Proposed Amendments to the *Cannabis Regulations*: Edible Cannabis, Cannabis Extracts and Cannabis Topicals

Health Canada's 2019 Regulatory Consultation

Purpose

- The purpose of this presentation is to provide an overview of the proposed amendments to the *Cannabis Regulations* so that individuals and organizations can provide feedback on the rules and requirements related to edible cannabis, cannabis extracts and cannabis topicals.

- The proposals set out in this presentation are for consultation purposes only, and should not be interpreted as representing the final views of the Governor in Council, the Minister of Border Security and Organized Crime or the Government of Canada.

Overview

- On October 17, 2018, the *Cannabis Act* came into force, legalizing and strictly regulating access to cannabis for adults in Canada.

- Adult Canadians now have legal access to a range of quality controlled cannabis products that are produced and sold under strict regulatory controls. These products include: dried cannabis, fresh cannabis, cannabis oil, cannabis plants and cannabis seeds.

- Health Canada is developing regulations governing the production and sale of additional classes of cannabis, namely, edible cannabis, cannabis extracts and cannabis topicals.

- Products within these new classes of cannabis will be permitted for legal sale no later than October 17, 2019. Regulations must be in place by that date to address the unique public health and safety risks posed by these new products.

Policy Principles

- The proposed amendments are based on the following policy principles:
  - **Integrated into the existing cannabis control framework**
    - Consistent with the Government of Canada's stated public health and public safety objectives, all cannabis products are to be strictly regulated under the *Cannabis Act* and its regulations.
  - **Evidence informed**
    - New regulatory requirements are based on the best available public health information on the risks and harms posed by the new classes, and relevant experience from U.S. states that have legal cannabis regimes.
  - **Consistent with analogous regulatory frameworks**
    - New regulatory requirements draw from, and are consistent with, other relevant control frameworks – including those for food, vaping products and cosmetics – to the extent they support the government's public health approach to cannabis.
  - **Comprehensive**
    - Consistent with the objective of enabling the legal industry to displace the illegal industry, the new requirements are proposed with a view to enabling a comprehensive range of product forms.

Policy Objectives

- The proposed regulatory amendments aim to address the unique public health and safety risks posed by edible cannabis, cannabis extracts and cannabis topicals:
  - Appeal of such products to young persons;
  - Risk of accidental consumption;
  - Risk of overconsumption;
  - Risk of foodborne illness if edible cannabis has been produced or handled improperly; and
  - Risk of negative health outcomes associated with cannabis products with a higher concentration of THC or those containing certain ingredients.

- At the same time, the proposed amendments aim to enable the production and sale of a comprehensive range of cannabis products by the legal industry.

Elements of the Regulatory Framework

- The proposed new rules would amend the following parts of the existing *Cannabis Regulations*:
  - Licensing;
  - Good Production Practices;
  - Products; and
  - Packaging and Labelling.

- No changes are being proposed to the medical access part of the regulations.

Licensing

- Under the existing *Cannabis Regulations*, cannabis products can only be produced with the appropriate licence (e.g. cultivation, processing) from Health Canada.

- A processing licence would be required in order to manufacture edible cannabis, cannabis extracts and cannabis topicals, and to package and label these types of products for sale to consumers.
  - Existing licence holders (micro or standard) would be required to seek a licence amendment in order to sell the new classes of cannabis.

- No changes are proposed to the existing physical or personnel security requirements associated with processing licences.

Good Production Practices (GPP)

- Under the existing *Cannabis Regulations*, all licence holders must meet GPP requirements. GPP covers issues such as the use of pesticides, sanitation, standard operating procedures, the role of the Quality Assurance Person and testing.

- It is proposed to expand existing GPP requirements with new production controls intended to reduce the risks of contamination and foodborne illness.
  - Many of the proposed new requirements are based on controls that apply to food manufacturing (e.g. handling and use of ingredients, sanitation, use of potable water, waste disposal, temperature and humidity controls).

- It is proposed to maintain existing record keeping and reporting requirements (e.g. testing results, batch/lot production records, recall reporting). In addition, licence holders would be required to maintain records about ingredients used.

Good Production Practices (GPP) (cont'd)

- Key proposed changes:
  - **Preventive Control Plan:** Processors producing edible cannabis or cannabis extracts would be required to develop and implement a Preventive Control Plan (PCP).
  - **Standard Operating Procedures (SOPs):** SOPs would need to demonstrate that GPP and relevant product rules are being met. SOPs would need to cover cannabis and the ingredients used to make cannabis products (e.g. storage of ingredients).
  - **Sanitation:** Buildings where cannabis is produced would be required to have hand cleaning stations and lavatories. Employees of processors would be required to wear appropriate clothing, footwear and protective coverings.
  - **Quality Assurance Person (QAP):** The QAP would be required to investigate any suspected risks of injury to human health, and if necessary, take immediate measures to mitigate the risk.
  - **Separate Manufacturing:** It would be prohibited to produce edible cannabis in a building where food is produced.

Good Production Practices (GPP): Testing

- Licensed processors would be required to conduct analytical testing of edible cannabis, cannabis extracts and cannabis topicals.
  - Potency (THC and CBD content), microbial and chemical contaminants, and dissolution or disintegration (if applicable).

- It is proposed to allow flexibility as to the timing of certain contaminant testing:
  - Microbial and chemical contaminant testing could be conducted on the cannabis used to produce edible cannabis, cannabis extracts or cannabis topicals OR on the final form of the cannabis product.

Products

- Licensed processors would be permitted to produce a broad diversity of products within the three new classes, provided that the following rules are met:
  - Products cannot be appealing to young persons. Such products are clearly prohibited under the *Cannabis Act*.
  - Products would need to respect maximum THC limits.
  - Products would need to respect limits on the use of certain ingredients that risk making products more appealing, that risk increasing the addiction potential of products or that increase the risk of contamination and illness.

Products: THC limits

- **Edible Cannabis:** No more than 10 mg of THC per package.

- **Cannabis Extracts:** No more than 1,000 mg of THC per package. Extracts intended for ingestion (e.g. capsule, spray) limited to 10 mg per unit/activation.

- **Cannabis Topicals:** No more than 1,000 mg of THC per package.

Products: Product Forms and Ingredients

- **Edible Cannabis**
  - Ingredients could only be food and food additives.
  - Would need to be shelf stable (i.e. not require refrigeration or freezing).
  - Restrictions on ingredients that pose a food safety risk (e.g. raw meat), a public health risk (e.g. caffeine limited to 30 mg per package; no alcoholic beverages) or that could increase appeal (e.g. added vitamins).
- **Cannabis Extracts**
  - Ingredients could only be carrier substances, flavouring agents, or substances necessary to preserve quality or stability.
  - Restrictions on ingredients that pose a public health risk (e.g. no caffeine or nicotine) or that could increase appeal (e.g. no sugars, colouring agents, vitamins, probiotics).
- **Cannabis Topicals**
  - Ingredients could not cause injury to the health of the user.
  - Products could not be designed to be used in the area of the eye or on broken skin.

Packaging and Labelling

- The existing *Cannabis Regulations* require:
  - Plain packaging;
  - Mandatory labelling information (e.g. THC and CBD content, Health Warning Messages, standardized cannabis symbol); and
  - Child-resistant containers.

- It is proposed to require the following labelling information:
  - **Edible Cannabis:** List of ingredients; cannabis-specific Nutrition Facts Table; sources of allergens, gluten and sulphites;
  - **Cannabis Extracts:** List of ingredients; standardized cannabis symbol on pre-filled vaping accessories; and
  - **Cannabis Topicals:** List of ingredients; warning statement.

Packaging and Labelling (cont'd)

- For all cannabis products, propose to prohibit claims related to health or cosmetic benefits, and associations with alcoholic beverages.

- For cannabis extracts, propose to prohibit representations with respect to specified flavours that are appealing to young persons.

- For edible cannabis, propose to prohibit representations that a product is suitable for a particular diet (e.g. part of a low-calorie diet).

- For all cannabis products, propose labelling allowances for small packages (i.e. ability to use peel-back or fold-out labels to display certain required information).

Public Consultation

- Individuals and organizations can provide feedback on the proposed amendments to the *Cannabis Regulations* via an online questionnaire available at: https://www.canada.ca/en/health-canada/programs/consultation-strict-regulation-edible-cannabis-extracts-topicals.html

- Written submissions can be sent to:
  - Email: cannabis@canada.ca
  - Mail: Cannabis Legalization and Regulation Branch
    Address locator: 0302B
    Health Canada
    Ottawa, ON K1A 0K9

- The 60 day public consultation period will end on February 20, 2019.