February 20, 2019

Dietitians of Canada (DC) response to Health Canada Consultation: proposed regulations for edible cannabis, cannabis extracts, and cannabis topicals

Dietitians of Canada (DC) is a professional association with strong roots connecting more than 5000 unique and diverse members across all areas of food, nutrition and health. DC proudly represents dietitians, fostering growth and passion in the profession through advocacy, engagement and professional development. After more than 80 years, DC remains an innovative organization with strong member leadership and common purpose: to advance the health of Canadians through food and nutrition.

The focus of this response from Dietitians of Canada is on Edible Cannabis only.

We agree with the purpose of these Draft Regulations and appreciate the regulatory details aimed at protecting public health and public safety.

The following are questions asked by Health Canada and DC’s answers, with recommendations and comments.

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

   A: The dose limit for edible cannabis – to a maximum of 10 mg THC per discrete unit is reasonable, especially given the fact this limit is similar to edible products already for sale in the USA. (We note that the French and English abbreviations for “THC” are the same letters, in the same order – a very useful alignment for bilingual labelling in Canada.)

   In the Health Canada Consumer Information, the advice is “START LOW AND GO SLOW - Start with small amounts; Choose products with a low amount of THC (delta-9-tetrahydrocannabinol) and an equal or higher amount of CBD (cannabidiol)” – but we are not aware of further detail that defines what a “small amount” is. Ideally, the “small amount” should be an amount that is commonly available in discrete units of edible cannabis products.

   We recommend measures be taken to decrease risk, as follows:
   • option 1) the consumer information could be edited to include a warning for new consumers, with a suggestion for initial dosage amounts (e.g., a dose of not more than 2-5 mg THC to start and wait for a few hours before consuming any more product). If the maximum amount in a serving was 10 mg THC, this would necessitate clear instruction to new consumers to start with a partial serving, or...
• option 2) a more cautious, lower risk approach would be to set the maximum “usual” amount in a discrete unit at a lower level, such as 5 mg THC. There could be further option for a special category for “extra-strength concentration” at maximum of 10 mg THC per unit. In that way, the potential for accidental over-dose from one unit would be diminished. A person who is knowledgeable about his/her usual individual reaction to a given dose could purchase “extra-strength”, whereas a beginning consumer would be more inclined to begin with one unit or serving of a usual concentration and be at lesser risk of overdose/ unwelcome side effects.

**Our question to Health Canada:** Since a package may contain no more than 10 mg THC, does this mean that products like “gummies” could contain as much as 10 mg THC in each candy, and would these products then need to be sold in packages containing only 1 “gummy” per package? In our view, the proposed regulations do not clearly address the packaging of edible cannabis in candy format (or any other “candy-size” product that might easily be consumed in multiple units at one time). For edibles in single-serving packages, e.g., the size of a granola bar, can the products be sold in larger packages, with individually labelled and wrapped bars inside (e.g., a box containing 5 bars – but each bar might contain 5 mg THC)? **Note:** There does not appear to be clear guidance about whether or how a product is considered to be “appealing” to children/teens, e.g., as per the introduction and purpose of these regulations, “Requiring child-resistant and plain packaging for edible cannabis to lower the risk of accidental ingestion and making packages less appealing to young persons.” We address this concern in question #2 below.

**We agree** with the restrictions that prohibit addition of temporarily marketed foods and vitamins/minerals to an edible cannabis product. **We further recommend that this restriction should be extended to other ingredients sometimes added to foods, e.g., anti-oxidants, concentrates of herbal preparations, and any of the ingredients that might currently be allowed in the Food Regulations under the category of “Supplemented Foods”**. It is essential that consumers not be confused about the difference between Natural Health Products (or “self-care” products) and Foods and Drugs (or pharmacologically active compounds). Dietitians of Canada has already responded to earlier consultations on Supplemented Foods (and specifically, products known as Caffeinated Energy Drinks) – we have expressed our concern for products that look and taste and are marketed as food, but contain additional ingredients that may be assumed to make a product “healthier” or more “potent” in some manner. Whereas the Supplemented Foods category includes foods with higher doses of added nutrients and/or herbals, the potency and effect of THC is likely more problematic and risky in a short-term manner – e.g., potential impact on personal safety, driving a vehicle, in contrast to our longer-term concerns about nutrient additions in excess of the Tolerable Upper Level in Supplemented Foods.

**We recommend that manufacturers of edible cannabis products be required to clearly label the source of and format of the cannabis in the edible product.** For example, is the THC dose per unit incorporated using whole plant material or an extraction thereof, with all of the plant’s bioactive compounds in the edible product or was the THC added using a THC isolate extraction, such that there are no other cannabis plant-derived compounds in the product. This also relates to the earlier caution that other herbals/plants commonly found in Natural Health Products NOT be allowed to be added to edible cannabis products – given problems with dosing, potential consumer confusion and potential for bio-interactions between active ingredients (that may potentiate or reduce physical effects of the ingredients, compared to when they are consumed in isolation).

There is an additional question here regarding addition of whole cannabis plant material to an edible product: **will there be a requirement to identify other bioactive compounds in the plant –**
including but not limited to CBD? (CBD is mentioned in the introduction, but there do not appear to be applicable regulations for CBD limits/dosing/variability or other compounds in cannabis). How will consumers know what amount of CBD is in one unit/serving of the edible product? We recommend that edible cannabis products be required to list the dosages of THC and CBD in one serving or unit of product, including when the level is zero. (While this may be assumed by Health Canada, it did not appear to be clear in the Regulations as proposed.)

With respect to the variability limit for THC (and CBD): What is the basis of the proposed limits of variability for the doses of THC in edible products? We note that variability of dosage for medicinal ingredients in Canada’s Food & Drug Regulations (C.01.062 (1)) is not less than 90% or more than 110% of the amount of the medicinal ingredient shown on the label. Is there a specific reason for the proposed variation in edible cannabis products, with variation up to +/- 25%? (we suspect this is due to challenges of accuracy with smaller dosages?) We recommend that the variability should be not more than +/- 10%, applicable for edible cannabis and cannabis extracts, regardless of the dosage amount in a serving. Consumers need to be able to count on precision dosing, equal to that in any medications. While we appreciate that the variability allowed in the Food Regulations for addition of nutrients is a broader range of variability, THC is not a standard food ingredient and these regulations are specific to cannabis. If a person consumed 4 servings or units of an edible product, each with 2.5 mg THC /serving, the expected variability in dosage should be the same as what is allowed for 1 serving containing 10 mg THC. (As the regulation is currently proposed, a person could receive up to 12.5 mg THC from 4 units/servings with 2.5 mg THC in each unit... hence the equivalent of an extra or fifth unit.) This requirement for +/- 10% variability would mean that a manufacturer needs to include a special process to ensure the food product is thoroughly mixed, for consistent distribution of THC in the entire batch.

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?

A: Referring to the results from Nov 2017 consultation: We note that, “it was proposed that a limit of 10 milligrams of THC per dose or unit for any cannabis product intended for ingestion be established”, which most respondents supported. We therefore support the statement that “the proposed limit is generally regarded to be a prudent safeguard to mitigate risks of accidental overconsumption of a product class primarily intended for ingestion”.

We suggest however that there may be need for some testing of different products and impact on rate of absorption of THC/CBD from edibles – e.g., might there be a way to predict “low and slow” vs “fast release” products, perhaps in a starch/sugar base vs fatty base – factors that would be important for consumers who want to estimate when it is safe to for them to drive a vehicle, when they can expect to experience the full impact of the THC effect. As well, we wonder if there might be some provision in these regulations for future concerns, e.g., additives in foods that could impact absorption of THC, since the research may not yet be available. How will the regulations be updated in the event there is new research that changes potency or impacts of THC in edible cannabis products.

While we used the example of a “gummy” above in our response to question #1, we recommend that products commonly consumed by children and teens should either be banned from containing cannabis/THC or that there be specific guidance such that the products are not seen to be “appealing” and are easily identified as different from other food products – this could include
specifications for “plain packaging” with no colourful or cartoon-like branding, discrete units that are not manufactured to include an “appealing” shape or colour – e.g., while candies and similar products are likely to be perceived as appealing to children and ideally should be banned as a form of cannabis edible, there should be at least be clear guidance for candy and confection products - a ‘gummy’ must be of plain colour and not in the shape of an animal etc, a chocolate product must not be in the shape of a common chocolate bar or boxed chocolates – with the rationale that all edible cannabis products must be clearly identifiable as “different” from similar non-cannabis-containing food products. The specifications for “child-resistant” packaging are not clear in this guidance – this too should be defined in the regulations (including a general warning to keep out of reach of children and risk for poisoning), so that all guidelines for edible cannabis are clear to manufacturers and enforceable by inspection agencies.

A final question: Could Canada add a requirement to the Edible Cannabis regulations, whereby a discrete unit of a product is stamped to identify the presence of cannabis/THC in each discrete unit/serving? e.g., whereby a cookie or candy would be imprinted, so that one could pick out the cannabis products from other plain products on a plate? We note Colorado’s requirement for edible products (not just packaging) to be marked with the universal THC symbol to help adults, youth and children recognize and differentiate cannabis products from non-cannabis products. (Not clear: what is the difference between using the universal THC symbol vs the marijuana leaf symbol.... would they mean the same thing in Canada?) (Reference: State of Colorado. New Colorado rules make marijuana packaging safer for adults, less appealing to children [Internet]. 2018. Available from: https://www.colorado.gov/pacific/marijuana/news/new-colorado-rules-make-marijuana-packaging-safer-adults-less-appealing-children)

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?

A: No response.

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

A: No response.

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

A: We note that “all edible cannabis products would need to be shelf-stable (i.e. they could not require refrigeration or freezing) and the use of meat products, poultry products and fish as ingredients would be prohibited” – we agree with this proposal.

We also agree with the limit on naturally occurring caffeine in edible cannabis – which we understand to be not in excess of 30 mg caffeine in one discrete unit or serving, the prohibition of the addition of caffeine to a product, and the allowance for a small concentration of ethyl alcohol in edible cannabis (that does not exceed 0.5% w/w).
We agree with the aim of packaging and labelling requirements “to protect the health of young persons by restricting their access to cannabis and to protect young persons and others from inducements to use cannabis” and “to promote informed consumer choice and encourage the safe handling and storage of cannabis”. This should include regulation for core plain packaging, the standardized cannabis symbol, health warning messages, THC and CBD content, and child-resistant packaging, with aim to reduce the risk of accidental consumption and overconsumption.

It is not specified how Health Canada will update the Cannabis health warning messages to include new health warning messages pertaining to edible cannabis, but we certainly agree with the aim of “more effectively distinguish between lower THC-concentration and higher THC-concentration cannabis products, and thereby to promote informed consumer choices”.

Our question: where are the regulations that specify the conditions for carrying each of the warning messages? We recommend that there be clear guidance to trigger mandatory warnings on edible cannabis products, as per other cannabis products (re: caution against consumption by adolescents/children etc) and also a message that clearly warns consumers that the effects of THC dose in an edible product will be delayed for at least one hour and therefore consumers should NOT take additional doses during that time period. We note furthermore, some online literature suggesting different outcomes depending on whether the edible product is consumed on an empty or full stomach [http://profofpot.com/marijuana-edibles-food/ - a common specification with instructions for taking pharmaceutical preparations].

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?

A: We agree that these regulations must be consistent with requirements that apply to food under the FDR, and include:

- A list of ingredients – we recommend including mandatory specification of the format of cannabis added to that batch of edibles (i.e., plant, isolate, concentrated oil etc);
- The common name of the cannabis product;
- An indication of the source of an allergen or gluten, or that sulphites have been added to the product (alternatively, this information could appear as part of the ingredient list);
- A “durable life date” (more commonly known as a “best-before date”), which would apply only to edible cannabis products whose qualities are expected to deteriorate over a period of 90 days or less; and

With respect to the proposed “cannabis-specific Nutrition Facts table (NFT)” for edible cannabis products, we disagree with the proposed inconsistencies from the standard format NFT for pre-packaged foods and beverages.

Instead, we recommend that the font size, font type, leading and spacing of the NFT be entirely consistent with the labelling requirements specified in the Food & Drug Act for pre-packaged foods, as per changes to the NFT specified in 2016 ([https://www.canada.ca/en/health-canada/services/food-labelling-changes.html](https://www.canada.ca/en/health-canada/services/food-labelling-changes.html)). Note: We understand this requirement for NFT on cannabis edibles to be effective as of October 2019, without the flexibility of current phase in period of other pre-packaged food products up to 2022.
Our rationale for the above comments about the NFT is that edible cannabis products are a form of food, and the NFT should be a standardized label on all food products. In this proposal, the font size of 6 is too small, the background is not specified to be white in colour, there is no requirement to use an upper/lower case format (easier to read than “ALL CAPS”) – these are not acceptable exemptions, as they would make the NFT on edible cannabis products potentially quite different from the standardized NFT on other food products. The exception here is that we do agree with the proposed allowance for a statement of “not a significant source of ....” – recognizing that many edible cannabis products would not contain appreciable amounts of naturally occurring micronutrients and may not be fortified with the addition of vitamins/minerals etc.

We agree that these amended Cannabis Regulations should prohibit any representations regarding health benefits or nutrient content (e.g., nutrient/health claims allowed on pre-packaged foods should not appear on edible cannabis products) or association with an alcoholic beverage, applicable on all packages and labels of cannabis products. We also agree with the proposed prohibition to represent edible cannabis as being a suitable means of meeting the particular dietary requirements of an individual (e.g., suitable for people with a particular physical/physiological condition, or part of a low-calorie diet, for weight loss).

We agree that plain packaging requirements for all cannabis products should be maintained, including the requirement for child-resistant packaging. We also agree that the immediate container of cannabis extracts must be designed in such a way that the extract could not easily be poured, or drunk directly from the container (thereby mitigating against the risk of accidental consumption) and that “food-grade” packaging (i.e. packaging that meets requirements set out in the FDR and the SFCR for food) be required for the immediate container of edible cannabis and any wrappers.

It is reasonable and prudent to prohibit the co-packaging of edible cannabis and a food, to prevent the sale of sampler packs, and discourage use of pressurized containers, except for carbonated beverages.

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?

A: With respect to the following text in this proposal: “...that the Regulations would be amended to enable the use of expanded panels and alternative display formats for certain required information when the immediate container is too small to otherwise accommodate all required information on the exterior display surface. Tags and package inserts would continue to not be permitted...The cannabis health warning messages, standardized cannabis symbol and information pertaining to the THC and CBD content of the product would always be required on the exterior display surface, regardless of the size of the container. However, information such as the packaging date, recommended storage conditions, the list of ingredients, and the NFT could be displayed on a peel-back or accordion panel. In such cases, regulated parties would be required to maximize the display of required information on the exterior display surface, and would be prohibited from adding any additional “voluntary” information to the alternative display. Brand elements appearing on the outer display could not be any larger than the minimum size of the standardized cannabis symbol (i.e. 1.27 cm by 1.27 cm), and no brand elements would be allowed on the peel-back or accordion panel..... These amendments are considered to be necessary given the proposed restrictions on the package sizes (e.g. the maximum package size of 7.5 g for cannabis extracts containing ethyl
alcohol), and also in light of the new labelling requirements that increase the amount of required information (e.g. the NFT that is proposed for edible cannabis or the directions for use that are proposed for cannabis topicals)."

We recommend:

- **The list of ingredients must be visible on the exterior display surface** – this provides important information about the presence of allergens.
- **The exterior panel (when NFT is not visible)** must include a clearly visible statement, that says “xx calories per serving (and specify size/amount of serving). See inside panel for Nutrition Facts Table”.
- **The above information on the exterior panel must be black font on white background, and a font size consistent with Food Regulations regarding NFT.**
- **The NFT information must be readily available to consumers in the retail setting (e.g., a sign, a separate printout – in proximity to the product display) or when ordering online.**

We understand that the NFT will require more space than what is available on a small package – especially as we have recommended it should be printed in the format/size of the Food Regulations, so the above is a possible compromise. Ideally however – the NFT should be entirely consistent with Food Regulations, and always visible on the exterior display surface.

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

   A: No comment.

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?**

   A: We note and agree with the consistency with the SFCR. Also agree with the testing controls – e.g., Testing “to determine the content of THC, tetrahydrocannabinolic acid (THCA), cannabidiol (CBD), and cannabidiolic acid (CBDA)”; “for microbial and chemical contaminants”; “for the residues of solvents used in the production of cannabis oil”.

   We assume the potency and dosage of the THC listed on the package would only be expressed as “active” or heated THC. Is there a consistent way to define THC in ‘active equivalents’? The concern here is that there should be no increase in THC potency if a consumer heated the edible product or exposed the product to UV light, after purchase – is this understood in the Regulations or should it be specified?
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?

A: We agree – “it is proposed that the production of edible cannabis at a site where conventional food products are also being manufactured for sale could only be done provided the edible cannabis were being produced within another building within the licensed site”.

Rationale: this is very important for allergen control/ cross-contamination with other foods. We agree with stated rationale, “This proposal is intended to mitigate against the food safety and public health concerns associated with multiproduct manufacturing facilities, and in particular to mitigate against the risks of cross-contamination between ingredients and products, and the increased risk of mislabelling and product mix-ups. It also provides Canada’s international trade partners or importers of Canadian food products with assurance that there can be absolutely no cross-contamination of Canadian food products with cannabis.”

Another comment: Manufacturers must ensure that edible cannabis products be labelled with a batch number, to facilitate recall if there is an identified dosing or food safety concern.

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

A: No comment

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

A: No comment

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?

A: We would appreciate receiving more information about HC’s plans regarding public education and awareness, metrics baseline and evaluation, and consulting Indigenous peoples. (These factors were also emphasized in the report from the House of Commons Health Committee study - https://www.ourcommons.ca/Committees/en/HESA/StudyActivity?studyActivityId=9603581)

It will also be important to inform consumers of possession limits for cannabis, as related to all different cannabis products – this could also be included in label/packaging requirements and/or in an information sheet available at retail and online for consumers. It is not clear if the maximum possession limit includes a total of cannabis plant material or THC, and if that total would apply to cannabis products together in one residence or in the possession of one individual. This is an important concept for consumers, given the need for awareness about new legislation and regulations in a newly legalized, recreational market.
Additional articles of interest, suggested by various members in Dietitians of Canada:

**Food Safety and Cannabis Edibles**

**Why Cannabis Edibles Are Creating a Buzz**

**Tasty THC: Promises and Challenges of Cannabis Edibles**
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5260817/

**Aurora Cannabis to Acquire Mexico’s Farmacias Magistrales S.A.**
http://www.cannabisbusinesstimes.com/article/3-takeaways-washington-new-edibles-regulations/

**Spotlight: Edible Cannabis in Canada, Part 1 of 4**

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