reduce cannabis use among youth. Given the risks involved, the decision to permit the production and sale of flavoured cannabis extracts in Canada should be postponed allowing for analysis of the effect of recent regulations around vaping products on youth.

13. Are there any additional comments you would like to share regarding the legalization and strict regulation of cannabis in Canada? For example, are there measures the Government could take to support individuals to be in compliance with the public possession limits for cannabis (i.e. 30 grams of dried cannabis "or equivalent")? Do you have views on how to minimize environmental concerns associated with packaging, while maintaining key aspects, such as child resistant packaging, that help to prevent accidental consumption?

Yes. Efficient enforcement of impaired driving laws when it comes to cannabis use is still dependent upon investments on:

- Research that improves and refines our current understanding of the THC levels associated with impairment and impairment duration;
- Improvement on existing and/or development of new reliable and affordable roadside testing devices with satisfactory sensitivity and specificity for THC; and
- Training and equipping enforcement officials with the necessary knowledge and technology to detect cannabis impairment in drivers.



AUMA believes that the funding necessary for these investments should come from the cannabis excise tax revenue and that municipalities will be fully supported to implement the necessary changes with local police forces.