
REGULATORY IMPACT ANALYSIS STATEMENT ON CANNABIS EDIBLES

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1 Executive Summary

Cannabis or marijuana is a psychoactive drug that is derived from the Cannabis plant. It is produced from the plant cannabis sativa. Along with psychoactive properties, it also has therapeutic effects. The many forms of cannabis are as follows

1. Dried flowers
2. Dried leaves
3. Extracts such as oil
4. Hash
5. Edibles including candies or baked goods
6. Drops
7. Solutions

They contain about hundred of chemicals in them. These chemicals are called cannabinoids and they are specific to this plant. The main compound that is responsible for the psychoactive property of feeling *high* is THC; also called delta-9-tetrahydrocannabinol. Another such compound is CBD or cannabidiol. This CBD does not have any psychoactive properties thus counteracting the negative side-effects of tetrahydrocannabinol

The cannabis plant grows in tropical places having a temperate climate; however, people grow cannabis throughout the world

It comes from dried flower and leaves of cannabis plant and it may also contain stems and seeds along with flower buds and leaves. It is grayish-green to brown colored. The tetrahydrocannabinol content varies from different cannabis products. However, it is seen that hash has more content of THC as compared to the plant making it more potent and oil has usually more concentrated content of cannabis as compared to others.

According to a survey done by the Canadian Tobacco, Alcohol and Drugs Survey, around 12 percent (approximately 3.6 million) Canadians used cannabis in the year 2015; out of which around 24 percent said that the reason for them using cannabis was purely medical.

Some of the physical effects of cannabis are:

1. Red eyes
2. Xerostomia
3. Increased appetite
4. Palpitations
5. Hypotension
6. Decrease in stability
7. Drowsiness

The therapeutic effects are:

1. Managing nausea in chemotherapy patients
2. Pain management
3. Uplifting mood and helping insomnia for people suffering from chronic diseases.

2 Issues

Cannabis is an illicit drug that is most commonly used. Its illicit use is mostly among the youth. In the year 2015, more than eleven million youth that were aged between eighteen to twenty-five used cannabis.

The biggest challenge would be the labelling and packaging of cannabis infused edibles. The packaging has to be done in such a way that is not appealing to the youth. The primary target is the youth as they get attracted to appealing labels and packaging. Another major issue is the youth smoking marijuana and then driving to school or college.

The use of marijuana has increased by 400% in the last decade. For people who use medical marijuana should be properly educated by their healthcare providers to ensure that they do not start using marijuana recreationally. The companies would manufacture cannabis edibles that are appealing and that would make them stand out from their competitors; however, it is imperative that these regulations have to be stringent so as to decrease promotion of marijuana for recreational use.

3 Background

The Government of Canada passed Bill C-45 also known as Cannabis Act on April 13, 2017 in the House of Commons. This Act restricted access to the cannabis that was regulated and it also controlled its production, distribution, export, import and storage. Following this, the Cannabis Act received an acceptance from the Royal Assent on June 21, 2018 and it was enforced on October 17, 2018.

The Cannabis Regulation regulates the following:

1. It is mandatory to have a license to produce cannabis, sell it for medical reasons, manufacture drugs containing cannabis or conduct any research related to cannabis
2. The ones who hold license are subjected to stringent physical security requirement

3. License holders who produce cannabis products are subjected to strict rules. These rules include the strength of tetrahydrocannabinol content, dosage of additives that are used in the products
4. The labelling and packaging for products related to cannabis should be plain and non-appealing. The rules are set for the logos and colors that can be used
5. Access of cannabis to patients who are in need of medical marijuana.

4 Objective

The objective of this proposal is ensuring that the regulatory framework that is proposed for cannabis edibles is stringent and addresses important topics like health and safety risks to the public due to edibles, extracts and topicals.

The current proposal for cannabis aims to ensure safety of public health by doing the following:

1. Ensuring that the products are not appealing to the youth
2. Decrease use of accidental ingestion on cannabis edibles by children and youth;
3. Reducing the risk of over-consuming cannabis edibles and other related products containing higher dosage of tetrahydrocannabinol.
4. Legalize cannabis infused edibles to decrease illicit buying of these products from the black market thereby reducing illegal activities related to cannabis
5. Promote suitable sanctions and measures to decrease illegal activities that are in relation with cannabis and similar products
6. Decrease the burden of the justice system that may be related to cannabis
7. Ensuring access to cannabis supply that is quality-controlled.
8. Educate the public about the various health risks that are related to the use of cannabis.

5 Description

5.1 Licensing

1. The regulation puts forward the requirement of licenses that allow the authorization of activities that are related to cannabis at the federal level. These rules also are subjected to the class of subclass of each license group.
2. A standard or a micro license would be required for production, labelling and packaging of cannabis edibles, cannabis oil, dried and fresh cannabis, cannabis topical products and extracts.

3. It is also mandatory for the license holders to have a system that is able to control and support recalls. Once every 12 months, it is proposed that the license holders will have to set up a recall simulation to evaluate the efficacy of the recall systems. This simulation has to be documented describing how the simulation was performed as well as the results of the same. They would have to keep this documentation for at least two years.

5.2 Personnel security

Parts of the regulation set the measures for physical and security clearances. License holders who intend on conducting activities with new strains of cannabis are subjected to stringent physical security and personnel measures.

5.3 Good manufacturing measures

A part of the regulation focuses on the requirement needed to produce, distribute and store cannabis. These requirements are needed to ensure good quality of cannabis that are produced by people holding federal license.

These requirements include the type of equipment used for production, sanitation conditions, storage, distribution, quality control and assurance and lastly, the standard operating procedures.

An additional requirement in the regulation is the need to incorporate further good manufacturing practices like preventing contamination of cannabis and addressing risks related to edible cannabis.

Building appropriate air filtration system to prevent the escape of the cannabis odor. There would also be a further requirement for have a system for ventilation that promotes clean air and clears unclean air that may affect the production of cannabis or have an effect on its contents. This step would be mandatory for both cultivators and processors who have a valid license.

Licensed producers of cannabis will conduct processes that involve edible cannabis or contents that are used to produce edible cannabis.

It would also be mandatory to make sure that pets or any animal does not enter the premises where cannabis is produced.

6 Testing

A part of regulation also ensures requirements for testing and sampling of cannabis. The following tests have to be conducted:

1. Test to measure the concentration of tetrahydrocannabinol (THC), cannabidiol (CBD), tetrahydrocannabinolic acid and lastly, cannabidiolic acid
2. Tests to ensure no microbial contaminant or any contaminant that would alter the chemical properties
3. Testing to check the solvents used to produce cannabis
4. Disintegration testing

7 THC limit testing

To reduce over-consumption of accidental ingestion of cannabis, an important test is to check the amount of tetrahydrocannabinol used in cannabis or cannabis edibles. It is proposed that

The limit of THC for cannabis edibles would be ten milligrams of THC per single package.

For extracts containing cannabis, there is a limit of ten milligrams of THC per unit if it is edible or for capsule for rectal, vaginal or nasal use. In addition to this requirement, another limit is that in a single package, the content of THC should be one gram or thousand milligrams.

For topicals that contain cannabis, the limit would be not more than one gram of THC in a single package.

A further addition to this new set of requirements is that a lower limit of content would apply to any product that has more than 3% of THC w/w.

Another set of regulations to establish the limits of variability for the concentration of THC and CBD in cannabis are as following:

1. If the total concentration of CBD or THV content that is displayed on the label of edible cannabis exceeds by five milligrams, the product would undergo a variability limit of 15% .
2. If the quantity exceeds by five milligrams, then the variability limit would exceed by 20% .
3. If the content of THC or CBD is lower than two milligrams, then the variability limit will be 25% .

4. The variability limit for cannabis topicals will be 15% .

8 Edible cannabis

The major requirement for edible cannabis is that they have to be stable with a stable shelf-life without needing the requirement of freezing the product.

The other content besides cannabis that can be used in cannabis edibles are food or food additives. These limits are set according to the Food and Drug regulations.

They should not contain any poisonous substances or any harmful substances. It should also not be mixed with any nutrients containing minerals or vitamins.

If any edible cannabis contains poisonous substances that may be regarded unsafe, then the product would be considered prohibited under both Food and Drugs Act as well as the Cannabis Act.

Substances like meat/meat products, dairy products, poultry substances are prohibited in such products.

An exception to the above rule will be that the products that contain poultry, fish or meat products; however, it should be produced by a person who is authorized under territorial or provincial laws. Another exception to this rule is that the water activity of the product should be 0.85 or less.

The sale of cannabis is banned in any container that is hermetically sealed, have a pH above 4.6 with water activity higher than 0.85

The amount of caffeine that any natural ingredient has should not exceed by thirty milligrams in a single package.

Ingredients like chocolate, coffee or tea that contain caffeine can be used in cannabis edibles. However, using any ingredient containing caffeine as a food additive is banned.

Another regulation proposed for cannabis edibles is that only a small amount of ethyl alcohol (whose concentration should not exceed by 0.5% w/w) is permitted in these products. The rule is valid only if ethyl alcohol is a by-product of the existing fermented products.

9 Packaging and labelling

The regulations for packaging and labelling are particularly stringent to restrict the youth from having access to it. The most important part of packaging and labelling is that they should be non-appealing and should have a child-resistant packaging to prevent children from accidentally ingesting cannabis or cannabis related products like cannabis edibles.

10 Information that should be mandatory for labelling

The following should be mandatory on the labelling of edible cannabis or cannabis related products:

1. Contents of the products
2. Generic name of the products
3. Indication of any allergen or gluten
4. Indication of any sulphates that may be present in the product
5. The shelf-life of the product. This applies to products whose quality may get affected after 90 days or less than 90 days
6. A nutrition chart that is specific to cannabis.

11 Requirements for packaging

The most mandatory regulation for packaging of products containing cannabis is that they should have a child resistant packaging.

The container of cannabis should be designed in such a way that the extract of the product should not be easily poured out.

For extracts of cannabis that are in a liquid form and not intended to be inhaled; the container should have a mechanism for integrated dispensing that should not dispense more than ten milligrams. The only exception to this rule would be that the dispenser can dispense more than ten milligrams only if the product is in the form of a discrete unit like a capsule.

The exterior pack of the product should not be in contact with more than one immediate container to prevent the sale of sampling packs.

12 Development of Regulations

12.1 Consultations

A task force has been formed to consult with Canadian citizens to take their advice on the new legislative framework. The Task Force made around 84 regulations from the recommendations that were provided to them. These recommended varied from topics like cannabis edibles, cannabis extracts and extracts containing higher content of THC.

Some of the recommendations provided by the Task Force were:

1. The products that are specifically banned are the ones that can be appealing to children, which may resemble similar food items or look like candy or chocolates.
2. The products that have single serving should have the cannabis symbol that is standardized.
3. Products containing alcohol/tobacco/caffeine with cannabis are banned.

13 Regulatory Analysis

13.1 Costs and Benefits

It is estimated that the proposed regulations would cost Canadians approximately 40\$ million dollars. This cost will be borne by the licensed processors, the regulated industry to comply with the new regulations of labelling, packaging, manufacturing, good manufacturing practices, testing, etc.

Despite the cost, the benefits include decreasing black market and providing people with quality-controlled cannabis.

13.2 Regulatory Impacts Analysis

These analyses have been estimated using these approaches:

1. Quantitative analysis
2. Qualitative analysis

Health Canada gives out questionnaire to license holders. If any data is not available from the questionnaire, then Health Canada takes the information from previous cost-benefit analysis and data from the United States.

13.3 Stakeholders

As written above, no special license is required to produce cannabis. However, a standard or micro cannabis processing license will be required to manufacture cannabis related products.

All the license holders will be subjected to these new regulations that apply to the new class of cannabis. Therefore, it is imperative to know that the costs will be borne by the license holders.

13.4 Benefits

1. Increased safety to the public health
2. Increased allowances for smaller packages
3. Decrease of black market

14 Contact

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