

Contents

CHAPTER 1 Introduction.....	1
Introduction to the author: it's personal	1
I work in the cannabis industry, and I don't get high.....	1
Note.....	1
My first exposure to weed was at a dry cleaner.....	1
Note.....	2
My role as a consultant.....	2
Purchasing cannabidiol.....	3
Field trips.....	5
Introduction to cannabis vocabulary	7
Introduction to cannabis regulation	8
I'm just curious, where is cannabis legal?.....	8
A brief history of cannabis regulations	9
Marihuana Tax Act of 1937.....	9
Controlled Substances Act of 1970	9
Decriminalization	9
Marijuana Freedom and Opportunity Act of 2018	10
Agriculture Improvement Act of 2018.....	10
Descheduling is the future.....	11
The National Cannabis Industry Association's four lanes of regulation proposal	11
November 2019: Marijuana Opportunity Reinvestment and Expungement Act.....	12
The Food and Drug Administration regulation	12
What is food?	13
What is a dietary supplement?	13
Here's a question I can't answer: will cannabis concentrate be regulated as a food additive, after descheduling of marijuana?....	14
What is a food additive?	14
What is a functional food?	14
A tale of homonyms.....	15
Opinion on cannabis regulation	15
License for growing operations and harvesting.....	15
License for drying, extraction, processing, and manufacturing operations.....	16
License for dispensaries.....	17
License for transportation.....	17
License for cannabis laboratories.....	18

Conclusion	18
The Canadians	19
Safe Food for Canadians	19
Cannabis Act	19
Quality assurance person.....	20
References.....	21
CHAPTER 2 Overview of the cannabis industry.....	25
Vertical integration.....	27
Growing operations.....	28
What type of plant is <i>Cannabis</i> ?.....	28
Cannabis is a crop	28
Marijuana grown for research	30
Postharvest steps for cannabis products	30
Marijuana licensing in Colorado.....	31
Retail marijuana testing facility.....	31
Retail marijuana transporter.....	31
Retail marijuana cultivation facility	31
Retail marijuana products manufacturing	31
Hemp-derived and cannabis concentrate	32
Heat/pressure-based extraction	32
Winterization	32
Decarboxylation	33
Distillation	33
Cannabis-infused edibles.....	33
Retail marijuana store.....	34
References.....	35
CHAPTER 3 Begin with the end in mind®: the dispensary	37
The dispensary	37
Washington.....	37
Florida.....	38
California.....	39
Colorado.....	40
Michigan.....	40
Nevada	40
Home delivery	40
Taxation and licensing.....	41
References.....	44

CHAPTER 4	Good manufacturing practice compliance is not optional.....	47
	Introduction to good manufacturing practices	47
	What are GMPs?	47
	Food and Drug Administration authority.....	48
	Alignment of 21 CFR 111 and 21 CFR 117	49
	FDA GMP inspections and warning letters.....	51
	Implementation of GMPs.....	52
	Documentation.....	52
	GMP training.....	54
	Absolutes for training in the cannabis industry.....	57
	The immunocompromised consumer.....	57
	Handwashing and personal protective equipment.....	57
	Traffic patterns.....	58
	GMPs are only the beginning of safety for cannabis-infused edibles	58
	What is the food safety team called at a cannabis-infused edible facility?	59
	Elements of an edible safety plan	59
	Supply chain program	62
	Allergen management program	62
	GMP certification is facility-specific	62
	GMP certification is earned	63
	Applying GMP certification to the cannabis industry	64
	GMP certification does not ensure the safety of products.....	65
	References.....	67
CHAPTER 5	Chemistry of cannabidiol and Δ^9-tetrahydrocannabinol	69
	Concentrates are the products of extraction	69
	Biochemistry	69
	Endocannabinoid system.....	70
	Phytocannabinoids.....	70
	Terpenes	70
	Entourage effect	71
	Flavonoids.....	71
	Organic chemistry.....	71
	Extraction.....	72
	Decarboxylation	73
	Distillation	74

Analytical chemistry	74
References.....	75
CHAPTER 6 The hazard analysis	77
Beyond Hazard Analysis and Critical Control Points (HACCP)	77
Reminder	78
Definition of hazard analysis	78
Importance of doing a good job the first time	80
Importance of teamwork	80
Resources for the hazard analysis	82
Personnel	82
Food and Drug Administration rule and guidance.....	82
State code for marijuana regulations	84
The steps of writing a hazard analysis	88
Summary.....	89
References.....	90
CHAPTER 7 Preventive controls	91
Definition of a preventive control by the FSPCA.....	92
Allergen preventive controls	93
Step-by-step directions for the identification of allergen preventive controls.....	94
Application to cannabis-infused edibles.....	96
Supply chain preventive controls	96
Step-by-step directions for the identification of supply chain preventive controls.....	97
Application to cannabis-infused edibles.....	99
Process preventive controls.....	100
Step-by-step directions for the identification of process preventive controls.....	100
Application to cannabis-infused edibles.....	101
A warning to cannabis-infused edible manufacturers.....	102
Sanitation preventive controls	102
Step-by-step directions for the identification of sanitation preventive controls.....	103
Application to cannabis-infused edibles.....	104
Monitoring cleaning and sanitizing	106
Verification of cleaning and sanitizing.....	106
Implementation of a sampling plan.....	107
References.....	109

CHAPTER 8 Nobody is talking about environmental monitoring

111

Environmental monitoring.....	111
Where is environmental monitoring conducted?.....	112
What if an edible does not have a kill step?	112
What if an edible is further processed after packaging?.....	112
Hazard of environmental pathogen identified in the hazard analysis.....	113
Pathogen testing of edibles.....	113
Water activity (a_w).....	114
The fallacy of finished product testing of cannabis-infused edibles with pathogen tests.....	114
Factors to consider for a representative sample	115
Indicator tests	116
Adenosine triphosphate bioluminescence	117
<i>Staphylococcus aureus</i>	118
Total Yeast and Mold Count.....	118
Aerobic Plate Count.....	119
Enterobacteriaceae count.....	120
Coliform count.....	120
<i>E. coli</i> count.....	121
Kornacki Microbiology Solutions, Inc.	122
Pathogen testing for environmental monitoring.....	123
Identify hygienic zones.....	123
Determine the pathogen of concern in the environment.....	125
The food industry would be shocked!.....	128
Initiation of an environmental monitoring program.....	129
Clean break	129
Use of dedicated HEPA-filtered vacuums.....	129
Sanitation preventive controls	130
Create a master site list.....	130
Seek and destroy	131
What to do when a site confirms positive for a pathogen	131
Investigational swabbing.....	134
Summary.....	135
References.....	137

CHAPTER 9 Operation: manufacturing of edibles

139

Characteristics of cannabis-infused edibles.....	139
Homogeneous	139
Portion-evident or individually packaged	140

Shelf-stable.....	140
Foods made into cannabis-infused edibles.....	140
Product development.....	141
Food science.....	142
Cannabis science.....	143
Homogenization of cannabidiol and Δ^9 -tetrahydrocannabinol, again.....	143
Build food safety into product development.....	144
Validation of process preventive controls.....	144
Supply chain preventive controls.....	145
Written standard operating procedures.....	145
References.....	146
CHAPTER 10 Operation: packaging and labeling of edibles ...	147
The role of packaging.....	147
Colorado field trip.....	147
Important points about packaging of cannabis-infused edibles...	148
Functional and opaque.....	148
Portioned or individually wrapped.....	149
Tamper-evident.....	149
Child-resistant.....	150
Unattractive to minors.....	150
Edibles and their packaging unlike certain commercially available products.....	151
A protection of the contents from contamination.....	151
The role of labeling.....	151
Nutrition Facts and Supplement Facts.....	152
Allergen declaration.....	152
The role of security.....	153
Food defense resembles security in the cannabis industry.....	153
Security in the cannabis industry.....	154
References.....	157
CHAPTER 11 Training needed in the cannabis industry.....	159
Importance of training.....	159
Resources specific to the cannabis industry.....	161
Reading materials.....	161
Events for networking.....	162
Cannabis courses, certificates, workshops and webinars, and degrees.....	163
Offerings for degrees, certificates, workshops, and webinars.....	164

University degrees	165
Undergraduate degrees in the United States in medicinal plant chemistry.....	165
Graduate degrees in Canada	165
Resources in related fields.....	165
Training needed for personnel in cannabis-infused edible manufacturing.....	166
General resources for personnel in cannabis-infused edible manufacturing.....	167
A final thought.....	167
References.....	168
CHAPTER 12 Jobs in the cannabis industry.....	173
Transferring skills to the cannabis industry.....	173
Myth	173
Myth	173
Where do I start for a job in the cannabis industry?.....	174
Read.....	174
Field trips.....	174
Network.....	174
Know the jobs.....	175
Availability of jobs in the cannabis industry	176
Departmental needs within a cannabis-infused edibles manufacturer.....	177
The food industry can learn from the cannabis industry.....	178
Characteristics of a cannabis industry employee.....	179
Flexibility.....	179
Integrity.....	179
Driven to work hard.....	180
Readiness for promotion	180
References.....	181
CHAPTER 13 Final thoughts	183
Marijuana Business Conference (MJBizCon).....	183
Cannabis associations.....	184
Presentations at MJBizCon.....	184
Exhibit hall at MJBizCon.....	185
Networking at MJBizCon.....	186
What did I learn about edibles at MJBizCon?.....	188
Nevada field trip.....	189
December 2019	190

Politics	190
Legalization of marijuana.....	190
Conclusion	192
Reference.....	193
Appendix 1.....	195
Appendix 2.....	203
Index.....	215