

**ANALYZING CANADIAN LAWS ON RECREATIONAL CANNABIS
EDIBLES FROM A PUBLIC HEALTH PERSPECTIVE**

A Thesis Submitted to the College of
Graduate and Postdoctoral Studies in Partial
Fulfillment of the Requirements for the
degree of Master of Public Health in the
School of Public Health
University of Saskatchewan
Saskatoon

By

Priyashni Goundar

PERMISSION TO USE

In presenting this thesis in partial fulfillment of the requirements for a Postgraduate degree from the University of Saskatchewan, I agree that the Libraries of this University may make it freely available for inspection. I further agree that permission for copying of this thesis in any manner, in whole or in part, for scholarly purposes may be granted by the professor or professors who supervised my thesis work or, in their absence, by the Head of the Department, the Dean of the College, or the Executive Director of the School in which my thesis work was done. It is understood that any copying or publication or use of this thesis or parts thereof for financial gain shall not be allowed without my written permission. It is also understood that due recognition shall be given to me and to the University of Saskatchewan in any scholarly use which may be made of any material in my thesis.

Requests for permission to copy or to make other uses of materials in this thesis/dissertation in whole or part should be addressed to:

Executive Director School of Public Health
University of Saskatchewan
104 Clinic Place
Saskatoon, Saskatchewan S7N 2Z4

or

Dean, College of Graduate and Postdoctoral Studies
University of Saskatchewan
116 Thorvaldson Building
110 Science Place
Saskatoon, Saskatchewan S7N 5C9

DISCLAIMER

Reference in this thesis to any specific commercial products, process, or service by trade name, trademark, manufacturer, or otherwise, does not constitute or imply its endorsement, recommendation, or favouring by the University of Saskatchewan. The views and opinions of the author expressed herein do not state or reflect those of the University of Saskatchewan, and shall not be used for advertising or product endorsement purposes. This work was financially supported by the Saskatchewan Ministry of Health, Regina, Saskatchewan. The interpretation and conclusions contained herein do not necessarily represent those of the Government of Saskatchewan or the Saskatchewan Ministry of Health.

ABSTRACT

Background

The Canadian government amended the *Cannabis Act* and *Cannabis Regulations* to legalize use of recreational cannabis edibles. Edibles are food products and beverages that contain chemical compounds from the cannabis plant. Developing legislation is challenging given both food and drug related hazards must be mitigated; additionally, few jurisdictions have experience regulating edibles. Besides Canada, the United States of America (USA) is the only other country with experience regulating cannabis edibles at the state-level. Hence the objectives for this thesis were to: (i) compare laws (within Canada and the U.S. states that have legalized the recreational use of cannabis edibles) that govern tetrahydrocannabinol (THC)-infused cannabis edibles and identify any associated gaps in Canada's cannabis regulatory framework; (ii) identify potential food safety hazards and health hazards associated with manufacturing cannabis edibles; and (iii) compare the *Safe Food for Canadians Act* (SFCA) and *Safe Food for Canadians Regulations* (SFCR) with the *Cannabis Act* and *Cannabis Regulations* to identify potential food safety gaps in the Canadian cannabis legislation.

Methods

The Canadian documents containing the information necessary for objective (i) are the Canadian *Cannabis Act*, *Cannabis Regulations*, and the Health Canada report: Final Regulations for New Cannabis Products published in the *Canada Gazette*. The necessary U.S. state-level statutes and regulations were retrieved for all U.S. states with laws on recreational cannabis from LexisAdvance Quicklaw. A comparative analysis of these documents highlighted similarities and differences in the cannabis regulatory framework of Canada and the U.S. states with laws on recreational cannabis edibles. For objective (ii), to identify potential food safety hazards and health hazards associated with manufacturing cannabis edibles, a rapid review was conducted. The PubMed database was searched. All 11 articles retrieved were reviewed. From the references within these articles, an additional 14 articles were identified and reviewed. Lastly, for research objective (iii), cannabis legislation (*Cannabis Act* and *Cannabis Regulations*) and food safety legislation (SFCA and SFCR) were taken from the Government of Canada website. The two sets

of legislation were compared to determine which food safety-related requirements were incorporated into the *Cannabis Act* and *Cannabis Regulations* and which were omitted.

Results

As of June 20th, 2019, twelve jurisdictions in the USA authorized recreational cannabis use, but only ten states outlined specific requirements for edibles. Overall, Canada and states in the USA that legalized recreational cannabis edibles implemented similar regulatory requirements; however, restrictions on THC per package and labelling requirements were more conservative in Canada. Differences in regulatory requirements between both countries were also identified. Requirements on reporting of test results and data collection via the cannabis tracking system differed between Canada and the USA. Moreover, four U.S. states require cannabis manufacturers to directly imprint edibles with a cannabis symbol, which is not mandated in Canada. With respect to food safety, to prevent food-borne illnesses, the *Cannabis Regulations* adapted food safety requirements from the SFCR to prevent contamination of ingredients during the production of edibles. These requirements pertain to standard operating procedures, filtration systems, sanitation, quality assurance and hazard control plans. Gaps in regulatory requirements were also identified and include: (i) two food-safety related clauses from the SFCR that were not incorporated in the *Cannabis Regulations*; and (ii) the Cannabis Tracking and Licensing System (CTLS) does not collect data from licensed laboratories.

Conclusion

This thesis project analyzed Canada's regulatory framework for recreational cannabis edibles to determine whether legislative requirements would adequately mitigate public health risks by comparing it to state-level statutes in the USA and to understand Canadian legislative requirements on food safety as applied to cannabis edibles and assess the legislation's adequacy in mitigating potential food safety related risks. Overall, Canada's regulatory requirements on cannabis edibles are comprehensive and will be critical in minimizing public health risks, including food safety related risks. Canada's cannabis legislation can be further strengthened by mandating manufacturers to directly imprint edibles with a cannabis symbol and addressing requirements on test result reporting and data collection via the CTLS.

ACKNOWLEDGEMENTS

I would like to extend my heartfelt gratitude to Dr. Michael Szafron for his guidance, patience, and unwavering support for this project. There are not enough words to express how grateful I am for this opportunity. Thank you.

Special thanks to my advisory committee member, Dr. Holly Mansell, for her invaluable insight, helpful feedback, and advice. Your contributions have greatly improved the quality of this thesis.

Many thanks to my committee chairs, Dr. Philip Griebel and Dr. Suresh Tikoo, for their direction on this project.

Tim Macaulay and Kelsie Dale – my practicum experience was such a wonderful and transformative experience, all thanks to your positivity, kindness, words of encouragement, and professionalism. I cannot thank you enough.

Lastly, to my parents, sisters, and friends - thank you for all your love and support.

TABLE OF CONTENTS

PERMISSION TO USE	i
DISCLAIMER	ii
ABSTRACT.....	iii
ACKNOWLEDGEMENTS	v
TABLE OF CONTENTS.....	vi
LIST OF TABLES.....	viii
LIST OF FIGURES	ix
LIST OF ABBREVIATIONS.....	x
COVID-19 IMPACT STATEMENT.....	xi
CHAPTER 1 : INTRODUCTION	1
1.1 Cannabis.....	1
1.2 Prevalence and patterns of cannabis use	1
1.3 Potential health effects of recreational cannabis use.....	2
1.4 Regulatory approaches for cannabis	3
1.5 Research objectives.....	5
INTRODUCTION TO CHAPTER 2.....	7
CHAPTER 2 : A COMPARATIVE ANALYSIS OF LAWS ON RECREATIONAL CANNABIS EDIBLES BETWEEN CANADA AND THE UNITED STATES OF AMERICA.....	8
2.1 Abstract	8
2.2 Background	9
2.3 Methodology	10
2.4 Results.....	11
2.4.1 Vertical integration	12
2.4.2 Production and manufacturing.....	13
2.4.3 Testing	15
2.4.4 Packaging and labelling requirements	16
2.4.5 Distribution and retail	17
2.4.6 Taxation	18
2.4.7 Cannabis tracking systems.....	19
2.5 Discussion	19
2.6 Limitations	21
2.7 Conclusion.....	22
INTRODUCTION TO CHAPTER 3.....	23
CHAPTER 3 : LEGALIZING CANNABIS EDIBLES IN CANADA: FOOD SAFETY IMPLICATIONS.....	24
3.1 Abstract	24
3.2 Introduction	26
3.3 Methodology	27

3.4 Results of the rapid review: potential food safety hazards and associated health risks	27
3.5 Addressing food safety in Canada’s <i>Cannabis Act</i> and <i>Cannabis Regulations</i>	30
3.6 Comparing the SFCA and SFCR with relevant components of the <i>Cannabis Act</i> and <i>Cannabis Regulations</i>	32
3.7 Potential gaps in the Canadian cannabis legislation	34
3.8 Limitations	35
3.9 Conclusion.....	35
CHAPTER 4 : KEY FINDINGS, DISCUSSION, AND FUTURE DIRECTIONS.....	37
4.1 Discussion of key findings	37
4.2 Policy and public health implications	42
4.3 Future work	43
4.4 Conclusion.....	45
REFERENCES	47

LIST OF TABLES

Table 2.1: Jurisdictions in the USA that permit the production, distribution, and sale of recreational cannabis as of June 20 th , 2019.....	12
Table 2.2: Regulatory restrictions on cannabis edibles in Canada and the USA.....	16
Table 3.1: Summary of requirements outlined in the Canadian <i>Cannabis Act</i> and <i>Cannabis Regulations</i>	33

LIST OF FIGURES

- Figure 2.1: Example of a cannabis edible product directly stamped with the THC label. Note each square of the chocolate bar has THC stamped on it..... 17
- Figure 3.1: Cannabis Edibles Processing and Associated Hazards. Reproduced with permission from the American Public Health Association. Source: White AE, Van Tubbergen C, Raymes B, Contreras AE, Scallan Walter EJ. Cannabis-Infused Edible Products in Colorado: Food Safety and Public Health Implications. Am J Public Health. 2020;110(6):790-5 (106)..... 29

LIST OF ABBREVIATIONS

AK	Alaska
CA	California
CBD	Cannabidiol
CBDA	Cannabidiolic acid
CO	Colorado
CTLS	Cannabis Tracking and Licensing System
FDA	<i>Food and Drugs Act</i>
FDR	<i>Food and Drugs Regulations</i>
IL	Illinois
MA	Massachusetts
ME	Maine
MI	Michigan
NV	Nevada
OR	Oregon
SFCA	<i>Safe Food for Canadians Act</i>
SFCR	<i>Safe Food for Canadians Regulations</i>
THC	Delta-9-Tetrahydrocannabinol
THCA	Tetrahydrocannabinolic acid
USA or U.S.	United States of America
WA	Washington

COVID-19 IMPACT STATEMENT

Due to the COVID-19 pandemic, completion of this thesis was delayed. The data for this research project was collected in the summer of 2019, however, progress on data analysis, writing, and compilation of the thesis were delayed due to professional and personal reasons resulting from the pandemic. Productivity was also directly affected by ongoing health challenges related to COVID-19.

CHAPTER 1: INTRODUCTION

1.1 Cannabis

Cannabis sativa, *Cannabis indica*, and *Cannabis ruderalis* plants have been cultivated and utilized since ancient times as food sources, and for their fiber, medicinal and psychoactive properties (1). While cannabis plants contain hundreds of different chemical compounds, the primary chemical compound found in recreational cannabis products is THC, used for its intoxicating effects (2, 3). Cannabis plants have been legally classified into two categories: those containing 0.3 percent or less THC are referred to as hemp and those containing more than 0.3 percent THC are commonly referred to as marijuana. The term ‘marijuana’ is a non-scientific slang that scholars argue has been historically associated with racial and xenophobic propaganda (4) leading policy makers to progressively adopt the more scientifically precise term ‘cannabis’. Throughout this thesis, the term cannabis will be used to refer to products with THC concentration greater than 0.3 percent, which other jurisdictions may refer to as marijuana. The term ‘cannabis’ is used broadly to describe the various preparations of the plant material (5). In the last several decades, improvements in cultivation techniques have led to cannabis with increased levels of THC and more diverse products. The dried leaves and flowering parts of the cannabis plant are typically smoked while chemical compounds are extracted to produce oils, chemically concentrated extracts known as shatter or budder, and physically concentrated extracts called hashish (1, 6). Cannabis concentrates can also be combined with alcohols and other solvents to make tinctures or mixed with food ingredients to make edibles (6). One upshot of all these forms of cannabis is cannabis use in developed countries has accelerated at a higher rate compared to other illicit substances (7). Note that in countries where cannabis has not been legalized, it is still treated as an illicit substance.

1.2 Prevalence and patterns of cannabis use

Globally, cannabis is a widely used illicit substance with more than 147 million people consuming it annually (5, 8, 9). While cannabis use is reported in nearly every country, over the past few

decades, use of cannabis has accelerated at a higher rate compared to other illicit substances in developed countries, particularly in North America (7). Comparable to trends observed globally, prevalence of cannabis use in North America is higher among younger age demographics (7, 9). Canadian youth aged 11-15 years had one of the highest rates of recreational cannabis use among countries with advanced economies from 2001 to 2010 (10). Recent data from the 2017 Canadian Tobacco, Alcohol and Drugs Survey reported 33 percent past-year cannabis use among young adults aged 20-24 years, and for adolescents aged 15-19 years, prevalence of past-year cannabis use was 19 percent (11). By comparison, past-year cannabis use in individuals over the age of 25 was 13 percent in 2017 (11). Other surveys, such as the 2017 Canadian Cannabis Survey, reported higher rates of cannabis use with 41% of respondents (aged 16-19 years) and 45% of respondents (aged 20-24 years) reporting cannabis use in the past 12 months (12).

In Canada, the average age of cannabis initiation is at 13 years which has remained stable over time (2004-2014) and is comparable to the age of initiation in the USA (13). Within the youth demographic, certain subsets of the population report more cannabis use than others. Epidemiological studies analyzing data between 2010 to 2018 highlight a greater prevalence of cannabis use among males compared to females (14, 15). Indigenous youth in Canada report more frequent cannabis use and a younger age of first use compared to non-Indigenous youth (13, 15). Cannabis consumption among Indigenous youth has considerably increased since 2017 after years of steady decline (15). The relatively limited data available on factors associated with cannabis use among Indigenous youth make it a challenge to determine the reasons behind this increase.

1.3 Potential health effects of recreational cannabis use

Over the past several decades, as our understanding of cannabis and the effects of cannabinoids on human health has evolved, many poor social and health outcomes have been found to be associated with high rates of cannabis use, especially among youth (16). While cannabis use does not lead to overdose fatalities as seen with opioids, it has been indirectly linked to increased mortality from motor vehicle accidents, suicide, cannabis use disorders, and cancer (17, 18). The effects of cannabis can vary depending on numerous factors including potency of products, mode of administration, age of initiation, frequency of use, user's prior experience, and simultaneous use with other substances (19-25). Adverse effects of cannabis use are primarily observed in users who

consume high-potency products frequently, and individuals who initiate cannabis use early (21, 22, 26, 27).

Cannabis use, particularly if initiated prior to the age of 25, is associated with acute and chronic adverse health risks (16) and social harms such as lowered academic performance (28), increased cases of impaired driving (29), and the potential for cannabis dependency (9). Furthermore, poor mental health status is also strongly associated with cannabis use (14). Several epidemiological studies highlight the relationship between cannabis use and poor mental health in youth (30-32). One theory for this relationship is cannabis use, especially during adolescence, may affect brain development particularly in areas of the brain associated with “decision making, judgement, emotional regulation, planning and problem solving”(16 p.10). These regions undergo significant growth during adolescence and developmental abnormalities attributed to cannabis use are linked to the development of mental illnesses like schizophrenia in those susceptible (16). Given the potential social harms associated with recreational cannabis use, many countries around the world have started adopting different regulatory approaches to address health and safety concerns arising from cannabis use.

1.4 Regulatory approaches for cannabis

Internationally, movement of cannabis is controlled under the United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol (33). For 59 years, under this convention, cannabis was classified as a Schedule IV substance (drugs considered to pose a serious risk to public health with limited therapeutic use) (34). Recently, in 2020, the Commission on Narcotic Drugs (United Nations’ main drug policy-making body) followed the World Health Organization’s directive and reclassified cannabis from a Schedule IV drug to a Schedule I drug; a category reserved for drugs with both harmful effects and therapeutic benefits (34).

Given the classification of cannabis under the United Nations Convention, most countries around the world have criminalized all activities pertaining to cannabis use (7). Regulation of cannabis, like other controlled substances, falls on a regulatory continuum from criminalization to decriminalization to legalization (35). Furthermore, in addition to these three broad categories, jurisdictions can adopt both formal approaches (*de jure*) or informal approaches (*de facto*) to regulation (35). *De jure* refers to approaches that are written in policy or legislation while examples

of *de facto* approaches include informal practices and flexible enforcement strategies (35). While most countries globally have criminalized recreational cannabis use, gradually more countries are liberalizing cannabis policies, and shifting towards decriminalization (7). In the Netherlands, cannabis cultivation and distribution remain illegal; however, starting in the late 1970s, a *de facto* system of decriminalization emerged, whereby possession, use, and retail sale of small amounts of cannabis in Dutch coffee shops were not criminally charged (36). Given cultivation remains illegal in the Netherlands, the cannabis sold in Dutch coffee shops originate from illegal sources. Regulated primarily at the municipal level, these coffee shops are restricted from advertising products and must limit sales to five grams per customer (36). Other countries like Luxembourg, Croatia, Portugal, and Slovenia have decriminalized personal use of cannabis while Austria, Poland, and Germany eliminated criminal penalties for possession (37).

Uruguay, in 2013, adopted a drastic measure and legalized cannabis, becoming the first country to regulate the cultivation, production, and distribution of cannabis for recreational and medicinal use on a federal level (38). Uruguayan legal provisions require all cannabis users to register with the state regulatory body prior to obtaining cannabis, which is only accessible to adults over the age of eighteen (7). Furthermore, access to recreational cannabis is limited to three avenues: (i) purchases from authorized pharmacies; (ii) memberships in cannabis clubs; and (iii) personal cultivation (7). Pharmacies must limit cannabis purchases to forty grams per month for each registered user and are further prohibited from advertising or engaging in promotional activities (7). While recreational and medicinal use of cannabis was legalized simultaneously in Uruguay, the recreational market was implemented sooner than the medicinal one; medicinal users continue to face challenges when accessing cannabis (39). Meeting the public's demand for greater public safety and reducing drug-related criminal activity were the primary driving factors behind Uruguay's decision to legalize cannabis (40).

While eliminating drug-related criminal activity factored into the Canadian government's decision to legalize recreational cannabis, protecting youth and ensuring public health and safety played a much larger role (41). The Government of Canada, in 2015, committed to legalizing the recreational use of cannabis and subsequently enacted legislation (*Cannabis Act* and *Cannabis Regulations*) on October 17, 2018 (42). This cannabis legislation initially outlined a regulatory framework for the production, distribution, and sale of five classes of cannabis: (i) dried cannabis;

(ii) fresh cannabis; (iii) cannabis plants; (iv) cannabis plant seed; and (v) and cannabis oil (42). To legalize other forms of cannabis products (one class being cannabis edibles), the Government of Canada amended the Canadian *Cannabis Act* to authorize three new classes of cannabis: (i) edible cannabis; (ii) cannabis topicals; and (iii) cannabis extracts by October 17, 2019 (42).

The legalization of recreational cannabis edibles in Canada raised many questions about regulating this relatively novel class of cannabis. Because “edibles” do not meet the legal definition of a “food”, the SFCA and SFCR do not apply to cannabis edibles. To address food safety concerns for cannabis edibles, the Government of Canada amended the *Cannabis Act* and *Cannabis Regulations* to include portions of the SFCR.

Given the prohibition of cannabis in most countries around the world, few studies have analyzed regulatory frameworks for cannabis, and even fewer studies have investigated laws specifically on recreational cannabis edibles. Only a handful of studies have explored best practices for designing a regulatory system for cannabis edibles (43-46). This dearth of literature is what motivates the work presented in this thesis.

1.5 Research objectives

Besides Canada, the USA is the only other country with experience regulating cannabis edibles (though at a state-level). The dearth of literature on cannabis edibles, especially with respect to appropriate dosing, packaging, labelling, manufacturing, and distribution, is what motivates the first objective of this thesis:

Objective 1: To compare laws (within Canada and the U.S. states that have legalized the recreational use of cannabis edibles) that govern THC-infused cannabis edibles and identify any associated gaps in Canada's cannabis regulatory framework (cf. Chapter 2).

The two objectives related to the food safety of cannabis edibles (cf. Chapter 3) are:

Objective 2: To identify potential food safety hazards and health hazards associated with manufacturing cannabis edibles; and

Objective 3: To compare the SFCA and SFCR with the food safety components in the *Cannabis Act* and its supporting *Cannabis Regulations* and identify potential food safety gaps in the Canadian cannabis legislation.

The remainder of this thesis is organized as follows. First, the thesis is a manuscript-style thesis with all the references provided at the end of the thesis (instead of at the end of each chapter) to avoid duplication. In Chapter 2, we explore the similarities and differences between Canadian laws on recreational cannabis edibles and laws from states in the USA that have legalized recreational cannabis edibles (Objective 1). In Chapter 3, we describe potential food safety hazards associated with manufacturing cannabis edibles identified in the literature and highlight results from a comparative analysis between the *Cannabis Act* and the SFCA and their supporting regulations (Objectives 2 and 3). Lastly, in Chapter 4, we summarize key findings from this work, assess the implications of the findings on public health, offer recommendations to other jurisdictions considering legalization, and discuss future research directions.

INTRODUCTION TO CHAPTER 2

A modified version of Chapter 2 has been published in the *International Journal of Drug Policy* (47):

Goundar P, Macaulay T, Szafron M. A comparative analysis of laws on recreational cannabis edibles between Canada and the United States of America. *International Journal of Drug Policy*. 2021; 94:103191.

In Chapter 2, we present findings from the comparative analysis of laws on recreational cannabis edibles between Canada and the U.S.A. As outlined in Section 1.5, the research objective was to compare laws that govern THC-infused cannabis edibles between Canada and the U.S. states that have legalized edibles and identify potential gaps in Canada's cannabis regulatory framework.

The following research questions, associated with the research objectives outlined above, guide Chapter 2: (i) what states in the USA have legalized the recreational use of cannabis edibles?; (ii) what are the similarities and differences between laws on recreational cannabis edibles in Canada and states that have legalized recreational use of cannabis edibles?; and (iii) what are the gaps (if any) in Canada's regulatory framework for cannabis edibles

CHAPTER 2: A COMPARATIVE ANALYSIS OF LAWS ON RECREATIONAL CANNABIS EDIBLES BETWEEN CANADA AND THE UNITED STATES OF AMERICA

2.1 Abstract

Background

The Canadian government amended the *Cannabis Act* and *Cannabis Regulations* to legalize use of recreational cannabis edibles. Besides Canada, the USA is the only other country with experience regulating cannabis edibles, albeit at the state-level. Because of the potential health risks associated with consuming THC, we sought to compare laws (within Canada and the U.S. states that have legalized the recreational use of cannabis edibles) that govern THC-infused cannabis edibles and identify any associated gaps in Canada's cannabis regulatory framework.

Methods

For all U.S. states with laws on recreational cannabis, state-level statutes and regulations were retrieved from LexisAdvance Quicklaw and compared to requirements contained in the Canadian *Cannabis Act*, *Cannabis Regulations*, and new regulatory controls specific to cannabis edibles from the Health Canada report: Final Regulations for New Cannabis Products published in the *Canada Gazette*. A comparative analysis of these documents highlighted similarities and differences in the cannabis regulatory framework of the two countries.

Results

Twelve jurisdictions in the USA authorize recreational cannabis use as of June 20th, 2019, but only ten states outline specific requirements for edibles. Overall, regulatory requirements for cannabis edibles are largely similar in Canada and the USA; however, requirements on test result reporting and data collection are different. Canada's limits on per package THC and labelling requirements tend to be more conservative when compared to the USA.

Conclusion

To further prevent accidental consumption, Canada should require cannabis manufacturers to directly imprint edibles with a cannabis symbol, which four American states mandate.

2.2 Background

THC, a psychoactive cannabinoid produced by cannabis plants, is utilized recreationally for its intoxicating properties (48). THC may be consumed through several modes, which include ingestion, topical application, and vaporization (49). To accommodate different means of consumption, a wide range of THC-infused products with different THC levels, have surfaced in the illicit market over the years (50). In order to mitigate the public health risks associated with illicit cannabis products, on October 17, 2018, the Government of Canada enacted the *Cannabis Act* (51) and *Cannabis Regulations* (52) to legalize use of recreational cannabis products on a federal level. Initially, the *Cannabis Act* only authorized production, distribution, and sale (wholesale and retail) of five classes of cannabis (dried cannabis, fresh cannabis, cannabis plants, cannabis plant seeds, and cannabis oil). Amendments to the legislation, enacted exactly a year later, legalized three additional classes of cannabis (edible cannabis, cannabis extracts, and cannabis topicals). The delay in drafting legislation for the new classes of cannabis was partly to give regulators sufficient time to address the complexities associated with regulating these products, especially cannabis edibles.

Cannabis edibles (food products and beverages infused with cannabinoids) are particularly challenging to regulate. Few countries have codified laws on recreational cannabis edibles for regulators to draw upon. While in 2013, the Uruguayan government legalized recreational cannabis use on a federal level, sales of edibles and concentrates remain illegal (7, 38, 53). The USA is the only country with experience regulating recreational cannabis edibles, albeit only at the state level as cannabis production, distribution, and possession is still illegal under federal law (7).

Following state-level cannabis legalization in the USA, cannabis edibles, a discreet and palatable means of consuming THC, surged in popularity (23). In Colorado, cannabis edibles constituted 40 percent of the total \$700 million generated through medical and recreational cannabis sales in 2014 (54). Furthermore, cannabis edibles are increasing in popularity particularly among young adults

following legalization. One study conducted on young adults in Colorado reported 93% of respondents had used cannabis edibles in their lifetime (55). Similarly, another study found that youth from U.S. states with provisions for legal cannabis production and distribution were more likely to use cannabis edibles and the age of first use was younger (45).

Colorado's experience with the legalization of recreational cannabis edibles provides important insights into the unforeseen challenges of regulating THC-infused food products. Unlike inhaled THC, intoxication effects are delayed with the ingestion of cannabis edibles given the lengthy digestion and metabolic processes required to breakdown the THC in food products. It can take between 30 minutes to 2 hours for intoxication to manifest following the ingestion of edibles (56). Moreover, ingested THC pharmacokinetically differs from inhaled THC. During digestion, enzymes in the liver convert ingested THC into an active metabolite, 11-hydroxytetrahydrocannabinol (57), which penetrates the brain barrier more rapidly than THC (58) and results in longer lasting intoxicating effects compared to smoking (56). Inexperienced cannabis users who are unaware of the delayed intoxication effects of cannabis edibles may consume excessive amounts of THC, especially if per serving limits are not clearly indicated. For some individuals, it can lead to death as seen by the two psychosis-related suicide cases in Colorado (59). Another key concern with edibles emerging out of Colorado's cannabis legalization is unintentional consumption. Given most cannabis-infused edibles closely resemble popular conventional food items such as cookies, chocolates, and brownies, inadvertent consumption of THC products by adults and children can result in hospital emergency departments seeing increased numbers of patients (60). We sought to compare the laws (within Canada and the U.S. states that have legalized the recreational use of cannabis edibles) that govern THC-infused cannabis edibles and identify any associated gaps in Canada's cannabis regulatory framework.

2.3 Methodology

For all states with laws on recreational cannabis use, state-level statutes and regulations were retrieved from LexisAdvance Quicklaw, a legal database available through the University of Saskatchewan Law Library. Cannabis laws from three states (Maine, Michigan, and Illinois) were not available on LexisAdvance Quicklaw. For these states, regulations and bills published on state government websites were utilized instead. To determine Canadian regulatory requirements for cannabis, federal cannabis law (*Cannabis Act* and *Cannabis Regulations*) available publicly

through the Government of Canada website was reviewed while new regulatory controls specific to cannabis edibles were extracted from the Health Canada report: Final Regulations for New Cannabis Products published in the *Canada Gazette*, Part II on June 26, 2019 (61). All information contained in the laws from Canada and the USA were verified with other grey literature sources and collated into comparative tables. We present our comparisons as the laws apply to vertical integration (a business strategy where a company manages more than one component of the supply chain) (62), production and manufacturing, testing, packaging and labelling requirements, distribution and retail, taxation, and cannabis tracking systems.

2.4 Results

As of June 20th, 2019, cannabis regulations in the following jurisdictions permit production, distribution, and sale of recreational cannabis including edible forms: i. Colorado; ii. Washington; iii. Alaska; iv. Oregon; v. Massachusetts; vi. California; vii. Maine; viii. Nevada; ix. Michigan; x. and Illinois (Table 2.1). Note that while recreational cannabis use is legal in Vermont and the District of Columbia, both jurisdictions have not established regulated cannabis retail systems as of June 20th, 2019 (7). As a result, we did not analyze any laws regarding recreational cannabis from Vermont and the District of Columbia. The results presented are based on the U.S. states that have legalized recreational cannabis edibles as of June 20th, 2019.

Table 2.1: Jurisdictions in the USA that permit the production, distribution, and sale of recreational cannabis as of June 20th, 2019

State	Legislation	Year a voter initiative, bill, or legislative process was passed
Colorado	Retail Marijuana Rules, 1 Colo. Code Regs.	2012
Washington	Marijuana Licenses, Application Process, Requirements, and Reporting, Wash. Admin. Code	2012
Alaska	Regulations for the Marijuana Control Board, Alaska Admin. Code	2014
Oregon	Recreational Marijuana, Or. Admin. R	2014
District of Columbia*		2014
Massachusetts	Adult use of Marijuana, 935 Mass. Code Regs.	2016
California	Bureau of Cannabis Control, Cal. Code Regs.; Manufactured Cannabis Safety, Cal. Code Regs.	2016
Maine	Marijuana Legalization Act, Me. Rev. Stat. Ann.	2016
Nevada	Regulation and Taxation of Marijuana, Nev. Admin. Code	2016
Michigan	Marijuana Legalization Act, Me. Rev. Stat. Ann.	2018
Vermont *		2018
Illinois	Cannabis Regulation and Tax Act, 410 Ill. Comp. Stat.	2019

*Indicates jurisdictions that have not established regulated cannabis retail systems as of June 20th, 2019

2.4.1 Vertical integration

In Canada the possibility of vertical integration of the edible forms of cannabis depends on both federal and provincial law. The federal government has implemented a licensing system whereby licenses are required to engage in all aspects of the supply chain: cultivation, processing, wholesale distribution, and testing. The provincial governments issue retail licenses. Alberta, Manitoba, Ontario, Saskatchewan, and Newfoundland & Labrador do permit vertical integration. Because the provincial laws in Quebec, Prince Edward Island, New Brunswick, and Nova Scotia only permit government-owned monopolies on retail distribution and the provincial laws in British Columbia do not permit licensed producers to also be licensed retailers, complete vertical integration is not possible in these provinces. In the USA legislative requirements on vertical integration vary from

state to state. In Massachusetts (63) and Maine (64) only vertically integrated cannabis facilities can apply for a licence. Vertical integration is limited or prohibited in California, Washington, and Illinois (63). Laws in Oregon and Nevada permit vertical integration; however, it is not mandatory (63). Colorado initially required vertical integration, but it has been phased out (63). Alaska and Michigan permit vertically integrated cannabis facilities.

2.4.2 Production and manufacturing

Production of cannabis edibles (edibles containing cannabinoids) requires cultivating cannabis plants, extracting concentrated oils from plant material, manufacturing food products, testing to ensure product safety, and packaging and labelling. Canadian and U.S. state governments implemented regulatory requirements at each stage in the production of cannabis edibles to ensure public health and safety. In Canada, cannabis cultivation and cannabis edible manufacturing and testing are regulated federally by Health Canada, while provincial governments oversee the retail sales of cannabis edibles (65). In American states that have legalized recreational cannabis use, all components of cannabis edible production and distribution are primarily regulated at the state-level.

Canadian edible manufacturing facilities require a processing licence from Health Canada (61). To ensure all food safety requirements are met during the production of edibles, Health Canada integrated relevant regulatory controls from the SFCR into the *Cannabis Regulations* (61). Consequently, Canadian manufacturing facilities do not require a food safety licence under the SFCA. Health Canada can revoke an existing processing licence or refuse a new one for previous convictions under the SFCA (61). To maintain the integrity of Canada's food production system, edible cannabis products cannot be manufactured in the same building as conventional food products (61). In the USA, how food safety surrounding cannabis edibles is managed varies by state. For example, Alaska, Oregon, and Washington require edible manufacturing facilities to acquire both a food safety licence and a cannabis processing licence (66-68). Maine requires edible manufacturing facilities to obtain a commercial kitchen licence as part of the cannabis processing license (64). In Colorado, edible manufacturing facilities must complete a food safety course and are expected to comply with requirements all applicable to retail food establishments (69). Colorado, California, Oregon, and Washington, similar to Canada,

prohibit cannabis edible manufacturing in conventional food production facilities to prevent cross-contamination of products and reduce the risk of mislabelling and other errors (67-70).

As mandated by laws in Canada and ten U.S states, cannabis edibles must not be manufactured to appeal to children or youth (61). Health Canada released guidance documents informing industry of characteristics which may be taken into consideration when determining a product's appeal to children, however, licensing officials will assess on a case-by-case basis. Unlike Colorado's state regulation, which prohibits edibles shaped like a human, animal or fruit (69), Canada's federal *Cannabis Act* and *Cannabis Regulations* do not ban specific shapes or colors (61). Quebec's regulations under the provincial *Cannabis Regulation Act*, prohibit resemblance of cannabis edibles to a “toy, fruit, animal or real or fictional character” (71). Additionally, Quebec does not permit cannabis edibles that are sweets, confectionary, dessert, or chocolate (71).

Alaska, Colorado, Maine, Massachusetts, Nevada, and Oregon permit a wide range of edibles, which include refrigerated products (64, 67, 69, 72-74). Similar to California, Michigan, and Washington, cannabis edibles in Canada must be shelf stable (61, 68, 70, 75). Cannabis-infused meat, poultry, and fish products are generally prohibited unless they are dried (61). Low-acid canned cannabis edibles are also not permitted given the reduced oxygen levels in such containers present a risk of botulism (61). In terms of additives, Canada does not permit the addition of nicotine, vitamins, or minerals to cannabis edibles (61). Small concentrations of alcohol are permitted given it is a fermentation by-product in some ingredients (61). For caffeine, only ingredients with naturally occurring caffeine are permitted in cannabis edibles (61). California and Oregon have similar restrictions on nicotine and caffeine, but Oregon further prohibits polyethylene glycol and chemicals with carcinogenic effects (67, 70).

Laws on recreational cannabis edibles place limits on THC “per serving” (in the USA) or “discreet unit” (in Canada) as well as restrictions on per container amount of edible product. In both countries, a single package may contain multiple servings; however, servings must be clearly separated or distinguishable through demarcations. Health Canada restricted THC levels to 10 milligrams (mg) both per discreet unit and per container of edible product (Table 2.2). Health Canada's decision to use the term “discreet unit” as opposed to “per serving” commonly utilized in laws from the USA was to emphasize that 10 mg should not be considered a safe “dose” or standard

“serving size” for THC (61). Quebec's provincial government, however, opted to further reduce THC content in a “distinguishable portion unit” of edible cannabis product to 5 mg (71). The states Colorado, California, Illinois, Maine, Nevada, and Washington all limit the per serving THC content in edibles to 10 mg (64, 68-70, 74, 76). Three states Alaska, Massachusetts, and Oregon have a limit of 5 mg per serving while Michigan's per serving THC limit is the highest at 50 mg (66, 67, 73, 75, 77). For limits on THC per container, the states Colorado, California, Illinois, Maine, Massachusetts, Nevada, and Washington opted for a much higher limit at 100 mg (64, 68-70, 73, 74, 76). Alaska and Oregon limit THC content to 50 mg per container while Michigan, at 500 mg has the highest THC per container limit for cannabis edibles (66, 67, 75). To promote homogenous distribution of THC in cannabis edibles, Canada and seven U.S states also outline limits on THC variability (Table 2.2).

2.4.3 Testing

Regulatory bodies, both in Canada and the USA mandate testing standards to ensure safety and quality of all cannabis products, including cannabis edibles. Any cannabis that is used in the production of edibles (and the edibles themselves) must be tested for microbial contaminants, chemical impurities, and the cannabinoid content. Measuring quantities of key chemical compounds (THC, cannabidiol (CBD), tetrahydrocannabinolic acid (THCA), and cannabidiolic acid (CBDA)) helps determine the potency while microbial tests detect presence of pathogens such as *Escherichia coli*. Additionally, levels of microbial contaminants and levels of pesticides, residual solvents, and other chemical contaminants must also meet limits deemed safe for human consumption.

Under Canada's federal *Cannabis Regulations*, cultivation and processing facilities bear sole responsibility for sampling cannabis products, verifying test results received from licensed laboratories, and ensuring overall compliance with testing standards. In contrast, laws in California, Michigan, Maine, and Oregon require only trained laboratory employees to engage in the sampling process, thus safeguarding against sample tampering (64, 67, 70, 75). In Canada, testing laboratories communicate all test results directly to cannabis facilities. Licensed testing laboratories in Canada are not required to communicate failed test results directly to Health Canada (52) whereas Illinois, Maine, Massachusetts and Michigan each require laboratories to inform the state's regulatory body via electronic mail if a batch of product fails testing (64, 73, 75, 76, 78).

Table 2.2: Regulatory restrictions on cannabis edibles in Canada and the USA

THC restrictions	Canada	USA
<i>Per serving (USA) or Per discrete unit (Canada) (mg)</i>	10	5 (AK, MA, OR)
		10 (CO, CA, IL, ME, NV, WA)
		50 (MI)
<i>Per container (mg)</i>	10	50 (AK, OR)
		100 (CO, CA, IL, ME, MA, NV, WA)
		500 (MI)
<i>THC variability limits (%)</i>	15-25	10 (CA, OR)
		15 (CO, IL, MI, NV)
		20 (AK)
Product requirements	Canada	USA
<i>Restrictions on additives</i>	✓	✓ (CO, CA, MA, OR)
<i>Products must be shelf-stable</i>	✓	✓ (CA, MI, MA)
<i>Products must not be appealing to children or youth</i>	✓	✓ (AK, CO, CA, ME, MA, MI, OR, WA)
Packaging and labelling requirements	Canada	USA
<i>Plain, child-resistant, not appealing to children</i>	✓	✓ (AK, CO, CA, IL, ME, MA, MI, NV, OR, WA)
<i>Display cannabinoid content</i>	✓	✓ (AK, CO, CA, IL, ME, MA, MI, NV, OR, WA)
<i>Display universal cannabis symbol</i>	✓	✓ (CO, CA, ME, MA, OR, WA)
<i>Health warning messages</i>	✓	✓ (AK, CO, CA, IL, ME, MA, NV, OR, WA)
<i>No health or dietary claims</i>	✓	✓ (CO, CA, OR, WA)
<i>Imprint THC symbol directly on the product for solid edibles</i>	X	✓ (CO, ME, MA, NV)

2.4.4 Packaging and labelling requirements

Packaging for cannabis edibles, in both Canada and the USA, must be plain, child-resistant, and unappealing to children (Table 2.2). Additionally, in Canada, all packages for cannabis products must include the universal cannabis symbol and the cannabinoid content. Health warning messages must also be affixed to containers (61). For cannabis edibles, health warning messages should

inform consumers about the expected onset and duration of THC-related effects. Moreover, labels on cannabis edibles cannot make any health or dietary claims. For instance, cannabis-infused edibles cannot claim a product is suitable for diabetics or low in fat (61).

In the USA, all states (with laws for recreational cannabis edibles) mandate packaging and labelling requirements at least as stringent as Canada. Laws in Colorado, Maine, Massachusetts, and Nevada further require solid cannabis edibles to be directly imprinted or stamped with the THC symbol (64, 69, 73, 74). An example of an edible stamped with the THC label is shown in Figure 2.1. This requirement ensures cannabis edibles remain identifiable to consumers as a THC-infused product even when left outside the package. For liquid cannabis edibles, such as beverages, the universal THC symbol is imprinted on the package.



Figure 2.1: Example of a cannabis edible product directly stamped with the THC label. Note each square of the chocolate bar has THC stamped on it.

2.4.5 Distribution and retail

While Canada’s national legislation (*Cannabis Act* and *Cannabis Regulations*) provides regulatory oversight to federally licensed cultivating, processing, and testing facilities, provincial and territorial governments are largely responsible for implementing a regulatory framework for cannabis edible wholesale distributors and retailers (65). In all Canadian provinces and territories (with the exception of Saskatchewan), the government has a monopoly on wholesale distribution of cannabis products. In all provinces (except for Saskatchewan) if a federally licensed cannabis processor is interested in selling edibles to consumers, they would have to first sell to it the

government-operated wholesale business and buy it back before selling it to customers directly from a stand-alone retail store. In Saskatchewan, both wholesale and retail distribution are managed by the private sector (79).

In terms of in-store retail distribution, Prince Edward Island, New Brunswick, Nova Scotia, Northwest Territories, and Quebec opted for a public model while Alberta, Saskatchewan, Manitoba, Newfoundland and Labrador, and Ontario opted for a private model (80). British Columbia and Yukon have a combination of both private and public models while Nunavut does not have retail stores (80). All Canadian provinces and territories allow online sales of cannabis edibles through government-operated websites except for Manitoba and Saskatchewan where authorized private licensed retailers may sell online (65). The legal age to purchase cannabis edibles is 19 in all Canadian provinces and territories except for Alberta and Quebec, where the legal age is 18 (65). In U.S. states, where recreational cannabis use is legal and edibles are regulated, cannabis edibles are only available to consumers over the age of 21 with proof of identification at licensed retail cannabis stores. In Maine, Michigan, and Massachusetts, local municipalities have the authority to regulate or limit the operation of cannabis retail stores (7). In Washington, cannabis can only be purchased at state-licensed retail stores (68). California also issues licenses for non-storefront retailer licenses (7).

2.4.6 Taxation

In Canada, cannabis edibles are not subject to an *ad valorem* duty rate, unlike dried cannabis, fresh cannabis, cannabis plants, and cannabis plant seeds. Instead, the *Excise Act, 2001* imposes a flat-rate cannabis duty on cannabis edibles at \$0.0025 per milligram of the total THC of the product (81). In all provinces except for Manitoba, a secondary flat-rate additional cannabis duty is calculated at \$0.0075 per milligram of the total THC of the cannabis product (81). In select Canadian provinces – Alberta, Nunavut, Ontario, and Saskatchewan – the flat-rate additional cannabis duty is adjusted by 16.8%, 19.3%, 3.9%, and 6.45% respectively (81). Consumers, at the time of purchase pay a consumer sales tax which varies from 5% to 15% depending on the province (82). In the US, tax rates vary greatly from state to state with all states (except for Alaska) implementing *ad valorem* taxes ranging from 10% to 37% of retail price. Alaska, California, Colorado and Michigan impose additional cultivation taxes while Colorado and Michigan apply additional taxes to wholesale distribution (83). In Illinois, in addition to the 10% retail excise tax,

cannabis-infused edibles are taxed 20% (84). Washington has the highest excise tax (37%) collected at point of sale (7).

2.4.7 Cannabis tracking systems

To monitor the movement of all cannabis products, including cannabis edibles across the supply chain, regulatory bodies in both Canada and the USA implemented cannabis tracking systems. Canada's national CTLS is a web-based data collection tool, which collects monthly cannabis inventory from cannabis cultivators, processors, and retailers through an online portal (61). This system does not collect data from licensed testing laboratories (85). Meanwhile, in the USA, BioTrackTHC, MJ Freeway, and Metrc, three real-time seed-to-sale tracking systems are deployed, which differ from the CTLS. All licensed facilities, including testing laboratories must utilize the tracking systems to report data; however, test results are also communicated through a Certificate of Analysis.

2.5 Discussion

Currently, twelve jurisdictions in the USA authorize recreational cannabis use, however only ten states outline specific requirements for edibles. Licensing requirements, enforcement approaches, and non-compliance penalties vary across these ten U.S. states. Overall, Canada's regulation of cannabis edibles is largely comparable to regulatory controls implemented in the USA.; notably, stringent standards mandated at the testing stage of Canada's cannabis edible production closely parallel requirements outlined in laws from American states. Mandating testing standards for edible cannabis products ensures regulated products do not contain dangerous levels of chemical or physical contaminants and packages accurately represent the cannabinoid content. Furthermore, Canada's decision to monitor the flow of cannabis across the supply chain through a tracking system is another key similarity between the Canadian and American regulatory frameworks.

Comparatively analyzing laws on recreational cannabis edibles between Canada and the USA also highlighted broader differences in the test reporting requirements of these two countries. Analytical testing laboratories in Illinois, Maine, Massachusetts, and Michigan are required to communicate failed test results directly to the state's cannabis regulatory body. In contrast to these requirements in Illinois, Maine, Massachusetts, and Michigan, Canadian analytical testing laboratories are not required to communicate failed test results directly to Health Canada. In Canada, all test results are

communicated directly to cannabis cultivating and processing facilities. Consequently, these facilities are solely responsible for ensuring cannabis products that fail testing do not get distributed to retailers. Furthermore, while cannabis cultivators, processors, and retailers all provide Health Canada with inventory data through the CTLS, no data are collected from testing laboratories in Canada. This gap in Canada's regulation of cannabis can be addressed by expanding the functionality and regulatory role of the CTLS. Remodelling the current passive reporting framework of the CTLS into a more active, real-time data collection tool may be more effective for data collection and regulatory enforcement. In the USA, traceability systems such as Metrc may be promoted as advanced data collection tools providing real-time information updates; however, these systems do not always function as advertised. In Oregon, an audit of cannabis licensees revealed information was misrepresented in the state's tracking system (Metrc) allowing diversion to the illicit market (86). Canadian and U.S. states with recreational cannabis markets should evaluate their tracking systems to ensure regulatory aims are being met.

To mitigate health risks associated with accidental or overconsumption of cannabis edibles, Health Canada adopted limits on THC per package, restricted the range of available products, and implemented strict packaging and labelling requirements. Canada's conservative restrictions on THC content is significantly lower than THC limits in some U.S. states. While the 10 mg per container limit on THC was heavily criticized by industry and some members of the public, setting THC limits lower than 10 mg per container and per serving are crucial to reducing cannabis-induced acute illness in users. In addition to limits on the amount of THC, Health Canada also implemented stringent packaging and labelling requirements, which are comparable to standards implemented by most states in the USA. Given cannabis-infused edibles bear close resemblance to popular conventional food items such as cookies, chocolates, and brownies, it is likely children and adults alike may inadvertently ingest cannabis. To further reduce the risk of accidental consumption, Health Canada should consider mandating direct stamping or imprinting of cannabis edibles with the universal THC symbol, a requirement currently implemented by four states in the USA. Through a government monopoly on whole-sale distribution, most Canadian provinces have made it challenging for cannabis businesses to completely vertically integrate. A monopoly on wholesale distribution may have implications for product safety. If all cannabis edibles are distributed to retail outlets from a government-operated business, this may ensure products meet all quality and safety requirements. In Saskatchewan, while the private retail model may be better

positioned to compete with the illicit market, a potential downside is the vertical integration in the retail component may lead to price inflation of edibles as more dominant businesses emerge and the market competitiveness declines.

Appropriate pricing and taxation of cannabis edibles can play a key role in promoting public health; however, implementing rates that are high enough to deter widespread use but low enough to eliminate the illicit market is a challenge faced by regulators everywhere. While Canada and all U.S states that have legalized recreational cannabis edibles implemented taxes to increase the price of edibles, an important distinction with the Canadian taxation structure is the THC-based taxes. The Government of Canada implemented a potency-based tax for cannabis edibles, on the advice of the Task Force on Cannabis Legalization and Regulation, primarily to discourage consumers from purchasing products with high levels of THC (41). It is still too early to determine if Canada's pricing and taxation model will have the intended impact and extensive data would need to be gathered to evaluate how changes in prices affect public health, especially in terms of cannabis initiation among youth. In the USA, Colorado and Washington, the first two states to legalize recreational cannabis have experienced declining cannabis prices over the years as more efficient means of cannabis production emerged and lead to decreased taxation revenue for the state governments (7). Washington is now considering adopting a potency-based tax scheme; however, more information on the public health consequences, consumer behaviour, and feasibility is needed to guide policy decisions (87). Over the coming years, the successes and failures of Canada's taxation structure will provide invaluable evidence for other jurisdictions seeking to implement new regulatory regimes or improve existing ones.

2.6 Limitations

This analysis only compared recreational cannabis edible regulations and laws in Canada and U.S. states and did not investigate the implementation of the regulatory requirements. While the requirements outlined for cannabis edibles in the laws and regulations are stringent, they may not be executed as intended. For instance, the retail distribution of recreational cannabis edibles is outside the scope of the federal *Cannabis Act* and will likely be implemented differently across the different provinces and territories. Further research that includes discussions with regulators, policy makers and enforcement officials in each jurisdiction could develop our understanding of how

recreational cannabis edible laws are truly implemented and will be particularly useful for other jurisdictions considering legalization.

2.7 Conclusion

A comparative analysis of laws on recreational cannabis edibles between Canada and the USA offers insight into the complexities of cannabis regulation. It is evident Canadian policy makers adopted many lessons from the USA as highlighted by comparable restrictions on potency, product characteristics, packaging, and labelling. However, differences in the cannabis tracking systems and approaches to test result reporting also exist. While the long-term public health consequences of legalization are still early to determine, the similarities and differences in cannabis laws between the first jurisdictions to codify laws and regulations may, in the future, be educational for other jurisdictions considering regulation.

INTRODUCTION TO CHAPTER 3

Findings from the comparative analysis of laws on recreational cannabis edibles between Canada and the USA, presented in Chapter 2, revealed the need to further investigate the food safety element of the cannabis legislation. As a result, the following two research objectives were developed: (i) to identify potential food safety hazards and health hazards associated with manufacturing cannabis edibles; and (ii) to compare the SFCA and SFCR with the food safety components in the *Cannabis Act* and its supporting *Cannabis Regulations* and identify potential food safety gaps in the Canadian cannabis legislation.

The associated research questions explored in Chapter 3 are: (i) what are the potential food safety hazards and health hazards associated with manufacturing cannabis edibles?; (ii) how does Canada's *Cannabis Act* and its supporting *Cannabis Regulations* address food safety, and how do these requirements compare to food safety requirements outlined in the SFCA and SFCR?; and (iii) are there any food safety-related gaps in the *Cannabis Act* and its supporting regulations

CHAPTER 3: LEGALIZING CANNABIS EDIBLES IN CANADA: FOOD SAFETY IMPLICATIONS

3.1 Abstract

Background

Edibles are food products and beverages that contain chemical compounds from the cannabis plant. Compared to inhaled cannabis, edibles cause more pronounced and prolonged intoxicating effects. Developing legislation is challenging given both food and drug related hazards must be mitigated; additionally, few jurisdictions have experience regulating edibles. The Canadian government amended the *Cannabis Act* to legalize recreational cannabis edibles becoming the first country to regulate this market nationally. The research objectives were: (i) to identify potential food safety hazards and health hazards associated with manufacturing cannabis edibles; and (ii) to compare the SFCA and SFCR with the food safety components in the *Cannabis Act* and its supporting *Cannabis Regulations* and identify potential food safety gaps in the Canadian cannabis legislation.

Methods

First, to identify potential food safety hazards and health hazards associated with manufacturing cannabis edibles, a rapid review of the PubMed database was conducted. Using a ‘snowballing’ technique (that is, reviewing references within identified articles), other relevant research articles were included in the rapid review from the reference lists of eligible studies. Subsequently, the *Cannabis Act* and *Cannabis Regulations* were compared to the SFCA and the SFCR to determine how food safety-related requirements were incorporated. Omitted clauses were identified.

Results

Findings from the 25 articles reviewed in the rapid review indicated that, aside from food safety hazards, other potential hazards can also be introduced during cannabis edible production including chemical and biological contaminants like pesticides, fungus, bacteria, residual solvents, and heavy

metals. To prevent food-borne illnesses, the *Cannabis Regulations* adapted food safety requirements from the SFCR to prevent contamination of ingredients during the production of edibles. These requirements pertain to standard operating procedures, filtration systems, sanitation, quality assurance and hazard control plans. Potential gaps in the Canadian cannabis legislation were also identified. Notably, two food-safety related clauses from the SFCR were not incorporated into the *Cannabis Regulations*. Another potential gap is the lack of data collection from licensed laboratories via the CTLS, which could also have food safety implications.

Conclusion

Food safety hazards with potentially harmful health effects can be introduced during cannabis edible production. To ensure public health and safety, the Canadian government is regulating cannabis edibles like a drug rather than as food. The food safety-related requirements in the *Cannabis Regulations* are comprehensive and will play a critical role in minimizing health risks; however, potential gaps with implications for food safety were also identified.

3.2 Introduction

Edibles are food products and beverages infused with chemical compounds extracted from the cannabis plant; notable cannabinoids are THC, which has intoxicating properties, and CBD. A key distinction between ingesting cannabis edibles versus inhaling cannabis is the variation in intoxication effects. With cannabis edibles, firstly, the onset of intoxication is delayed as digestive processes must breakdown the edible to release THC, which leads some users, especially inexperienced ones to consume more product to achieve the desired intoxicating effects (56, 88). Secondly, the metabolic pathways during digestion convert ingested THC into a different metabolite (11-hydroxy-THC), which is known to cause a more pronounced and prolonged intoxicating effect (56, 89). There have been several reported cases of psychosis-related suicides among inexperienced edible users, but no such cases have been reported in cannabis smokers (88, 90). Despite these risks specific to edibles, ingesting edibles is a popular means of consuming cannabis (45, 91, 92) because they are inconspicuous, more palatable, and may also reduce users' exposures to the toxins found in smoked cannabis (43, 92).

Because there are different intoxicating effects between smoked and ingested cannabis and the production of edibles requires combining food ingredients with drugs, crafting legislation for edibles is especially complex: any regulatory requirements implemented must adequately mitigate hazards related to both food and drugs. Globally, there are few regulatory regimes that have developed regulations for cannabis edibles (7). On October 17, 2019, one year after legalizing the recreational use of select classes of cannabis, the Government of Canada amended the *Cannabis Act* to authorize production, distribution, and sale of cannabis edibles, becoming the first country to federally regulate this market. As part of this amendment, components of the SFCR were incorporated into the *Cannabis Regulations*.

In this paper, we first identify potential food safety hazards and health hazards associated with manufacturing cannabis edibles. Then, we compare the SFCA and SFCR with the food safety components related to cannabis edibles that were incorporated into the *Cannabis Act* and its supporting *Cannabis Regulations*. Lastly, we identify potential food safety gaps in the Canadian cannabis legislation.

3.3 Methodology

First, to identify potential food safety hazards and health hazards associated with manufacturing cannabis edibles, a rapid review of the literature was conducted. Rapid reviews do not have the same scientific rigour as systematic reviews and other types of evidence syntheses; however, health organizations globally are increasingly recognizing the usefulness of rapid reviews, particularly in settings where policy or decision makers require evidence within a shortened time frame (93). Rapid reviews streamline or accelerate the steps of systematic reviews and produce evidence in a timely, cost-effective, and efficient manner (93). While there are no established protocols for conducting a rapid review, various institutions, including the World Health Organization have provided guidance on the topic. It is important to note that there is no standardized one-size-fits-all approach to rapid reviews (93).

In terms of the methodology for the rapid review, the PubMed database was searched. PubMed was selected because it is a large database with literature on topics covering medicine, science, and epidemiology. Assistance on the search strategy was sought from a librarian at the University of Regina library. The following search terms were used to search the database: “cannabis edibles” AND “food safety”, “marijuana edibles” AND “food safety”. An initial search of the database was completed in June 2019, and a subsequent search using the same search terms was completed in September 2021. One reviewer compiled a list of all articles retrieved from PubMed, reviewed all the papers, and extracted the data. Using the ‘snowballing’ technique, other relevant research articles were included in the review from the reference lists of eligible studies (93). The search yielded 11 articles, all of which were reviewed. After searching the reference lists of the original articles, an additional 14 articles were identified and reviewed.

In the second component of this research undertaking, to compare the federal food safety legislation (SFCA and SFCR) with *Cannabis Act* and its supporting *Cannabis Regulations*, all laws were compiled from the Government of Canada website. A side-by-side review of the two sets of legislation was completed. Differences in clauses were noted and documented.

3.4 Results of the rapid review: potential food safety hazards and associated health risks

Potential food safety hazards may be introduced at any stage of the cannabis edible production pathway (Figure 3.1). To manufacture edibles, cannabis plants are first cultivated, and then

processed to extract chemical compounds, primarily THCA and CBDA, which are decarboxylated to produce THC and CBD, respectively. These extracted chemical compounds are then combined with food ingredients to make edibles.

During cultivation, cannabis plants can be exposed to a wide range of chemical and biological contaminants such as pesticides, fungal and bacterial pathogens, and heavy metals. Pathogenic microbes, such as fungi (*Penicillium* sp., *Aspergillus* sp., and *Fusarium* sp.), and bacteria (*Acinetobacter baumannii*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Ralstonia pickettii*, *Salmonella enterica*, *Stenotrophomonas maltophilia*, and *Clostridium botulinum*) have been detected in cannabis plants (94, 95). Mycotoxins and aflatoxins produced by the fungal pathogens *Penicillium* sp., *Aspergillus* sp., and *Fusarium* sp. can adversely affect human health as they are carcinogenic, and can also potentially damage the lungs, liver, kidneys, and the nervous system, especially in immunocompromised individuals (96). Of the fungal pathogens, *Aspergillus* is of the greatest concern as cannabis infected with this pathogen has previously been directly associated with human illness and death (94). While most bacterial pathogens present on cannabis plants have not been directly linked to illness in humans, some pathogens pose a potential risk. *Escherichia coli*, *Salmonella*, and *Clostridium* are a few common species of bacteria that have been associated with cannabis and are known to cause serious illness in humans (94).

Besides pesticides and biological pathogens, heavy metals, including cadmium, lead, magnesium, and copper have also been detected in cannabis plants and in products derived from them (97-101). Cannabis plants absorb and accumulate heavy metals in plant tissue from contaminated soil, and upon consumption, these heavy metals remain in the human body causing health problems such as cancers and neurological disorders (102, 103). Notably, of the heavy metals, lead is of particular concern because it has previously been added to cannabis to increase its weight (97). For example, in Germany, hundreds of people suffered from symptoms of lead poisoning after consuming cannabis which had been deliberately cultivated with high levels of lead (97).

After cultivation, cannabis plants are processed to extract chemical compounds, primarily THCA and CBDA. The primary hazards during the extraction process are pesticides and residual solvents. Since many of the pesticides used during cannabis cultivation are lipid soluble, they dissolve readily in solvents used for cannabinoid extraction, raising further concerns about the concentration

of these pesticides in extracts (96). While solvent-less methods of cannabis extraction are an option, they usually offer reduced yields of cannabinoids and decreased concentrations compared to solvent-based methods (104). Commonly used solvent-based methods utilize: (i) hydrocarbons such as butane; (ii) liquid hetero-hydrocarbons like ethanol; or (iii) inert gas such as supercritical carbon dioxide. Butane extractions are popular in the USA as they produce highly concentrated extracts; however, the downsides of this method are toxic residues from the fuel additives and the fire hazard it creates (104). Carbon-dioxide-based extractions are generally considered to be safe, non-toxic, and environmentally friendly (104).

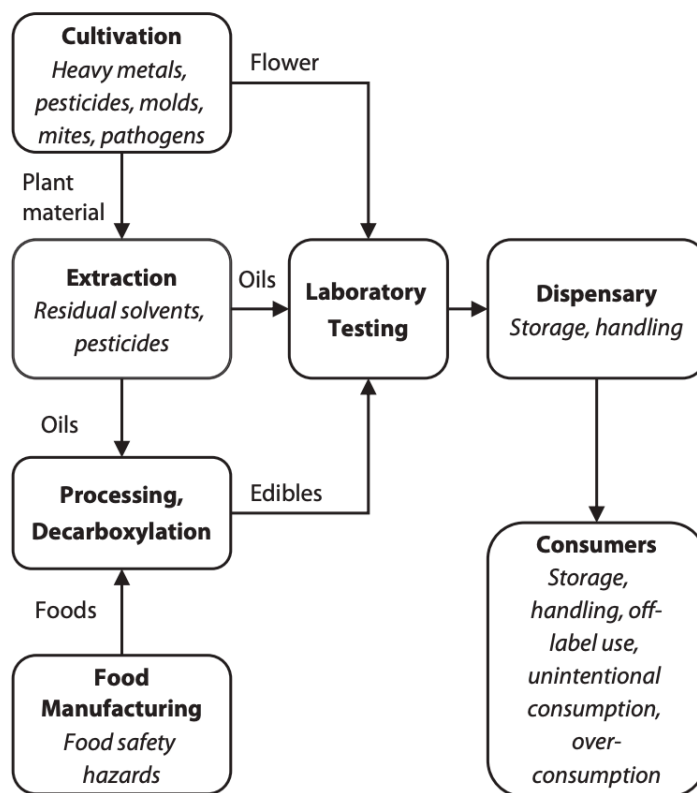


Figure 3.1: Cannabis Edibles Processing and Associated Hazards. Reproduced with permission from the American Public Health Association. Source: White AE, Van Tubbergen C, Raymes B, Contreras AE, Scallan Walter EJ. Cannabis-Infused Edible Products in Colorado: Food Safety and Public Health Implications. Am J Public Health. 2020;110(6):790-5 (106).

Following cannabinoid extraction, THCA and CBDA must be converted to THC and CBD respectively using heat in a process known as decarboxylation, which can occur prior to food processing or during food processing (105).

When manufacturing edibles by combining THC and/or CBD with food ingredients, food safety plans, hazard analysis critical control point plans, and standard operating procedures should be developed (106). After production, products should be tested to ensure levels of biological and chemical contaminants, product homogeneity, and the cannabinoid content are within acceptable levels prior to packaging (106). Proper labeling and packaging guidelines must be followed to prevent unintentional or overconsumption by consumers and safe food handling protocols must be followed at all stages, even during distribution and retail sales, to avoid product contamination (43, 106).

Several studies have detected a wide range of chemical and biological contaminants (such as pesticides, fungal and bacterial pathogens, and heavy metals), not only in cannabis plants, but also in their derivative products (96, 98, 100, 107). A 2016 U.S. study conducted on legally sourced cannabis products found 85% (22 out of 26) of the samples studied tested positive for pesticides and exceeded permissible contaminant limits with many samples containing multiple contaminants (insecticides, miticides, and fungicides) (107). The adverse health effects of these contaminants range from changes in weight to disruptions in hormone production; plant growth regulators are also known to be carcinogenic to humans (108-110). The question then becomes, “What is being done in Canada to mitigate the food safety hazards associated with cannabis edibles?”

3.5 Addressing food safety in Canada’s *Cannabis Act* and *Cannabis Regulations*

In Canada, food products are regulated under the FDA and its supporting *Food and Drugs Regulations* (FDR) as well as the more recent SFCA and SFCR. The primary food safety legislation, FDA and FDR outline requirements on food labelling, advertising, fortification, additives, chemical hazards, microbial hazards, and pesticides. The other food safety legislation, SFCA and SFCR, which came into force on January 15, 2019, consolidated 14 different regulations and outlined additional requirements for businesses that import or prepare food for export or interprovincial trade. In addition to federal requirements, food production facilities must also abide by provincial and territorial regulations.

Since cannabis edibles are not legally considered food in Canada, the FDA, FDR, SFCA, and SFCR do not directly apply to cannabis edible manufacturers. Instead, Health Canada has opted to

integrate relevant requirements from these regulations into the *Cannabis Act* and *Cannabis Regulations* to help minimize food safety risks during cannabis edible production. As such, all levels of cannabis production, including the manufacturing of edibles, are primarily regulated under the *Cannabis Act* and *Cannabis Regulations*. This approach minimizes any confusion arising from having facilities subjected to multiple legislations. Consequently, to manufacture cannabis edibles, cannabis processing facilities must only acquire a license from Health Canada under the *Cannabis Act*; a food safety license under the SFCA is not required.

3.6 Comparing the SFCA and SFCR with relevant components of the *Cannabis Act* and *Cannabis Regulations*

To reduce the risks associated with hazards such as pesticides, heavy metals, fungal pathogens, and bacteria, which have the potential to be introduced during cannabis cultivation, the *Cannabis Regulations* require each contaminant to be within limits considered safe for human consumption (Table 3.1). Similarly, for chemical contaminants such as residual solvents which are used in cannabinoid extraction, concentrations must be within generally accepted tolerance limits for human use as identified in the FDA (Table 3.1). For cannabis edibles specifically, processors are required to test the “input” cannabis prior to combining it with food ingredients to manufacture edibles. In addition to these requirements, which also apply to other classes of cannabis products, the most extensive requirements pertaining to cannabis edibles have been adapted from the SFCR.

To prevent food-borne illnesses, Part 5 of the *Cannabis Regulations* outlines good production practices, many of which have been adapted from the SFCR to prevent contamination of ingredients during the production of edibles (Table 3.1). Firstly, if a cannabis processor intends to process cannabis and manufacture other food products on the same site then activities related to each must be conducted in separate buildings. This requirement is critical in mitigating the risk of cross-contamination, mislabelling, and product errors. Furthermore, each building used for cannabis processing must have a ventilation system that circulates clean air into the facility and filters out unclean air. Cannabis processing facilities are also required to develop standard operating procedures for production, packaging, labelling, distribution, sampling and testing of each ingredient that will be used. In addition to standard operating procedures, they must also develop sanitation programs and a written preventive control plan. For sanitation programs, the *Cannabis Regulations* outlines explicit requirements for hand cleaning and sanitizing stations, lavatories, and protective employee clothing, all of which are consistent with the SFCR. In terms of preventive control plans, cannabis processing facilities must prepare a plan that identifies potential hazards posing a contamination risk and outline control measures to address each risk. Facilities will be required to implement the preventive control plan and provide supporting documentation as evidence that the requirements outlined in the plan are met. The preventive control plan is partly administered by a Quality Assurance Person, who is trained and qualified to investigate and mitigate any hazard that poses a risk to human health. Furthermore, while the *Cannabis Regulations*

do not outline specific educational requirements for workers employed at licensed processing facilities, all employees involved in cannabis edible processing must be appropriately qualified to undertake responsibilities. Table 3.1 provides a summary of the key food safety-related requirements that Health Canada has adapted for the *Cannabis Act* and *Cannabis Regulation*.

Table 3.1: Summary of requirements outlined in the Canadian *Cannabis Act* and *Cannabis Regulations*

Hazards associated with processing cannabis edibles by stage	Requirements outlined in the Canadian <i>Cannabis Act</i> and <i>Cannabis Regulations</i>
Cultivation	
Pesticides Fungal pathogens Bacterial pathogens Heavy metals	<ul style="list-style-type: none"> • Must be on Health Canada’s list of pest control products approved for use on cannabis under the <i>Pest Control Products Act</i> • Limits of quantification for pesticide active ingredients • Must be within generally accepted tolerance limits for human use as identified in the <i>Food and Drugs Act</i> • Must be within generally accepted tolerance limits for human use as identified in the <i>Food and Drugs Act</i> • Must be within generally accepted tolerance limits for human use as identified in the <i>Food and Drugs Act</i>
Extraction	
Chemical contaminant (e.g., residual solvents) Pesticides	<ul style="list-style-type: none"> • Must be within generally accepted tolerance limits for human use as identified in the <i>Food and Drugs Act</i> • Must be within maximum residue limits that are specified in relation to cannabis in the <i>Pest Control Products Act</i>
Food Manufacturing	
Food safety hazards	Good Production Practices: <ul style="list-style-type: none"> • Standard Operating Procedures • Filtration System and Ventilation • Sanitation Program • Quality Assurance • Preventive Control Plan
Distribution	
Storage and handling	<ul style="list-style-type: none"> • Standard Operating Procedures

3.7 Potential gaps in the Canadian cannabis legislation

To ensure that Health Canada adapted all food safety-related requirements from the SFCR into the *Cannabis Regulations*, we compared the two sets of regulations to identify potential gaps.

While all the key food safety requirements outlined in the SFCR were integrated, the following two clauses were omitted:

i. Reporting of disease, illness, symptoms and lesions (111) p.46

“Any person who works in an area where a food is manufactured, prepared, stored, packaged or labelled or where a food animal is slaughtered and who has a disease or illness, symptoms of a disease or illness or an open or infected lesion must report them to the operator.” And;

ii. Communicable disease and lesions — risk of contamination (112) p.47

“The operator must prevent any person who is suffering from, or is a known carrier of, a communicable disease or who has an open or infected lesion from entering or being in an area of an establishment where a food is manufactured, prepared, stored, packaged or labelled or where a food animal is slaughtered if the person’s condition presents a risk of contamination of the food.”

Omission of these clauses likely will not have significant implications for food safety in cannabis processing facilities; however, these requirements seem important in mitigating risks associated with communicable disease and likely should have been included in the *Cannabis Regulations*. Workers infected with a communicable disease can potentially transfer pathogens in the processing facility, contaminating ingredients and increasing the risk of disease transmission.

Another potential gap in Canada’s cannabis legislation pertains to the cannabis tracking system. Part 6 of the *Cannabis Act* authorizes the federal government to establish a national cannabis tracking system to collect data primarily for the purposes of ensuring cannabis is not diverted to the illicit market. Under the *Cannabis Act*, the federal government issued the Cannabis Tracking System Order, which requires cannabis licence holders to provide inventory data to Health Canada on a monthly-basis using a public-facing web-based application. This requirement only applies to cannabis cultivators, processors, distributors, and retailers; data is not collected from cannabis testing laboratories. In Canada, if a batch of cannabis edibles fail any of the mandatory testing requirements, cannabis testing laboratories are not required to promptly disclose the failed test results to Health Canada as is required in some US states. Failed test results are communicated directly to the cannabis facilities and the onus is on them to ensure products meet quality standards prior to distribution. This gap may have significant implications in terms of food safety, especially

if Health Canada will not closely monitor products that fail testing requirements. While the tracking system requirements outlined for cannabis facilities are primarily implemented for the purposes of ensuring legality, improving the tracking system to collect data on potential public health hazards and collecting data from testing laboratories can greatly assist cannabis processing facilities and Health Canada respond promptly to incidents posing a risk to human health.

3.8 Limitations

The main limitation of this research is the use of the rapid review methodology, which in general is less comprehensive and more prone to bias compared to systematic or scoping reviews. Furthermore, due to time and resource constraints, the review was completed by an individual researcher, and a quality assessment of the studies was not conducted. Lastly, only a single database was searched for literature. With respect to the comparative analysis between the cannabis legislation (*Cannabis Act* and *Cannabis Regulations*) and the food safety legislation (SFCA and SFCR), the main limitation of the analysis is that it was restricted to a review of the written legislation. An investigation into how legal requirements are implemented and enforced would have provided valuable information; however such research was feasible at the time the research was conducted.

3.9 Conclusion

Regulating the production of cannabis edibles is challenging because it combines two vastly different industries of food and drugs; therefore, any policies implemented must effectively address potential risks to human health in both fields. There are numerous hazards associated with cannabis edible production and they can be introduced at any stage in the production pathway. To ensure public health and safety, Health Canada opted to regulate cannabis edibles like a drug rather than as food. As such, the *Cannabis Act* and *Cannabis Regulations* are the sole legislation regulating the production of cannabis edibles in Canada and any requirements pertaining to food safety were adapted from the SFCR. Overall, the requirements addressing food safety in the *Cannabis Regulations* are extensive and will be critical in minimizing risks associated with food manufacturing. Potential gaps with implications for food safety were also identified. Improving the existing cannabis tracking system to collect and monitor data on product quality could greatly reduce food-borne illness and other risks associated with edibles. While it is still early to determine

whether the cannabis legislation will adequately reduce food safety-related risks, Canada's approach to regulating cannabis edibles will provide important insight for other jurisdictions considering legalization.

CHAPTER 4: KEY FINDINGS, DISCUSSION, AND FUTURE DIRECTIONS

This work focuses on Canada's regulatory framework for recreational cannabis edibles. First, we compared Canadian laws on recreational cannabis edibles to state-level statutes and regulations implemented in the USA and examined the differences. Then we examined how Canada dealt with food safety issues related to cannabis edibles by comparing Canada's food safety legislation (SFCA and SFCR) to the cannabis legislation (*Cannabis Act* and *Cannabis Regulations*) and highlighted potential gaps. In this chapter, we summarize key findings associated with our study objectives, discuss potential implications for cannabis policy, examine implications for public health, and explore avenues for future research.

4.1 Discussion of key findings

Ten U.S. states (Colorado, Washington, Alaska, Oregon, Massachusetts, California, Maine, Nevada, Michigan, and Illinois) had legalized and implemented a market for cannabis edibles as of June 20th, 2019. Two other jurisdictions, Vermont and District of Columbia legalized recreational cannabis use but had not implemented cannabis retail systems as of June 20th, 2019 (7) consequently, laws on recreational cannabis edibles from Vermont and the District of Columbia could not be analyzed. This was an unexpected finding from the comparative analysis given the U.S. federal government's prohibition on cannabis. In the absence of an overarching federal legislation, cannabis statutes varied considerably among states. The path to cannabis legalization varied from state to state and the overall regulatory systems implemented differed. Nevertheless, there is a gradual trend towards liberalizing cannabis policies in the USA. An increasing number of U.S. states are considering the legalization of cannabis and in the future, more states will likely move towards legalizing or decriminalizing recreational cannabis use.

Through the comparative analysis of laws on recreational cannabis edibles, we found that state-level requirements in the USA were similar to Canadian requirements in the following areas: (i) stringent standards mandated at the testing stage of cannabis edible production; (ii) the requirement

for packaging to be plain, child-resistant, and unappealing to children; and (iii) the implementation of tracking systems to monitor the movement of cannabis across the supply chain. Important differences were also identified in the following regulatory requirements: (i) the limits on THC permitted per package of cannabis edibles; (ii) the requirement to report failed test results by cannabis testing laboratories to the regulatory body; and (iii) the requirements pertaining to the application of THC labels directly on the product itself.

With respect to food safety, through the rapid review, we found that a wide range of chemical and biological contaminants, such as pesticides, bacterial and fungal pathogens, heavy metals, and residual solvents used during cannabis cultivation or cannabinoid extraction can serve as potential hazards in the production of cannabis edibles. In addition, biological and chemical food safety hazards arising from improper food handling or storage protocols and due to poor hygiene practices can also be introduced during the production of cannabis edibles. Examples of biological hazards include bacteria, fungi, and viruses while common chemical hazards are cleaning agents or additives.

To address potential food-safety hazards, the *Cannabis Regulations* incorporated many food-safety related requirements from the SFCR and FDA. A key adaptation from the FDA is the requirement for pesticides, heavy metals, fungal pathogens, and bacteria to be within limits considered safe for human consumption. Similarly, to prevent the introduction of food safety hazards, the *Cannabis Regulations* also incorporated a comprehensive list of good production practices from the SFCR such as the development of standard operating procedures, installation of filtration and ventilation systems, implementation of sanitation programs, and ensuring a qualified quality assurance person is present during production who can also administer a written preventive control plan. Potential gaps, however, were also identified. Two clauses in the SFCR were omitted from the *Cannabis Regulations*. The first clause pertains to the reporting of diseases, and the second clause is related to restricting access of individuals infected with communicable diseases in the food processing area. While we recognize cannabis processing facilities are required to develop written Preventative Control Plans and it is possible that requirements to report communicable diseases and other illnesses will be addressed through these plans, there is no guarantee.

Considering that Canada moved forward with the legalization of edibles despite the limited research available on the topic, restricting THC in edibles to 10 mg per package will play a vital role in minimizing the potential harms associated with edibles. Canada's per package limit on THC is 10 times lower than the amounts permitted per package in most U.S. states that have legalized edibles. Though legal cannabis markets have been established in USA, Uruguay, and now Canada, there is currently no established scientific consensus on the quantity of THC that constitutes a standard serving size; this has led to variable THC limits on cannabis edibles in different markets as found through the comparative analysis. Evidence from the scientific literature indicates that 2.5 mg of orally-ingested THC is sufficient to illicit an intoxicating response in an average healthy adult (113). In alignment with this finding, while Canada's current guidance on 'lower risk cannabis use' does recommend novice users start with products that contain 2.5 mg THC or less, there is a possible risk of inadvertent overconsumption with edibles (114). For instance, if a package contains a single cookie with 10 mg THC, novice cannabis users would likely consume it all in one sitting rather than slowly ingesting it in halves or quarters. Results from a recent study corroborate this assumption, reporting that less than 15% of cannabis edible consumers can correctly identify a standard serving of THC; respondents provided an average value of 26 mg as a standard serving, a value notably higher than the suggested 2.5 mg (115). While ingesting 10 mg of THC has shown to cause strong, albeit acute, overall drug effects in inexperienced users, (116) the dose-dependent risks associated with THC would rise markedly if THC limits increased.

In addition to protecting inexperienced cannabis users, the 10 mg limit also mitigates some of the risks associated with accidental consumption of edibles by young children. In 2022, a four-year old in the USA died after accidentally consuming THC-infused gummy bears (117). Emerging research indicates that since the legalization of edibles, an increasing number of children are presenting to the emergency department after accidentally ingesting edibles (118). While cannabis-related deaths in children have not been reported in Canada yet, the increased number of hospitalizations are concerning, and pose a burden to a resource-strained healthcare system. As policymakers work towards establishing standardized THC serving sizes (119), it would be prudent for regulators to maintain the current limits on per package THC to 10 mg. Capping THC levels per package, despite the pressure from the cannabis industry, will help mitigate the harms associated with overconsumption of edibles by adults and accidental consumption by children, and help promote

overall safer patterns of use. Restricting THC in edibles is an integral component of a public health approach to cannabis regulation, and current Canadian limits on THC should be maintained.

In addition to limits on THC, Canada's requirements for plain, child-resistant packaging are important restrictions for protecting the public. Canadian labelling requirements on cannabis edibles could have been further strengthened if Health Canada required THC labels to be directly applied on the product itself, a requirement mandated by four U.S. states. Not only would direct stamping of cannabis edibles with the THC symbol help consumers identify THC-infused edibles from similar non-THC confectionaries when left outside the package, recent research evidence suggests that THC stamps can help novice users judge THC serving sizes in a cannabis edible more accurately (115). One study found that when packaging was manipulated to include THC stamps, 50% of study participants were able to correctly identify a serving of THC (115). Colorado, one of the first states to legalize edibles, did not mandate THC stamps until 2016, four years after legalizing cannabis edibles. To comply with the requirements, edible manufacturers incurred costs ranging from \$35,000 to \$100,000, replacing their existing packaging and developing new stamp moulds (120). Regulators in Colorado could likely justify the high costs associated with this regulatory change given that manufacturers were permitted to sell cannabis edibles with THC levels as high as 100 mg, which is not the case in Canada. Given the high costs associated with implementing direct labels or THC stamps, this requirement, may be viewed by the cannabis industry as cost prohibitive. However, the *Cannabis Act* is currently undergoing a legislative review and public health participants have suggested labelling requirements for edibles be strengthened to include direct labelling of edibles (121). Whether the expert review panel includes this in their recommendations is yet to be determined; however, this is an important requirement for policymakers to consider especially if a public health-centered approach to cannabis legalization is adopted.

Another component of a public-health focused approach to cannabis legalization is monitoring the production of cannabis across the supply chain (122). In Canada, cannabis cultivators, processors, and retailers all provide Health Canada with inventory data through the CTLS; no data are collected from testing laboratories in Canada which we identified as a potential gap in Canada's cannabis regulatory system. In contrast, several U.S. states require licensed laboratories to report failed test results directly to the state regulator. While it may not be necessary for analytical testing

laboratories in Canada to report all failed test results to Health Canada directly, some regulatory mechanism should be implemented to closely monitor the testing component of the supply chain. Researchers have noted that the absence of a nationally validated method for cannabinoid testing is a key weakness in Canada's cannabis quality control standards, which could result in lab-to-lab variability in testing and inconsistencies in the results reported (123). In U.S. states with legal cannabis markets, laboratories have been found to be non-compliant with testing requirements (124, 125). Regulators in Washington, for instance, noted systematic variances in the test results reported by certified laboratories, and upon investigation, suspended licenses of several certified laboratories citing deficiencies in testing practices (124). As recently as this year, regulators in Washington suspended licenses of cannabis testing labs for noncompliance, and reportedly, similar action has been taken by regulators in other states including Florida, Michigan, and Nevada (125). Regulators in these states were likely able to trace the activities of non-compliant testing laboratories through seed-to-sale tracking systems, an important tool that can be used to comprehensively monitor the activities of licensed cannabis facilities.

Both Canada and the U.S. states that have legalized recreational cannabis edibles have implemented tracking systems to monitor the flow of products across the supply chain, however there are differences in the programs employed in the two countries. In the USA, states that have legalized recreational cannabis employ real-time tracking systems such as BioTrackTHC, MJ Freeway, and Metrc, which were derived from medical software originally created to track prescription drugs and assist regulators with preventing the diversion of drugs (122). While the US-based seed-to-sale tracking systems are promoted as advanced data collection tools providing real-time information updates; they may not always function as advertised (86). Furthermore, there are recommendations from policymakers in the USA to implement a single, federal, seed-to-sale tracking system for the best public health outcomes (122). There is very little research published on the cannabis seed-to-sale tracking systems in the USA to determine best practices for implementing similar systems in Canada. Research on data from Washington's seed-to-sale tracking system, one of the few states in the USA to make their seed-to-sale data publicly available, has helped improve the knowledge base on the legal cannabis market (122). Based on the demonstrated utility of Washington's seed-to-sale tracking system, remodelling the current passive reporting framework of Canada's CTLS into a comprehensive data collection tool, with oversight

provided by the regulator, may not only improve data collection and regulatory enforcement, but also provide valuable data for public health research.

4.2 Policy and public health implications

Canada has developed a comprehensive national legislative framework for recreational cannabis edibles centered around public health and safety. While the national cannabis legislation (*Cannabis Act* and *Cannabis Regulations*) incorporated key restrictions to protect public health, through this research undertaking, we identified opportunities to strengthen Canada's regulatory requirements, to better protect the health of Canadians. The findings will also be useful for policymakers who are considering the legalization of cannabis edibles for recreational purposes in their jurisdictions, and for researchers investigating cannabis edible policies.

Firstly, from a public health perspective, the potency cap of 10 mg per-package on cannabis edibles, is a critical component of Canada's legislative framework. Not only will this reduce some of the risks associated with inadvertent overconsumption of edibles by adults or accidental consumption by young children, but limits on THC also promote moderation in cannabis use long term. As the market for recreational cannabis edibles expands and more Canadian cannabis consumers, particularly inexperienced users, learn how to correctly identify what "high" vs. "low" THC is, how to correctly identify the level of THC in their product or how much to consume to get the desired intoxicating effect, maintaining the limit to 10 mg will help prevent edible-related harms such as accidental overdoses and increased poisoning-related hospitalizations. We recommend the Canadian government maintain the current restriction on cannabis edibles to 10 mg per-package.

Secondly, in terms of packaging and labelling requirements, Canadian requirements currently do not require cannabis edibles to be directly labelled or imprinted with the universal THC symbol. Direct labelling or stamping of products with the THC symbol helps edibles remain identifiable as cannabis products outside of the package, helping to mitigate accidental consumption, reducing cases of acute cannabis-related poisoning, and minimizing the need for emergency hospital care. Importantly, direct labelling of cannabis edibles helps more cannabis users correctly identify standard serving sizes and is an additional reminder to users that while edibles may look like regular food items or confectionaries, they are in fact infused with THC. While implementing direct labelling requirements in Canada will incur additional costs for edible manufacturers and may lead

to resistance from the cannabis industry, labelling products directly is important in protecting public health. We recommend that policy makers consider mandating the direct labelling of cannabis edibles with a THC symbol.

Lastly, the findings from this research undertaking suggest that there is opportunity to improve the existing cannabis tracking system to have a greater focus on public health. With the current tracking system mostly collecting inventory data from cannabis license holders, and laboratories not being required to report products that failed testing, the tracking system appears to have been implemented with the primary aim of monitoring the diversion of products between the licit and illicit market. Expanding the existing tracking system to allow regulators to actively monitor the activities of cannabis license holders would help ensure cannabis products remain safe for public consumption. While there is limited published research on developing public-health focused cannabis tracking systems, government-backed seed-to-sale tracking systems implemented in USA appear to have more advanced data collection tools, although there have been challenges identified with these programs as well (86). While implementing a similar cannabis tracking system in Canada would require significant resources, investing in a more robust tracking, and data collection systems will be useful for protecting public health and safety. Our recommendation is for policy makers to consider expanding the functionality of the cannabis tracking system to allow more active compliance monitoring.

The federal government's primary aim with cannabis legalization was to protect public health and safety. More specifically, the objectives of legalization were to prevent young persons from accessing cannabis, to protect public health by establishing stringent regulatory requirements that ensure product safety, minimize criminal activity linked to the illicit cannabis market and reduce the associated burden of enforcement. While Canada has developed a comprehensive, public-health focused legislative framework, findings from our research undertaking indicate that there may be potential regulatory gaps. Addressing these gaps may help strengthen Canadian laws on recreational cannabis edibles and further protect the health of the population.

4.3 Future work

Cannabis, and more specifically recreational cannabis edibles were legalized in Canada based on relatively little research evidence. One of the mandates of the *Cannabis Act* is a three-year

independent review of the legislation by an external expert panel, which is currently in progress. Findings from the first phase of the review, which included extensive consultations with a wide range of stakeholders and experts, noted participants' disappointment with the lack of evidence and the slow progress of research in many areas, partly linked to the COVID-19 pandemic. Post-pandemic, the scope of future research on cannabis is expansive, and studies that collect long-term data will be particularly helpful in determining whether establishing a regulatory framework aided in minimizing public health risks, as intended.

This thesis exclusively analyzed written laws, focusing on legislative differences, to draw meaningful lessons for Canada's regulatory framework for cannabis edibles; the extent to which these laws are implemented and enforced was not examined. A follow-up study focussing on implementation that incorporates interviews with stakeholders, policy makers, industry, and enforcement officials would offer further insight into how different jurisdictions are managing the complexities of regulating recreational cannabis edibles. More research is needed to understand the differences between the various cannabis tracking systems implemented in the USA. (Biotrack, MJ Freeway, and Metrc) and in Canada (CTLS) to understand whether these programs are functioning as intended. In terms of investigating the safety of legal cannabis edibles products, studies that test a random selection of products from licensed Canadian retailers would be useful to determine whether license-holders are complying with legislative requirements for contaminants and cannabinoid content. Similar studies conducted previously in U.S. states with legal markets for cannabis edibles found that a sizeable portion of products exceeded permissible cannabinoid and contaminant levels (107, 126).

Prior to the implementation of the *Cannabis Act*, in 2017, Health Canada launched the Canadian Cannabis Survey to obtain baseline population-level data on knowledge and behaviours related to cannabis use, patterns of use, modes of consumption, and sources of obtaining cannabis. Every year since then, Health Canada has continued to collect data. Few research studies have quantitatively analyzed the available data, especially in terms of investigating use of cannabis edibles. Analyzing the available data will provide additional valuable information for policy makers and public health professionals and can play a key role in improving cannabis policy and development of targeted health promotion initiatives.

Lastly, while this thesis primarily focused on the federal legislation for cannabis, provinces do have jurisdiction over the retail component of the supply chain, and each province has set up a unique retail system and crafted separate provincial legislation. A few provinces (Nova Scotia, Quebec, and Prince Edward Island) have implemented exclusively government-operated retail systems while others like Manitoba, Alberta, Saskatchewan and Nunavut have only private systems. Other provinces (British Columbia, Newfoundland and Labrador, New Brunswick, Ontario, Northwest Territories and Yukon) have opted for a combination of both (127-129). A few studies have contemplated the potential public health implications of each retail model (130, 131), however a focused study exploring the inter-provincial differences in retail systems, provincial legislation, vertically integrated versus non-integrated facilities, and various taxation schemes can provide important information for other jurisdictions considering cannabis legalization.

4.4 Conclusion

With the legalization of recreational cannabis (including edibles), Canada is paving the path for progressive, harm-reduction focused drug policies. Many jurisdictions will seek insight from the Canadian regulatory system as they consider the legalization of cannabis. Overall, Canada's regulatory framework for recreational cannabis edibles is well-developed and evidence informed with a strong focus on public health. The single most important requirement adopted by Canadian policymakers is the conservative limit of 10 mg per-package of cannabis edible product. Maintaining this stringent requirement will help reduce many of the harms associated with recreational cannabis edibles.

While the requirements outlined in the *Cannabis Act* and *Cannabis Regulations* will play a critical role in reducing the public health risks associated with recreational use of cannabis edibles; there are opportunities for further strengthening the requirements. Other areas for improvement include: (i) strengthening existing labelling requirements by mandating the direct labelling or stamping of the THC symbol directly on cannabis edibles; and (ii) expanding the functionality of the existing tracking system to better monitor product quality and safety. By improving these areas of the current regulatory system, Canada's legislative framework can become a standard for other countries considering the legalization of cannabis. While the Canadian regulatory experience offers useful insight to other jurisdictions considering legalization, more research on cannabis is needed in many areas including appropriate dosing, effective packaging and labelling requirements,

cannabis tracking systems, the benefits and risks associated with different regulatory systems, and the impacts of private versus public retail models on public health and safety.

REFERENCES

1. Russo EB. History of Cannabis and Its Preparations in Saga, Science, and Sobriquet. *Chem Biodivers*. 2007;4(8):1614-48.
2. Gaoni Y, Mechoulam R. Isolation, Structure, and Partial Synthesis of an Active Constituent of Hashish. *J Am Chem Soc*. 1964;86(8):1646-7.
3. Atakan Z. Cannabis, a complex plant: different compounds and different effects on individuals. *Ther Adv Psychopharmacol*. 2012;2(6):241-54.
4. MacDonald T. A Weed by Any Other Name: Culture, Context, and the Terminology Shift from Marijuana to Cannabis. *Ohio State Legal Studies Research Paper No 750*. 2023.
5. World Health Organization. Cannabis [Internet]. Geneva: World Health Organization; [cited 2019 Oct]. Available from: <https://www.who.int/teams/mental-health-and-substance-use/alcohol-drugs-and-addictive-behaviours/drugs-psychoactive/cannabis>.
6. Government of Canada. The Different Forms of Cannabis [Internet]. Ottawa: Government of Canada; 2018 [cited 2019]. Available from: <https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/about.html>.
7. World Drug Report 2019. Vienna: United Nations; 2019 [cited 2019 Jun]. Available from: https://wdr.unodc.org/wdr2019/prelaunch/WDR19_Booklet_5_CANNABIS_HALLUCINOGEN_S.pdf.
8. Bahji A, Stephenson C. International Perspectives on the Implications of Cannabis Legalization: A Systematic Review & Thematic Analysis. *Int J Environ Res Public Health*. 2019;16(17):3095.
9. Degenhardt L, Ferrari AJ, Calabria B, Hall WD, Norman RE, McGrath J, et al. The Global Epidemiology and Contribution of Cannabis Use and Dependence to the Global Burden of Disease: Results from the GBD 2010 Study. *PLoS One*. 2013;8(10):e76635.
10. Adamson P. Child Well-Being in Rich Countries: A comparative overview. Florence: UNICEF Office of Research; 2013.
11. Government of Canada. Canadian Tobacco, Alcohol and Drugs Survey (CTADS): summary of results for 2017 [Internet]. Ottawa: Government of Canada; 2021 [cited 2019 Oct]. Available from: <https://www.canada.ca/en/health-canada/services/canadian-alcohol-drugs-survey/2017-summary.html>.
12. Health Canada. Canadian cannabis survey 2017 - summary [Internet]. Ottawa: Health Canada; 2017 [cited 2019 Oct]. Available from: <https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/canadian-cannabis-survey-2017-summary.html>.
13. Leos-Toro C, Rynard V, Murnaghan D, MacDonald J-A, Hammond D. Trends in cannabis use over time among Canadian youth: 2004–2014. *Prev Med*. 2019;118:30-7.
14. Bonner WIA, Andkhoie M, Thompson C, Farag M, Szafron M. Patterns and factors of problematic marijuana use in the Canadian population: Evidence from three cross-sectional surveys. *Can J Public Health*. 2017;108(2):e110-e6.
15. Zuckermann AME, Battista K, de Groh M, Jiang Y, Leatherdale ST. Prelegalisation patterns and trends of cannabis use among Canadian youth: results from the COMPASS prospective cohort study. *BMJ Open*. 2019;9(3):e026515.
16. George T, Vaccarino F. Substance abuse in Canada: The Effects of Cannabis Use during Adolescence. Ottawa: Canadian Centre on Substance Abuse; 2015.

17. Calabria B, Degenhardt L, Hall W, Lynskey M. Does cannabis use increase the risk of death? Systematic review of epidemiological evidence on adverse effects of cannabis use. *Drug Alcohol Rev.* 2010;29(3):318-30.
18. National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on the Health Effects of Marijuana: An Evidence Review and Research Agenda. *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research.* Washington (DC): National Academies Press (US); 2017.
19. Ashton CH. Pharmacology and effects of cannabis: A brief review. *Br J Psychiatry.* 2001;178(2):101-6.
20. Wilson J, Freeman TP, Mackie CJ. Effects of increasing cannabis potency on adolescent health. *Lancet Child Adolesc Health* 2019;3(2):121-8.
21. Hall W, Degenhardt L. The adverse health effects of chronic cannabis use. *Drug Test Anal.* 2014;6(1-2):39-45.
22. Stefanis NC, Dragovic M, Power BD, Jablensky A, Castle D, Morgan VA. Age at Initiation of Cannabis Use Predicts Age at Onset of Psychosis: The 7- to 8-Year Trend. *Schizophr Bull.* 2013;39(2):251-4.
23. Russell C, Rueda S, Room R, Tyndall M, Fischer B. Routes of administration for cannabis use - basic prevalence and related health outcomes: A scoping review and synthesis. *Int J Drug Policy.* 2018;52:87-96.
24. LaFrance EM, Stueber A, Glodosky NC, Mauzay D, Cuttler C. Overbaked: assessing and predicting acute adverse reactions to Cannabis. *J Cannabis Res.* 2020;2(1):3.
25. Lopez-Quintero C, Granja K, Hawes S, Duperrouzel JC, Pacheco-Colón I, Gonzalez R. Transition to drug co-use among adolescent cannabis users: The role of decision-making and mental health. *Addict Behav.* 2018;85:43-50.
26. Leos-Toro C, Rynard V, Hammond D. Prevalence of problematic cannabis use in Canada: Cross-sectional findings from the 2013 Canadian Tobacco, Alcohol and Drugs Survey. *Can J Public Health.* 2018;108(5-6):e516-22.
27. Asbridge M, Duff C, Marsh DC, Erickson PG. Problems with the identification of 'problematic' cannabis use: examining the issues of frequency, quantity, and drug use environment. *Eur Addict Res.* 2014;20(5):254-67.
28. Horwood LJ, Fergusson DM, Hayatbakhsh MR, Najman JM, Coffey C, Patton GC, et al. Cannabis use and educational achievement: Findings from three Australasian cohort studies. *Drug Alcohol Depend.* 2010;110(3):247-53.
29. Hartman RL, Huestis MA. Cannabis effects on driving skills. *Clin Chem.* 2013;59(3):478-92.
30. Patton GC, Coffey C, Carlin JB, Degenhardt L, Lynskey M, Hall W. Cannabis Use And Mental Health In Young People: Cohort Study. *BMJ.* 2002;325(7374):1195-8.
31. Henquet C, Krabbendam L, Spauwen J, Kaplan C, Lieb R, Wittchen H, et al. Prospective cohort study of cannabis use, predisposition for psychosis, and psychotic symptoms in young people. *BMJ.* 2005;330(7481):11-4.
32. Copeland J, Rooke S, Swift W. Changes in cannabis use among young people: impact on mental health. *Curr Opin Psychiatry.* 2013;26(4).
33. United Nations Office on Drugs and Crime. *The International Drug Control Conventions.* New York: United Nations Office on Drugs and Crime; 2013.
34. World Health Organization. *Consideration of the notification from the World Health Organization concerning scheduling under the Single Convention on Narcotic Drugs of 1961 as*

amended by the 1972 Protocol, and the Convention on Psychotropic Substances of 1971. Vienna: Commission on Narcotic Drugs; 2020.

35. Jesseman R, Payer D. Decriminalization: Options and Evidence [Policy Brief]. Ontario: Canadian Centre on Substance Use and Addiction; 2018.
36. Caulkins JP, Kilmer B, Kleiman MAR, MacCoun RJ, Midgette G, Oglesby P, et al. Considering Marijuana Legalization: Insights for Vermont and Other Jurisdictions. Santa Monica: RAND Corporation; 2015.
37. European Monitoring Centre for Drugs and Drug Addiction. Cannabis Legislation in Europe: An Overview. Luxembourg: Publications Office of the European Union; 2018.
38. The Law Library of Congress. Decriminalization of Narcotics. Washington (DC): Library of Congress; 2016.
39. Alvarez E, Queirolo R, Sotto B. Conflicting forces in the implementation of medicinal cannabis regulation in Uruguay. *J Cannabis Res.* 2023;5(1):26.
40. Queirolo R, Rossel C, Álvarez E, Repetto L. Why Uruguay legalized marijuana? The open window of public insecurity. *Addiction.* 2019;114(7):1313-21.
41. Government of Canada. Toward the Legalization, Regulation and Restriction of Access to Marijuana. Ottawa: Government of Canada; 2016 [cited 2019 Oct]. Available from: <https://www.canada.ca/content/dam/hc-sc/healthy-canadians/migration/health-system-systeme-sante/consultations/legalization-marijuana-legalisation/alt/legalization-marijuana-legalisation-eng.pdf>.
42. Government of Canada. Proposed Regulations Amending the Cannabis Regulations (New Classes of Cannabis) and Proposed Order Amending Schedules 3 and 4 to the Cannabis Act. Ottawa: Government of Canada; 2019.
43. Barrus DG, Capogrossi KL, Cates SC, Gourdet CK, Peiper NC, Novak SP, et al. Tasty THC: Promises and Challenges of Cannabis Edibles. *Methods Report RTI Press.* 2016;2016:10.3768/rtipress.2016.op.0035.1611.
44. Gourdet C, Giombi KC, Kosa K, Wiley J, Cates S. How four U.S. states are regulating recreational marijuana edibles. *Int J Drug Policy.* 2017;43:83-90.
45. Borodovsky JT, Lee DC, Crosier BS, Gabrielli JL, Sargent JD, Budney AJ. U.S. cannabis legalization and use of vaping and edible products among youth. *Drug Alcohol Depend.* 2017;177:299-306.
46. Parnes JE, Bravo AJ, Conner BT, Pearson MR. A burning problem: cannabis lessons learned from Colorado. *Addict Res Theory.* 2018;26(1):3-10.
47. Goundar P, Macaulay T, Szafron M. A comparative analysis of laws on recreational cannabis edibles between Canada and the United States of America. *Int J Drug Policy.* 2021;94:103191.
48. Adams IB, Martin BR. Cannabis: pharmacology and toxicology in animals and humans. *Addiction.* 1996;91(11):1585-614.
49. Hall W, Solowij N. Adverse effects of cannabis. *Lancet.* 1998;352(9140):1611-6.
50. Di Forti M, Morgan C, Dazzan P, Pariante C, Mondelli V, Marques TR, et al. High-potency cannabis and the risk of psychosis. *Br J Psychiatry.* 2009;195(6):488-91.
51. *Cannabis Act*, SC 2018, c 16.
52. *Cannabis Regulations*, SOR/2018-144.
53. Walsh J, Ramsey G. Uruguay's Drug Policy: Major Innovations, Major Challenges. Washington (DC): Washington Office on Latin America; 2016.
54. Weiss S. Edibles: for experts only? Ingesting marijuana, as opposed to smoking it, has come a long way since the days of homemade pot brownies. *State Legis.* 2015;41(3):23.

55. McDonald EA, Popova L, Ling PM. Traversing the triangulum: the intersection of tobacco, legalised marijuana and electronic vaporisers in Denver, Colorado. *Tob Control*. 2016;25(Suppl 1):i96.
56. Grotenhermen F. Pharmacokinetics and Pharmacodynamics of Cannabinoids. *Clin Pharmacokinet*. 2003;42(4):327-60.
57. Mura P, Kintz P, Dumestre V, Raul S, Hauet T. THC Can Be Detected in Brain While Absent in Blood. *J Anal Toxicol*. 2005;29(8):842-3.
58. Schwilke EW, Schwoppe DM, Karschner EL, Lowe RH, Darwin WD, Kelly DL, et al. Δ^9 -Tetrahydrocannabinol (THC), 11-Hydroxy-THC, and 11-Nor-9-carboxy-THC Plasma Pharmacokinetics during and after Continuous High-Dose Oral THC. *Clin Chem*. 2009;55(12):2180-9.
59. Subritzky T, Pettigrew S, Lenton S. Issues in the implementation and evolution of the commercial recreational cannabis market in Colorado. *Int J Drug Policy*. 2016;27:1-12.
60. Monte AA, Shelton SK, Mills E, Saben J, Hopkinson A, Sonn B, et al. Acute Illness Associated With Cannabis Use, by Route of Exposure. *Ann Intern Med*. 2019;170(8):531-7.
61. Government of Canada. Final Regulations for New Cannabis Products: Edible Cannabis, Cannabis Extracts and Cannabis Topicals. Ottawa: Government of Canada; 2019.
62. Ewing P. Growing Up: Vertical Integration in the Cannabis Industry. *SSRN Electronic Journal*. 2021.
63. Leynseele AV. Vertical Integration: What it is and why it matters to cannabis. *Cannabis Law Journal*. 2017.
64. Marijuana Legalization Act, Me. Rev. Stat. Ann. tit. 28-B, §§ 102-704 (2019).
65. Government of Canada. Cannabis in the Provinces and Territories [Internet]. Ottawa: Government of Canada; 2019 [cited 2020 Feb]. Available from: <https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/laws-regulations/provinces-territories.html>.
66. Regulations for the Marijuana Control Board, Alaska Admin. Code tit. 3, §§ 306.005-.850 (2014).
67. Recreational Marijuana, Or. Admin. R. 845-025-1000 to 8560 (2014).
68. Marijuana Licenses, Application Process, Requirements, and Reporting, Wash. Admin. Code §§ 314-55-005 to -540 (2012).
69. Retail Marijuana Rules, 1 Colo. Code Regs. § 212-2. (2012).
70. Bureau of Cannabis Control, Cal. Code Regs. tit. 16, §§ 5025 – 5800 (2016).
71. *Regulation to determine other classes of cannabis that may be sold by the Société québécoise du cannabis and certain standards respecting the composition and characteristics of cannabis*, CQLR c C-5.3, r.0.1.
72. Regulations for the Marijuana Control Board - Alaska Admin. Code (2019).
73. Adult use of Marijuana, 935 Mass. Code Regs. 500.105, 500.130 to -160 (2016).
74. Regulation and Taxation of Marijuana, Nev. Admin. Code §§ 453D.018-828 (2016).
75. Michigan Regulation and Taxation of Marihuana Act, Mich. Comp. Laws §§ 333.27951 to 333.27961 (2018).
76. Cannabis Regulation and Tax Act, 410 Ill. Comp. Stat. 705/1-5 to 705/55-75 (2019).
77. Retail Marijuana Item Concentration and Serving Size Limits, Or. Admin. R. 333-007-0210 (2014).
78. Commonwealth of Massachusetts. Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-Infused Products for Massachusetts Registered Medical Marijuana Dispensaries. Boston: Cannabis Control Commission; 2017.

79. Shanahan M, Cyrenne P. Cannabis policies in Canada: How will we know which is best? *Int J Drug Policy*. 2021;91:102556.
80. Statistics Canada. The retail cannabis market in Canada: A portrait of the first year [Internet]. Ottawa: Statistics Canada; 2019 [cited 2020 Feb]. Available from: <https://www150-statcan-gc-ca.cyber.usask.ca/n1/pub/11-621-m/11-621-m2019005-eng.htm>.
81. Government of Canada. Calculation of Cannabis Duty and Additional Cannabis Duty on Cannabis Oil, Edible Cannabis, Cannabis Extracts and Cannabis Topicals [Internet]. Ottawa: Canada Revenue Agency; 2019 [cited 2020 Mar]. Available from: <https://www.canada.ca/en/revenue-agency/services/forms-publications/publications/edn60/calculation-cannabis-duty-additional-cannabis-duty-cannabis-oil-cannabis-edibles-extracts-topicals.html>.
82. Government of Canada. Charge and Collect the Tax - Which Rate to Charge [Internet]. Ottawa: Canada Revenue Agency; 2019 [cited 2020 Aug]. Available from: <https://www.canada.ca/en/revenue-agency/services/tax/businesses/topics/gst-hst-businesses/charge-collect-which-rate.html>
83. Hansen B, Miller K, Seo B, Weber C. Taxing The Potency Of Sin Goods: Evidence From Recreational Cannabis And Liquor Markets. *Nat Tax J*. 2020;73(2):511-44.
84. Illinois Department of Revenue. Cannabis Tax Frequently Asked Questions [Internet]. Chicago: Illinois Department of Revenue; 2020 [cited 2020 Sep]. Available from: https://www2.illinois.gov/rev/research/taxinformation/other/Documents/cannabis_FAQs.pdf.
85. Cannabis Tracking System Order, SOR/2019-202.
86. Oregon Liquor Control Commission, Oregon Health Authority. Oregon’s Framework for Regulating Marijuana Should be Strengthened to Better Mitigate Diversion Risk and Improve Laboratory Testing. Salem: Oregon Secretary of State; 2019.
87. Prieger J, Hampsher-Monk S, Oglesby P, Davenport S, Manning C, Hahn R. Cannabis Potency Tax Feasibility Study: A Report for the Washington State Liquor & Cannabis Board. *SSRN Electronic Journal*. 2019.
88. Hudak M, Severn D, Nordstrom K. Edible Cannabis–Induced Psychosis: Intoxication and Beyond. *Am J Psychiatry*. 2015;172(9):911-2.
89. Huestis MA, Henningfield JE, Cone EJ. Blood Cannabinoids. I. Absorption of THC and Formation of 11-OH-THC and THCCOOH During and After Smoking Marijuana. *J Anal Toxicol*. 1992;16(5):276-82.
90. Hancock-Allen Jb Fau - Barker L, Barker L Fau - VanDyke M, VanDyke M Fau - Holmes DB, Holmes DB. Notes from the Field: Death Following Ingestion of an Edible Marijuana Product--Colorado, March 2014. (1545-861X (Electronic)).
91. Charlebois S, Somogyi S, Sterling B. Cannabis-infused food and Canadian consumers’ willingness to consider “recreational” cannabis as a food ingredient. *Trends Food Sci Technol*. 2018;74:112-8.
92. Friese B, Slater MD, Battle RS. Use of Marijuana Edibles by Adolescents in California. *J Primary Prev*. 2017;38(3):279-94.
93. Tricco AC, Langlois EV, Straus SE. Rapid reviews to strengthen health policy and systems: a practical guide. Geneva: World Health Organization; 2017.
94. McKernan K, Spangler J, Helbert Y, Lynch R, Devitt-Lee A, Zhang L, et al. Metagenomic analysis of medicinal Cannabis samples; pathogenic bacteria, toxigenic fungi, and beneficial microbes grow in culture-based yeast and mold tests. *F1000 Res*. 2016;5(2471).
95. McPartland JM, Hillig KW. Cannabis Fusarium Wilt. *J Ind Hemp*. 2004;9(2):67-77.

96. Montoya Z, Conroy M, Vanden Heuvel BD, Pauli CS, Park S-H. Cannabis Contaminants Limit Pharmacological Use of Cannabidiol. *Front Pharmacol*. 2020;11.
97. Busse FP, Fiedler GM, Leichtle A, Hentschel H, Stumvoll M. Lead poisoning Due to Adulterated Marijuana in Leipzig. *Dtsch Arztebl Int*. 2008;105(44):757-62.
98. Dryburgh LM, Bolan NS, Grof CPL, Galettis P, Schneider J, Lucas CJ, et al. Cannabis contaminants: sources, distribution, human toxicity and pharmacologic effects. *Br J Clin Pharmacol*. 2018;84(11):2468-76.
99. Gauvin DV, Zimmermann ZJ, Yoder J, Tapp RL. Marijuana Toxicity: Heavy Metal Exposure Through State-Sponsored Access to “la Fee Verte”. *Pharmaceut Reg Affairs*. 2018;7.
100. McPartland JM, McKernan KJ. Contaminants of Concern in Cannabis: Microbes, Heavy Metals and Pesticides. In: Chandra S, Lata H, ElSohly MA, editors. *Cannabis sativa L - Botany and Biotechnology*. Cham: Springer International Publishing; 2017. p. 457-74.
101. Siegel BZ, Garnier L, Siegel SM. Mercury in Marijuana: Some of the problems arising from marijuana use might result from the intake of bioaccumulated mercury. *Bioscience*. 1988;38(9):619-23.
102. Mahurpawar M. Effects of heavy metals on human health. *Int J Res Granthaalayah*. 2015;3:1-7.
103. Vardhan KH, Kumar PS, Panda RC. A review on heavy metal pollution, toxicity and remedial measures: Current trends and future perspectives. *J Mol Liq*. 2019;290:111197.
104. Blake A, Nahtigal I. The evolving landscape of cannabis edibles. *Curr Opin Food Sci*. 2019;28:25-31.
105. Peng H, Shahidi F. Cannabis and Cannabis Edibles: A Review. *J Agric Food Chem*. 2021;69(6):1751–74.
106. White AE, Van Tubbergen C, Raymes B, Contreras AE, Scallan Walter EJ. Cannabis-Infused Edible Products in Colorado: Food Safety and Public Health Implications. *Am J Public Health*. 2020;110(6):790-5.
107. Russo EB. Pesticide Contamination of Cannabis in the Legal Market [Internet]. 2016 [cited 2021 Sep]. Available from: <https://www.nurturingnature.com/files/2017-Russo-PESTICIDE-CONTAMINATION-OF-CANNABIS-IN-THE-LEGAL-MARKET.pdf>.
108. Goetz AK, Rockett JC, Ren H, Thillainadarajah I, Dix DJ. Inhibition of Rat and Human Steroidogenesis by Triazole Antifungals. *Syst Biol Reprod Med*. 2009;55(5-6):214-26.
109. Hester SD, Wolf DC, Nesnow S, Thai S-F. Transcriptional Profiles in Liver from Rats Treated with Tumorigenic and Non-tumorigenic Triazole Conazole Fungicides: Propiconazole, Triadimefon, and Myclobutanil. *Toxicol Pathol*. 2006;34(7):879-94.
110. Zarn JA, O’Brien CD. Current pesticide dietary risk assessment in light of comparable animal study NOAELs after chronic and short-termed exposure durations. *Arch Toxicol*. 2018;92(1):157-67.
111. Safe Food for Canadians Regulations Sect. Subdivision G, section 80 (2018).
112. Safe Food for Canadians Regulations Sect. Subdivision G, section 81 (2018).
113. Beitzke B, Pate DW. A broader view on deriving a reference dose for THC traces in foods. *Crit Rev Toxicol*. 2021;51(8):695-722.
114. Government of Canada. Cannabis: lower your risks [Internet]. Ottawa: Government of Canada; 2019 [cited 2021 Sep]. Available from: <https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/resources/lower-your-risks.html>.
115. Goodman S, Hammond D. THC labeling on cannabis products: an experimental study of approaches for labeling THC servings on cannabis edibles. *J Cannabis Res*. 2022;4(1):17.

116. Sholler DJ, Strickland JC, Spindle TR, Weerts EM, Vandrey R. Sex differences in the acute effects of oral and vaporized cannabis among healthy adults. *Addict Biol.* 2021;26(4):e12968.
117. Carey J, Cook G. Virginia mother pleads guilty in 4-year-old son's death from THC gummies [Internet]. 2023 [cited 2023 Oct]. Available from: <https://www.nbcwashington.com/news/local/virginia-mother-pleads-guilty-in-4-year-old-sons-death-from-thc-gummies/3365697/#:~:text=Tanner%20Clements%20died%20two%20days%20later.,arrested%20and%20charged%20with%20murder.>
118. Hall W, Stjepanović D, Dawson D, Leung J. The implementation and public health impacts of cannabis legalization in Canada: a systematic review. *Addiction.* 2023;118(11):2062-72.
119. Canadian Centre on Substance Use and Addiction. A Standard THC Unit and Its Value in Cannabis Research, Public Education and Regulation in Canada [Internet]. Ottawa: Canadian Centre on Substance Use and Addiction; 2022 [cited 2023 Oct]. Available from: https://www.ccsa.ca/sites/default/files/2023-01/CCSA_Standard_THC_Unit_Event_Summary_Report_en.pdf.
120. MJBizDaily. New Colorado edible rules: Major cost for producers, 'blip on the radar' for others [Internet]. 2016 [cited 2023 Oct]. Available from: <https://mjbizdaily.com/new-co-edibles-rules-major-cost-producers-blip-radar-others/>.
121. Government of Canada. Legislative Review of the Cannabis Act: What We Heard Report. Ottawa: Government of Canada; 2023 [cited 2023 Oct]. Available from: <https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-medication/cannabis/laws-regulations/cannabis-act-legislative-review/expert-panel/legislative-review-cannabis-act-report/legislative-review-cannabis-act-report.pdf>.
122. Pacaula RP, Seema; Zhu, Joy; Kritikos, Alexandra; Smart, Rosanna. Federal Regulation of Cannabis for Public Health in the United States. Los Angeles: USC Schaeffer Leonard D. Schaeffer Center for Health Policy & Economics; 2022.
123. Pusiak RJP, Cox C, Harris CS. Growing pains: An overview of cannabis quality control and quality assurance in Canada. *Int J Drug Policy.* 2021;93:103111.
124. Caulkins JP, Bao Y, Davenport S, Fahli I, Guo Y, Kinnard K, et al. Big data on a big new market: Insights from Washington State's legal cannabis market. *Int J Drug Policy.* 2018;57:86-94.
125. MJBizDaily. Washington state suspends marijuana testing laboratory's certification [Internet]. 2023 [cited 2023 Oct]. Available from: <https://mjbizdaily.com/washington-state-suspends-marijuana-testing-laboratorys-certification/>.
126. Steigerwald S, Wong PO, Khorasani A, Keyhani S. The Form and Content of Cannabis Products in the United States. *J Gen Intern Med.* 2018;33(9):1426-8.
127. Government of Canada. Authorized cannabis retailers in the provinces and territories [Internet]. Ottawa: Government of Canada; 2022 [cited 2023 Oct]. Available from: <https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/laws-regulations/provinces-territories.html>.
128. Cannabis New Brunswick. Private Retail [Internet]. [cited 2023 Oct]. Available from: <https://www.cannabis-nb.com/PrivateRetailers-DetailantPrive/>.
129. Cohen S. NWT opens up bidding on contract for private pot shop in Yellowknife [Internet]. CBC News; 2020 [cited 2023 Oct]. Available from: <https://www.cbc.ca/news/canada/north/nwt-private-cannabis-store-rfp-1.5604001>.

130. Myran DT, Staykov E, Cantor N, Taljaard M, Quach BI, Hawken S, et al. How has access to legal cannabis changed over time? An analysis of the cannabis retail market in Canada 2 years following the legalisation of recreational cannabis. *Drug Alcohol Rev.* 2022;41(2):377-85.
131. Mahamad S, Wadsworth E, Rynard V, Goodman S, Hammond D. Availability, retail price and potency of legal and illegal cannabis in Canada after recreational cannabis legalisation. *Drug Alcohol Rev.* 2020;39(4):337-46.