MEMORANDUM OF REGULATORY ANALYSIS ("MORA")

TABLE OF CONTENTS

Part 3: Licenses and Permits

Part 4: General Authorizations

Part 5: Ministerial Orders

Part 6: Cannabis and Psilocybin Tracking System

Part 7: Inspections

Part 8: Search Warrant

Part 9: Disposition of Seized Things

Part 11: General

Part 12: Transitional Provisions and Related, Consequential and Coordinating Amendments

CANNABIS REGULATIONS

Interpretation

Part 2: Licensing

Part 5: Good Production Practices

Part 6 – Cannabis Products

Part 7: Packaging and Labelling

Part 11: Retention of Documents and Information

Part 12 - Reporting and Disclosure

Part 13: Test Kits

Part 14: Access to Cannabis for Medical Purposes

NARCOTIC CONTROL REGULATIONS

CONTROLLED DRUGS AND SUBSTANCES ACT

CANNABIS EXEMPTION (FOOD AND DRUGS ACT) REGULATIONS

FOOD AND DRUG REGULATIONS

Executive Summary

The Memorandum of Regulatory Analysis (MORA) is a framework for the regulation of medicinal psilocybin. It sets out the changes to the current legislation which would allow psilocybin to be approved for medical use, produced, distributed and consumed in a safe and responsible manner. Each step in the process is designed to protect the health and safety of Canadians while providing access for those in need.

The MORA provides two sources of psilocybin, one natural and one synthetic. A psilocybin licencing system modelled on the *Cannabis Regulations* would permit the cultivation of natural psilocybin mushrooms and psilocybin extracts from those psilocybin mushrooms. The *Cannabis Regulations* would permit licences that authorize psilocybin cultivation, processing and sale. The robust cannabis licencing rules would regulate quality control, record-keeping, and security.

The MORA does not authorize personal medical growing. Some will criticize this approach. As the psilocybin rules evolve personal medical growing will undoubtedly be included. However, the first iteration should be cautious. The government has a longstanding concern with drug diversion. With that in mind, every step in the MORA process is secure. Some might say that psilocybin under the MORA is excessively secure, but nobody can say it is not secure enough. The MORA seeks to reassure the government that there is no risk of diversion.

As with the medical cannabis system, a health care practitioner would authorize psilocybin by signing a medical document for patients under their care. Unlike the medical cannabis system, the psilocybin mushrooms and extracts would only be forwarded to the authorizing health care practitioner. The psilocybin consumption would be directed by the authorizing health care practitioner. The health care practitioner would have to approve the clinic where the psilocybin would be consumed. The patient and health care practitioner could discuss clinic options, but once a clinic was decided upon the individual would be obliged to consume the psilocybin at that clinic.

The health care practitioner would have the option of forwarding the psilocybin directly to the approved clinic or to a therapeutic regulated professional at the approved clinic. The practitioner could also provide the psilocybin directly to the patient. The patient would be advised that the psilocybin must be consumed at the approved clinic and must be supervised by a therapeutic regulated professional at the approved clinic. The health care practitioner would sign a consent approving the clinic which would be forwarded to the clinic and the therapeutic regulated professional.

Therapeutic regulated professionals would include medical practitioners, nurse practitioners, psychologists, psychotherapists, registered nurses, registered practical nurses, licensed practical nurses, social workers, physiotherapists, occupational

therapists, and pharmacists. These are all professionals who are accountable to their provincial regulators. The therapeutic regulated professional would be present at all times while the individual was experiencing the effects of psilocybin. This would be the statutory minimum, but there might also be a psychotherapist or perhaps psychologist or other therapist present for portions of the treatment. The health care practitioner, the clinic and the therapeutic regulated professional would all be obliged to keep the psilocybin secure and keep records of the psilocybin.

The second source of psilocybin would permit licensed dealers authorized under the *Narcotics Control Regulation* to manufacture synthetic psilocybin. The licensed dealer would also possess a drug establishment licence. Psilocybin would be added to the *Narcotic Control Regulations* scheduled narcotics and be removed from the *Food and Drug Regulations*' restricted drug list. The *Narcotic Control Regulations* would allow a practitioner (defined in the same manner as a health care practitioner under the *Cannabis Regulations*) to write a prescription for psilocybin to patients under their care as they are currently permitted for other narcotics such as ketamine. A licensed dealer could then sell the synthetic psilocybin to the practitioner. Unlike other narcotics under the *Narcotic Control Regulations*, psilocybin would be forwarded only to the practitioner. The practitioner would then have the same options as with psilocybin provided under the *Cannabis Regulations*.

The MORA would allow hospital pharmacists to provide psilocybin to hospital employees, health care practitioners and patients. The hospital employees or practitioners can provide it to the patient or to the therapeutic regulated professional acting in accordance with the *Cannabis Regulations*. Non-hospital pharmacists can act as therapeutic regulated professionals, but cannot receive and dispense as a pharmacist. As much as is reasonable, the MORA has tried to follow the *Cannabis Regulations*. Pharmacists play a limited role in dispensing cannabis under the *Cannabis Regulations*. This approach has been adopted in the MORA. This reflects the MORA's cautious approach. However, in time, pharmacists should play their traditional role of distributing, storing and advising on drugs, both psilocybin and cannabis.

The MORA would permit therapeutic regulated professionals to have legal experiences with psilocybin in order to be better trained. This would allow therapists and other professionals working in this field to better understand what the individual is experiencing. This is important from both a safety and efficacy standpoint. The professionals would access the psilocybin in the same manner as an individual using psilocybin for medicinal purposes. The professional would be required to obtain a medical document, consume the psilocybin at a health care practitioner-approved clinic and be supervised by a therapeutic regulated professional.

Explanatory Note

The MORA sets out the proposed changes to the *Cannabis Act*, *Cannabis Regulations*, *Narcotic Control Regulations*, *Controlled Drugs and Substances Act*, *Cannabis Exemption (to the Food and Drug Act) Regulations*, and the *Food and Drug Regulations* in order to regulate psilocybin in this manner. In the MORA all legislation is in bold while the changed or amended parts of the legislation are underlined. The MORA has not replicated every provision of the above legislation, only the additions and amendments. As a result, the MORA contains, in places, parts of sections or subsections, but not all. The MORA might omit parts of sections that were not changed and do not need to be listed in order to understand the addition or amendment.

Cannabis Act S.C. 2018, c. 16 (the "*CA*")

There is no need to amend the prohibitions in the *CA* as prohibitions in the *Controlled Drugs and Substances Act* remain.

Interpretation

Amend the definition section

CA – Amend section 2(1) to add:

brand element **includes a brand name, trademark, tradename, distinguishing guise, logo, graphic arrangement, design or slogan that is reasonably associated with, or that evokes,**

(a) cannabis, a cannabis accessory, ~~or~~ a service related to cannabis, psilocybin, psilocybin accessory or a service related to psilocybin; or

(b) a brand of any cannabis, cannabis accessory, ~~or~~ service related to cannabis, psilocybin, psilocybin accessory or a service related to psilocybin.

brand-preference promotion **means promotion of cannabis or psilocybin by means of its brand characteristics, promotion of a cannabis or psilocybin accessory by means of its brand characteristics or promotion of a service related to cannabis or psilocybin by means of the brand characteristics of the service**

cannabis-related licence **means a licence for cultivation, a licence for processing, a licence for analytical testing, a licence for sale, a licence for research, and a cannabis drug licence.**

dried psilocybin **means any part of a psilocybin mushroom that has been subjected to a drying process.**

illicit psilocybin **means psilocybin that is or was sold, produced or distributed by a person prohibited from doing so under this Act or any provincial Act or that was imported by a person prohibited from doing so under this Act.**

informational promotion **means a promotion by which factual information is provided to the consumer about**

(a) cannabis, psilocybin or ~~its~~ their characteristics;

(b) a cannabis accessory, a psilocybin accessory or ~~its~~ their characteristics;

(c) a service related to cannabis or psilocybin; or

(d) the availability or price of cannabis or psilocybin, a cannabis or psilocybin accessory, or a service related to cannabis or psilocybin.

label **includes a legend, word or mark that is, or is to be, applied or attached to or included in, or that accompanies or is to accompany, cannabis, ~~or~~ a cannabis accessory, psilocybin, a psilocybin accessory or a package.**

licence **means a licence issued under subsection 62(1) of the Act in relation to cannabis or psilocybin.**

produce**, in respect of cannabis or psilocybin, means to obtain it by any method or process, including by**

(a) manufacturing;

(b) synthesis, only for cannabis;

(c) altering its chemical or physical properties by any means; or

(d) cultivating, propagating or harvesting it or any living thing from which it may be extracted or otherwise obtained.

psilocybin **means:**

Psilocybin mushrooms,

Psilocybin extracts,

Psilocybin (3–[2–(dimethylamino)ethyl]–4–phosphoryloxyindole) and any salt thereof.

Psilocin (3–[2–(dimethylamino)ethyl]–4–hydroxyindole) and any salt thereof,

It does not include psilocybin mushroom spores.

psilocybin accessory **means a thing that is represented to be used in the consumption or possession of psilocybin**

psilocybin extract **means**

(a) a substance produced by subjecting psilocybin mushrooms to extraction processing, or

(b) a substance or mixture of substances that contains or has on it a substance produced in a manner referred to in paragraph (a).

psilocybin mushrooms **are any species of fungi which produce psilocybin**

psilocybin product **means psilocybin of only one of the classes set out in Schedule 7 to the Act — or a psilocybin accessory that contains such psilocybin**

psilocybin-related licence **means a licence for psilocybin cultivation, a licence for psilocybin processing, a licence for psilocybin analytical testing, a licence for psilocybin sale, and a licence for psilocybin research**

Add equivalency schedule for psilocybin

CA – New section 2(5).

Psilocybin would have an equivalency schedule so that the volumes of different types of psilocybin can be compared.

2(4) For the purposes of this Act, a quantity referred to in column 2 of Schedule 3 in respect of any class of cannabis referred to in column 1 of that Schedule is deemed to be equivalent to 1 g of dried cannabis.

(5) For the purposes of this Act, a quantity referred to in column 2 of Schedule 8 in respect of any class of psilocybin referred to in column 1 of that Schedule is deemed to be equivalent to 1 g of dried psilocybin.

Purpose

The purpose of the amended *CA* and its *Cannabis Regulations* would be to provide for a quality controlled supply (s. 7(f)). In providing for a quality controlled supply, the Act would also reduce illicit activities as medicinal users do not need to resort to the black market (s. 7(c)). By reducing illicit activities, the Act would have the effect of restricting young persons' access to psilocybin (s. 7(a)) and reducing the burden on the criminal justice system (s. 7(e)). The Act would protect young people from psilocybin inducements by regulating the promotion of psilocybin and psilocybin services that could appeal to young persons (s. 7(b)).

CA – Amend section 7.

7 The purpose of this Act is to protect public health and public safety and, in particular, to

(a) protect the health of young persons by restricting their access to cannabis or psilocybin;

(b) protect young persons and others from inducements to use cannabis or psilocybin;

(c) provide for the licit production of cannabis and psilocybin to reduce illicit activities in relation to cannabis;

(d) deter illicit activities in relation to cannabis through appropriate sanctions and enforcement measures;

(e) reduce the burden on the criminal justice system in relation to cannabis and psilocybin;

(f) provide access to a quality-controlled supply of cannabis and psilocybin; and

(g) enhance public awareness of the health risks associated with cannabis use.

Part 1: Prohibitions, Obligations and Offences

Non application - promotion

The *CA* prohibitions promotion and exceptions on promotion would apply to psilocybin, psilocybin accessories, or services related to psilocybin.

CA – Amend section 16.

16 Subject to the regulations, this Subdivision does not apply

(a) to a literary, dramatic, musical, cinematographic, scientific, educational or artistic work, production or performance that uses or depicts cannabis, a cannabis accessory, ~~or~~ a service related to cannabis, psilocybin, psilocybin accessory, or a service related to psilocybin or a brand element of any of those things, whatever the mode or form of its expression, if no consideration is given, directly or indirectly, for that use or depiction in the work, production or performance;

(b) to a report, commentary or opinion in respect of cannabis, a cannabis accessory ~~or~~ a service related to cannabis, psilocybin, psilocybin accessory or a service related to psilocybin, or a brand element of any of those things, if no consideration is given, directly or indirectly, for the reference to the cannabis, cannabis accessory, service, psilocybin, psilocybin accessory, or brand element in that report, commentary or opinion;

(c) to a promotion, by a person that is authorized to produce, sell or distribute

cannabis or psilocybin, that is directed at any person that is authorized to produce, sell or distribute cannabis or psilocybin, but not, either directly or indirectly, at consumers; or

(d) to a promotion, by a person that sells or distributes cannabis accessories or that provides a service related to cannabis or that sells or distributes psilocybin accessories or that provides a service related to psilocybin that is directed at any person that sells or distributes cannabis accessories, at any person that is authorized to produce, sell or distribute cannabis or psilocybin, but not, either directly or indirectly, at consumers.

Promotion

Many aspects to the promotion prohibition in section 17 have limited relevance to psilocybin, but applying the more robust cannabis promotion rules to psilocybin would be the safer and more responsible approach. Practitioners and therapeutic regulated professionals would have their own professional rules with respect to promotion and advertising which apply in addition to these rules. Sections 17(4) and (5) do not apply because there is no in-person retail sale of psilocybin.

CA – Amend section 17.

17(1) Unless authorized under this Act, it is prohibited to promote cannabis, or a cannabis accessory or any service related to cannabis, or psilocybin, a psilocybin accessory, or a service related to psilocybin including

(a) by communicating information about its price or distribution;

(b) by doing so in a manner that there are reasonable grounds to believe could be appealing to young persons;

(c) by means of a testimonial or endorsement, however displayed or communicated;

(d) by means of the depiction of a person, character or animal, whether real or fictional; or

(e) by presenting it or any of its brand elements in a manner that associates it or the brand element with, or evokes a positive or negative emotion about or image of, a way of life such as one that includes glamour, recreation, excitement, vitality, risk or daring.

(2) Subject to the regulations, a person that is authorized to produce, sell or distribute cannabis or psilocybin may promote cannabis or psilocybin by means of informational promotion or brand-preference promotion if the promotion is

(a) in a communication that is addressed and sent to an individual who is 18 years of age or older and is identified by name;

(b) in a place where young persons are not permitted by law;

(c) communicated by means of a telecommunication, where the person responsible for the content of the promotion has taken reasonable steps to ensure that the promotion cannot be accessed by a young person;

(d) in a prescribed place; or

(e) done in a prescribed manner.

(3) Subject to the regulations, a person may promote a cannabis accessory or a service related to cannabis or a psilocybin accessory or a service related to psilocybin by means of informational promotion or brand-preference promotion if the promotion is

(a) in a communication that is addressed and sent to an individual who is 18 years of age or older and is identified by name;

(b) in a place where young persons are not permitted by law;

(c) communicated by means of a telecommunication, where the person responsible for the content of the promotion has taken reasonable steps to ensure that the promotion cannot be accessed by a young person;

(d) in a prescribed place; or

(e) done in a prescribed manner.

(6) Subject to the regulations, a person may promote cannabis, a cannabis accessory, ~~or~~ a service related to cannabis or psilocybin, a psilocybin accessory, or a service related to psilocybin by displaying a brand element of cannabis, of a cannabis accessory, ~~or~~ of a service related to cannabis, psilocybin, a psilocybin accessory, or a service related to psilocybin on a thing that is not cannabis or a cannabis accessory, or psilocybin or a psilocybin accessory, other than

(a) a thing that is associated with young persons;

(b) a thing that there are reasonable grounds to believe could be appealing to young persons; or

(c) a thing that is associated with a way of life such as one that includes glamour, recreation, excitement, vitality, risk or daring.

False promotion

False promotion of psilocybin would be prohibited.

CA – Amend section 18.

18(1) It is prohibited to promote cannabis or psilocybin in a manner that is false, misleading or deceptive or that is likely to create an erroneous impression about its characteristics, value, quantity, composition, strength, concentration, potency, purity, quality, merit, safety, health effects or health risks.
(2) It is prohibited to promote a cannabis accessory or a psilocybin accessory in a manner that is false, misleading or deceptive or that is likely to create an erroneous impression about its design, construction, performance, intended use, characteristics, value, composition, merit, safety, health effects or health risks.

Use of certain terms

Any prohibited prescribed term, expression, logo, symbol or illustration would apply to psilocybin, psilocybin accessories, or a service related to psilocybin.

CA – Amend section 19.

19 It is prohibited to use any term, expression, logo, symbol or illustration specified in regulations made under paragraph 139(1)(z.1) in the promotion of cannabis, a cannabis accessory, ~~or~~ a service related to cannabis, psilocybin, a psilocybin accessory or a service related to psilocybin.

Promotion using foreign media

Prohibited promotion of psilocybin, a psilocybin accessory or a service related to psilocybin would not be permitted in foreign media.

CA – Amend section 20.

20 It is prohibited to promote, in a way that is prohibited by this Part, cannabis, a cannabis accessory, a service related to cannabis, psilocybin, a psilocybin accessory, a service related to psilocybin or a brand element of any of those things in a publication that is published outside Canada, a broadcast that originates outside Canada or any other communication that originates outside Canada.

Sponsorship

The rules on sponsorship would apply to psilocybin, psilocybin accessories and services related to psilocybin.

CA – Amend section 21.

21 It is prohibited to display, refer to or otherwise use any of the following, directly or indirectly in a promotion that is used in the sponsorship of a person, entity, event, activity or facility:

(a) a brand element of cannabis, of a cannabis accessory, ~~or~~ of a service related to cannabis, psilocybin, of a psilocybin accessory or of a service related to psilocybin; and

(b) the name of a person that

(i) produces, sells or distributes cannabis or psilocybin,

(ii) sells or distributes a cannabis accessory or a psilocybin accessory, or

(iii) provides a service related to cannabis or psilocybin.

Name of facility

The rules on naming facilities would apply to psilocybin, psilocybin accessories and services related to psilocybin.

CA – Amend section 22.

22 It is prohibited to display on a facility, as part of the name of the facility or otherwise, if the facility is used for a sports or cultural event or activity,

(a) a brand element of cannabis, a cannabis accessory, ~~or~~ a service related to cannabis, psilocybin, of a psilocybin accessory or a service related to psilocybin; or

(b) the name of a person that

(i) produces, sells or distributes cannabis or psilocybin,

(ii) sells or distributes a cannabis accessory or a psilocybin accessory, or

(iii) provides a service related to cannabis or psilocybin.

Inducements

The rules on inducements would apply to psilocybin, psilocybin accessories and services related to psilocybin.

CA – Amend section 24.

24(1) Unless authorized under this Act, it is prohibited for a person that sells cannabis or a cannabis accessory or psilocybin or a psilocybin accessory

(a) to provide or offer to provide cannabis or a cannabis accessory or psilocybin or a psilocybin accessory if it is provided or offered to be provided without monetary consideration or in consideration of the purchase of any thing or service or the provision of any service;

(b) to provide or offer to provide any thing that is not cannabis or a cannabis accessory or psilocybin or a psilocybin accessory, including a right to participate in a game, draw, lottery or contest, if it is provided or offered to be provided as an inducement for the purchase of cannabis or a cannabis accessory or psilocybin or a psilocybin accessory; or

(c) to provide or offer to provide any service if it is provided or offered to be provided as an inducement for the purchase of cannabis or a cannabis accessory or psilocybin or a psilocybin accessory.

(2) Subject to the regulations, subsection (1) does not apply in respect of a person that is authorized to sell cannabis or psilocybin that provides or offers to provide any thing, including cannabis or a cannabis accessory or psilocybin or a psilocybin accessory, or service referred to in any of paragraphs (1)(a) to (c) to a person that is authorized to produce, sell or distribute cannabis or psilocybin.

(3) Subject to the regulations, subsection (1) does not apply in respect of a person that sells a cannabis accessory or a psilocybin accessory that provides or offers to provide any thing, including cannabis or a cannabis accessory or psilocybin or a psilocybin accessory, or service referred to in any of paragraphs (1)(a) to (c) to a person that is authorized to produce, sell or distribute cannabis or psilocybin.

Packaging and Labeling

It would be prohibited to sell psilocybin not packaged or labelled in accordance with the regulations.

CA – Amend section 25.

25 It is prohibited for a person that is authorized to sell cannabis or psilocybin to sell cannabis or psilocybin that has not been packaged or labelled in accordance with the regulations.

Prohibited packaging and labelling

Psilocybin would have to be packaged and labelled in a responsible manner.

CA – Amend section 26.

26 Unless authorized under this Act, it is prohibited for a person that is authorized to sell cannabis or psilocybin to sell it in a package or with a label

(a) if there are reasonable grounds to believe that the package or label could be appealing to young persons;

(b) that sets out a testimonial or endorsement, however displayed or communicated;

(c) that sets out a depiction of a person, character or animal, whether real or fictional;

(d) that associates the cannabis or psilocybin or one of its brand elements with, or evokes a positive or negative emotion about or image of, a way of life such as one that includes glamour, recreation, excitement, vitality, risk or daring; or

(e) that contains any information that is false, misleading or deceptive or that is likely to create an erroneous impression about the characteristics, value, quantity, composition, strength, concentration, potency, purity, quality, merit, safety, health effects or health risks of the cannabis or psilocybin.

Prohibited packaging and labelling – accessory

Psilocybin would have to be packaged and labelled in a responsible manner.

CA – Amend section 27.

27 Unless authorized under this Act, it is prohibited for a person that sells a cannabis accessory or a psilocybin accessory to sell it in a package or with a label

(a) if there are reasonable grounds to believe that the package or label could be appealing to young persons;

(b) that sets out a testimonial or an endorsement, however displayed or communicated;
(c) that sets out a depiction of a person, character or animal, whether real or fictional;

(d) that associates the cannabis accessory or psilocybin accessory or one of its

brand elements with, or evokes a positive or negative emotion about or image of, a way of life such as one that includes glamour, recreation, excitement, vitality, risk or daring; or

(e) that contains any information that is false, misleading or deceptive or that is likely to create an erroneous impression about the design, construction, performance, intended use, characteristics, value, composition, merit, safety, health effects or health risks of the cannabis accessory or psilocybin accessory.

Use of certain terms, etc.

Any prohibited prescribed term, expression, logo, symbol or illustration would apply to the packaging and labelling of psilocybin and psilocybin accessories.

CA – Amend section 28.

28 Unless authorized under this Act, it is prohibited to use any term, expression, logo, symbol or illustration specified in regulations made under paragraph 139(1)(z.1) on a package or label of cannabis, ~~or~~ a cannabis accessory, psilocybin or a psilocybin accessory.

Display

There would be rules governing the display of psilocybin accessories. There would not be rules concerning displays of psilocybin as there would be no retail sales of psilocybin.

CA – Amend section 30.

30 Unless authorized under this Act, it is prohibited for a person that sells a cannabis accessory or psilocybin accessory to display it, or any package or label of a cannabis accessory or psilocybin accessory, in a manner that may result in the cannabis accessory, psilocybin accessory, package or label being seen by a young person.

Selling and Distributing - Appeal to young persons

There would be limits on the appearance of psilocybin and psilocybin accessories.

CA – Amend section 31.

31 Unless authorized under this Act, it is prohibited to sell cannabis, ~~or~~ a cannabis accessory, psilocybin or a psilocybin accessory that has an appearance, shape or other sensory attribute or a function that there are reasonable grounds to believe could be appealing to young persons.

Selling cannabis accessory to young person

There would be a prohibition on selling a psilocybin accessory to young people.

CA – Amend section 32.

32(1) Unless authorized under this Act, it is prohibited to sell a cannabis accessory or a psilocybin accessory to a young person.

Prohibited sales

Only classes of psilocybin listed in Schedule 7 would be sold.

CA – New section 33.1.

33.1 Unless authorized under this Act, it is prohibited for a person that is authorized to sell psilocybin of any class that is not referred to in Schedule 7.

Prohibited substances

It would be prohibited to mix psilocybin with schedule 5 substances such as nicotine, caffeine or ethyl alcohol.

CA – New section 34.1.

34.1 Unless authorized under this Act, it is prohibited to sell any mixture of substances that contains psilocybin and any substance that is referred to in column 1 of Schedule 5.

Selling or distributing recalled cannabis

It would be prohibited to distribute recalled psilocybin.

CA – Amend section 35.

35 It is prohibited to sell or distribute cannabis or psilocybin that is the subject of a recall order made under section 76.

Self-service display

It would be prohibited to sell or distribute psilocybin or psilocybin accessories by self - service.

CA – Amend section 36.

36 Unless authorized under this Act, it is prohibited to sell or distribute cannabis, ~~or~~ a cannabis accessory, psilocybin or a psilocybin accessory by means of a display that allows for self-service.

Dispensing device

It would be prohibited to sell or distribute psilocybin or psilocybin accessories by a dispensing device.

CA – Amend section 37.

37 Unless authorized under this Act, it is prohibited to sell or distribute cannabis, ~~or~~ a cannabis accessory, psilocybin or a psilocybin accessory by means of a dispensing device.

Public disclosure

Producers, sellers and distributers of psilocybin under the *CA* must comply with regulations with respect to public disclosure.

CA – Amend section 42.

42 Every person that is authorized under this Act to produce, sell or distribute cannabis or psilocybin must make available to the public, in the prescribed form and manner and within the prescribed time, information about cannabis or psilocybin that is required by the regulations.

Promotion-related information

Producers, sellers and distributers of psilocybin under the *CA* must comply with regulations with respect to disclosure to Minister.

CA – Amend section 43.

43(1) Every person that is authorized under this Act to produce, sell or distribute cannabis or psilocybin must provide to the Minister, in the prescribed form and manner and within the prescribed time, information that is required by the regulations about any promotion of cannabis or psilocybin that they conduct, including a promotion referred to in paragraph 16(c).

(2) Every person that sells or distributes a cannabis accessory or a psilocybin accessory, or that provides a service related to cannabis or psilocybin, must provide to the Minister, in the prescribed form and manner and within the prescribed time, information that is required by the regulations about any promotion of cannabis accessories or psilocybin accessories or their service related

to cannabis or psilocybin, as the case may be, that they conduct, including a promotion referred to in paragraph 16(d).

(3) Every person that sells cannabis, ~~or~~ cannabis accessories, ~~or~~ psilocybin or psilocybin accessories must provide to the Minister, in the prescribed form and manner and within the prescribed time, information that is required by the regulations about any thing, including cannabis, ~~or~~ a cannabis accessory, ~~or~~ psilocybin, a psilocybin accessory, or service referred to in any of paragraphs 24(1)(a) to (c) that they provide or offer to provide.

Part 3: Licences and Permits

Authority to issue, renew and amend

The powers of the Minister with respect to licences and permits applies to psilocybin as well as cannabis.

CA – Amend section 62.

62(1) Subject to orders made under subsection 61(1), the regulations and subsection (2), the Minister may, on application, issue, renew or amend licences and permits that authorize the importation, exportation, production, testing, packaging, labelling, sending, delivery, transportation, sale, possession or disposal of cannabis or psilocybin or any class of cannabis or psilocybin.

(2) Licences and permits authorizing the importation or exportation of cannabis or psilocybin may be issued only in respect of cannabis or psilocybin for medical or scientific purposes or in respect of industrial hemp.

(7) The Minister may refuse to issue, renew or amend a licence or permit if

> **(a) the issuance, the renewal or the amendment is likely to create a risk to public health or public safety, including the risk of cannabis or psilocybin being diverted to an illicit market or activity;**

Amendment on own initiative

The Minister can consider psilocybin diversion in considering whether to amend a licence.

CA – Amend section 63.

63(1) The Minister may, in accordance with the regulations, on his or her own initiative, amend a licence or permit if he or she is of the opinion that the

amendment is necessary to protect public health or public safety, including to prevent cannabis or psilocybin from being diverted to an illicit market or activity.

Suspension

The Minister can suspend a licence in relation to psilocybin activities if psilocybin is being diverted.

CA – Amend section 64.

64(1) Subject to the regulations, the Minister may suspend a licence or permit without prior notice to its holder in respect of any or all authorized activities in relation to any cannabis or psilocybin specified by the Minister if

(a) the Minister has reasonable grounds to believe that the suspension is necessary to protect public health or public safety, including to prevent cannabis or psilocybin from being diverted to an illicit market or activity; or

(b) any prescribed circumstance exists.

Part 4: General Authorizations

Administration and enforcement activities — Federal acts

Persons administering or enforcing federal statutes would be authorized to possess psilocybin if it occurs in the course of their duties. No provincial act authorizes work with psilocybin so no provincial psilocybin equivalent would be necessary.

CA – Amend subsection 70(1).

70(1) Unless the regulations provide otherwise, every individual who obtains cannabis or psilocybin in the course of activities performed in connection with the administration or enforcement of this Act or any other Act of Parliament is authorized to do anything that is prohibited by any provision of Division 1 of Part 1 if they do so in a manner that is consistent with the activities they are authorized to perform.

Employees and contractors

Employees and contractors of licensees would be authorized to work with psilocybin if they do so as part of their duties and functions.
CA – Amend section 71.

71(1) Unless the regulations provide otherwise, every employee of a person that is authorized under this Act to possess, sell, distribute or produce cannabis or

psilocybin may do anything that is prohibited by any provision of Division 1 of Part 1 if they do so as part of their employment duties and functions and in a manner that is consistent with the conditions that apply to their employer's authorization.

(2) Unless the regulations provide otherwise, every person who is acting as the agent or mandatary of a person that is authorized under this Act to possess, sell, distribute or produce cannabis or psilocybin may do anything that is prohibited by any provision of Division 1 of Part 1 if they do so as part of their role as agent or mandatary and in a manner that is consistent with the conditions that apply to their principal's or mandatory's authorization.

(3) Unless the regulations provide otherwise, every person who is acting under a contract with a person that is authorized under this Act to possess, sell, distribute or produce cannabis or psilocybin — other than an employee or an agent or mandatary of the authorized person — may do anything that is prohibited by any provision of Division 1 of Part 1 if they do so in the performance of their contract and in a manner that is consistent with the conditions that apply to the authorized person's authorization.

Part 5: Ministerial Orders

Provision of information

The Minister would be able to require holders of psilocybin-related licences to provide information.

CA – Amend section 73.

73(1) The Minister may, by order, require a person that is authorized under this Act to conduct any activity in relation to cannabis or psilocybin — or a person that is authorized under a provincial Act to sell cannabis or psilocybin — to provide the Minister with any information that the Minister considers necessary

(a) to address an issue of public health or public safety; or

(b) to verify compliance or prevent non-compliance with the provisions of this Act or of the regulations.

Tests and studies

Minister would be able to require a person authorized by this Act to work with psilocybin to conduct activities with psilocybin. No provincial act authorizes work with psilocybin so no provincial psilocybin equivalent would be necessary.

CA – Amend section 74.

74(1) For the purpose of verifying compliance or preventing non-compliance with the provisions of this Act or of the regulations or to address an issue of public health or public safety, the Minister may, by order, require a person that is authorized under this Act to conduct any activity in relation to cannabis or psilocybin — or a person that is authorized under a provincial Act to sell cannabis — to

(a) conduct tests or studies on the cannabis or psilocybin to which their activities relate or that they are authorized to sell, as the case may be, in order to obtain the information that the Minister considers necessary; and

(b) provide the Minister with that information and the results of the tests or studies.

Measures

The Minister would be able to require holders of psilocybin-related licences to take any measures the Minister considers necessary.

CA – Amend section 75.

75(1) The Minister may, by order, require a person that is authorized under this Act to conduct any activity in relation to cannabis or psilocybin — or a person that is authorized under a provincial Act to sell cannabis — to take any measures that the Minister considers necessary

(a) to address an issue of public health or public safety; or

(b) to prevent non-compliance with the provisions of this Act or of the regulations or, if the Minister has reasonable grounds to believe that there is such non-compliance, to remedy it.

Recall

The Minister would be able to require a recall.

CA – Amend section 76.

76(1) If the Minister believes on reasonable grounds that a recall of any cannabis or class of cannabis or psilocybin or class of psilocybin is necessary to protect public health or public safety, he or she may, by order, require a person that sells or distributes that cannabis or class of cannabis or psilocybin or class of psilocybin to recall it or send it — or cause it to be sent — to a place specified in the order, or

to do both those things.

Part 6: Cannabis and Psilocybin Tracking System

Tracking System

The Minister would be able to establish a national psilocybin tracking system.

CA – Amend section 81.

81 The Minister may, using the information collected under section 82 and any other information to which the Minister has access, establish and maintain a national cannabis or psilocybin tracking system to

(a) enable the tracking of cannabis or psilocybin;

(b) prevent cannabis or psilocybin from being diverted to an illicit market or activity; and

(c) prevent illicit cannabis or psilocybin from being a source of supply of cannabis or psilocybin in the legal market.

Order requiring information

Minister would be able to require persons working with psilocybin to provide information.

CA – Amend section 82.

82(1) For the purpose of section 81, the Minister may, by order, require a class of persons that are authorized to import, export, produce, test, package, label, send, deliver, transport, sell, or dispose of cannabis or psilocybin to provide the Minister with information respecting their activities in relation to cannabis or psilocybin.

Disclosure of information

Minister would be able to disclose information gathered under tracking system.

CA – Amend section 83.

83 The Minister may disclose any information contained in the national cannabis or psilocybin tracking system as follows:

(b) he or she may disclose it to any federal Minister if the disclosure is for a purpose related to verifying compliance or preventing non-compliance with the

provisions of any Act of Parliament, other than this Act, that applies directly or indirectly to cannabis <u>or psilocybin</u> or any activity in relation to cannabis <u>or psilocybin</u>;

(c) he or she may disclose it if he or she has reasonable grounds to believe that the disclosure is necessary to protect public health or public safety, including to prevent cannabis <u>or psilocybin</u> from being diverted to an illicit market or activity;

<u>Part 7: Inspections</u>

<u>Provision of documents, information or samples</u>

The powers of an inspector would apply to psilocybin.

CA – Amend section 85.

85(1) An inspector may, for a purpose related to verifying compliance or preventing non-compliance with the provisions of this Act or of the regulations, order a person that is authorized under this Act to conduct any activity in relation to cannabis <u>or psilocybin</u> to provide, on the date, at the time and place and in the manner specified by the inspector, any document, information or sample specified by the inspector.

<u>Power to enter</u>

An inspector's powers of entry would apply to a search for documents related to the promotion of psilocybin, psilocybin accessories or services related to psilocybin.

CA – Amend section 86(1) and (2).

86(1) Subject to subsection (7), an inspector may, for a purpose related to verifying compliance or preventing non-compliance with the provisions of this Act or of the regulations, enter any place, including a conveyance, in which they believe on reasonable grounds

(c) any record, report, electronic data or other document relating to the promotion of cannabis, a cannabis accessory, ~~or~~ a service related to cannabis, <u>or psilocybin, a psilocybin accessory, or a service related to psilocybin</u> is located;

(2) The inspector may in the place entered under subsection (1)

(b) examine anything found in the place that is used or may be capable of being used for the production, preservation, packaging, labelling or storage of

cannabis or psilocybin;

(c) examine any record, report, electronic data or other document, or any label or promotional material, found in the place with respect to cannabis or psilocybin, other than the records of the medical condition of individuals, and make copies of them or take extracts from them;

(j) seize and detain in accordance with this Part, cannabis, psilocybin or any other thing found in the place that the inspector believes on reasonable grounds is something in relation to which the Act was contravened or is something the seizure and detention of which is necessary to prevent non-compliance with the provisions of this Act or of the regulations;

(k) order the owner or person having possession of cannabis, psilocybin or any other thing to which the provisions of this Act or of the regulations apply that is found in that place to move it or, for any time that may be necessary, not to move it or to restrict its movement;

(l) order the owner or person having possession of any conveyance that is found in the place and that the inspector believes on reasonable grounds contains cannabis or psilocybin to stop the conveyance, to move it or, for any time that may be necessary, not to move it or to restrict its movement;

Part 8: Search Warrant

Information for search warrant

Search warrant grounds, searches and seizures and would include psilocybin offences under the *CA*. The police would have the power to apply for a search for a psilocybin offence warrant under the *CA*, but possession, trafficking, production and importing offences would still be dealt with under the *CDSA*. This means that possession, trafficking, production and importing offences would be investigated by way of a *CDSA* search warrant.

CA – Amend section 87.

87(1) A justice who, on *ex parte* application, is satisfied by information on oath that there are reasonable grounds to believe that any of the following is in a place may, at any time, issue a warrant authorizing a peace officer, at any time, to search the place for it and to seize it:

(a) cannabis or psilocybin in respect of which this Act has been contravened;

(b) anything in which cannabis or psilocybin in respect of which this Act has been contravened is contained or concealed;

(5) If a peace officer who executes a warrant issued under subsection (1) has reasonable grounds to believe that any individual found in the place referred to in the warrant has on them any cannabis, psilocybin, property or thing referred to in the warrant, the peace officer may search the individual for it and seize it.

(6) A peace officer who executes a warrant issued under subsection (1) may seize, in addition to any cannabis, psilocybin, property or thing referred to in the warrant,

(a) any cannabis or psilocybin in respect of which the peace officer believes on reasonable grounds that this Act has been contravened;

(b) anything that the peace officer believes on reasonable grounds contains or conceals cannabis or psilocybin;

(c) anything that the peace officer believes on reasonable grounds is offence-related property; or

(d) anything that the peace officer believes on reasonable grounds will afford evidence in respect of an offence under this Act.

(8) A peace officer who executes a warrant issued under subsection (1) or exercises powers under subsection (5) or (7) may seize, in addition to any cannabis, psilocybin, property or thing referred to in the warrant and in subsection (6), anything that the peace officer believes on reasonable grounds has been obtained by or used in the commission of an offence or that will afford evidence in respect of an offence.

Part 9: Disposition of Seized Things

Disposition of Seizure, Etc.

The obligation to report on seizures would apply to psilocybin seizures.

CA – Amend section 89.

89(1) Subject to the regulations, every peace officer, inspector or prescribed person that seizes, finds or otherwise acquires cannabis or psilocybin in the course of the administration or enforcement of this Act or any other Act of Parliament must, within 30 days after doing so, cause a report to be sent to the Minister setting out

(a) a description of the cannabis or psilocybin;

<u>*Cannabis Act* applicable</u>

The *Cannabis Act* would apply to seizures of psilocybin.

CA – Amend section 90.

90(3) The provisions of this Act and of the regulations apply in respect of

(a) any cannabis, <u>psilocybin,</u> or chemical offence-related property that is seized under this Act or any other Act of Parliament or under a power of seizure at common law; and

<u>Return of cannabis or psilocybin</u>

Legal psilocybin would be able to be returned.

CA – Amend section 102.

102(1) A peace officer, inspector or prescribed person that seizes, finds or otherwise acquires cannabis<u>, psilocybin</u> or chemical offence-related property in the course of the administration or enforcement of this Act or any other Act of Parliament — or that seizes, finds or otherwise acquires any chemical or thing that is referred to in paragraph (b) or (c) of the definition *chemical property* in subsection 2(1) in the course of the administration or enforcement of this Act — may return it to the person that is its owner or that is entitled to its possession if the peace officer, inspector or prescribed person is satisfied

(a) that there is no dispute as to who owns it or is entitled to its possession; and

(b) that its continued detention is not required for the purposes of a preliminary inquiry, trial or other proceeding under this Act or any other Act of Parliament.

(2) When the cannabis<u>, psilocybin</u> or property is returned, the peace officer, inspector or prescribed person must obtain a receipt for it.

<u>Application for order to return</u>

A person would be able to apply for the return of seized psilocybin. The psilocybin would be returned, forfeited or compensation payment in lieu ordered.

CA – Amend section 103.

103(1) If cannabis<u>, psilocybin</u> or chemical property has been seized, found or otherwise acquired by a peace officer, inspector or prescribed person, any person may, within 60 days after the date of the seizure, finding or acquisition, on prior

notification being given to the Attorney General in the prescribed manner, apply, by notice in writing to a justice in the jurisdiction in which it is being detained, for an order to return it to the person.

(2) If, on the hearing of the application, a justice is satisfied that the applicant is the owner or is entitled to possession of the cannabis, psilocybin or the property and the Attorney General does not indicate that it or any part of it may be required for the purposes of a preliminary inquiry, trial or other proceeding under this or any other Act of Parliament, the justice must, subject to subsection (5), order that it, or the part that is not required, as the case may be, be returned as soon as feasible to the applicant.

(3) If, on the hearing of the application, a justice is satisfied that the applicant is the owner or is entitled to possession of the cannabis, psilocybin or property but the Attorney General indicates that it or any part of it may be required for the purposes of a preliminary inquiry, trial or other proceeding under this Act or any other Act of Parliament, the justice must, subject to subsection (5), order that it, or the part that is required, as the case may be, be returned to the applicant

(a) on the expiry of 180 days after the day on which the application was made, if no proceeding in relation to the cannabis, psilocybin or property has been commenced before that time; or

(b) on the final conclusion of the proceeding or any other proceeding in relation to the cannabis, psilocybin or property if the applicant is not found guilty in those proceedings of an offence committed in relation to it.

(4) If, on the hearing of the application, a justice is not satisfied that the applicant is the owner or is entitled to possession of the cannabis, psilocybin or property, and it or a part of it is not required for the purposes of a preliminary inquiry, trial or other proceeding under this Act or any other Act of Parliament, the justice must order that it, or the part that is not required, as the case may be, be forfeited to Her Majesty to be disposed of or otherwise dealt with in accordance with the regulations or, if there are no applicable regulations, in the manner that the Minister directs.

(5) If, on the hearing of the application, a justice is satisfied that the applicant is the owner or is entitled to possession of the cannabis, psilocybin or property, but it was disposed of or otherwise dealt with under section 105, the justice must make an order that an amount equal to its value be paid to the applicant.

Forfeiture if no application

The seized psilocybin would be forfeited if no application and it was no longer needed.

CA – Amend section 104.

104 If no application for the return of the cannabis, psilocybin or the chemical property has been made under subsection 103(1) within 60 days after the date of its seizure, finding or acquisition by a peace officer, inspector or prescribed person and it or any part of it is not required for the purposes of a preliminary inquiry, trial or other proceeding under this Act or any other Act of Parliament, the cannabis, psilocybin or the property, or the part that is not required, as the case may be, is forfeited to Her Majesty and may be disposed of or otherwise dealt with in accordance with the regulations or, if there are no applicable regulations, in the manner that the Minister directs.

Expedited disposition

The seized psilocybin would be disposed of its storage poses a safety risk and it was no longer needed.

CA – Amend section 105.

105 If all or any part of any cannabis, psilocybin or chemical property whose storage or handling poses a risk to health or safety is not required for the purposes of a preliminary inquiry, trial or other proceeding under this Act or any other Act of Parliament, the Minister or a peace officer or prescribed person may dispose of or otherwise deal with it in accordance with the regulations or, if there are no applicable regulations, in the manner that the Minister directs.

Destruction of plants

The Minister would be able to have illegal psilocybin mushroom destroyed.

CA – Amend section 106.

106 The Minister may, on prior notification being given to the Attorney General, cause to be destroyed any cannabis plant or psilocybin mushroom that is being produced contrary to the provisions of this Act or of the regulations.

Disposition following proceedings

The psilocybin would be either returned or forfeited after the court proceeding.

CA – Amend section 107.

107 Subject to section 103, if, in a preliminary inquiry, trial or other proceeding under this Act or any other Act of Parliament, the court before which the proceedings have been brought is satisfied that any cannabis, psilocybin or

chemical property that is the subject of proceedings before the court is no longer required by that court or any other court, the court

(a) must order that it be returned to

(i) the person from which it was seized if the court is satisfied that the person came into its possession lawfully and continued to deal with it lawfully, or

(ii) the person that is its owner or that is entitled to its possession, if that person is known and if the court is satisfied that its possession by the person from which it was seized was unlawful; and

Disposal with consent

The owner of the psilocybin would be able to consent to disposal after court proceeding.

CA – Amend section 108.

108 If cannabis, psilocybin or chemical property has been seized, found or otherwise acquired by a peace officer, inspector or prescribed person and it or a part of it is not required for the purposes of a preliminary inquiry, trial or other proceeding under this Act or any other Act of Parliament, its owner may consent to its disposal and, if the consent is given, the cannabis, psilocybin or property, or the part that is not required, as the case may be, is forfeited to Her Majesty and may be disposed of or otherwise dealt with in accordance with the regulations or, if there are no applicable regulations, in the manner that the Minister directs.

Disposition report

Officers, inspectors and officials who dispose of psilocybin or deal with psilocybin would file a report.

CA – Amend section 109.

109(1) Subject to the regulations, every peace officer, inspector or prescribed person that disposes of or otherwise deals with cannabis, psilocybin or chemical property under this Act must, within 30 days after doing so, cause a report to be sent to the Minister setting out

(a) a description of the cannabis, psilocybin or property;

(2) For the purposes of subsection (1), otherwise dealing with cannabis, psilocybin or chemical property by a peace officer includes using it to conduct an investigation or for training purposes.

Part 11: General

Regulations

The Govern in Council would be able to make regulations regarding a wide array of psilocybin-related matters. There would be no need for regulation concerns the display of psilocybin (s. 139 (1) (p)) as there will be no retail psilocybin sales.

CA – Amend section 139.

139(1) The Governor in Council may make regulations for carrying out the purposes and provisions of this Act, including for the administration and enforcement of this Act, and regulations

(b) establishing, in addition to dried cannabis, other classes of cannabis, and in addition to psilocybin, other classes of psilocybin;

(d) respecting the importation, exportation, production, testing, packaging, labelling, storage, preservation, sale, distribution, possession, disposal or obtaining of or other dealing in cannabis or any class of cannabis or psilocybin or any class of psilocybin;

(e) respecting the importation, exportation, production, testing, sale, distribution, possession, disposal or obtaining of or other dealing in of any substance that may be used in the production of cannabis or psilocybin;

(f) respecting the packaging, labelling, distribution or sale of cannabis accessories or psilocybin accessories;

(g) respecting the issuance of licences, permits or other authorizations that authorize, as the case may be, the importation, exportation, production, testing, packaging, labelling, sending, delivery, transportation, sale, possession or disposal of cannabis or any class of cannabis or psilocybin or any class of psilocybin, and their renewal, amendment, suspension, revocation, duration and conditions;

(i) respecting the qualifications required to be met by individuals who are engaged in the production, testing, packaging, labelling, storage, preservation, selling, distributing or otherwise dealing in cannabis or any class of cannabis or psilocybin or any class of psilocybin;

(k) respecting the characteristics, composition, strength, concentration, potency, intended use, sensory attributes — such as appearance and shape — purity, quality or any other property of cannabis or any class of cannabis or psilocybin

or any class of psilocybin;

(k.1) respecting the characteristics, composition, design, construction, performance, intended use, sensory attributes — such as appearance and shape — purity, quality or any other property of cannabis accessories or psilocybin accessories;

(k.2) respecting the emissions produced by the consumption of cannabis or psilocybin or the use of cannabis accessories or psilocybin accessories and defining "emission" for the purpose of regulations made under this paragraph;

(l) requiring persons to take or keep samples of any cannabis or any class of cannabis or psilocybin or any class of psilocybin, or of any package or label of cannabis or psilocybin, and to provide the Minister or an inspector with, or with access to, those samples;

(n) respecting the promotion of cannabis, cannabis accessories, ~~or~~ services related to cannabis, psilocybin, psilocybin accessories, services related to psilocybin, or the display or promotion of their brand elements;

(o) respecting the information, including information about health risks and health effects arising from the use of cannabis or psilocybin, that must appear on packages or labels of cannabis, ~~or~~ cannabis accessories, psilocybin or psilocybin accessories or that must be provided when cannabis, ~~or~~ cannabis accessories, psilocybin or psilocybin acessories are promoted;

(p) respecting the display of cannabis by persons that are authorized to sell cannabis or the display of cannabis accessories or psilocybin accessories by persons that sell cannabis accessories or psilocybin accessories;

(q) respecting the records, reports, electronic data or other documents in respect of cannabis or psilocybin — or in respect of activities related to cannabis, cannabis accessories, services related to cannabis, psilocybin, psilocybin accessories, services related to psilocybin, or their brand elements, including their promotion — that are required to be prepared, retained or provided by any person or class of persons and

(s) respecting the detention and the return, disposition of or otherwise dealing with

> **(i) any cannabis, cannabis accessory, psilocybin, psilocybin accessory, or offence-related property that is seized, detained, found or otherwise acquired under this Act or any other Act of Parliament or under a power of seizure at common law,**

(x) respecting the recall of cannabis or any class of cannabis or psilocybin or any class of psilocybin;

(z) exempting, on any terms and conditions that are specified in the regulations, any person or class of persons, any cannabis or any class of cannabis or any cannabis accessory or any class of cannabis accessory or any psilocybin or class of psilocybin or any psilocybin accessory or any class of psilocybin accessory, from the application of all or any of the provisions of this Act or of the regulations;

(6) The Governor in Council, on the recommendation of the Minister of Public Safety and Emergency Preparedness, may make regulations that pertain to investigations and other law enforcement activities conducted under this Act by a member of a police force or of the military police and other persons acting under the direction and control of the member, including regulations

(d) respecting the detention, storage and disposition of or other dealing with cannabis or psilocybin;

(e) respecting records, reports, electronic data or other documents in respect of cannabis or psilocybin that are required to be prepared, retained or provided by any person or class of persons; and

(7) The Governor in Council, on the recommendation of the Minister of Public Safety and Emergency Preparedness, may, for the purpose of an investigation or other law enforcement activity conducted under another Act of Parliament, make regulations authorizing a member of a police force or of the military police or other person under the direction and control of the member to commit an act or omission — or authorizing a member of a police force or of the military police to direct the commission of an act or omission — that would otherwise constitute an offence under Division 1 of Part 1 or under section 44 in respect of the contravention of a provision of the regulations, including regulations

(d) respecting the detention, storage and disposition of or other dealing with cannabis or psilocybin;

(e) respecting records, reports, electronic data or other documents in respect of cannabis or psilocybin that are required to be prepared, retained or provided by any person or class of persons; and

Exemption by Minister — persons

The Minister would be able to exempt a person, class of persons or psilocybin from the Act's psilocybin laws.

CA – Amend section 140.

140(1) The Minister may, on any terms and conditions that the Minister considers necessary, by order, exempt any person, or any cannabis or any class of cannabis or any psilocybin or any class of psilocybin in relation to a person, from the application of all or any of the provisions of this Act or of the regulations if, in the opinion of the Minister, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest.

(2) The Minister may, on any terms and conditions that the Minister considers necessary, by order, exempt any class of persons, or any cannabis or any class of cannabis or any psilocybin or any class of psilocybin in relation to any class of persons, from the application of all or any of the provisions of this Act or of the regulations if, in the opinion of the Minister, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest.

Fees

The Minister would be able to fix fees in relation to psilocybin.

CA – Amend section 142.

142(1) The Minister may, by order, fix the following fees in relation to cannabis or psilocybin:

(a) fees to be paid for a service, or the use of a facility, provided under this Act;

(c) fees to be paid in respect of products, rights and privileges that are provided under this Act, including those provided in relation to the cannabis tracking system or the psilocybin tracking system established under section 81.

Schedules

Governor in Council would have the power to amend Schedule 7 by adding or deleting classes of psilocybin.

CA – New subsections 151(5) and (6).

151(5) The Governor in Council may, by order, amend Schedule 7 by adding or deleting the name of any class of psilocybin.
(6) The Governor in Council may, by order, amend Schedule 8 by adding or deleting, in column 1, the name of a class of psilocybin or by adding or deleting, in column 2, in relation to a class of psilocybin in column 1, a quantity that is equivalent to 1 g of dried psilocybin.

Schedule 7

(Sections 33.1 and 151(5))

Classes of Psilocybin That an Authorized Person May Sell

Item	Class of Psilocybin
1	psilocybin mushrooms
2	dried psilocybin
3	psilocybin extracts

Schedule 8

(Subsection 2(5) and subsection 151(6))

Equivalent Amounts

Item	Class of Psilocybin	Quantity that is equivalent to 1 g of dried psilocybin
1	dried psilocybin	1 g
2	fresh psilocybin	10 g
3	psilocybin extract	0.25 g

Part 12: Transitional Provisions and Related, Consequential and Coordinating Amendments

Decisions

Minister's decisions relating to psilocybin under the *Controlled Drugs and Substances Act* are deemed decisions under the *CA.*

CA – Amend section 153.

153 Subject to regulations made under subsection 161(1), every decision made by the Minister under the *Controlled Drugs and Substances Act* that relates to cannabis or psilocybin is deemed to be a decision made by the Minister under this Act.

Cannabis Regulations, SOR/ 2018-144 (the "*CRs*")

Amend the definitions section.

CRs – Amend section 1 to add:

cannabis-related licence **means a licence for cultivation, a licence for processing, a licence for analytical testing, a licence for sale, a licence for research, and a cannabis drug licence.**

contaminated **means, in respect of cannabis, a cannabis accessory, ~~or~~ psilocybin, psilocybin accessory, or psilocybin spores, an ingredient, containing or having on it anything — including a micro-organism but excluding anything referred to in item 1 or 3 of Schedule 1 to the Act —that may render the cannabis, cannabis accessory, ~~or~~ psilocybin, psilocybin accessory, or psilocybin spores, or ingredient injurious to human health or unsuitable for human use.**

dried psilocybin **means any part of a psilocybin mushroom that has been subjected to a drying process.**

export permit **means a permit issued under subsection 62(1) of the Act that authorizes the exportation of cannabis or psilocybin for medical or scientific purposes.**

grow area **means, in respect of a site set out in a licence, an area of the site where cannabis plants are cultivated, harvested or propagated or where psilocybin mushrooms and their substrate media are cultivated, harvested or inoculated.**

import permit **means a permit issued under subsection 62(1) of the Act that authorizes the importation of cannabis or psilocybin for medical or scientific purposes.**

ingredient **means**

> **(a) in the case of a cannabis extract, a psilocybin extract or a cannabis topical, a substance, other than anything referred to in item 1 or 3 of Schedule 1 to the Act, that is used to produce the cannabis extract, psilocybin extract or cannabis topical, including any substance used in the manufacture of that substance, and that is present in the final form of the cannabis extract, psilocybin extract or cannabis topical; and**

licence **means a licence issued under subsection 62(1) of the Act in relation to cannabis or psilocybin.**

operations area **means, in respect of a site set out in a licence, an area of the site — other than a storage area — where cannabis or psilocybin is present as a result of any activities conducted under a licence. It includes a grow area.**

psilocybin extract **means**

(a) a substance produced by subjecting psilocybin mushrooms to extraction processing, or

(b) a substance or mixture of substances that contains or has on it a substance produced in a manner referred to in paragraph (a).

psilocybin **means:**
Psilocybin mushrooms,
Psilocybin extracts,
Psilocybin (3–[2–(dimethylamino)ethyl]–4–phosphoryloxyindole) and any salt thereof.
Psilocin (3–[2–(dimethylamino)ethyl]–4–hydroxyindole) and any salt thereof,
It does not include psilocybin mushroom spores.

psilocybin mushrooms **are any species of fungi which produce psilocybin**

psilocybin product **means psilocybin of only one of the classes set out in Schedule 7 to the Act — or a psilocybin accessory that contains such psilocybin**

psilocybin-related licence **means a licence for psilocybin cultivation, a licence for psilocybin processing, a licence for psilocybin analytical testing, a licence for psilocybin sale, and a licence for psilocybin research**

storage area **means, in respect of a site set out in a licence, an area of the site where cannabis or psilocybin is stored.**

test kit **means a kit**

(a) that contains

(i) cannabis or psilocybin, and

(ii) a reagent system or buffering agent, or both;

(b) that is designed to be used during the course of a chemical or analytical procedure to test for the presence or quantity of cannabis or psilocybin for a medical, laboratory, industrial, educational, law administration or enforcement, or research purpose; and

(c) the contents of which are not intended or likely to be consumed or administered.

Part 2: Licensing

Pre-licensing Requirements

The pre-licensing requirements for cannabis cultivation and processing would apply to psilocybin cultivation and processing.

CRs - Amend section 7.

7(1) Before submitting an application to the Minister for a licence for cultivation, a licence for processing or a licence for sale that authorizes the possession of cannabis or a license to cultivate or process psilocybin, the person that intends to submit the application must provide a written notice to the following authorities in the area in which the site referred to in the application is located

(a) the local government;

(b) the local fire authority; and

(c) the local police force or the Royal Canadian Mounted Police detachment that is responsible for providing policing services to that area.

(2) The notice must contain the following information:

(a) the person's name;

(b) the date on which the person expects to submit the application;

(c) the class and the subclass of licence that will be sought, the activity that the person expects to conduct under the licence and an indication that the activity will be conducted in relation to cannabis or psilocybin; and

(d) the address of the site where the person proposes to conduct the activities and, if applicable, of each building within the site.

Classes of licences

The classes of licenses will have to be expanded to include licenses for psilocybin cultivation, psilocybin processing, psilocybin analytical testing, licence for psilocybin research and psilocybin medical sale.

CRs – New section 8.1.

8.1 The following are established as classes of licences that authorize activities in relation to psilocybin:

(a) a license for psilocybin cultivation;

(b) a license for psilocybin processing;

(c) a license for psilocybin sale;

(d) a licence for psilocybin analytical testing; and

(e) a licence for psilocybin research.

Licences for Cultivation

The psilocybin cultivators would be regulated.

CRs – New section 11.1.

11.1(1) Subject to the other provisions of these Regulations, a holder of a licence for psilocybin cultivation is authorized to conduct those of the following activities that are authorized by the licence:

(a) to possess psilocybin;

(b) to obtain psilocybin, psilocybin mushrooms, or psilocybin spores by cultivating, propagating or harvesting psilocybin and/ or psilocybin spores;

(c) for the purpose of testing, to obtain psilocybin by altering its chemical or physical properties by any means; and

(d) to sell psilocybin.

(2) A holder of a licence for psilocybin cultivation that is authorized to conduct the activity referred to in paragraph (1)(b) is also authorized to offer to conduct that activity.

(3) A holder of a licence for psilocybin cultivation that is authorized to conduct the activity referred to in paragraph (1)(b) is also authorized, to the extent necessary to conduct that activity, to conduct ancillary activities such as sterilizing substrate, inoculating substrate, harvesting and drying psilocybin mushrooms.

(4) A holder of a licence for psilocybin cultivation that is authorized to conduct the

activity referred to in paragraph (1)© is also authorized to alter the chemical or physical properties of psilocybin by the use of an organic solvent when conducting that activity.

(5) A holder of a licence for psilocybin cultivation whose licence authorizes the sale of psilocybin is authorized to conduct the following activities:

(a) to sell and distribute psilocybin and psilocybin spores to any of the following:

(i) a holder of a licence for psilocybin cultivation,

(ii) a holder of a licence for psilocybin processing,

(iii) a holder of a licence for psilocybin analytical testing,

(iv) a holder of a licence for research, and

(v) the Minister.

(b) to sell and distribute psilocybin mushrooms or psilocybin mushroom spores to any of the following:

(i) a holder of a licence for psilocybin cultivation;

(ii) a holder of a licence for psilocybin analytical testing; and

(iii) a holder of a licence for research.

Master Growers

Psilocybin mushroom growers would have a master grower, just as cannabis cultivators must have master growers.

CRs - Amend section 12.

12(1) A holder of a licence for micro-cultivation or standard cultivation or psilocybin cultivation must retain the services of one individual as a master grower.

(2) The master grower is responsible for the cultivation, propagation and harvesting of cannabis or psilocybin mushrooms and must have sufficient knowledge of the provisions of the Act and these Regulations in relation to those activities.

(3) A holder of a licence for micro-cultivation or standard cultivation or psilocybin

cultivation may designate one individual as the alternate master grower who is qualified to replace the master grower.

Processing Licences

Psilocybin mushroom processing licences would follow similar rules as cannabis processing licences.

CRs – New section 17.1.

17.1(1) Subject to the other provisions of these Regulations, a holder of a licence for psilocybin processing is authorized to conduct those of the following activities that are authorized by the licence:

(a) to possess psilocybin;

(b) to produce psilocybin, other than obtain it by cultivating, propagating or harvesting it; and

(c) to sell psilocybin.

(2) A holder of a licence for psilocybin processing that is authorized to conduct the activity referred to in paragraph (1)(b) is also authorized to offer to obtain psilocybin by any method authorized by the licence.

(3) A holder of a licence for psilocybin processing that is authorized to conduct the activity referred to in paragraph 1(b) is also authorized to alter or offer to alter the chemical or physical properties of psilocybin by the use of an organic solvent when conducting that activity.

(4) A holder of a licence for psilocybin processing whose licence authorizes the sale of psilocybin is authorized to conduct the following activities:

(a) to sell and distribute psilocybin to any of the following:

(i) a holder of a licence for psilocybin processing,

(ii) a holder of a licence for analytical testing,

(iii) a holder of a licence for research,

(iv) the Minister,

(v) a person to which an exemption has been granted under section 56 of the *CDSA* in relation to psilocybin that is sold or distributed,

(b) to sell and distribute the following to a holder of a licence for psilocybin cultivation:

(i) psilocybin mushrooms,

(ii) psilocybin mushroom spores,

(iii) any psilocybin that was obtained or produced for the purpose of conducting testing that is necessary to determine the chemical characterization of psilocybin;

(c) to sell and distribute psilocybin to a holder of a licence for psilocybin sale.

Quality assurance person

Holders of psilocybin processing licences would have a quality assurance person.

CRs – New section 19.1.

19.1(1) A holder of a licence for processing must retain the services of one individual as a quality assurance person who has the training, experience and technical knowledge related to the requirements of Parts 5 and 6 that are applicable to psilocybin in respect of which activities are conducted under the licence.

(2) The quality assurance person is responsible for

(a) assuring the quality of the psilocybin before it is made available for sale;

(b) investigating every complaint received in respect of the quality of the psilocybin and, if necessary, immediately taking measures to mitigate any risk; and

(c) if they suspect, on reasonable grounds, that the psilocybin or anything that will be used as an ingredient presents a risk of injury to human health or that the applicable requirements of Part 5 or 6 are otherwise not being met, immediately investigating the matter and, if necessary, immediately taking measures to mitigate any risk.

(3) A holder of a licence for processing may designate up to two individuals as alternate quality assurance persons who are qualified to replace the quality assurance person.

Changing QA Person

Holders of a psilocybin processing licences would have the same rules regarding changing the quality assurance person as holders of cannabis processing licences.

CRs - Amend section 20.

20(1) A holder of a licence for processing or psilocybin processing must obtain the Minister's approval before

(a) designating or replacing an alternate quality assurance person; an

(b) replacing the quality assurance person by an individual, other than by the alternate quality assurance person.

(2) The holder of a licence for processing or psilocybin processing must, for the purpose of obtaining the Minister's approval, submit an application that includes the following:

(a) the name and date of birth of the proposed alternate quality assurance person or the proposed quality assurance person;

(b) a description of the proposed quality assurance person's or the proposed alternate quality assurance person's qualifications in respect of the matters referred to in subsection 19(1); and

(c) a declaration, signed and dated by the responsible person referred to in section 37, indicating that all information provided in support of the application is correct and complete to the best of their knowledge.

Licence for Psilocybin Analytical Testing

Psilocybin analytical testing licences would be permitted.

CRs – New section 22.1.

22.1(1) Subject to the other provisions of these Regulations, a holder of a licence for psilocybin analytical testing is authorized, for the purpose of testing, to conduct those of the following activities that are authorized by the licence:

(a) to possess psilocybin; and

(b) to obtain psilocybin by altering its chemical or physical properties by any means.

(2) A holder of a licence for psilocybin analytical testing that is authorized to conduct the activity referred to in paragraph (1)(b) is also authorized to offer to conduct that activity.

(3) A holder of a licence for psilocybin analytical testing that is authorized to conduct the activity referred to in paragraph (1)(b) is also authorized to alter or offer to alter the chemical or physical properties of psilocybin by the use of an organic solvent when conducting that activity.

(4) A holder of a licence for psilocybin analytical testing is also authorized, for the purpose of testing, to distribute psilocybin to another holder of a licence for psilocybin analytical testing.

Head of laboratory

The holder of an analytical testing licence would have a head of laboratory.

CRs – New section 23.1.

23.1 A holder of a licence for psilocybin analytical testing must retain the services of one individual as the head of laboratory who must work at the site set out in the licence and who is responsible for the testing referred to in sections 90.1 to 91.1.

(2) The head of laboratory must have sufficient knowledge of the provisions of the Act and these Regulations that apply to the holder of the licence for psilocybin analytical testing, have knowledge and experience related to the duties of the position and possess a degree in a science related to the work to be carried out that is awarded by a Canadian university or, if awarded by a foreign university, that is recognized by a Canadian university or a Canadian professional association.

(3) A holder of a licence for psilocybin analytical testing may designate one or more individuals as the alternate heads of laboratory who are qualified to replace the head of laboratory.

Minister's approval for replacing head of laboratory

The holder of an analytical testing licence would need the Minister's approval to replace the head of the laboratory.

CRs – New section 24.1.

24.1(1) A holder of a licence for psilocybin analytical testing must obtain the Minister's approval before

(a) designating or replacing an alternate head of laboratory; and

(b) replacing the head of laboratory by an individual, other than by an alternate head of laboratory.

(2) The holder of a licence for psilocybin analytical testing must, for the purpose of obtaining the Minister's approval, submit an application that includes the following:

(a) the name and date of birth of the proposed alternate head of laboratory or the proposed head of laboratory;

(b) a description of the proposed head of laboratory's or the proposed alternate head of laboratory's qualifications in respect of the matters referred to in subsection 23(2); and

(c) a declaration, signed and dated by the responsible person referred to in section 37, indicating that all information provided in support of the application is correct and complete to the best of their knowledge.

(3) The Minister may, on receiving an application for approval, require the submission of any additional information that pertains to the information contained in the application and that is necessary for the Minister to consider the application.

Destruction

Holders of psilocybin analytic testing licences would have rules requiring destruction of psilocybin after testing.

CRs – New section 25.1.

25.1(1) A holder of a licence for psilocybin analytical testing must destroy the sample of a lot or batch of psilocybin that has been distributed to them, and all psilocybin obtained from that sample, within 90 days after completing the testing of the sample of the lot or batch.

(2) If testing of the sample of a lot or batch of psilocybin distributed to the holder of the licence for psilocybin analytical testing is not initiated within 120 days of its receipt, the holder must, by the end of that period, either destroy the sample or distribute it to another holder of a licence for psilocybin analytical testing.

Psilocybin medical selling licence

A psilocybin medical selling licence would be required to sell directly to a practitioner, a clinic, or therapeutic regulated professional at a clinic.

CRs – New section 26.1.

26.1 Subject to the other provisions of these Regulations, a holder of a licence for sale of psilocybin for medical purposes is authorized to conduct those of the following activities that are authorized by the licence:

(a) to possess psilocybin; and

(b) to sell psilocybin.

Psilocybin medical selling licence sales

The holder of a licence for sale of psilocybin for medical purposes would be able to sell to prescribed individuals.

CRs – New section 27.1.

27.1(1) Subject to subsection (2), a holder of a licence for sale of psilocybin for medical purposes that authorizes the sale of psilocybin is authorized to sell or distribute

(a) psilocybin to any of the following:

(i) a holder of a psilocybin licence, other than a licence for psilocybin cultivation,

(ii) the Minister,

(iii) a person to which an exemption has been granted under section 56 of the *CDSA* in relation to psilocybin that is sold or distributed,

(iv) a practitioner as defined by the *Narcotic Control Regulations*,

(v) a clinic as defined by the *Narcotic Control Regulations*, or

(vi) a therapeutic regulated professional as defined by the *Narcotic Control Regulations* at a clinic as defined by the *Narcotic Control Regulations*.

(b) psilocybin mushrooms and psilocybin spores to a holder of a licence for psilocybin cultivation.

(c) to a hospital employee if the employee's possession of the psilocybin is for the purpose of, and in connection with, their duties.

(2) A holder of a licence for sale of psilocybin for medical purposes must sell the psilocybin referred to in subsection (1) in the packaging in which they were sold or distributed to the holder.

Licence for Psilocybin Research

The holder of a psilocybin research would be permitted to conduct prescribed activities.

CRs – New section 28.1.

28.1(1) Subject to the other provisions of these Regulations, a holder of a licence for psilocybin research is authorized to conduct those of the following activities, that are authorized by the licence:

(a) for the purpose of research,

(i) to possess psilocybin,

(ii) to produce psilocybin, and

(iii) to transport, send or deliver psilocybin between the sites that are set out by the licence; and

(b) to sell psilocybin mushrooms and psilocybin spores to any of the following:

(i) a holder of a licence for psilocybin cultivation,

(ii) another holder of a licence for psilocybin research,

(iii) the Minister, or

(iv) a person to which an exemption has been granted under section 56 of the *CDSA* in relation to the psilocybin that is sold or distributed.

(2) A holder of a licence for psilocybin research that is authorized to conduct the activity referred to in subparagraph (1)(a)(ii) is also authorized to offer to obtain psilocybin by any method authorized by the licence.

(3) A holder of a licence for psilocybin research that is authorized to obtain psilocybin by altering its chemical or physical properties by any means is also authorized to alter or offer to alter its chemical or physical properties by the use of an organic solvent when conducting that activity.

(4) A holder of a licence for psilocybin research is also authorized, for the purpose

of research, to administer and distribute psilocybin to a research subject.

(5) A holder of a licence for psilocybin research is also authorized to distribute

(a) psilocybin to any of the following:

(i) another holder of a licence for psilocybin research,

(ii) a holder of a licence for psilocybin analytical testing, or

(iii) the Minister.

(b) psilocybin mushrooms or psilocybin spores to the following:

(i) a holder of a licence for psilocybin cultivation, or

(ii) a person to which an exemption has been granted under section 56 of the *CDSA* in relation to the cannabis or class of cannabis that is sold or distributed.

Refusal to issue, renew or amend — other grounds

The *CRs* would prevent psilocybin cultivation, processing and selling at the same site as cannabis cultivation, processing and selling.

CRs - Amend section 29.

29 For the purpose of paragraph 62(7)(h) of the Act, other grounds for refusing to issue, renew or amend a licence are the following:

(a) an individual who is required to hold a security clearance under section 50 in respect of an application does not hold such a security clearance;

(b) in respect of the renewal or amendment of a licence, the holder of the licence does not hold a cannabis licence issued under subsection 14(1.1) of the *Excise Act, 2001*, if it is required;

(c) in respect of the issuance or amendment of a licence for cultivation or psilocybin cultivation, the site proposed in the application would be authorized by another licence for cultivation or psilocybin cultivation;
(d) in respect of the issuance or amendment of a licence for micro-cultivation, the site proposed in the application would be authorized by a licence for standard processing and a licence for micro-cultivation;

(e) in respect of the issuance or amendment of a licence for standard cultivation, the site proposed in the application would be authorized by a licence for micro-processing and a licence for standard cultivation;

(f) in respect of the issuance or amendment of a licence for a nursery, the site proposed in the application would be authorized by a licence for processing and a licence for a nursery;

(g) in respect of the issuance or amendment of a licence for processing, the site proposed in the application would be authorized by another licence for processing;

(h) in respect of the issuance or amendment of a licence for processing, the site proposed in the application would be authorized by a licence for processing and a licence for a nursery;

(i) in respect of the issuance or amendment of a licence for micro-processing, the site proposed in the application would be authorized by a licence for standard cultivation and a licence for micro-processing;

(j) in respect of the issuance or amendment of a licence for standard processing, the site proposed in the application would be authorized by a licence for micro-cultivation and a licence for standard processing; and

(k) in respect of a licence for processing or psilocybin processing , the applicant has, in the past 10 years, been convicted of an offence under the *Safe Food for Canadians Act* or an Act referred to in subsection 374(2) of the *Safe Food for Canadians Regulations;* and

(l) in respect of a the issuance or amendment of a licence for cultivation, processing, nursery, or sale, the site proposed in the application would be authorized by a licence for psilocybin cultivation, psilocybin processing, or psilocybin medical selling.

Holder of psilocybin processing convicted

Convictions would impact ability to hold a psilocybin processing licence.

CRs - Amend section 31.

31(e) in respect of a licence for processing or psilocybin processing , the holder has, since its issuance, been convicted of an offence under the *Safe Food for Canadians Act* or an Act referred to in subsection 374(2) of the *Safe Food for Canadians Regulations*.

Notification — various changes

Minister notification requirements would apply to psilocybin licences.

CRs - Amend section 34.

34(1) A holder of a licence must notify the Minister of any of the following changes within five days after the change occurs:

(a) a change to the mailing address, telephone number, email address or facsimile number of the holder;

(b) a change to the site plan, other than a change referred to in subsection 33(1);

(c) the replacement of an individual who must hold a security clearance referred to in any of paragraphs 50(b) to (g), (i) and (j) or the addition of another such individual, other than an individual who is designated as an alternate for the position of quality assurance person referred to in section 19 or 19.1; and

(d) in the case of a holder of a licence for cultivation, a licence for processing, a licence for sale, a licence for psilocybin cultivation, a licence for psilocybin processing, or a licence for psilocybin sale, a change to the organizational security plan.

Notification to local authorities

Notification to local authority requirements would apply to psilocybin licences.

CRs - Amend section 35 (1).

35(1) A holder of a licence for cultivation, a licence for processing or a licence for sale that authorizes the possession of cannabis or a licence for psilocybin cultivation, a licence for psilocybin processing, or a licence for psilocybin sale that authorizes the possession of psilocybin must, within 30 days after the issuance, amendment, suspension, reinstatement or revocation of the licence, provide a written notice to the local authorities referred to in paragraphs 7(1)(a) to (c) in the area in which the site set out in the licence is located and provide a copy of the notice to the Minister.

Cessation of activities

Requirements surrounding cessation of activities would apply to psilocybin licences.

CRs - Amend section 36(2).

36(2) The notice must be signed and dated by the responsible person referred to in section 37 and contain the following information:

(a) the date on which activities are expected to cease;

(b) a description of the manner in which any cannabis or psilocybin remaining at the site as of the date referred to in paragraph (a) will be disposed of by the holder of the licence, including

(i) if the cannabis or psilocybin will be sold or distributed, in whole or in part, the name and address of the person to which it will be sold or distributed, and

(ii) if it will be destroyed, in whole or in part, the day on which and the location at which the destruction is to take place;

Activities at approved site

Only certain activities permitted at approved site.

CRs – Amend section 39.

39(1) A holder of a licence must only conduct activities that are authorized by the licence at the site and, if applicable, the building within the site, set out in the licence.

(2) Subsection (1) does not apply to the possession of cannabis or psilocybin for the purpose of antimicrobial treatment or destruction or the distribution of the cannabis or psilocybin.

Antimicrobial treatment

The regulations concerning location of antimicrobial treatment apply to psilocybin. This requires an amendment and a new section.

CRs - Amend section 42.

42(1) A holder of a cannabis-related licence, other than a licence for analytical, may conduct antimicrobial treatment of cannabis, at a location other than the site set out in the licence only if

(a) the holder ensures that the cannabis that is at the location is, at all times, in the presence of at least one individual referred to in paragraph 43(2)(a), or in the case of a holder of a licence for research, an individual referred to in paragraph 43(2)(b); and

(b) the cannabis is subsequently returned to the site set out in the licence or distributed in accordance with these Regulations.

CRs – New section 42.1.

42.1(1) A holder of a psilocybin-related licence, other than a licence for psilocybin analytical testing, may conduct antimicrobial treatment of psilocybin, at a location other than the site set out in the licence only if

(a) the holder ensures that the psilocybin that is at the location is, at all times, in the presence of at least one individual referred to in paragraph 43(2)(a), or in the case of a holder of a licence for research, an individual referred to in paragraph 43(2)(b); and

(b) the psilocybin is subsequently returned to the site set out in the licence or distributed in accordance with these Regulations.

Destruction

Destruction regulations would apply to psilocybin.

CRs - Amend section 43.

43(1) A holder of a cannabis-related licence is authorized to destroy cannabis only and a holder of psilocybin-related is authorized to destroy psilocybin only

(a) in accordance with a method that

(i) complies with all federal, provincial and municipal environmental protection legislation applicable to the location where it is to be destroyed, and

(ii) does not result in any individual being exposed to cannabis or psilocybin smoke or cannabis or psilocybin vapour;

(b) in the presence of at least two individuals who are qualified to witness the destruction and, except in the case of a holder of a licence for analytical testing or a licence for research, one of whom is an individual referred to in paragraph (2)(a); and

(c) in the case where the cannabis or psilocybin is destroyed at a location other than the site set out in the licence, the holder of the licence ensures that the cannabis and psilocybin that is at the location is, at all times, in the presence of at least one individual referred to in paragraph (2)(a) or, in the case of a holder of a licence for analytical testing, a licence for psilocybin analytical testing, a

license for psilocybin research, or a licence for research, an individual referred to in paragraph (2)(b).

(2) The following individuals are qualified to witness the destruction of cannabis or psilocybin:

(a) an individual who holds a security clearance; and

(b) an employee of the holder of the licence.

Security clearance holder

Rules around possession would apply to psilocybin.

CRs - Amend section 44.

44 A holder of a cannabis-related licence, other than a holder of a licence for analytical testing, a licence for research, or a licence for sale that does not authorize the possession of cannabis, must ensure that an individual who holds a security clearance is present at the site when activities are conducted by other individuals in an operations area or a storage area.

CRs – New section 44.1.

44.1 A holder of a psilocybin-related licence, other than a holder of a licence for psilocybin analytical testing, a licence for psilocybin research, or a licence for psilocybin sale that does not authorize the possession of psilocybin, must ensure that an individual who holds a security clearance is present at the site when activities are conducted by other individuals in an operations area or a storage area.

Recall

The cannabis recall rules would apply to psilocybin.

CRs - Amend section 46.

46(1) A holder of a cannabis-related licence, other than a licence for analytical testing, must establish and maintain a system of control that permits the rapid and complete recall of every lot or batch of cannabis, that has been sold or distributed.

CRs – New section 46.1.

46.1(1) A holder of a psilocybin-related licence, other than a licence for psilocybin analytical testing, must establish and maintain a system of control that permits the

rapid and complete recall of every lot or batch of psilocybin, that has been sold or distributed.

Safekeeping during distribution

The cannabis safekeeping rules would apply to psilocybin.

CRs - Amend section 47.

47 A holder of a cannabis-related licence must take any steps that are necessary to ensure the safekeeping of cannabis when distributing it.

CRs – New section 47.1.

47.1 A holder of a psilocybin-related licence must take any steps that are necessary to ensure the safekeeping of cannabis when distributing it.

Identification of holder of licence

The cannabis rules concerning identifying holder of a licence would apply to psilocybin.

CRs - Amend section 48.

48 A holder of a cannabis-related licence must include their name, as set out in the licence, in all the means by which they identify themself in relation to cannabis, including advertising, purchase orders, shipping documents and invoices.

CRs – New section 48.1.

48.1 A holder of a psilocybin-related licence must include their name, as set out in the licence, in all the means by which they identify themself in relation to psilocybin, including advertising, purchase orders, shipping documents and invoices.

Part 3: Security Clearances

Requirement for security clearance

Security clearance requirements would apply to prospective holders of psilocybin licences.

CRs - Amend section 50.

50 The following individuals must hold a security clearance:

(a) an individual who holds a licence for cultivation, processing, ~~or~~ sale, psilocybin cultivation, psilocybin processing, or psilocybin sale,

(b) in the case of a corporation that holds a licence for cultivation, processing, ~~or~~ sale, psilocybin cultivation, psilocybin processing, or psilocybin sale,

(c) in the case of a cooperative that holds a licence for cultivation, processing, ~~or~~ sale, psilocybin cultivation, psilocybin processing, or psilocybin sale,

(d) in the case of a partnership that holds a licence for cultivation, processing, ~~or~~ sale, psilocybin cultivation, psilocybin processing, or psilocybin sale,

(e) in the case of a licence for cultivation, processing, ~~or~~ sale, psilocybin cultivation, psilocybin processing, or psilocybin sale the responsible person referred to in section 37,

(f) in the case of a licence for cultivation, processing, ~~or~~ sale, psilocybin cultivation, psilocybin processing, or psilocybin sale the head of security referred to in section 38,

(g) in the case of a licence for cultivation or psilocybin cultivation, the master grower referred to in section 12 or 15,

(h) in the case of a licence for processing or psilocybin processing, the quality assurance person referred to in section 19,

Checks

Ministerial check requirements would apply to holders of psilocybin-related licences.

CRs - Amend section 52.

52 The Minister may, at any time, conduct checks that are necessary to determine whether an applicant for, or the holder of, a security clearance poses a risk to public health or public safety, including the risk of cannabis or psilocybin being diverted to an illicit market or activity. Such checks include

(a) a check of the applicant's or holder's criminal record; and

(b) a check of the relevant files of law enforcement agencies that relate to the applicant or holder, including intelligence gathered for law enforcement purposes.

Grant of security clearance

The risk of psilocybin diversion would be added as a consideration for the Minister in granting a security clearance.

CRs - Amend section 53.

53(1) Before granting a security clearance, the Minister must, taking into account any licence conditions that he or she imposes under subsection 62(10) of the Act, determine that the applicant does not pose an unacceptable risk to public health or public safety, including the risk of cannabis or psilocybin being diverted to an illicit market or activity.

Validity period

The risk of psilocybin diversion would be added as a consideration for the Minister in determining the validity period for a security clearance.

CRs - Amend section 56.

56(1) The Minister must establish a validity period for a security clearance in accordance with the level of risk to public health or public safety — including the risk of cannabis or psilocybin being diverted to an illicit market or activity — posed by the applicant, but the period must not exceed five years.

(2) If the validity period of a security clearance is less than five years, the Minister may subsequently extend the period to a total of five years if the Minister, taking into account any licence conditions that he or she imposes under subsection 62(10) of the Act, determines that the holder does not pose an unacceptable risk to public health or public safety, including the risk of cannabis or psilocybin being diverted to an illicit market or activity.

(3) The factors that the Minister may consider to determine the level of risk posed by the holder include those set out in subsection 53(2).

Suspension of security clearance

The risk of psilocybin diversion would be added as a consideration for the Minister in determining whether to suspend a security licence.

CRs - Amend section 58.

58(1) Before suspending a security clearance, the Minister must have reasonable grounds to believe that the risk to public health or public safety posed by the holder, including the risk of cannabis or psilocybin being diverted to an illicit

market or activity, has become unacceptable.

Reinstatement of security clearance

The risk of psilocybin diversion would be added as a consideration for the Minister in determining whether to reinstate a security licence.

CRs - Amend section 59.

59(1) The Minister must reinstate a suspended security clearance if

(a) the reasons for the suspension no longer exist or the holder of the security clearance demonstrates to the Minister that the suspension was unfounded; or

(b) the Minister determines, taking into account any licence conditions that he or she imposes under subsection 62(10) of the Act, that the holder of the security clearance does not pose an unacceptable risk to public health or public safety, including the risk of cannabis or psilocybin being diverted to an illicit market or activity.

Cancellation of security clearance

The risk of psilocybin diversion would be added as a consideration for the Minister in determining whether to cancel a security licence.

CRs - Amend section 60.

60(1) A security clearance may not be cancelled unless

(a) it is suspended and the period within which the holder may make representations in respect of the suspension has expired; and

(b) the Minister has determined that the holder poses an unacceptable risk to public health or public safety, including the risk of cannabis or psilocybin being diverted to an illicit market or activity.

Part 4: Physical Security Measures

Security measures

The security measures set out in sections 63-72 would apply to psilocybin cultivation, processing, and sale.

CRs - Amend section 62.

62(1) The security measures set out in sections 63 to 72 apply in respect of the sites set out in the following licences:

(a) a licence for standard cultivation;

(b) a licence for standard processing;

(c) a licence for sale that authorizes the possession of cannabis; ~~and~~

(d) a cannabis drug licence if the amount of cannabis that is sold or distributed to the holder of the licence is, as determined in accordance with the table to section 21, equivalent to more than 600 kg of dried cannabis per calendar year;

(e) a licence for psilocybin cultivation;

(f) a licence for psilocybin processing; and

(g) a licence for psilocybin sale that authorizes the possession of psilocybin.

(2) A holder of a licence referred to in subsection (1) must ensure that the security measures are complied with.

(3) The cannabis referred to in paragraph (1)(d) is exempt from the application of subsection 2(4) of the Act and a quantity referred to in column 2 of the table to section 21 in respect of any class of cannabis referred to in column 1 is deemed to be equivalent to 1 kg of dried cannabis.

Security for analytical testing

The security regulations for analytical testing would apply to psilocybin analytical testing.

CRs - Amend section 75.

75 A holder of a licence for analytical testing or psilocybin analytic testing must ensure that the following security measures are complied with in respect of the site set out in the licence:

(a) storage areas are surrounded by a physical barrier that prevents unauthorized access; and

(b) access to each storage area is restricted to individuals whose presence in the area is required by their duties.

Security for research

The security regulations for a licence for research would apply to a licence for psilocybin research.

CRs - Amend section 77.

77 A holder of a licence for research or a licence for psilocybin research must ensure that operations areas at the site set out in the licence are designed in a manner that prevents unauthorized access.

Part 5: Good Production Practices

The definitions would need to be amended to add psilocybin.

CRs – Amend definitions as follows:

78.1 The following definitions apply in this Part.

acceptable level **means a level of a biological, chemical or physical hazard that does not present a risk of contamination of cannabis or psilocybin mushrooms or anything that will be used as an ingredient.**

control measure **means a measure that can be applied to prevent or eliminate any biological, chemical or physical hazard that presents a risk of contamination of cannabis or psilocybin mushrooms or anything that will be used as an ingredient, or to reduce the hazard to an acceptable level.**

critical control point **means a step at which the application of a control measure is essential to prevent or eliminate any biological, chemical or physical hazard that presents a risk of contamination of cannabis or psilocybin mushrooms or anything that will be used as an ingredient, or to reduce the hazard to an acceptable level.**

sanitary condition **means a condition that does not present a risk of contamination, allergen cross-contamination or introduction of an extraneous substance to cannabis or psilocybin mushrooms or anything that will be used as an ingredient.**

Sale, distribution and exportation

General requirements would apply to psilocybin.

CRs – Amend section 79.

79(1) A holder of a cannabis-related licence must not sell, distribute or export

cannabis unless the applicable requirements set out in sections 80 to 88.94 have been met.

CRs – New section 79(2).

79(2) A holder of a psilocybin-related licence must not sell, distribute or export psilocybin unless the applicable requirements set out in sections 80 to 88.94 have been met.

Non-application — holder of licence for analytical testing or research

CRs – Amend section 79.2.

79.2 Sections 80 to 87.1 do not apply to a holder of a licence for analytical testing, ~~or~~ a licence for research, a licence for psilocybin analytical testing or a licence for psilocybin research.

Standard operating procedures

Requirement for standard operating procedures would apply to psilocybin-related licenses.

CRs – Amend section 80.

80 Cannabis or psilocybin and anything that will be used as an ingredient must be produced, packaged, labelled, distributed, stored, sampled and tested in accordance with standard operating procedures that are designed to ensure that those activities are conducted in accordance with the applicable requirements of this Part and Part 6.

Pest control products

Rules around pest control products would apply to psilocybin.

CRs – New section 81.1(1).

81.1(1) Psilocybin must not be treated with a pest control product unless the product is registered for use on cannabis under the *Pest Control Products Act* or is otherwise authorized for use under that Act.

Exception — edible cannabis

The exception for edible cannabis would apply to psilocybin.

CRs – New section 81.1(2).

81.1(2) Despite subsection (1), psilocybin that is intended to be edible may be treated during the course of production with a pest control product referred to in subparagraph 3(1)(b)(ii) of the *Pest Control Products Regulations*.

Sanitizers, agronomic inputs and non-food chemical agents

The rules around chemical agents at the site would apply to psilocybin.
CRs – Amend section 81.1.

81.1 Any sanitizer, agronomic input or non-food chemical agent that is present at a site must

(a) be properly and clearly identified;

(b) be suitable for its intended use and not present a risk of contamination of cannabis or psilocybin or anything that will be used as an ingredient; and

(c) be handled and used in a manner that does not present a risk of contamination of cannabis or psilocybin or anything that will be used as an ingredient and that is in accordance with the manufacturer's instructions.

Storage

The storage rules would apply to psilocybin.

CRs – Amend section 82.

82 Cannabis or psilocybin and anything that will be used as an ingredient must be stored under conditions that maintain their quality.

Distribution

The distribution rules would apply to psilocybin.

CRs – Amend section 83.

83 Cannabis or psilocybin and anything that will be used as an ingredient must be distributed in a manner that maintains their quality.

Building or part of building

The rules around building and site safety would apply to psilocybin.

CRs – Amend section 84.

84 Any building or part of a building where cannabis <u>or psilocybin</u> or anything that will be used as an ingredient is produced, packaged, labelled, stored or tested must be designed, constructed and maintained in a manner that permits those activities to be conducted appropriately and under sanitary conditions and, in particular, that

(a) permits the building or part of the building to be kept clean and orderly;

(b) permits the effective cleaning of all surfaces in the building or part of the building;

(c) prevents the contamination of the cannabis <u>or psilocybin</u> or thing that will be used as an ingredient; and

(d) prevents the introduction of an extraneous substance to the cannabis <u>or psilocybin</u> or thing that will be used as an ingredient.

<u>System — filtration and ventilation</u>

The air filtration and ventilation rules would apply to psilocybin.
CRs – New section 85.01(1).

<u>85.01(1) Any building or part of a building where psilocybin or anything that will be used as an ingredient is produced, packaged, labelled, stored or tested must be equipped with a system that</u>

<u>(a) filters air to prevent the escape of particulate associated with psilocybin or fungal in general to the outdoors;</u>

<u>(b) provides natural or mechanical ventilation with sufficient air exchange to provide clean air and to remove unclean air in order to prevent the contamination of the fruiting body of the mushroom or thing that will be used as an ingredient;</u>

<u>(c) is accessible and, if necessary for its cleaning, maintenance or inspection, is capable of being disassembled;</u>

<u>(d) is capable of withstanding repeated cleaning; and</u>

<u>(e) functions in accordance with its intended use.</u>

Exception — cultivation, inoculation or harvesting of cannabis

The exception would apply to both cannabis and psilocybin.

CRs – Section 85.01(2) is created as follows:

85.01(2) Paragraph (1)(b) does not apply in respect of any building or part of a building where the only activities being conducted in respect of psilocybin are its cultivation, inoculation, or harvesting.

Exception — cultivation, propagation or harvesting of anything used as an ingredient

The exception would apply to both cannabis and psilocybin.

CRs – New section 85.01(3).

85.01(3) Paragraphs (1)(b) to (e) do not apply in respect of any building or part of a building where the only activities being conducted in respect of anything that will be used as an ingredient are its cultivation, propagation or harvesting.

Supply of water

The supply of water provisions remain the same and would apply to both psilocybin and cannabis.

CRs – Amend section 85.1(1).

85.1(1) Any system that supplies water to a site must be appropriate for any activity being conducted in respect of cannabis or psilocybin or anything that will be used as an ingredient.

Water access cross-connection

CRs – Amend section 85.1(2).

Rules on water access cross-connection apply to both psilocybin and cannabis.

85.1(2) Any system that supplies potable water to a site must not be cross-connected with any other system, unless measures are taken to eliminate any risk of contamination of cannabis or psilocybin or anything that will be used as an ingredient as a result of the cross-connection.

Lighting

The rules on lighting for cannabis would apply equally to psilocybin although the

lighting requirements are much different. The legislation's language would be flexible enough to accommodate both.

CRs – Amend section 85.2(1).

85.2 (1) Any building or part of a building where cannabis or psilocybin or anything that will be used as an ingredient is produced, packaged, labelled, stored or tested must be equipped with natural or artificial lighting that is appropriate for the activity being conducted.

Light fixtures

The light fixtures rules would apply to both cannabis and psilocybin.

CRs – Amend section 85.2(2).

85.2(2) Any light fixtures in the building or part of the building where the activities referred to in subsection (1) are conducted must

(a) be capable of withstanding repeated cleaning and, if necessary to prevent contamination of the cannabis or psilocybin or thing that will be used as an ingredient, repeated sanitizing; and

(b) not present a risk of contamination of the cannabis or psilocybin or thing that will be used as an ingredient in the event of breakage.

Equipment

The rules for equipment apply equally to cannabis and psilocybin.

CRs – Amend section 86(1).

86(1) Cannabis or psilocybin and anything that will be used as an ingredient must be produced, packaged, labelled, stored, sampled and tested using equipment that is designed, constructed, maintained, operated and arranged in a manner that

(a) permits the effective cleaning of its surfaces;

(b) permits it to function in accordance with its intended use;

(b.1) is accessible and, if necessary for its cleaning, maintenance or inspection, is capable of being easily disassembled;

(c) prevents the contamination of the cannabis or psilocybin or thing that will be

used as an ingredient;

(d) prevents the introduction of an extraneous substance to the cannabis or psilocybin or thing that will be used as an ingredient; and

(e) protects the cannabis or psilocybin or thing that will be used as an ingredient against allergen cross-contamination.

Conveyances

The rules for conveyances apply to both cannabis and psilocybin.

CRs – Amend section 86(1.1).

86(1.1) Cannabis or psilocybin and anything that will be used as an ingredient must be distributed using a conveyance that is designed, constructed, maintained and operated in a manner that prevents the contamination of the cannabis or thing that will be used as an ingredient.

Non-application

The non-application would apply to psilocybin.

CRs – Amend section 86(2).

86(2) Paragraphs (1)(d) and (e) do not apply to the outdoor cultivation, propagation, inoculation or harvesting of cannabis or psilocybin or anything that will be used as an ingredient.

Sanitation program

The sanitation program requirements would apply to psilocybin.

CRs – Amend section 87(1).

87(1) Cannabis or psilocybin and anything that will be used as an ingredient must be produced, packaged, labelled, distributed, stored, sampled and tested in accordance with a sanitation program that sets out

(a) procedures for effectively cleaning the building or part of the building in which those activities are conducted;

(b) procedures for effectively cleaning the equipment and conveyances used in those activities;

(c) procedures for handling any substance used in those activities; and

(d) all requirements, in respect of the health and hygienic behaviour of the personnel who are involved in those activities, that are necessary to ensure that those activities are conducted in sanitary conditions.

Outdoor activities - non-application

The non-application in relation to outdoor activities would apply to psilocybin.

CRs – Amend section 87(2).

87(2) Paragraph (1)(a) does not apply to the outdoor cultivation, propagation, inoculation or harvesting of cannabis or psilocybin or anything that will be used as an ingredient.

Hand cleaning and hand sanitizing stations and lavatories

The rules on hand cleaning and sanitizing stations and lavatories would apply to psilocybin.

CRs – Amend section 87.1(1).

87.1(1) If necessary to prevent the contamination of cannabis or psilocybin or anything that will be used as an ingredient, a site must be equipped with hand cleaning and hand sanitizing stations and lavatories that

(a) are appropriately equipped and adequate in number and size for the number of individuals using them;

(b) are located so that they are readily accessible to the individuals using them; and

(c) are capable of withstanding repeated cleaning and, as necessary, repeated sanitizing.

Hand cleaning and hand sanitizing stations

The rules on hand sanitizing and hand sanitizing stations would apply to psilocybin.

CRs – Amend section 87.1(3).

87.1(3) The lavatories must be located and maintained so that they do not present any risk of contamination of cannabis or psilocybin or anything that will be used

as an ingredient.

Quality assurance

The rules around quality assurance would apply to psilocybin.

CRs – Amend section 88.

88 A holder of a licence for processing or psilocybin processing must ensure that

(a) every investigation in respect of the matters referred to in paragraphs 19(2)(b) and (c) is conducted under the responsibility of the quality assurance person referred to in section 19;

(b) if necessary, following an investigation, the quality assurance person immediately causes measures to be taken to mitigate any risk;

(c) cannabis or psilocybin and anything that will be used as an ingredient are produced, packaged, labelled, distributed, stored, sampled and tested using methods and procedures that, prior to their implementation, have been approved by the quality assurance person;

(d) in the case of psilocybin or a cannabis extract or edible cannabis, the quality assurance person approves the preventive control plan referred to in section 88.94 prior to its implementation; and

(e) every lot or batch of cannabis or psilocybin is approved by the quality assurance person before it is made available for sale.

Competencies and qualifications

Rules for competency and qualifications would apply to psilocybin.

CRs – Amend section 88.1.

88.1 A holder of a licence for processing or psilocybin processing must ensure that any individual who conducts activities in relation to edible cannabis or edible psilocybin or anything that will be used as an ingredient in the production of edible cannabis or edible psilocybin has the competencies and qualifications that are necessary to conduct those activities at the site set out in the licence.

Temperature and humidity

The atmospheric controls would apply to psilocybin.

CRs – Amend section 88.2.

88.2(1) A holder of a licence for processing or psilocybin processing must ensure that the temperature and humidity of any building or part of a building where cannabis or psilocybin or anything that will be used as an ingredient is produced, packaged, labelled, stored or tested are maintained at levels that are appropriate for the activity being conducted with the cannabis or psilocybin or thing that will be used as an ingredient.

(2) If the building or part of the building is equipped with a heating, cooling or humidity-control system, the holder of the licence must ensure that the system

(a) if necessary to prevent contamination of the cannabis or psilocybin or thing that will be used as an ingredient, is equipped with instruments to control and indicate the temperature and humidity levels;

(b) is accessible and, if necessary for its cleaning, maintenance or inspection, is capable of being disassembled;

(c) is capable of withstanding repeated cleaning; and

(d) functions in accordance with its intended use.

Incompatible activities

The activities imagined as incompatible would also apply to psilocybin.

CRs – Amend section 88.3(1).

88.3(1) A holder of a licence for processing or psilocybin processing must ensure that physical or other effective means are used to separate incompatible activities in order to prevent contamination of cannabis or psilocybin or anything that will be used as an ingredient.

Production of food

Production of food rules would apply to psilocybin although some psilocybin production sites may exist at food production facilities which is addressed in the new exception provision. The exception would apply to psilocybin.

CRs – Amend section 88.3(3).

(3) Despite subsection (2), a holder of a licence for processing or psilocybin processing may produce, package, label or store cannabis or psilocybin in a

building within a site where food that is to be sold is produced, packaged or labelled if the food is not produced, packaged or labelled in the same building.

Separation of cannabis or psilocybin and ingredients from contaminants

Anything that poses a contamination risk must be kept separate from the psilocybin.

CRs – Amend section 88.4.

88.4 A holder of a licence for processing or psilocybin processing must ensure that physical or other effective means are used to separate cannabis or psilocybin or anything that will be used as an ingredient from anything that presents a risk of contamination of the cannabis or psilocybin or thing that will be used as an ingredient.

Ingredients — risk of injury to human health

Psilocybin ingredients that pose a risk would be stored in a designated area.

CRs – Amend section 88.5.

88.5 A holder of a licence for processing or psilocybin processing must ensure that anything that will be, or was intended to be, used as an ingredient that presents a risk of injury to human health is identified as such and is stored in a designated area within the site.

Potable water

The rules regarding potable water would apply to psilocybin in extract, topical, or edible form, although it is not imagined at present that such products would exist.

CRs – Amend section 88.6.

88.6(1) A holder of a licence for processing or psilocybin processing must ensure that any water that might come into contact with a cannabis extract, a cannabis topical, edible cannabis or psilocybin anything that will be used as an ingredient is potable and, if the water is not potable, must ensure that it does not present a risk of contamination of the cannabis extract, cannabis topical, edible cannabis or psilocybin or thing that will be used as an ingredient.

Steam and ice from potable water

The rules regarding steam and ice from potable water would apply to psilocybin.

CRs – Amend section 88.6(2).

88.6(2) A holder of a licence for processing or psilocybin processing must ensure that any steam or ice that might come into contact with a cannabis extract, a cannabis topical, edible cannabis or a psilocybin extract, psilocybin mushroom or anything that will be used as an ingredient is made from water that meets the requirements of subsection (1) and, if the steam or ice does not meet those requirements, must ensure that it does not present a risk of contamination of the cannabis extract, cannabis topical, edible cannabis or psilocybin extract, psilocybin mushroom or thing that will be used as an ingredient.

No presence of animals

The rules on presence of animals would apply to psilocybin.

CRs – Amend section 88.7.

88.7 A holder of a licence for processing or psilocybin processing must ensure that no animal is present in any building or part of a building where cannabis or psilocybin or anything that will be used as an ingredient is produced, packaged, labelled or stored.

Land — risk of contamination

The rules around land use contamination risks would apply to psilocybin.

CRs – Amend section 88.8.

88.8 If any land that forms part of a site set out in a licence for processing or psilocybin processing, or any land that is located near such a site, presents a risk of contamination of cannabis or psilocybin or anything that will be used as an ingredient, the holder of the licence must take measures to eliminate the risk.

Removal and disposal of contaminated materials and waste

The rules around removal and disposal of contaminated materials would apply to psilocybin.

CRs – Amend section 88.9(1).

88.9(1) A holder of a licence for processing or psilocybin processing must ensure that any building or part of a building where cannabis or psilocybin or anything that will be used as an ingredient is produced, packaged, labelled or stored has means for the removal and disposal of contaminated materials and waste and, if necessary to prevent contamination of the cannabis or psilocybin or thing that will be used as an ingredient, that the building or part of the building is equipped with a drainage, sewage and plumbing system that functions in accordance with its

intended use.

(2) The holder of the licence must ensure that contaminated materials and waste are removed and disposed of at a frequency that is sufficient to prevent contamination of the cannabis or psilocybin or thing that will be used as an ingredient and in a manner that does not present a risk of contamination of the cannabis or psilocybin or thing that will be used as an ingredient.

Conveyances and equipment

Rules on conveyances and equipment would apply to psilocybin.

CRs – Amend section 88.91.

88.91 A holder of a licence for processing or psilocybin processing must ensure that any conveyance or equipment that is used at the site set out in the licence to handle any contaminated materials or any waste, unless that conveyance or equipment does not come into contact with those materials or waste,

(a) is used only for that purpose;

(b) is identified as being reserved for that purpose; and

(c) meets the applicable requirements of section 86.

Clothing, footwear and protective coverings

The rules regarding outerwear in licensed sites would apply to psilocybin.

CRs – Section 88.92 is amended.

88.92 A holder of a licence for processing or psilocybin processing must ensure that any individual who enters or is in any building or part of a building where cannabis or psilocybin or anything that will be used as an ingredient is produced, packaged, labelled, stored, sampled or tested wears clothing, footwear and protective coverings, including gloves, a hairnet, a beard net and a smock, that are in good condition, clean and in sanitary condition and that are appropriate for the activity being conducted with the cannabis or thing that will be used as an ingredient.

Identification and analysis of hazards

Rules around hazard analysis and identification would apply to psilocybin.
CRs – Amend section 88.93(1).

88.93(1) A holder of a licence for processing or psilocybin processing that produces a cannabis extract or edible cannabis or psilocybin must identify and analyze the biological, chemical and physical hazards that present a risk of contamination of the cannabis or psilocybin or anything that will be used as an ingredient in the production of the cannabis extract or edible cannabis or psilocybin.

(2) The holder of the licence must prevent, eliminate or reduce to an acceptable level the hazards referred to in subsection (1) by using control measures that are shown by evidence to be effective, including any treatment or process.

Preventive control plan

The rules for preventive control plans would apply to psilocybin.

CRs – Amend section 88.94(1).

88.94(1) A holder of a licence for processing or psilocybin processing that conducts activities in relation to a cannabis extract or edible cannabis or psilocybin must prepare, retain, maintain and implement a written preventive control plan for any activity they conduct in respect of the cannabis or psilocybin or anything that will be used as an ingredient in the production of the cannabis extract or edible cannabis or psilocybin.

(2) The preventive control plan must include

(a) a description of the measures for ensuring that the applicable requirements of sections 101.3, 101.4, 102, 102.2, 102.3, 102.5 and 102.6 are met;

(b) in relation to the applicable requirements of these Regulations,

(i) a description of the biological, chemical and physical hazards that are identified under subsection 88.93(1) that present a risk of contamination of the cannabis extract, edible cannabis, psilocybin or anything that will be used as an ingredient in the production of the cannabis extract or edible cannabis, or psilocybin.

Sale and exportation

The rule on sale and exportation would apply to psilocybin.

CRs – Amend section 89.

89 A holder of a cannabis-related licence must not sell or export a cannabis product unless the applicable requirements set out in sections 90 to 92 have been met.

CRs – New section 89.1.

89.1 A holder of a psilocybin-related licence must not sell or export psilocybin unless the applicable requirements set out in sections 90 to 92 have been met.

Testing for psilocybin

This section would be expanded to include psilocin, psilocybin, and any derivative salts should it be necessary and possible.

CRs – New section 90.1.

90.1(1) Testing for the quantity or concentration, as the case may be, of psilocybin or psilocin must be conducted on each lot or batch of psilocybin that

(a) is or will become a psilocybin product; or

(b) is or will be contained in a psilocybin accessory that is or will become a psilocybin product.

(2) The testing must be conducted on the final form of the psilocybin, either before or after it – or the psilocybin accessory that contains it – is packaged and labelled as a psilocybin product.

Testing for contaminants

The rules on testing for microbial and chemical contaminants would apply to psilocybin.

CRs – Amend section 91(1) by adding (c) and (d).

91 (1) Testing for microbial and chemical contaminants — other than residues of a pest control product or its components or derivatives — must be conducted on

(c) each lot or batch of psilocybin that

(i) is or will become a psilocybin product, or

(ii) is or will be contained in a psilocybin accessory that is or will become a psilocybin product, or

(d) each lot or batch of psilocybin that

(i) is used to produce the psilocybin referred to in paragraph (c), or

(ii) is used to produce edible psilocybin that is or will become a psilocybin product, or that is or will be contained in a psilocybin accessory that is or will become a psilocybin product.

Timing of testing

Psilocybin would be included in the requirements for timing on conducting of testing.

CRs – Amend section 91(2).

91(2) The testing on a lot or batch of cannabis or psilocybin must be conducted as follows:

(a) the testing referred to in paragraph (1)(a) must be conducted on the final form of the cannabis or psilocybin, either before or after it — or the cannabis or psilocybin accessory that contains it — is packaged and labelled as a cannabis or psilocybin product; and

(b) the testing referred to in paragraph (1)(b) must be conducted after the final step in the production process during which the contaminants referred to in subsection (1) could have been introduced or could be concentrated, whichever is later.

Dissolution and disintegration testing

Testing would apply to psilocybin.

CRs – Amend section 91.1(1).

91.1(1) If cannabis — or a cannabis accessory that contains cannabis — or psilocybin – or a psilocybin accessory that contains psilocybin – is or will become a cannabis product to which subsection 95(1) applies, testing must be conducted on each lot or batch of the cannabis or cannabis accessory or psilocybin or psilocybin accessory to determine whether the requirements referred to in that subsection are, or will be, met.

Timing of testing

Testing would apply to psilocybin. Psilocybin is a naturally edible and as such the product definitions and categories urged on it by the Cannabis Regulations are not a perfect match, but do create sufficient regulatory guidance to be useful and functional.

CRs – Amend section 91.1(2).

91.1(2) The testing must be conducted on the final form of the cannabis or

psilocybin, either before or after it — or the cannabis accessory that contains it or the psilocybin that contains it — is packaged and labelled as a cannabis product or psilocybin.

Testing method

The testing method requirements would apply to psilocybin.

CRs – Amend section 92(1).

92(1) Testing that is conducted under sections 90 to 91.1 — or to determine whether the applicable requirements in Part 6 are, or will be, met — must be conducted using validated methods on a representative sample of each lot or batch of cannabis or cannabis accessory that contains cannabis or psilocybin or psilocybin accessory that contains psilocybin.

Sufficient quantity

The quantity requirements for testing would apply to psilocybin.

CRs – Amend section 92(3) by adding section (c).

92(3) The portion of the sample retained under subsection (2) must be of sufficient quantity to enable a determination of

(a) whether the lot or batch meets the requirements of section 81, subsection 93(3), 94(2) or 95(1) or section 101.1, as applicable; and

(b) the quantity or concentration of THC, THCA, CBD and CBDA or

(c) the quantity or concentration of psilocybin and psilocin.

Part 6 – Cannabis Products

Residues of Pest Control Products

Psilocybin and psilocybin spores would have the same regulations as cannabis with respect to the residues of pest control products.

CRs - Amend section 92.2.

92.2 Cannabis plants or cannabis plant seeds that are cannabis products — or that are contained in a cannabis accessory that is a cannabis product — or psilocybin or psilocybin spores must not contain or have on them residues of a pest control

product that is registered for use on cannabis under the *Pest Control Products Act*, or that is otherwise authorized for use under that Act, unless the residues are within any maximum residue limits that are specified in relation to cannabis under section 9 or 10 of that Act.

Pest control products - psilocybin

Psilocybin would have the same regulations as cannabis with respect to pest control products.

CRs – New section 93.1.

93.1(1) Psilocybin must not contain or have anything on it.

(2) Despite subsection (1), psilocybin or psilocybin spores that are referred to in that subsection may contain or have on it residues of a pest control product that is registered for use on cannabis under the *Pest Control Products Act*, or that is otherwise authorized for use under that Act, if the residues are within any maximum residue limits that are specified in relation to cannabis under section 9 or 10 of that Act.

(3) Despite subsection (1), psilocybin or psilocybin spores that are referred to in that subsection may contain or have on it microbial or chemical contaminants if the contaminants are within generally accepted tolerance limits for human use that are

(a) established in a publication referred to in Schedule B to the *Food and Drugs Act*; and

(b) appropriate for the intended use and any reasonably foreseeable use of the psilocybin or psilocybin spores.

(4) If there are generally accepted tolerance limits referred to in subsection (3) that apply in respect of the residues of a pest control product referred to in subsection (2) for which a maximum residue limit has been specified in relation to cannabis under the *Pest Control Products Act*, the more stringent limit applies.

Psilocybin used in production

Psilocybin mushrooms, psilocybin and psilocybin spores used in the production of psilocybin extracts would have the same regulations as cannabis with respect to pest control products.

CRs – New section 94.1.

94.1(1) Psilocybin mushrooms, psilocybin, and psilocybin spores that are used in the production of the following psilocybin must not contain or have on it residues of a pest control product that is registered for use on cannabis under the *Pest Control Products Act*, or that is otherwise authorized for use under that Act, unless the residues are within any maximum residue limits that are specified in relation to cannabis under section 9 or 10 of that Act:

(a) a psilocybin extract; and

(b) psilocybin.

(2) Psilocybin and psilocybin extracts must not contain or have on it microbial or chemical contaminants unless the contaminants are within generally accepted tolerance limits for human use that are

(a) established in a publication referred to in Schedule B to the *Food and Drugs Act*; and

(b) appropriate for a product that is to be ingested.

Dissolution and disintegration

The rules for dissolution and disintegration of non-smoked cannabis would apply to psilocybin as an edible product ingested orally and processed by the digestive tract. While at first glance it may appear that psilocybin is being authorized for non-oral consumption (anal, vaginal, or nasal) in reality that mode of consumption would only be authorized if a dissolution test exists. Such a test does not exist for psilocybin other than for oral consumption (eating it or consuming a standardized pill) and therefore the most sensible amendment is as follows:

CRs – Amend section 95(1).

95(1) Each discrete unit of a cannabis product or psilocybin mushroom that is intended for ingestion or nasal, rectal or vaginal use must meet, if the form of the unit is similar to a dosage form for which a dissolution or disintegration test is set out in a publication referred to in Schedule B to the Food and Drugs Act, the requirements of the test or, if there is more than one applicable test, the requirements of any such test that is suitable for demonstrating that the cannabis product or psilocybin will perform as intended.

Exception

The exception for edible cannabis would apply to psilocybin.

CRs – Amend section 95(2).

95(2) Subsection (1) does not apply to edible cannabis or psilocybin.

Cannabis Extracts, Cannabis Topicals and Psilocybin Extracts

Psilocybin extracts would have limits similar to cannabis with respect to things injurious to health.

CRs – New section 101.1.

101.1(1) A psilocybin extract must not contain or have on it anything that may cause injury to the health of the user when the psilocybin extract is used as intended or in a reasonably foreseeable way.

(2) For the purposes of subsection (1), a psilocybin extract does not contain or have on it anything that may cause injury to the health of the user by reason only that it contains or has on it

(a) psilocybin or a psilocybin extract;

(b) residues of a pest control product that is registered for use on cannabis under the *Pest Control Products Act*, or that is otherwise authorized for use under that Act, if the residues are within any maximum residue limits that are specified in relation to cannabis under section 9 or 10 of that Act; or

(c) microbial or chemical contaminants — other than residues of a pest control product referred to in paragraph (b) — if the contaminants are within generally accepted tolerance limits for human use that are

(i) established in a publication referred to in Schedule B to the *Food and Drugs Act*, and

(ii) appropriate for the intended use and any reasonably foreseeable use of a psilocybin extract.

Microbial and chemical contaminants

Psilocybin would have similar limits on microbial or chemical contaminants as with cannabis extracts.

CRs - Amend section 101.1.

101.1 A cannabis extract, or a cannabis topical, that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — or a

psilocybin extract must not contain or have on it microbial or chemical contaminants unless the contaminants are within generally accepted tolerance limits for human use that are

(a) established in a publication referred to in Schedule B to the *Food and Drugs Act*; and

(b) appropriate for the intended use and any reasonably foreseeable use of the cannabis product.

Cannabis extract and psilocybin extract — content

Psilocybin extracts would have limits on the ingredients similar to cannabis extracts.

CRs - Amend section 101.3.

101.3(1) A cannabis extract that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — or a psilocybin extract must not contain any ingredients other than

(a) carrier substances;

(b) flavouring agents; and

(c) substances that are necessary to maintain the quality or stability of the cannabis product or the psilocybin extract.

(2) The following substances must not be used as ingredients to produce a cannabis extract or a psilocybin extract referred to in subsection (1):

(a) substances that are listed in column 1 of the table in Schedule 2 to the *Tobacco and Vaping Products Act*; or

(b) sugars or *sweeteners* or *sweetening agents*, as those terms are defined in subsection B.01.001(1) of the *Food and Drug Regulations*.

(3) Despite paragraph 2(a), a vitamin may be used as an ingredient to maintain the quality or stability of the cannabis extract referred to in subsection (1) if it is used in an amount that does not exceed what is necessary to maintain the quality or stability of the cannabis product.

(4) An ingredient that is used to produce the cannabis extract or the psilocybin extract referred to in subsection (1) may contain a substance referred to in

subsection (2) only if that substance is naturally present in the ingredient at a level that is not above the naturally occurring level for that ingredient.

(5) An ingredient — other than a flavouring agent — must not be used to produce a cannabis extract referred to in subsection (1) that is intended to be consumed by means of inhalation unless

(a) a standard for the ingredient is set out in a publication referred to in Schedule B to the *Food and Drugs Act*; and

(b) the ingredient complies with the standard.

(6) A cannabis extract <u>or a psilocybin extract</u> referred to in subsection (1) must not contain ethyl alcohol unless

(a) the cannabis extract is intended to be ingested; and

(b) the net weight of the cannabis extract in each immediate container of the cannabis product or psilocybin does not exceed 7.5 g.

<u>Uniform distribution — psilocybin extracts</u>

The requirement for uniform distribution of cannabinoids in cannabis extracts would apply to the psilocybin in psilocybin extracts.

CRs - New section 101.41.

<u>101.41 The psilocybin in a psilocybin extract must be uniformly distributed throughout the psilocybin extract.</u>

<u>Part 7: Packaging and labelling</u>

<u>Definitions</u>

Definitions that would apply to this Part would apply to psilocybin given the oral consumption of mushrooms. While no standardized nomenclature has yet been produced for psilocybin, it is anticipated.
CRs - Amend section 105.

105 (1)
energy value **means, in respect of a cannabis <u>or psilocybin</u> product, the amount of energy made available to a person's body when the chemical components of the cannabis <u>or psilocybin</u> product, including protein, fat, carbohydrate and alcohol,**

are metabolized following ingestion of the cannabis or psilocybin product by the person.

expiry date **means the date, expressed at minimum as a year and month, that is the end of the stability period of a cannabis or psilocybin product.**

food allergen source, gluten source and added sulphites statement **means a statement appearing on the label of any container in which edible cannabis or psilocybin mushrooms— that is a cannabis product or psilocybin is packaged that indicates the source of a food allergen or gluten that is present in the cannabis or psilocybin product or the presence in the cannabis product or psilocybin of added sulphites in an amount of 10 p.p.m. or more.**

standardized cannabis or psilocybin symbol **means the symbol set out in the document entitled Standardized Cannabis Symbol or Standardized Psilocybin Symbol, as amended from time to time and published by the Government of Canada on its website.**

General Provisions – Requirements

Requirements a licence holder would have related to sales and distribution. These general provisions would apply to psilocybin.

CRs - Amend section 106.

106(1) A holder of a licence must not sell or distribute a cannabis or psilocybin product unless the applicable requirements set out in sections 108 to 136 have been met.

(2) A holder of a licence must not export a cannabis or psilocybin product unless the requirements set out in paragraph 123(1)(a) and subparagraphs 123(1)(c)(ii) and (iv) have been met.

Packaging - Immediate container

Requirements would be for the immediate container of psilocybin mushrooms or extracts. These packaging requirements would apply to psilocybin.

CRs - Amend section 108.

108 The immediate container in which a cannabis or psilocybin product, other than a cannabis plant or cannabis plant seeds, is packaged must

(a) be opaque or translucent;

(b) prevent contamination of the cannabis or psilocybin;

(c) in the case of dried cannabis or dried psilocybin, keep the cannabis or psilocybin dry;

(d) have a security feature that provides reasonable assurance to consumers that it has not been opened prior to receipt;

(e) meet the requirements of a child resistant package under subsections C.01.001(2) to (4) of the *Food and Drug Regulations*; and

(f) not contain more than the equivalent of 30 g of dried cannabis or 100 g of dried psilocybin, as determined in accordance with subsections 2(4) and 2(5) of the Act.

Brand element

The rules on cannabis branding would apply to psilocybin.

CRs - Amend section 111.

111 Subject to the other provisions of these Regulations, the interior surface and exterior surface of any container in which a cannabis or psilocybin product is packaged must not display any brand element.

Image

Packaging containers would not display any images. This rule would apply to psilocybin.

CRs - Amend section 112.

112 Except as otherwise provided under the Act, any other Act of Parliament or any provincial Act, the interior surface, exterior surface and panel of any container in which a cannabis or psilocybin product is packaged must not display any image.

Uniform colour

Rules regarding packaging colour would apply to psilocybin.

CRs – Amend Section 113(1) and (2).

113(1) Except as otherwise provided under the Act, any other Act of Parliament or any provincial Act, the colour of the interior surface, exterior surface and panel of

any container in which a cannabis or psilocybin product is packaged must be one uniform colour. However, the colour of each surface and the panel may be different.

(2) The colour of the interior surface, exterior surface and panel must meet the following requirements:

(c) it must create a contrast with

(i) the yellow colour of the background of the health warning message, and

(ii) the red colour of the standardized cannabis or psilocybin symbol.

Texture

Rules relating to the texture of packaging would apply to psilocybin packaging.

CRs – Amend Section 115.

115(1) Except as otherwise provided under the Act, any other Act of Parliament or any provincial Act, the interior surface, exterior surface and panel of any container in which a cannabis or psilocybin product is packaged and any covering of such a container must have a smooth texture without any raised features, embossing, decorative ridges, bulges or other irregularities.

Hidden features

Rules regarding hidden features on packaging would apply to psilocybin packaging.

CRs – Amend section 116(1).

116(1) The interior surface, exterior surface and panel of any container in which a cannabis or psilocybin product is packaged and any covering of such a container must not include any hidden feature that is designed to change the appearance of the container, covering or panel, such as heat-activated ink or a feature that is visible only through technological means, except a feature that is used to prevent counterfeiting.

Feature designed to change surface area

CRs – Amend section 116(2).

116(2) Subject to section 132.27, the interior surface and exterior surface of any container in which a cannabis or psilocybin product is packaged and any covering of such a container must not include any feature that is designed to change the

surface area of the container or covering, such as a fold-out panel.

Scent and sound

Rules regarding the scent and sound of packaging would apply to psilocybin packaging.

CRs – Amend section 117.

117 The interior surface, exterior surface and panel of any container in which a cannabis or psilocybin product is packaged and any covering of such a container must not be capable of emitting a scent or sound.

Covering - brand element

The covering of containers would not display any branding. These covering rules would apply to psilocybin packaging.

CRs - Amend section 118.

118 The covering of any container in which a cannabis or psilocybin product is packaged must not display any brand element.

Covering - image or information

Rules on image or information display on coverings would apply to psilocybin. Package covering containers would not display any images or information unless otherwise stated.

CRs - Amend section 119.

119 Except as otherwise provided under the Act, any other Act of Parliament or any provincial Act, the covering of any container in which a cannabis or psilocybin product is packaged must not display any image or information.

Covering — transparent and colourless

The rules regarding coverings and their opacity and color would apply to psilocybin.
CRs – Amend Section 120.

120 Except as otherwise provided under the Act, any other Act of Parliament or any provincial Act, the covering of any container in which a cannabis or psilocybin product is packaged must be transparent and colourless.

Cut-out window

The rules on cut out windows would apply to psilocybin.

CRs – Amend Section 121.

121 The interior surface, exterior surface and panel of any container in which a cannabis or psilocybin product is packaged must not include any cut-out window.

Bar code

The rules for bar codes would apply to psilocybin (rectangular shape must be maintained without design).

CRs – Amend Section 122(1).

122(1) A bar code may be displayed only once on any container in which a cannabis or psilocybin product is packaged.

Shape and colour

CRs – Amend Section 122(2).

122(2) Every bar code must be rectangular in shape and not contain any image or design and must be printed in black and white.

Wrapper

When a wrapper would be used. The rules on wrappers would apply to psilocybin.

CRs - Amend section 122.1.

122.1 A wrapper may be used with respect to a cannabis or psilocybin product only if

(a) it is in direct contact with the cannabis or psilocybin and with one or both of the following:

(i) the immediate container of the cannabis or psilocybin product,

(ii) a wrapper that is in direct contact with the cannabis or psilocybin; and

(b) it is required to maintain the quality or stability of the cannabis or psilocybin product.

Packaging requirements — other Regulations

The rules regarding secondary regulations for containers and wrappers would apply to psilocybin.

CRs – Amend Section 122.2.

122.2 The following immediate container and wrappers must meet the requirements set out in Division 23 of Part B of the *Food and Drug Regulations* and subparagraphs 186(a)(i), (ii) and (v) to (vii) of the *Safe Food for Canadians Regulations* as if the cannabis or psilocybin that the immediate container contains or with which the wrappers are in direct contact were a food for the purposes of that Division and those subparagraphs:

(a) the immediate container in which edible cannabis or psilocybin — or a cannabis accessory that contains edible cannabis — that is a cannabis or psilocybin product is packaged;

(b) any wrapper that is in direct contact with edible cannabis or psilocybin — or a cannabis accessory that contains edible cannabis — that is a cannabis or psilocybin product; and

(c) any wrapper that is in direct contact with a cannabis extract that is intended for ingestion or psilocybin — or a cannabis accessory that contains cannabis extract intended for ingestion — that is a cannabis or psilocybin product.

Outermost container

What would not be contained in the outermost container, plus exceptions to those requirements. These rules would apply to psilocybin.

CRs - Amend section 122.4(1).

122.4(1) The outermost container in which a cannabis or psilocybin product is packaged must not contain

(a) food;

(b) more than one class of cannabis or psilocybin set out in Schedule 4 or 7 to the Act; or

(c) more than one immediate container.

Exception — multiple immediate containers

122.4(2) Despite paragraph (1)(c), the outermost container may contain more than one immediate container of edible cannabis or psilocybin if the following requirements are met:

(a) the outermost container meets the requirements of section 132.18;

(b) the immediate containers meet the requirements of section 132.18, if they contain edible cannabis or psilocybin that is in discrete units, or section 132.19, if they contain edible cannabis or psilocybin that is not in discrete units;

(c) the total quantity of THC in the immediate containers does not exceed 10 mg of THC, taking into account the potential to convert THCA into THC;

(d) the total quantity of cannabis or psilocybin in the immediate containers does not exceed the equivalent of 30 g of dried cannabis or 100 g of dried psilocybin, as determined in accordance with subsection 2(4) or 2(5) of the Act;

(e) the statement "Contains the equivalent of (the quantity of dried cannabis or dried psilocybin, in grams, that is equivalent to the total quantity of cannabis or psilocybin, in grams, as determined in accordance with subsection 2(4) or 2(5) of the Act, in the immediate containers) g of dried cannabis" is displayed on the label of the outermost container; and

(f) the properties of the edible cannabis or psilocybin in all the immediate containers are consistent.

(3) For the purposes of paragraph (2)(a), the word "unit" referred to in subsection 132.18(1) is to be read as "immediate container".

Control measures for dispensing cannabis extract

Rules around extract packaging that is not discreet would apply to psilocybin.

CRs – Amend section 122.5.

122.5(1) The immediate container of a cannabis extract or psilocybin that is a cannabis or psilocybin product and that is not in discrete units must

(a) not permit the extract to be easily poured or drunk directly from the container; and

(b) contain an integrated dispensing mechanism that dispenses no more than 10 mg of THC per activation, taking into account the potential to convert THCA

into THC, if the cannabis extract

(i) is in liquid form at a temperature of 22 ± 2°C,

(ii) is not intended to be consumed only by means of inhalation,

(iii) contains at least 10 mg of THC, taking into account the potential to convert THCA into THC, and

(iv) is not manipulated in a manner that could result in higher than normal levels of psilocybin in the psilocybin product given the volume.

(2) Paragraph (1)(b) does not apply to an immediate container in which a cannabis or psilocybin accessory referred to in paragraph 103.2(a) is packaged.

Labelling information

The information below would be included on the container label for packaged products. It would not include an expiry date unless there is data to establish the stability period. If an expiry date is included, a document with the required information as per s (2) would be retained for at least two years. Health warnings would be displayed on each brand of product packaged in year to ensure equal displays. Labelling information rules would apply to psilocybin.

CRs - Amend subsections 123(1)(2)(3)(4) and add subsections123(1)(c)(ii.1),(e.1),(2)(c)(i)

123 (1) The following information must be included on the label that is applied to any container in which a cannabis or psilocybin product is packaged:

(a) the name, telephone number and email address of the following:

(i) in the case of a cannabis plant or cannabis plant seeds, or psilocybin, the holder of a licence for cultivation that cultivated the cannabis plant or cannabis plant seeds, or psilocybin or

(ii) in the case of any other cannabis or psilocybin product, the holder of a licence for processing that manufactured the product;

(b) the class of cannabis set out in Schedule 4 to the Act to which the cannabis that is in the immediate container belongs or the class of psilocybin set out in Schedule 7 to the Act to which the psilocybin that is in the immediate container belongs;

(c) in respect of the product

(i) the brand name

(ii) the lot number, preceded by one of the following designations:

(A) "Lot number",

(B) "Lot no.",

(C) "Lot", or

(D) "(L)", or

(ii.1) the batch number in the context of psilocybin preceded by one of the following designations:

(A) "Batch number",

(B) "Batch no.",

(C) "Batch", or

(D) "(B)",

(v) except in the case of a cannabis plant, cannabis plant seeds, psilocybin or edible cannabis, either

(d) the warning "KEEP OUT OF REACH OF CHILDREN / TENIR HORS DE LA PORTÉE DES ENFANTS";

(e.1) one of the health warning messages set out in the proposed document entitled Psilocybin Health Warning Messages, as amended from time to time and published by the Government of Canada on its website, that applies to psilocybin;

(2) The label of a container in which cannabis or psilocybin other than edible cannabis or psilocybin is packaged must not include an expiry date unless the holder of the licence for processing that manufactured the cannabis or psilocybin product has data that establishes the stability period during which, after the cannabis or psilocybin is packaged in accordance with these Regulations and stored under its recommended storage conditions,

(c) in the case of psilocybin,

(i) it maintains its psilocybin content within the variability limits set out in the legislation and guidance documents.

(3) The holder of the licence for processing that manufactured the cannabis or psilocybin product must, if they include an expiry date on the label of the container, retain a document that contains the data referred to in subsection (2) for at least two years after the day on which the last sale or distribution of any portion of the lot or batch of the cannabis or psilocybin product with that expiry date takes place, other than for destruction.

(4) The health warning messages referred to in paragraph (1)(e) must be displayed in rotation on each type of container of each brand name of the cannabis or psilocybin product that is packaged in a year, so that each health warning message is displayed, to the extent possible, on equal numbers of containers of that product.

Standardized cannabis or psilocybin symbol

Standardized warning labels would apply to psilocybin and a "psilocybin" symbol would be needed.

CRs – Amend section 123.1(2),(3).

123.1(2) Despite paragraph (1)(b), the standardized cannabis or psilocybin symbol that must be obtained from the Minister in the form of an electronic file must be clearly and prominently displayed on the exterior surface of any wrapper if the concentration of THC in the cannabis that is in direct contact with the wrapper or that is in the cannabis accessory that is in direct contact with the wrapper is greater than 10 µg/g, taking into account the potential to convert THCA into THC.

(3) The standardized cannabis or psilocybin symbol must meet the following requirements:

(a) it must be at least 1.27 cm by 1.27 cm in size;

(b) it must be displayed with a white border of at least 2 points on all sides; and

(c) if a change is made to the size of the symbol, its dimensions must be proportional vertically and horizontally.

Dried cannabis or fresh cannabis or psilocybin — discrete units and not intended for inhalation

The rules regarding units for packaging would apply to psilocybin.

CRs – Amend section 124(1) and add section 124(1)(g.1).

124 (1) In the case of dried cannabis or fresh cannabis or psilocybin — or a cannabis accessory that contains dried cannabis or fresh cannabis — that is in discrete units and is not intended to be consumed by means of inhalation, the label of any container in which the cannabis or psilocybin product is packaged must also include the following information if applicable:

(a) the net weight, in grams, of dried cannabis or fresh cannabis or psilocybin;

(c) the net weight, in grams, of dried cannabis or fresh cannabis or psilocybin in each unit;

(g) the quantity of CBD, in milligrams, that each discrete unit could yield, taking into account the potential to convert CBDA into CBD, preceded by "Total CBD per unit";

(g.1) the quantity of psilocybin, in milligrams, in each unit, preceded by "psilocybin per unit"; and

(h) the intended use of the cannabis or psilocybin product.

Dried cannabis or fresh cannabis and psilocybin - not in discrete units

For products that are not in discrete units, the label of said containers would include information that covers net weight and concentration levels. These rules would apply to psilocybin.

CRs - Amend section 125 and add 125(e.1).

125 In the case of dried cannabis or fresh cannabis or psilocybin — or a cannabis accessory that contains dried cannabis or fresh cannabis — that is not in discrete units, the label of any container in which the cannabis or psilocybin product is packaged must also include the following information:

(a) the net weight, in grams, of dried cannabis or fresh cannabis or psilocybin;

(e) the concentration of CBD, in milligrams per gram, that the dried cannabis or fresh cannabis could yield, taking into account the potential to convert CBDA into CBD, preceded by "Total CBD"; and

(e.1) should the data be available pursuant to an approved testing method, the concentration in milligrams per gram, of psilocybin, preceded by "psilocybin".

Presentation of information - general requirement

Information included on the label would be in English and French.

CRs - Amend section 130(3).

130(3) All information that is required to be included on a label, other than the brand name, the standardized cannabis or psilocybin symbol and the health warning message must meet the following requirements:

Standardized cannabis and psilocybin symbol

The symbol standardization model that applies to cannabis would apply to psilocybin.

CRs – Amend Section 130(5).

130(5) The standardized cannabis or psilocybin symbol that is required to be included on a label must meet the following requirements:

Brand element

Rules regarding brand element communications would apply to psilocybin.

CRs – Amend Section 130(9).

130(9) A label may include only one brand element, other than a brand name, if that brand element meets the following requirements:

(d) if the brand element is an image, its surface area must be

(i) in the case where the standardized cannabis or psilocybin symbol must be included on the label in accordance with paragraph 123(1)(f), smaller than or equal to the surface area of the standardized cannabis symbol, or

Representation resembling standardized cannabis symbol

Rules regarding images that closely resemble the approved standardized symbols would apply to psilocybin.

CRs - Amend section 131.

131 A representation, such as an illustration, sign, mark, symbol or design, that so closely resembles the standardized cannabis or psilocybin symbol that it is likely to be mistaken for that symbol must not appear on any container in which a cannabis or psilocybin product is packaged.

Insert or leaflet

The rules regarding inserts and leaflets would apply to psilocybin.

CRs – Amend Section 132.

132 Except as otherwise provided under the Act, any other Act of Parliament or any provincial Act, any container in which a cannabis or psilocybin product is packaged must not include, or be accompanied by, an insert or leaflet.

Cannabis or psilocybin extract — discrete units and not intended for inhalation

Any unit-based rule for products would apply to psilocybin.

CRs – Amend section 132.1(1).

132.1(1) In the case of a cannabis extract or psilocybin — or a cannabis accessory that contains a cannabis extract or psilocybin accessory that contains psilocybin — that is in discrete units and is not intended to be consumed by means of inhalation, the label of any container in which the cannabis or psilocybin product is packaged must also include the following information if applicable:

(a) the net weight, in grams, of the cannabis extract or psilocybin;

(c) the net weight, in grams, of the cannabis extract or psilocybin in each unit;

(h) a list of the ingredients of the cannabis extract or psilocybin;

(i) the name of any food allergen that is present in the cannabis extract, or psilocybin except as a result of cross-contamination;

(j) the identity of the cannabis or psilocybin product in terms of its common name or in terms of its function; and

(k) the intended use of the cannabis or psilocybin product.

Cannabis or psilocybin extract — not in discrete units

Rules regarding extract products would apply to psilocybin.

CRs – Amend Section 132.12(1).

132.12(1) In the case of a cannabis extract or psilocybin — or a cannabis accessory that contains a cannabis extract or psilocybin accessory that contains psilocybin — that is not in discrete units, the label of any container in which the cannabis or psilocybin product is packaged must also include the following information if applicable:

(a) the net weight, in grams, of the cannabis extract or psilocybin;

(g) a list of the ingredients of the cannabis extract <u>or psilocybin product</u>;

(h) the name of any food allergen that is present in the cannabis extract <u>or psilocybin</u>, except as a result of cross-contamination;

(i) the identity of the cannabis <u>or psilocybin</u> product in terms of its common name or in terms of its function; and

(j) the intended use of the cannabis <u>or psilocybin</u> product.

<u>Flavours — cannabis and psilocybin extracts</u>

The flavour rules would apply to psilocybin.

CRs – Amend section 123.13(1).

132.13(1) It is prohibited to display on a cannabis <u>or psilocybin</u> extract that is a cannabis <u>or psilocybin</u> product or on a cannabis <u>or psilocybin</u> accessory that contains a cannabis <u>or psilocybin</u> extract and that is a cannabis <u>or psilocybin</u> product — or on the package of such a cannabis <u>or psilocybin</u> product or on the label or panel of a container in which such a cannabis <u>or psilocybin</u> product is packaged — an indication or illustration, including a brand element, that could cause a person to believe that the cannabis <u>or psilocybin</u> product has a flavour set out in column 1 of Schedule 3 to the <u>*Tobacco and Vaping Products Act*</u>, other than the flavour of cannabis (for cannabis products) <u>or psilocybin (for psilocybin products)</u>.

<u>List of ingredients — cannabis and psilocybin extract</u>

The rules regarding ingredient lists for cannabis extracts would apply to psilocybin products.

CRs – Amend Section 132.14(1).

132.14(1) The list of ingredients of a cannabis <u>or psilocybin</u> extract — or of a cannabis <u>or psilocybin</u> accessory that contains a cannabis <u>or psilocybin</u> extract — must meet the following requirements:

(c) the ingredients must be

(i) set out in descending order of their proportion of the cannabis <u>or psilocybin</u> extract by weight, determined before the ingredients are combined to form the extract,

Ingredients in proportion of 1% or less

Proportionality rules for ingredients would apply to psilocybin.

CRs – Amend section 132.14(2).

132.14(2) Despite subparagraph (1)(c)(i), ingredients that are present in a proportion of 1% or less of the cannabis or psilocybin extract may be listed in any order after the ingredients that are present in a proportion of more than 1% of the cannabis or psilocybin extract.

Exception — flavouring agent

The exceptions regarding flavouring agents would apply to psilocybin.

CRs – Amend Section 132.14(3).

132.14(3) Despite paragraph (1)(c), in the case where the cannabis or psilocybin extract contains one flavouring agent, it may be shown individually at the end of the list of ingredients by the name "flavouring agent" and in the case where the cannabis or psilocybin extract contains more than one flavouring agent, they may be shown collectively at the end of the list of ingredients by the name "flavouring agents".

Edible cannabis or psilocybin — discrete units

Rules regarding edible cannabis would apply to psilocybin.

CRs – Amend section 132.18(1) and add section 132.18(1)(i.1).

132.18(1) In the case of edible cannabis or psilocybin — or a cannabis or psilocybin accessory that contains edible cannabis or psilocybin — that is in discrete units, the label of any container in which the cannabis or psilocybin product is packaged must also include the following information if applicable:

(a) if the edible cannabis or psilocybin is in solid form, its net weight, in grams, and in any other case, its net volume, in millilitres;

(i.1) the quantity of psilocybin in milligrams that the psilocybin product contains, preceded by "psilocybin";

(k) a list of the ingredients of the edible cannabis or psilocybin, including constituents, if any;

(l) the source of any food allergen or gluten present in the edible cannabis or psilocybin, except as a result of cross-contamination,

(m) the sulphites that are present in the edible cannabis or psilocybin in an amount of 10 p.p.m. or more,

(o) the common name of the cannabis or psilocybin product;

(p) if the edible cannabis or psilocybin is irradiated under section 102.6, the symbol set out in subsection B.01.035(5) of the *Food and Drug Regulations* and one of the following statements or a statement that has the same meaning:

(q) if an irradiated food referred to in column 1 of the table to Division 26 of Part B of the *Food and Drug Regulations* is an ingredient or constituent of the edible cannabis or psilocybin and constitutes 10% or more of the edible cannabis, the statement "irradiated" preceding any mention of the ingredient or constituent on the label.

Risk of cross-contamination

The rules relating to allergen contamination would apply to psilocybin.

CRs – Amend section 132.18(4).

132.18(4) Despite paragraph (1)(l), the source of a food allergen or gluten must be shown on the label if it includes a declaration alerting consumers that, due to a risk of cross-contamination, the edible cannabis or psilocybin may contain the source of a food allergen or gluten.

Edible cannabis or psilocybin— not in discrete units

The rules for edible cannabis would apply to psilocybin.

CRs – Amend section 132.19(1).

132.19(1) In the case of edible cannabis or psilocybin — or a cannabis or psilocybin accessory that contains edible cannabis or psilocybin — that is not in discrete units, the label of any container in which the cannabis or psilocybin product is packaged must also include the following information if applicable:

(a) if the edible cannabis or psilocybin is in solid form, its net weight, in grams, and in any other case, its net volume, in millilitres;

(f) a list of the ingredients of the edible cannabis or psilocybin, including constituents, if any;

(g) the source of any food allergen or gluten present in the edible cannabis or psilocybin or psilocybin, except as a result of cross-contamination,

(h) the sulphites that are present in the edible cannabis or psilocybin in an amount of 10 p.p.m. or more,

(j) the common name of the cannabis or psilocybin product;

(k) if the edible cannabis or psilocybin is irradiated under section 102.6, the symbol set out in subsection B.01.035(5) of the *Food and Drug Regulations* and one of the following statements or a statement that has the same meaning:

(l) if an irradiated food referred to in column 1 of the table to Division 26 of Part B of the *Food and Drug Regulations* is an ingredient or constituent of the edible cannabis or psilocybin and constitutes 10% or more of the edible cannabis or psilocybin, the statement "irradiated" preceding any mention of the ingredient or constituent on the label.

Durable life date required

The rules regarding durable life notice requirements would apply to psilocybin.

CRs – Amend section 132.2(1).

132.2(1) In the case of edible cannabis or psilocybin having a durable life of 90 days or less, the durable life date must be shown on the label of any container in which the edible cannabis or psilocybin is packaged.

Format of durable life date

Rules on the format of the expiry date would apply.

CRs – Amend section 132.2(2).

132.2(2) Any durable life date on the label of any container in which edible cannabis or psilocybin is packaged must be shown in accordance with subsections B.01.007(4) and (5) of the *Food and Drug Regulations*.

List of ingredients – edible cannabis or psilocybin

The rules regarding ingredient lists for products would apply to psilocybin.

CRs – Amend section 132.21(1).

132.21(1) The list of ingredients of edible cannabis or psilocybin — or of a cannabis or psilocybin accessory that contains edible cannabis or psilocybin — must meet the following requirements if applicable:

(c) the ingredients and constituents must be

(i) set out in descending order of their proportion of the edible cannabis or psilocybin by weight, determined before the ingredients and the constituents are combined to form the edible cannabis or psilocybin,

(ii) set out in descending order of their proportion of the ingredient by weight, determined before they are combined to form the edible cannabis or psilocybin, and

(g) if the edible cannabis or psilocybin contains one or more sugars-based ingredients,

(i) the word "Sugars" in the English version of the list and the word "Sucres**" in the French version of the list must appear**

(A) despite subparagraph (c)(i), in descending order of the proportion of all the sugars-based ingredients in the edible cannabis or psilocybin by weight, determined before they are combined to form the edible cannabis, and

(B) separated from other ingredients by a comma, and

(ii) each sugars-based ingredient must be shown

(A) set out in parentheses, immediately following the word "Sugars" in the English version of the list and the word "Sucres**" in the French version of the list,**

(B) set out in descending order of its proportion of the edible cannabis or psilocybin by weight, determined before it is combined to form the edible cannabis, and

Nutrition facts table

The nutrient facts table would apply to psilocybin.

CRs – Amend section 132.22.

132.22(1) The percentage of the daily value for a nutrient shown in the nutrition facts table on the label of any container in which edible cannabis or psilocybin is packaged must be established on the basis of the amount, by weight, of the nutrient

per immediate container of edible cannabis or psilocybin, rounded off in the applicable manner set out in column 4 of the table to this section.

132.22(3) Despite section 130, the nutrition facts table must be presented in accordance with the format specified in the applicable figure in the *Directory of Nutrition Facts Table Formats for Edible Cannabis*, as amended from time to time and published by the Government of Canada on its website, having regard to matters such as order of presentation, dimensions, spacing and use of upper and lower case letters and bold type. For psilocybin reference must be made to the applicable nutrition facts made available by the Government of Canada.

CRs – Amend The Nutrition Facts Table.

Information to be Included in the Nutrition Facts Table

TABLE

	Column 1	Column 2	Column 3	Column 4
Item	Information	Description	Unit	Manner of expression
1	Immediate container size	"Per container (naming the amount of edible cannabis or psilocybin in the immediate container)"	The size is expressed per immediate container in grams or millilitres.	The size is rounded off • **(a)** if it is 0.1 g or more or 0.1 mL or more but less than 10 g or 10 mL, to the nearest multiple of 0.1 g or 0.1 mL; and • **(b)** if it is 10 g or more or 10 mL or more, to the nearest multiple of 1 g or 1 mL.
2	Energy value	"Calories", "Total Calories" or "Calories, Total"	The value is expressed in calories per immediate container.	The value is rounded off • **(a)** if it is less than 5 calories, to the nearest multiple of 1 calorie; • **(b)** if it is 5 calories or more but not more than 50 calories, to the nearest multiple of 5 calories; and • **(c)** if it is more than 50 calories, to the nearest multiple of 10 calories.

	Column 1	Column 2	Column 3	Column 4
Item	Information	Description	Unit	Manner of expression
3	Amount of fat	“Fat”, “Total Fat” or “Fat, Total”	The amount is expressed • **(a)** in grams per immediate container; and • **(b)** as a percentage of the daily value per immediate container.	• **(1)** The amount is rounded off ○ **(a)** if it is less than 0.5 g, to the nearest multiple of 0.1 g; ○ **(b)** if it is 0.5 g or more but not more than 5 g, to the nearest multiple of 0.5 g; and ○ **(c)** if it is more than 5 g, to the nearest multiple of 1 g. • **(2)** The percentage is rounded off ○ **(a)** if the amount is declared as “0 g”, to 0%; and ○ **(b)** in all other cases, to the nearest multiple of 1%.
4	Amount of saturated fatty acids	“Saturated Fat”, “Saturated Fatty Acids”, “Saturated” or “Saturates”	The amount is expressed in grams per immediate container.	The amount is rounded off • **(a)** if it is less than 0.5 g, to the nearest multiple of 0.1 g; • **(b)** if it is 0.5 g or more but not more than 5 g, to the nearest multiple of 0.5 g; and • **(c)** if it is more than 5 g, to the nearest multiple of 1 g.
5	Amount of trans fatty acids	“Trans Fat”, “Trans Fatty Acids” or “Trans”	The amount is expressed in grams per immediate container.	The amount is rounded off • **(a)** if it is less than 0.5 g, to the nearest multiple of 0.1 g; • **(b)** if it is 0.5 g or more but not more than 5 g, to the nearest multiple of 0.5 g; and • **(c)** if it is more than 5 g, to the nearest multiple of 1 g.

	Column 1	Column 2	Column 3	Column 4
Item	Information	Description	Unit	Manner of expression
6	The sum of saturated fatty acids and trans fatty acids	“Saturated Fat + Trans Fat”, “Saturated Fatty Acids + Trans Fatty Acids”, “Saturated + Trans” or “Saturates + Trans”	The sum is expressed as a percentage of the daily value per immediate container.	The percentage is rounded off • **(a)** if the amounts of saturated fatty acids and trans fatty acids are declared as “0 g”, to 0%; and • **(b)** in all other cases, to the nearest multiple of 1%.
7	Amount of cholesterol	“Cholesterol”	The amount is expressed in milligrams per immediate container.	The amount is rounded off to the nearest multiple of 5 mg.
8	Amount of sodium	“Sodium”	The amount is expressed • **(a)** in milligrams per immediate container; and • **(b)** as a percentage of the daily value per immediate container.	• **(1)** The amount is rounded off ○ **(a)** if it is less than 5 mg, to the nearest multiple of 1 mg; ○ **(b)** if it is 5 mg or more but not more than 140 mg, to the nearest multiple of 5 mg; and ○ **(c)** if it is more than 140 mg, to the nearest multiple of 10 mg. • **(2)** The percentage is rounded off ○ **(a)** if the amount is declared as “0 mg”, to 0%; and ○ **(b)** in all other cases, to the nearest multiple of 1%.
9	Amount of carbohydrate	“Carbohydrate”, “Total Carbohydrate” or “Carbohydrate, Total”	The amount is expressed in grams per immediate container.	The amount is rounded off • **(a)** if it is less than 0.5 g, to 0 g; and • **(b)** if it is 0.5 g or more, to the nearest multiple of 1 g.

	Column 1	Column 2	Column 3	Column 4
Item	Information	Description	Unit	Manner of expression
10	Amount of fibre	“Fibre”, “Fiber”, “Dietary Fibre” or “Dietary Fiber”	The amount is expressed • **(a)** in grams per immediate container; and • **(b)** as a percentage of the daily value per immediate container.	• **(1)** The amount is rounded off ○ **(a)** if it is less than 0.5 g, to 0 g; and ○ **(b)** if it is 0.5 g or more, to the nearest multiple of 1 g. • **(2)** The percentage is rounded off ○ **(a)** if the amount is declared as “0 g”, to 0%; and ○ **(b)** in all other cases, to the nearest multiple of 1%.
11	Amount of sugars	“Sugars”	The amount is expressed • **(a)** in grams per immediate container; and • **(b)** as a percentage of the daily value per immediate container.	• **(1)** The amount is rounded off ○ **(a)** if it is less than 0.5 g, to 0 g; and ○ **(b)** if it is 0.5 g or more, to the nearest multiple of 1 g. • **(2)** The percentage is rounded off ○ **(a)** if the amount is declared as “0 g”, to 0%; and ○ **(b)** in all other cases, to the nearest multiple of 1%.
12	Amount of protein	“Protein”	The amount is expressed in grams per immediate container.	The amount is rounded off • **(a)** if it is less than 0.5 g, to the nearest multiple of 0.1 g; and • **(b)** if it is 0.5 g or more, to the nearest multiple of 1 g.
13	Amount of potassium	“Potassium”	The amount is expressed • **(a)** in milligrams	• **(1)** The amount is rounded off ○ **(a)** if it is less than 5 mg, to 0 mg;

	Column 1	Column 2	Column 3	Column 4
Item	Information	Description	Unit	Manner of expression
			per immediate container; and • **(b)** as a percentage of the daily value per immediate container.	○ **(b)** if it is 5 mg or more but less than 50 mg, to the nearest multiple of 10 mg; ○ **(c)** if it is 50 mg or more but less than 250 mg, to the nearest multiple of 25 mg; and ○ **(d)** if it is 250 mg or more, to the nearest multiple of 50 mg. • **(2)** The percentage is rounded off ○ **(a)** if the amount is declared as “0 mg”, to 0%; and ○ **(b)** in all other cases, to the nearest multiple of 1%.
14	Amount of calcium	“Calcium”	The amount is expressed • **(a)** in milligrams per immediate container; and • **(b)** as a percentage of the daily value per immediate container.	• **(1)** The amount is rounded off ○ **(a)** if it is less than 5 mg, to 0 mg; ○ **(b)** if it is 5 mg or more but less than 50 mg, to the nearest multiple of 10 mg; ○ **(c)** if it is 50 mg or more but less than 250 mg, to the nearest multiple of 25 mg; and ○ **(d)** if it is 250 mg or more, to the nearest multiple of 50 mg. • **(2)** The percentage is rounded off ○ **(a)** if the amount is declared as “0 mg”, to 0%; and

	Column 1	Column 2	Column 3	Column 4
Item	Information	Description	Unit	Manner of expression
				○ **(b)** in all other cases, to the nearest multiple of 1%.
15	Amount of iron	"Iron"	The amount is expressed • **(a)** in milligrams per immediate container; and • **(b)** as a percentage of the daily value per immediate container.	• **(1)** The amount is rounded off ○ **(a)** if it is less than 0.05 mg, to 0 mg; ○ **(b)** if it is 0.05 mg or more but less than 0.5 mg, to the nearest multiple of 0.1 mg; ○ **(c)** if it is 0.5 mg or more but less than 2.5 mg, to the nearest multiple of 0.25 mg; and ○ **(d)** if it is 2.5 mg or more, to the nearest multiple of 0.5 mg. • **(2)** The percentage is rounded off ○ **(a)** if the amount is declared as "0 mg", to 0%; and ○ **(b)** in all other cases, to the nearest multiple of 1%.

Declaration on risk of cross-contamination

The labelling rules for declarations of cross-contamination would apply to psilocybin.

CRs – Amend section 132.24.

132.24 If the label of the container in which edible cannabis or psilocybin is packaged includes a declaration alerting consumers that, due to a risk of cross-contamination, the edible cannabis or psilocybin may contain the source of a food allergen or gluten, the declaration must meet the following requirements:

Presentation of food allergen statement

Rules regarding food allergen statements would apply to psilocybin.

CRs – Amend section 132.25.

132.25(1) A food allergen source, gluten source and added sulphites statement must meet the following requirements:

(d) it must include, even if any of the following information is also shown in the list of ingredients,

(i) the source of each food allergen that is present in the edible cannabis or psilocybin,

(ii) each source of any gluten that is present in the edible cannabis or psilocybin, and

(iii) one of the common names "sulfites", "sulfiting agents", "sulphites" or "sulphiting agents", if the total amount of sulphites present in the edible cannabis or psilocybin is 10 p.p.m. or more.

Constituents not required to be shown on label

The ingredient rules for labelling would apply to psilocybin.

CRs – Amend section 132.26(1).

132.26(1) Constituents of ingredients or of classes of ingredients set out in the table to subsection B.01.009(1) of the *Food and Drug Regulations* are not required to be shown on the label of a container in which edible cannabis or psilocybin — or a cannabis or psilocybin accessory that contains edible cannabis or psilocybin — that is a cannabis or psilocybin product is packaged.

Preparation or mixture

The rules for mixtures and preparations would apply to psilocybin.

CRs – Amend section 132.26(2).

132.26(2) Subject to subsection (3), if a preparation or mixture set out in the table to subsection B.01.009(2) of the *Food and Drug Regulations* is used to produce edible cannabis or psilocybin, the ingredients and constituents of the preparation or mixture are not required to be shown on the label of the container in which edible cannabis or psilocybin — or a cannabis or psilocybin accessory that

contains edible cannabis or psilocybin — that is a cannabis or psilocybin product is packaged.

Common name

The rules on common name usage would apply to psilocybin.

CRs – Amend section 132.26(3).

132.26(3) If a preparation or mixture set out in the table to subsection B.01.009(2) of the *Food and Drug Regulations* is used to produce edible cannabis or psilocybin and the preparation or mixture has one or more of the ingredients or constituents listed in subsection B.01.009(3) of the *Food and Drug Regulations*, those ingredients or constituents must be shown by their common names in the list of the ingredients of the edible cannabis or psilocybin to which they are added as if they were ingredients of that edible cannabis or psilocybin.

Constituents required to be shown in list of ingredients

The rules regarding constituents would apply to psilocybin.

CRs – Amend section 132.26(4).

132.26(4) Despite subsections (1) and (2), if any of the constituents listed in subsection B.01.009(4) of the *Food and Drug Regulations* is contained in an ingredient of edible cannabis or psilocybin set out in a table referred to in subsection (1) or (2), that constituent must be shown in the list of ingredients.

Small immediate container

The rules on immediate containers would apply to psilocybin.

CRs – Amend section 132.27(1).

132.27(1) In the case of a cannabis or psilocybin product whose immediate container is too small for all the required information to be displayed on its label in accordance with these Regulations,

Panel

The rules regarding panels would apply to psilocybin.

CRs – Amend section 132.27(3).

132.27(3) The panel must

(c) include any of the following information that cannot be included on the label because the immediate container of the cannabis or psilocybin product is too small for all the required information to be displayed in accordance with these Regulations if applicable:

(i) the class of cannabis or psilocybin set out in Schedule 4 or 7 to the Act to which the cannabis or psilocybin that is in the immediate container belongs,

(iv) except in the case of a cannabis plant, cannabis plant seeds or edible cannabis or psilocybin spores, either

(vi) the list of ingredients of the cannabis or psilocybin product, including constituents, if any,

(vii) in the case of dried cannabis or psilocybin or fresh cannabis, the net weight,

(viii) in the case of a cannabis or psilocybin extract,

(A) the net weight, including the net weight of cannabis or psilocybin extract in each unit, if the cannabis or psilocybin extract is in discrete units,

(x) in the case of edible cannabis or psilocybin,

(A) if the edible cannabis or psilocybin is in solid form, its net weight, and in any other case, its net volume,

(B) the durable life date,

(C) the source of any food allergen or gluten present in the edible cannabis or psilocybin, except as a result of cross-contamination,

(D) sulphites that are present in the edible cannabis or psilocybin in an amount of 10 p.p.m. or more, and

Statement on location of information

Rules on location of information apply to psilocybin.

CRs – Amend section 132.27(6).

132.27(6) The label of an immediate container in which a cannabis or psilocybin product is packaged and to which a panel is applied must include a statement that

clearly indicates the location of any information required under these Regulations that is not included on the label.

Prohibited representation — health and cosmetic benefits

The rules regarding prohibited representations as they relate to health and cosmetic benefits would apply to psilocybin.
CRs – Amend section 132.28.

132.28 It is prohibited to make an express or implied representation, including by way of a brand element, on a cannabis product or psilocybin — or on the package of a cannabis product or psilocybin or on the label or panel of a container in which such a cannabis or psilocybin product is packaged — if there are reasonable grounds to believe that the representation could create the impression that health or cosmetic benefits may be derived from the use of the cannabis or psilocybin product.

Prohibited representation — energy value and amount of nutrient

The rules regarding prohibited representations regarding energy value and nutrient amounts would apply to psilocybin.

CRs – Amend section 132.29(1).

132.29(1) It is prohibited to make an express or implied representation, including by way of a brand element, on edible cannabis or psilocybin that is a cannabis or psilocybin product or on a cannabis or psilocybin accessory that contains edible cannabis or psilocybin and that is a cannabis or psilocybin product — or on the package of such a cannabis or psilocybin product or on the label or panel of a container in which such a cannabis or psilocybin product is packaged — concerning the energy value referred to in item 2 of the table to section 132.22 or the amount of any nutrient referred to in items 3 to 15 of that table or in items 5 to 37 of the table to section B.01.402 of the *Food and Drug Regulations*.

Prohibited representation — dietary requirements

The rules around dietary requirements would apply to psilocybin.

CRs – Amend section 132.3.

132.3 It is prohibited to make an express or implied representation, including by way of a brand element, on edible cannabis or psilocybin s that is a cannabis or psilocybin product or on a cannabis or psilocybin accessory that contains edible cannabis or psilocybin and that is a cannabis or psilocybin product — or on the package of such a cannabis or psilocybin product or on the label or panel of a

container in which such a cannabis or psilocybin product is packaged — if there are reasonable grounds to believe that the representation could create the impression that the cannabis or psilocybin product is intended

Prohibited representation — alcoholic beverages

Rules prohibiting representations connected to alcohol would apply to psilocybin.

CRs – Amend section 123.31.

132.31 It is prohibited to make an express or implied representation, including by way of a brand element, on a cannabis or psilocybin product — or on the package of a cannabis or psilocybin product or on the label or panel of a container in which such a cannabis or psilocybin product is packaged — if there are reasonable grounds to believe that the representation could associate the cannabis or psilocybin product with an alcoholic beverage.

Prohibited representation — tobacco products and vaping products

Rules prohibiting representation relating to tobacco products and vaping products would apply to psilocybin.

CRs – Amend section 132.32.

132.32 It is prohibited to make an express or implied representation, including by way of a brand element, on a cannabis or psilocybin product — or on the package of a cannabis or psilocybin product or on the label or panel of a container in which such a cannabis or psilocybin product is packaged — if there are reasonable grounds to believe that the representation could associate the cannabis or psilocybin product with a *tobacco product*, as defined in section 2 of the *Tobacco and Vaping Products Act*, or a vaping product to which that Act applies.

Standardized cannabis or psilocybin symbol on cannabis or psilocybin product intended for inhalation

CRs – Amend section 132.34(1).

132.34 (1) The standardized cannabis or psilocybin symbol that must be obtained from the Minister in the form of an electronic file must be clearly and prominently displayed on the outer surface of a cannabis or psilocybin accessory that contains a cannabis or psilocybin extract and that is a cannabis or psilocybin product intended to be consumed by means of inhalation if the cannabis extract contains THC in a concentration greater than 10 µg/g, taking into account the potential to convert THCA into THC or if the psilocybin product does not qualify as an edible product.

Requirements

The standardized symbol requirements would apply to psilocybin.

CRs – Amend section 132.34.

132.34(2) The standardized cannabis or psilocybin symbols must meet the following requirements:

(a) it must be at least 1.27 cm by 1.27 cm in size;

(b) it must be displayed with a white border of at least 2 points on all sides; and

(c) if a change is made to the size of the symbol, its dimensions must be proportional vertically and horizontally.

Cannabis or psilocybin product accuracy rules net weight and volume

The rules relating to net weight and volume would apply to psilocybin although the prevailing publications have not yet been made available.

CRs – Amend section 133.

133 The net weight and volume that must be included on the label of a cannabis or psilocybin product in accordance with sections 124, 124.1, 125, 132.1, 132.11, 132.12, 132.15, 132.16, 132.18 and 132.19 must be within the tolerance limits set out for that product in the document entitled *Tolerance Limits for the Net Weight and Volume Declared on Cannabis Product Labelling*, as amended from time to time and published by the Government of Canada on its website and the documents published relating to psilocybin.

Part 10 - Importation and Exportation for Medical or Scientific Purposes

Importation and Exportation for Medical or Scientific Purposes

A license holder would have the authority to import psilocybin for medical or scientific purposes if they had a permit for each shipment that is imported.

CRs - Amend section 204.

204(1) A holder of a licence is authorized to import cannabis or psilocybin for medical or scientific purposes if they also hold an import permit for each shipment of cannabis or psilocybin that is imported.

(2) A holder of an import permit is also authorized to possess, transfer, transport, send or deliver the shipment of cannabis or psilocybin to the extent necessary to import the cannabis or psilocybin.

Import permit - content

Information that would be set out in the permit.

CRs - Amend section 205.

205 The import permit must set out the following information:

(a) the name and mailing address of the holder;

(b) the permit number and the licence number;

(c) in respect of the shipment of cannabis or psilocybin to be imported,

(i) a description of the cannabis or psilocybin,

(ii) the intended use of the cannabis or psilocybin,

(iii) if applicable, the brand name of the cannabis or psilocybin,

(iv) quantity of the cannabis or psilocybin,

(v) the percentage of THC w/w and CBD w/w of the cannabis, except in the case of cannabis plants and cannabis plant seeds, and

(vi) in the case of psilocybin, if the information is available, the w/w of psilocybin;

Import permit holder information

Permit holder would, in 15 days or less after release of the shipment of psilocybin, provide the Minister with the following information.

CRs - Amend section 209.

209 The holder of an import permit must, within 15 days after the date of release of a shipment of cannabis or psilocybin in Canada, provide the Minister with the following information:

(a) their name, the number of the licence referred to in paragraph 205(b) and the import permit number issued in respect of the shipment;

(b) the date of release of the shipment; and

(c) in respect of the shipment of cannabis or psilocybin that is imported,

(i) a description of the cannabis or psilocybin,

(ii) the intended use of the cannabis or psilocybin,

(iii) if applicable, the brand name of the cannabis or psilocybin,

(iv) the quantity of the cannabis or psilocybin,

(v) the percentage of THC w/w and CBD w/w of the cannabis, except in the case of cannabis plants and cannabis plant seeds, and

(vi) if the information is available, the w/w of psilocybin.

Transportation of imported cannabis

After the imported psilocybin is released, the import permit holder would ensure that it is transported directly to the license site.

CRs - Amend section 210.

210 The holder of an import permit must ensure that, after the imported cannabis or psilocybin is released, it is transported directly to the site set out in the licence referred to in paragraph 205(b).

Revocation - other circumstances

Circumstances that would prompt the revocation of an import permit.

CRs - Amend section 211.

211 For the purpose of paragraph 65(h) of the Act, other circumstances for the revocation of an import permit are the following:

(a) the permit holder has requested, in writing, the revocation;

(b) the licence referred to in paragraph 205(b) has been revoked;

(c) the importation of the cannabis or psilocybin is for the purpose of exporting

it; and

(d) a permit that has been suspended is not reinstated because the reasons for the suspension still exist or the permit holder has not demonstrated to the Minister that the suspension is unfounded.

Disclosure of information

For compliance reasons, the Minister could provide customs officers with information included in the import permit application, and inform them of suspensions or revocations.

CRs - Amend section 212.

212 The Minister may, for the purpose of verifying whether an importation of cannabis or psilocybin complies with these Regulations, provide to a customs officer any information provided in the import permit application or referred to in sections 205 and 209 and inform that customs officer whether the import permit has been suspended or revoked.

Export Permit

Licence holders would be authorized to export psilocybin for medical or scientific purposes with an export permit per exported psilocybin shipment. Export permit holders would be authorized to handle psilocybin to the extent needed for export.

CRs - Amend section 213.

213(1) A holder of a licence is authorized to export cannabis or psilocybin for medical or scientific purposes if they also hold an export permit for each shipment of cannabis or psilocybin that is exported.

(2) A holder of an export permit is also authorized to possess, transfer, transport, send, deliver or sell the shipment of cannabis or psilocybin to the extent necessary to export the cannabis or psilocybin.

Export Permit - content

Export permit would set out the information below.

CRs - Amend section 214.

214 The export permit must set out the following information:

(a) the name and mailing address of the holder;

(b) the permit number and the licence number;

(c) in respect of the shipment of cannabis <u>or psilocybin</u> to be exported,

(i) a description of the cannabis <u>or psilocybin</u>,

(ii) the intended use of the cannabis <u>or psilocybin</u>,

(iii) if applicable, the brand name of the cannabis <u>or psilocybin</u>,

(iv) the quantity of the cannabis <u>or psilocybin</u>,

(v) the percentage of THC w/w and CBD w/w of the cannabis, except in the case of cannabis plants and cannabis plant seeds<u>, and</u>

<u>(vi) in the case of psilocybin, if the information is available, the w/w of psilocybin;</u>

<u>Information</u>

Export permit holder would provide the Minister with the information below within 15 days after date of psilocybin export shipment.

CRs - Amend section 218.

218 The holder of an export permit must, within 15 days after the date of exportation of a shipment of cannabis <u>or psilocybin</u>, provide the Minister with the following information:

(a) their name and the number of the licence referred to in paragraph 214(b) and the export permit number issued in respect of the shipment;

(b) the date of exportation of the shipment; and

(c) in respect of the shipment of cannabis <u>or psilocybin</u> that is exported,

(i) a description of the cannabis <u>or psilocybin</u>,

(ii) intended use of the cannabis <u>or psilocybin</u>,

(iii) if applicable, the brand name of the cannabis <u>or psilocybin</u>,

(iv) the quantity of the cannabis or psilocybin,

(v) the percentage of THC w/w and CBD w/w of the cannabis, except in the case of cannabis plants and cannabis plant seeds, and

(vi) in the case of psilocybin, if the information is available, the w/w of psilocybin.

Disclosure of information

For compliance reasons, the Minister could provide customs officers with information included in the export permit application and inform them of suspensions or revocations.

CRs - Amend section 220.

220 The Minister may, for the purpose of verifying whether an exportation of cannabis or psilocybin complies with these Regulations, provide to a customs officer any information provided in the export permit application or referred to in sections 214 and 218 and inform that customs officer whether the export permit has been suspended or revoked.

Part 11 - Retention of Documents and Information

Inventory

The inventory rules would apply to psilocybin. While propagation and inoculation methods are different, the documentation procedure would largely be the same.

CRs – Amend section 224.

224(1) A holder of a licence must retain, for each lot or batch of cannabis or psilocybin — other than a cannabis extract, psilocybin extract, a cannabis topical or edible cannabis — that they produce, a document that contains the following information, as applicable:

(a) the date on which cannabis plants or psilocybin are propagated or inoculated by means other than sowing seeds and the number of new plants or fruiting bodies propagated in this manner;

(b) the date on which cannabis plant seeds or psilocybin spores are sown and their net weight on that date;

(c) the date on which cannabis or psilocybin is harvested and its net weight on that date;

(d) the date on which drying processes are completed for the cannabis or psilocybin and its net weight on that date;

(e) the date on which dried or fresh cannabis or psilocybin is put into a discrete unit form, the net weight of cannabis or psilocybin in each unit and the number of units;

(f) the date on which cannabis or psilocybin that is not of a class of cannabis or psilocybin set out in Schedule 4 to the Act is produced and its net weight or volume on that date; and

(g) except in the case of cannabis plants or cannabis plant seeds or psilocybin, any information that is obtained through testing and that relates to the phytocannabinoid and terpene content of the cannabis.

Packaging

The rules for packaging would apply to psilocybin. Psilocybin is exclusively edible, so the exception is not diversified as to product type.

CRs – Amend section 224(2).

224(2) A holder of a licence must retain, for each lot or batch of cannabis or psilocybin — other than a cannabis extract, psilocybin extract, a cannabis topical or edible cannabis — that they package, a document that contains the following information:

(a) a description of the cannabis or psilocybin, including, if applicable, the brand name;

(b) the date on which the cannabis or psilocybin is packaged and its net weight on that date; and

(c) in the case of a drug containing cannabis, the strength per unit of the drug so long as such data is calculable.

Inventory — cannabis extract etc.

Inventory rules for cannabis extracts would apply to psilocybin if packaged. This is best dealt with by inserting a new section dealing with psilocybin.

CRs – Amend section 225(1).

225(1) A holder of a licence must retain, for each lot or batch of cannabis extract,

cannabis topical or edible cannabis or psilocybin extract that they produce, a document that contains the following information:

(a) the date of production and the net weight or volume of the cannabis extract, cannabis topical or edible cannabis or psilocybin extract on that date;

(b) if applicable, the date on which the cannabis extract, cannabis topical or edible cannabis or psilocybin extract is put into a discrete unit form, the net weight or volume of each unit and the number of units;

Exception to subparagraph (1)(d)(ii)

This exception does not apply to psilocybin.

225(1.1) The document is not required to contain the information referred to in subparagraph (1)(d)(ii) in respect of an ingredient if

(a) the ingredient is part of a mixture of substances that was used in the production of cannabis referred to in paragraph (1)(d);

(b) the holder obtained the mixture from another person;

(c) the information has not been disclosed to the holder;

(d) the holder has made the necessary arrangements to ensure that the information will be provided to the Minister if, within the retention period referred to in subsection (3), the Minister requires the holder to provide it; and

(e) the document contains the net weight or volume of the mixture at the time it was used to produce the cannabis.

CRs – New section 225(1.3).

225(1.3) A holder of a licence must retain, for each lot or batch of psilocybin that they produce, a document that contains the following information:

(a) the date of production and the net weight or volume of the psilocybin on that date;

(b) if applicable, the date on which the psilocybin is put into a discrete unit form, the net weight or volume of each unit and the number of units;

(c) in respect of the psilocybin:

(i) its description,

(ii) its net weight or volume,

(iii) its lot or batch number, and

(iv) the date on which it was produced;

(d) if the psilocybin contains any other material,

(i) the list of ingredients that is required to appear on the label of the psilocybin product, and

(ii) the net weight, net volume or concentration by weight or volume of each of those ingredients;

(e) if the psilocybin will become a psilocybin product,

(i) an indication of whether each ingredient that is required to appear on the label of the psilocybin product is a carrier substance, flavouring agent or substance that is necessary to maintain the quality or stability of the psilocybin product,

(ii) any additional information in the possession of the holder that relates to the purpose of each ingredient, and

(iii) a description of the flavour, if any, of the psilocybin product; and

(f) any information that is obtained through testing and that relates to the psilocybin content of the psilocybin extract, psilocybin topical or edible psilocybin.

Exception to subparagraph (1.3)(d)(ii)

The exception would apply to the new amendment.

CRs – New section 225(1.4) and (1.5).

225(1.4) The document is not required to contain the information referred to in subparagraph (1)(d)(ii) in respect of an ingredient if

(a) the ingredient is part of a mixture of substances that was used in the production of psilocybin referred to in paragraph (1)(d);

(b) the holder obtained the mixture from another person;

(c) the information has not been disclosed to the holder;

(d) the holder has made the necessary arrangements to ensure that the information will be provided to the Minister if, within the retention period referred to in subsection (3), the Minister requires the holder to provide it; and

(e) the document contains the net weight or volume of the mixture at the time it was used to produce the psilocybin.

(1.5) The document is not required to contain the information referred to in subparagraph (1)(e)(i) in respect of an ingredient if

(a) the requirements in paragraphs (1.1)(a) to (d) are met; and

(b) the holder includes in the document an indication of whether the mixture referred to in paragraph (1.1)(a) contains carrier substances, flavouring agents, substances that are necessary to maintain the quality or stability of the psilocybin product, or a combination of any of these.

Packaging

The packaging rules would apply to psilocybin.

CRs – Amend section 225(2).

225(2) A holder of a licence must retain, for each lot or batch of cannabis extract, cannabis topical or edible cannabis or psilocybin that they package, a document that contains the following information:

(a) a description of the cannabis extract, cannabis topical or edible cannabis or psilocybin, including the brand name, if applicable;

(b) the date on which the cannabis extract, cannabis topical or edible cannabis or psilocybin is packaged and its net weight or volume on that date; and

(c) in the case of a drug containing cannabis or psilocybin, the strength per unit of the drug.

Cannabis obtained from another person

This provision would apply to psilocybin.

CRs – Amend section 226(1).

226(1) A holder of a licence must, if they obtain cannabis or psilocybin from another person, retain a document that contains the following information:

(a) the name of the person from which the cannabis or psilocybin is obtained;

(b) the address of the location at which the cannabis or psilocybin is obtained and, if that location is different from the site or sites at which the cannabis or psilocybin was produced, the address of the site or sites, if known;

(c) the date on which the cannabis or psilocybin is obtained;

(d) the quantity of cannabis or psilocybin that is obtained;

(e) a description of the cannabis or psilocybin, including, if applicable, the brand name;

(f) the lot or batch number of the cannabis or psilocybin;

(g) in the case of a drug containing cannabis or psilocybin, the form of the drug and its strength per unit; and

(h) in the case of cannabis plants, cannabis plant seeds or cannabis that is not of a class of cannabis set out in Schedule 4 to the Act or psilocybin, the intended use.

Things to be used as ingredients

This provision would apply to psilocybin.

CRs – Amend section 226.1(1).

226.1 (1) A holder of a licence for processing or psilocybin processing must, if they obtain or produce anything that will be used as an ingredient to produce a cannabis extract, a cannabis topical or edible cannabis or psilocybin, retain a document that contains the following information:

(a) the name and business address of the person, if any, that supplies the thing;

(b) the date on which the holder takes possession of the thing or, if the thing is produced by the holder, the date on which production is completed;

(c) a description of the thing, including the name by which it is generally known

and, if applicable,

(i) its chemical name,

(ii) its common name, if that name is not the name by which it is generally known,

(iii) its INCI name, and

(iv) its CAS registry number; and

(d) any lot code or other unique identifier that enables the thing to be traced.

Sale, distribution and export of cannabis

The rules relating to sale, distribution, and export would apply to psilocybin.

CRs – Amend section 227.

227(1) A holder of a licence, if they sell, distribute or export cannabis or psilocybin, must retain a document that contains the following information:

(e) a description of the cannabis or psilocybin, including, if applicable, the brand name;

(2) The obligation set out in subsection (1) does not apply if the cannabis or psilocybin is sold or distributed to

(a) an individual who has placed a purchase order for it under subsection 289(1); or

(b) an individual, other than an individual referred to in paragraph (a), who does not hold a licence and who is obtaining the cannabis or psilocybin for their personal use.

Antimicrobial treatment

Antimicrobial treatment rules would apply to psilocybin.

CRs – Amend section 228(1).

228(1) A holder of a licence, if they conduct antimicrobial treatment of cannabis or psilocybin at a location other than the site specified in the licence, must retain a document that contains the following information:

(a) a description of the cannabis or psilocybin, including, if applicable, the brand name;

(b) the date on which the cannabis or psilocybin leaves the site specified in the licence and the quantity that leaves the site;

(c) the name of the person that receives the cannabis or psilocybin at the location where the treatment is to be conducted;

(d) the address of the location referred to in paragraph (e);

(e) the name of the person from which the cannabis or psilocybin is received after the treatment;

(f) the address of the site to which the cannabis or psilocybin is returned, or of the location to which it is distributed, after the treatment; and

(g) the date on which the cannabis or psilocybin is received at the site or location referred to in paragraph (f) and the quantity that is received.

Destruction of cannabis

The rules around destruction of cannabis would apply to psilocybin.

CRs – Amend section 229.

229(1) A holder of a licence other than a cannabis drug licence, if they destroy cannabis or psilocybin or cause it to be destroyed, must retain a document that contains the following information:

(a) a description of the cannabis or psilocybin, including, if applicable, the brand name;

(b) the date on which the cannabis or psilocybin is destroyed and its pre-destruction net weight or volume on that date;

(c) the address of the location at which the cannabis or psilocybin is destroyed;

(d) a brief description of the method of destruction; and

(e) the names of the individuals who witness the destruction and are qualified to do so under paragraph 43(1)(b), together with the basis on which they are qualified under subsection 43(2).

(2) The holder must obtain, for each instance in which cannabis or psilocybin is destroyed, a statement signed and dated by two of the witnesses referred to in paragraph (1)(e) stating that they witnessed the destruction and that the cannabis was destroyed in accordance with a method referred to in paragraph 43(1)(a).

(3) The document referred to in subsection (1) and the statement referred to in subsection (2) must be retained for at least two years after the day on which the cannabis or psilocybin is destroyed.

Good production practices

The rules around good production practices would apply to psilocybin.

CRs – Amend section 231.

231(1) A holder of a licence other than a cannabis drug licence must

(a) for each lot or batch of cannabis or psilocybin any portion of which has been sold or exported, retain a document demonstrating that the cannabis or psilocybin and anything that was used as an ingredient was produced, packaged, labelled, distributed, stored, sampled and tested in accordance with the applicable provisions of Parts 5 and 6;

(b) if applicable, maintain a list of the brand names of cannabis — of any class of cannabis or psilocybin set out in Schedule 4 to the Act — that the holder has produced, packaged, labelled, distributed, stored, sampled or tested;

(c) in respect of each instance in which a substance — including a pest control product and a fertilizer but excluding water — is applied directly or indirectly to cannabis or psilocybin, retain a document that contains the following information:

(i) the name of the substance and the quantity used,

(ii) the method and date of application, and

(iii) the rationale for the use of the substance;

(d) in respect of the testing conducted under Part 5 or to meet the requirements set out in Part 6,

(i) maintain a document that describes the validated methods used, and

(ii) for each lot or batch of cannabis or psilocybin that is tested, retain a

document that contains the test results;

(e) in the case of a licence for processing or psilocybin processing, retain

(i) a document that describes the qualifications of the quality assurance person — and of any alternate quality assurance person — in respect of the matters referred to in subsection 19(1), and

(ii) a document that describes every investigation conducted under paragraph 19(2)(b) or (c) and any measures taken under that paragraph; and

(f) in the case of a licence for analytical testing or psilocybin analytical testing, retain a document that describes the qualifications of the head of laboratory in respect of the matters referred to in subsection 23(2).

Packaging and labelling

The rules on packaging and labeling would apply to psilocybin.

CRs – Amend section 233.

233 A holder of a licence other than a cannabis drug licence must retain the following samples and copies for at least two years after the day on which they are made:

(a) a sample or copy of each distinct package for a cannabis or psilocybin product that the holder makes available for sale; and

(b) a copy of each distinct label that relates to a cannabis or psilocybin product that the holder makes available for sale.

Cannabis Accessories

Cannabis accessory sale records would apply to psilocybin accessories.

CRs – Amend section 234.

234 A holder of a licence must maintain a list of the names and types of the cannabis or psilocybin accessories that they sell and must retain each version of the list for at least two years after the day on which it is replaced by a new version or, if it has not been replaced, at least two years after the day on which the licence expires or is revoked.

System of control for recalls

The product recall rules would apply to psilocybin.

CRs – Amend section 235(1).

235(1) A holder of a licence, other than a licence for analytical testing, psilocybin analytical testing or a cannabis drug licence must retain, for each lot or batch of cannabis or psilocybin that they sell or distribute, a document that contains the information that is necessary for the system of control referred to in subsection 46(1).

Research and development

The rules around research and development would apply to psilocybin.

CRs – Amend section 237.

237(1) A holder of a licence, if they undertake research and development activities, must retain a document that contains the following information:

(a) in respect of any cannabis or psilocybin that is used in the activities,

(i) its description, including, if applicable, its brand name,

(ii) the quantity used and, if applicable, the lot or batch number,

(iii) the date on which it is used, and

(iv) the purpose and a brief description of the activity;

(b) in respect of any cannabis or psilocybin that is produced in the course of the activities,

(i) its description,

(ii) the quantity produced,

(iii) the date on which it is produced,

(iv) if applicable, the date on which it is used for testing and the quantity used, and

(v) if applicable, the date on which it is placed in inventory intended for sale

and the quantity placed in inventory; and

(c) any other information that can be used to reconcile the quantities of cannabis or psilocybin referred to in paragraphs (a) and (b).

Record of key investors

The rules regarding record keeping of participants and investors would apply to psilocybin. All exceptions and definitions would apply to psilocybin.

CRs – Amend section 241.

241(1) A holder of a cannabis-related or psilocybin-related licence for cultivation, processing or sale must maintain a record that contains the following information in respect of each key investor:

(a) the key investor's name and mailing address;

(b) a detailed description of the means by which the key investor exercises, or is in a position to exercise, control over the holder;

Part 12 - Reporting and Disclosure

Notice — new cannabis product

The rules on notice would apply to psilocybin.

CRs – Amend section 244.

244(1) A holder of a licence for processing or psilocybin processing, at least 60 days before making available for sale a cannabis product or psilocybin — except cannabis plants or cannabis plant seeds — that they have not previously sold in Canada, must provide the Minister with a written notice that contains the following information:

(a) the class of cannabis or psilocybin set out in Schedule 4 or 7 to the Act to which the cannabis or psilocybin product belongs;

(b) a description of the cannabis product or psilocybin, including the brand name; and

(c) the date on which the cannabis product or psilocybin is expected to be made available for sale.

Information related to promotion

The informational rules on promotion would apply to psilocybin.

CRs – Amend section 245.

245(1) For the purpose of subsection 43(1) of the Act,

(a) the information that a person referred to in that subsection must provide to the Minister in respect of the promotion of cannabis or psilocybin is

(i) the total amount of money that the person spent in a given calendar year on promotion that is directed at consumers who purchase cannabis at the retail level in Canada, together with a description of the types of promotion on which the money was spent, and

(ii) the total amount of money that the person spent in a given calendar year on promotion conducted in Canada that is not directed at consumers referred to in subparagraph (i), together with a description of the types of promotion on which the money was spent; and

(b) the information must be provided, in writing, no later than March 31 of the year after the year to which the information relates.

Cannabis or psilocybin accessories and services

The rules on accessories and services would apply to psilocybin.

CRs – Amend section 245(2).

245(2) For the purpose of subsection 43(2) of the Act,

(a) the information that a person referred to in that subsection must provide to the Minister, in respect of the promotion of cannabis or psilocybin accessories that they sell or distribute or a service related to cannabis or psilocybin that they provide, is

(i) the total amount of money that the person spent in a given calendar year on promotion that is directed at consumers who purchase cannabis or psilocybin at the retail level in Canada, together with a description of the types of promotion on which the money was spent, and

Theft or loss of cannabis or psilocybin

Rules on theft or loss would apply to psilocybin.

CRs – Amend section 246.

246(1) A holder of a licence other than a cannabis drug licence must, if they experience a theft of cannabis or psilocybin or a loss of cannabis or psilocybin that cannot be explained on the basis of normally accepted business activities,

(a) notify a police force within 24 hours after becoming aware of its theft or loss; and

(b) provide the Minister with a written notice within 10 days after becoming aware of its theft or loss.

Voluntary recall

The rules regarding voluntary recalls would apply to psilocybin.

CRs – Amend section 247(1).

247(1) A holder of a licence must, before commencing a voluntary recall of a cannabis product or psilocybin that has been sold or distributed in Canada, provide the Minister with a document that contains the following information:

(a) a description of the cannabis product or psilocybin, including the brand name;

(b) the number of each lot or batch of the cannabis product or psilocybin to be recalled, together with, if known, the number of any lot or batch of cannabis or psilocybin that was used to make the cannabis product or psilocybin;

(c) if known, the name and address of each person that

(i) produced or imported into Canada the cannabis or psilocybin that is, or is contained in, the cannabis product or psilocybin,

(ii) packaged or labelled the cannabis or psilocybin referred to in subparagraph (i) before it became, or became part of, the cannabis product or psilocybin,

(iii) in the case of a cannabis or psilocybin accessory that is a cannabis product or psilocybin, produced or imported into Canada the cannabis or psilocybin accessory or any component of it, or

(iv) packaged or labelled the cannabis product or psilocybin;

(d) the reasons for commencing the recall;

(e) if the cannabis or psilocybin that is, or is contained in, the cannabis product or psilocybin was produced or imported into Canada by the holder, the quantity of cannabis or psilocybin that was produced or imported;

(f) the quantity of the cannabis product or psilocybin that was sold or distributed by the holder in Canada;

(g) if applicable, the quantity of the cannabis product or psilocybin that is affected by the problem or potential problem underlying the recall and that remains in the possession of the holder;
(h) the number of persons to which the holder sold or distributed the cannabis product or psilocybin in Canada;

(i) the period during which the holder sold or distributed the cannabis product or psilocybin in Canada;

(2) A holder of a licence must, before commencing a voluntary recall of cannabis or psilocybin that has been exported from Canada, provide the Minister with a document that contains the following information:

(a) a description of the cannabis or psilocybin, including, if applicable, the brand name;

(b) the number of each lot or batch of the cannabis or psilocybin;

(c) if known, the name and address of each person that

(i) produced or imported into Canada the cannabis or psilocybin, and, if applicable, packaged or labelled it, and

(ii) in the case where the cannabis or psilocybin is contained in a cannabis or psilocybin accessory, produced or imported into Canada the cannabis or psilocybin accessory or any component of it;

(d) the reasons for commencing the recall;

(e) if applicable, the quantity of the cannabis or psilocybin that was produced or imported into Canada by the holder;

(f) the quantity of the cannabis or psilocybin that was sold or distributed by the holder in foreign countries;

(g) if applicable, the quantity of the cannabis or psilocybin that is affected by the

problem or potential problem underlying the recall and that remains in the possession of the holder;

(h) the number of persons to which the holder sold or distributed the cannabis or psilocybin in foreign countries;

(i) the period during which the holder sold or distributed the cannabis or psilocybin in foreign countries;

(j) the time and manner in which the recall is to be carried out, including

Adverse reactions

Rules regarding adverse reaction reporting would apply to psilocybin. The retention period of 25 years would apply.

CRs – Amend section 248(1).

248(1) A holder of a licence that sells or distributes a cannabis product or psilocybin must

(a) within 15 days after becoming aware of a serious adverse reaction to the cannabis product or to the psilocybin, provide the Minister with a detailed report containing all information in their possession that is associated with the use of the cannabis product or the psilocybin by the individual who experienced the reaction; and

(b) prepare an annual summary report that contains a concise and critical analysis of all adverse reactions to the cannabis product or to the psilocybin product that the holder became aware of during the previous 12 months.

Definitions

CRs – Amend section 248(3).

248(3) The following definitions apply in this section.

adverse reaction means a noxious and unintended response to a cannabis or psilocybin product.

serious adverse reaction means a noxious and unintended response to a cannabis or psilocybin product that requires inpatient hospitalization or a prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death.

Disclosure to province

Required disclosure to provinces would apply to psilocybin.

CRs – Amend section 250.

250(1) For the purpose of paragraph 83(f) of the Act, information contained in the national cannabis or psilocybin tracking system may be disclosed to the government of a province, at its request, if the disclosure is for a purpose related to the implementation of public health programs or activities that are related to cannabis or to psilocybin.

250(2) The Minister may, at the request of the government of a province, disclose to the government any information obtained under section 297 if the disclosure is for a purpose related to the implementation of public health programs or activities that are related to cannabis or psilocybin.

International Narcotics Control Board

The rules under the international narcotics rules would apply to psilocybin.

CRs – Amend section 251(1).

251(1) In addition to the information that may be disclosed under sections 83, 128 and 129 of the Act, the Minister may disclose to the International Narcotics Control Board other information that is obtained under the Act if the disclosure is necessary to enable Canada to fulfill its international obligations in relation to cannabis and psilocybin.

(2) The Minister may also disclose to the International Narcotics Control Board any information relating to cannabis or psilocybin that was obtained under the Controlled Drugs and Substances Act before the day on which these Regulations come into force if the disclosure is necessary to enable Canada to fulfill its international obligations in relation to cannabis and psilocybin.

Competent authorities

The rules around international obligations would apply to psilocybin.

CRs – Amend section 252.

252 The Minister may, for the purposes of the administration or enforcement of the Act or these Regulations or if it is necessary to enable Canada to fulfill its international obligations in relation to cannabis and psilocybin, disclose to a competent authority

(a) information obtained from a person that has applied for or that holds an import or export permit;

Part 13: Test Kits

Test Kits Exemption

The test kits exceptions for cannabis would apply to psilocybin test kits.
CRs – Amend section 253.

253 The cannabis or the psilocybin that is contained in a test kit that meets the requirements of paragraphs 255(a) and (b) is exempt from Subdivisions A to D of Division 2 of Part 1 of the Act.

Non-application

The test kit exceptions would apply to psilocybin contained in the kit.

CRs – Amend section 254.

254 Part 5 and section 137 do not apply to the cannabis or the psilocybin that is contained in a test kit.

Individual — possession and distribution

Rules relating to individual authorizations and test kits would apply to psilocybin.

CRs – Amend section 256.

256 An individual is authorized to conduct the following activities, in relation to one or more test kits that contain a total amount of cannabis or psilocybin that, as determined in accordance with subsection 2(4) of the Act, is equivalent to more than the amount the individual may possess under the Act, if the registration number is included on the label of each test kit

(a) possess it in a public place; and

(b) distribute it for a medical, laboratory, industrial, educational, law administration or enforcement or research purpose.

Application for registration number

The rules regarding applications for registration numbers would apply to psilocybin.

CRs – Amend section 258.

258(1) The manufacturer or assembler of a test kit or, if the test kit is manufactured or assembled further to a custom order, the person for which the test kit was manufactured or assembled, may apply for a registration number for the test kit by submitting an application to the Minister containing the following information:

(d) a detailed description of the psilocybin contained in the test kit, including

(i) the class of psilocybin set out in column 1 of Schedule 7 to the Act, and

(ii) the quantity of psilocybin;

Refusal

Rules regarding refusal of registration number issuance would apply to psilocybin.

CRs – Amend section 260(2).

260(2) The Minister must refuse to issue a registration number if he or she has reasonable grounds to believe that

(a) the test kit is likely to create a risk to public health or safety, including the risk of cannabis or psilocybin being diverted to an illicit market or activity, because

(i) the quantity of cannabis or of psilocybin in the test kit is too high, or

(ii) the adulterating or denaturing agent in the test kit is not likely to prevent or deter consumption or administration of the cannabis or of the psilocybin; or

(b) the test kit is likely to be used for a purpose other than any of those set out in subsection (1).

Cancellation

Cancellation of registration number rules would apply to psilocybin.

CRs – Amend section 261.

261(1) The Minister must cancel the registration number of a test kit if

(a) the Minister receives a notice from the holder of the registration number

stating that it has ceased all authorized activities referred to in section 255, 256 or 257 with respect to the test kit;

(b) the Minister has reasonable grounds to believe that

(i) the test kit is likely to create a risk to public health or safety, including the risk of cannabis <u>or psilocybin</u> being diverted to an illicit market or activity, because

(A) the quantity of cannabis <u>or psilocybin</u> in the test kit is too high, or

(B) the adulterating or denaturing agent in the test kit is not likely to prevent or deter consumption or administration of the cannabis <u>or of the psilocybin</u>, or

<u>Part 14 - Access to Cannabis for Medical Purposes</u>

<u>Interpretation</u>

Definitions would be added.

CRs – Amend sections 264(1).

264(1) The following definitions apply in this Part <u>and Part 14.1</u>.

***<u>approval</u>* <u>means a health care practitioner's approval of a clinic under section 353.2</u>**

***<u>clinic</u>* <u>means a facility where psilocybin is used in accordance with these Regulations and is supervised by a therapeutic regulated professional</u>**

health care practitioner **means, except as otherwise provided, a medical practitioner or a nurse practitioner.**

***<u>health care practitioner-approved clinic</u>* <u>means a clinic that has been approved by an individual's health care practitioner, in the form as required by section 355.1, as a place where the individual will consume psilocybin in accordance with the Regulations</u>**

***<u>licence for sale</u>* <u>means a licence for sale for medical purposes with respect to cannabis or psilocybin.</u>**

***<u>licenced practical nurse</u>* <u>(LPN) means a person who is registered and entitled under the laws of the Province to practice in that Province as a licenced practical nurse.</u>**

medical document **means a document provided by a health care practitioner to support the use of cannabis or psilocybin for medical purposes or, in the case of psilocybin experiential training, for use by a therapeutic regulated professional for psilocybin experiential training purposes.**

medical practitioner **means an individual who**

(a) is entitled under the laws of a province to practise medicine in that province;

(b) is not restricted, under the laws of the province in which they practise, from authorizing the use of cannabis or psilocybin; and

(c) is not named in a notice issued under section 335 that has not been retracted.

nurse practitioner **means an individual who**

(a) is entitled under the laws of a province to practise as a nurse practitioner or an equivalent designation and is practising as a nurse practitioner or an equivalent designation in that province;

(b) is not restricted, under the laws of the province in which they practise, from authorizing the use of cannabis or psilocybin; and

(c) is not named in a notice issued under section 335 that has not been retracted.

occupational therapist **means an individual who is registered and entitled under the laws of the Province to practice in that Province as an occupational therapist.**

physiotherapist **means an individual who is registered and entitled under the laws of the Province to practice in that Province as an physiotherapist.**

provincial professional licensing authority **means**

(a) except in sections 343 to 345, an authority that is responsible for

(i) authorizing the practise of medicine in a province,

(ii) authorizing individuals to practise as nurse practitioners in a province,

(iii) authorizing individuals to practise as psychologists in a province,

(iv) authorizing individuals to practise as psychotherapists in a province,

(v) authorizing individuals to practise as registered nurses in a province,

(vi) authorizing individuals to practise as registered practical nurses in a province; or

(vii) authorizing individuals to practise as licensed practical nurses in a province,

(ix) authorizing individuals to practise as social workers in a province,

(x) authorizing individuals to practise as physiotherapists in a province,

(xi) authorizing individuals to practise as occupational therapists in a province,

(xii) authorizing individuals to practise as pharmacists in a province,

(b) in sections 343 to 345, an authority that is responsible for authorizing individuals to practise pharmacy in a province.

psilocybin experiential training **is learning about psilocybin by using psilocybin.**

psychologist **means a person who is registered and entitled under the laws of the Province to practice in that Province as a psychologist.**

psychotherapist **means a person who is registered and entitled under the laws of the Province to practice in that Province as a psychotherapist.**

social worker **means a person who is registered and entitled under the laws of the Province to practice in that Province as a social worker.**

therapeutic regulated professional **means**

(a) ***a practitioner*****, but excluding a practitioner of veterinary medicine;**

(b) ***a nurse practitioner*****;**

(c) ***a psychologist*****;**

(d) ***a psychotherapist*****;**

(e) ***a registered nurse*****;**

(f) a *registered practical nurse*;

(g) *a licenced practical nurse*;

(h) a social worker;

(i) an occupational therapist; and

(j) a physiotherapist.

and who is not restricted by their provincial professional licensing authority from supervising psilocybin usage.

provincial professional licensing authority **means**

(a) except in sections 343 to 345, an authority that is responsible for

(i) authorizing the practise of medicine in a province,

(ii) authorizing individuals to practise as nurse practitioners in a province,

(iii) authorizing individuals to practise as psychologists in a province,

(iv) authorizing individuals to practise as psychotherapists in a province,

(v) authorizing individuals to practise as registered nurses in a province,

(vi) authorizing individuals to practise as registered practical nurses in a province; or

(vii) authorizing individuals to practise as licensed practical nurses in a province,

(b) in sections 343 to 345, an authority that is responsible for authorizing individuals to practise pharmacy in a province.

psilocybin experiential training **is learning about psilocybin by using psilocybin**

registered nurse **(RN) means a person who is registered and entitled under the laws of the Province to practice in the Province as a registered nurse.**

registered practical nurse **(RPN) means a person who is registered and entitled under the laws of the Province to practice in that Province as a registered practical nurse.**

registration certificate means a certificate issued by the Minister under subsection 313(1).

registration document means a document provided under paragraph 282(2)(a) to a client by a holder of a licence for sale.

written order means a written authorization given by a health care practitioner that a stated amount of cannabis or psilocybin be dispensed for the individual named in the authorization.

Possession in public place — adults

The possession rules would apply to psilocybin.

CRs – New section 266.1.

266.1(1) The following individuals are authorized to possess, in a public place, psilocybin that has been obtained in accordance with the Regulations or in accordance with the *Narcotic Control Regulations*, subject to the applicable maximum amounts and purposes set out in this section:

(a) a person who is registered with a holder of a licence for sale on the basis of a medical document;

(b) an adult who is responsible for an individual and who possesses the psilocybin for the medical purposes of that individual; and

(c) an adult who possesses the psilocybin in the presence of an individual referred to in paragraph 267(1)(a), (b) or (c) for the purpose of providing assistance in administering it to the individual.

(d) a person who has received the psilocybin by way of a prescription under the *Narcotic Control Regulations*; and

(e) a person transporting psilocybin from a medical practitioner's office to a clinic in accordance with sections 353.1 and 353.4 or in accordance with sections 53.1 and 53.4 of the *Narcotic Control Regulations*.

(2) The maximum amount of psilocybin that an adult referred to in paragraph (1)(a) is authorized to possess in a public place is an amount that is equivalent to the lesser of

(a) the amount legally permitted pursuant to their medical document and the amount permitted pursuant to a legal prescription under the *Narcotic Control Regulations*; or

(b) 100 g of psilocybin.

(3) The maximum amount of psilocybin that an adult referred to in paragraph (1)(b) is authorized to possess in a public place, for the medical purposes of the individual for whom they are responsible, is the maximum amount that the individual is authorized to possess under subsection 267(2) or (3) as the case may be.

(4) This section does not authorize an adult who is referred to in more than one of paragraphs (1)(a) to (e) to possess, for their own medical purposes, more than the equivalent of 150 g of psilocybin.

Distribution

Responsible would be permitted to distribute to person to whom they are responsible.

CRs – New subsection 269(3).

(3) In addition to any other quantity of psilocybin that they may distribute under the Act, an adult referred to in paragraph 266.1(1)(b) is authorized to distribute — but not send or otherwise indirectly make available — to the individual for whom they are responsible, or transport for that individual, a quantity of psilocybin, other than psilocybin mushroom spores, that does not exceed the maximum amount that the adult is authorized to possess.

Authorization — health care practitioner

CRs – Section 272 would be amended to include psilocybin

272(1) A health care practitioner is authorized, in respect of an individual who is under their professional treatment and if cannabis or psilocybin is required for the condition for which the individual is receiving treatment,

(a) to provide a medical document;

(b) with respect to cannabis, while practising in a hospital, to issue a written order;

(c) to administer to the individual a cannabis product, other than cannabis plants or cannabis plant seeds, or a psilocybin product provided it is in accordance with Part 14.1; or

(d) to transfer to the individual, or to an adult who is responsible for them, a cannabis product, other than cannabis plants or cannabis plant seeds, or a psilocybin product

(i) that has been received from a holder of a licence for sale or a licence for processing or psilocybin processing, and

(ii) in respect of which the quantity of cannabis or of psilocybin does not exceed the quantity that the individual or adult is authorized to possess under section 266, ~~or~~ 266.1, or 267, as the case may be.

(2) A health care practitioner is authorized to possess a cannabis product, other than cannabis plants or cannabis plant seeds, or a psilocybin product in a public place if they have obtained it under the Act and require it for the practice of their profession in the province where they possess it.

Medical document

The medical document would list a monthly amount of psilocybin.

CRs – New section 273(1)(g).

273(1) A medical document that is provided under paragraph 272(1)(a) must indicate

(a) the health care practitioner's given name, surname, profession, business address and telephone number and, if applicable, their facsimile number and email address;

(b) the province in which the health care practitioner is authorized to practise their profession and the number assigned by the province to that authorization;

(c) the given name, surname and date of birth of the individual who is under the professional treatment of the health care practitioner;

(d) the address of the location at which the individual consulted with the health care practitioner;

(e) the daily quantity of dried cannabis, expressed in grams, that the health care practitioner authorizes for the individual; and

(g) the monthly quantity of psilocybin, expressed in grams, that the health care practitioner authorizes for the individual.

Obtaining from more than one source

It would be prohibited to seek psilocybin from more than one source based on one medical document.

CRs – Amend section 276.

276(1) It is prohibited to seek or obtain a cannabis product <u>or a psilocybin product</u> from more than one source at a time on the basis of the same medical document.

<u>Registration application</u>

Registering a psilocybin client would be similar to cannabis. The main difference would be that psilocybin would be sent to the medical practitioner.

CRs – Amend section 279.

279(1) Before registering an individual as a client, a holder of a licence for sale must receive a registration application, together with the original of the individual's medical document or a copy of their registration certificate.

(2) An application that is submitted on the basis of a medical document must include

(a) the applicant's given name, surname and date of birth;

(b) either

(i) the address of the place in Canada where the applicant ordinarily resides, as well as, if applicable, their telephone number, facsimile number and email address, or

(e) <u>if cannabis is being shipped,</u> an indication of whether the shipping address is to be

(i) the address referred to in subparagraph (b)(i),

(ii) the mailing address of the place referred to in subparagraph (b)(i), or

(iii) if the health care practitioner who provided the medical document has consented to receive cannabis products on behalf of the applicant, the address of the health care practitioner;

<u>(e.1) if psilocybin is being shipped, the address of the health care practitioner;</u>

(g)(iv) the medical document is not being used to seek or obtain cannabis products <u>or psilocybin</u> from another source,

(g)(v) in the case where the applicant is signing the statement, they intend to use any cannabis product <u>or psilocybin</u> that is supplied to them on the basis of the application only for their own medical purposes, and

(g)(vii) if psilocybin is being ordered, the Applicant is familiar with and agrees to comply with the requirements regarding the use of psilocybin in Part 14.1.

279(2) An application that is submitted on the basis of a medical document must include

(a) the applicant's given name, surname and date of birth;

(b) either

(i) the address of the place in Canada where the applicant ordinarily resides, as well as, if applicable, their telephone number, facsimile number and email address, or

(ii) if the applicant ordinarily resides in Canada but does not ordinarily reside at a specific place, the address as well as, if applicable, the telephone number, facsimile number and email address of a shelter, hostel or similar institution located in Canada that provides them with food, lodging or other social services;

(c) the mailing address of the place referred to in paragraph (b) if different from the address provided under that paragraph;

(d) if the place referred to in subparagraph (b)(i) is an establishment that is not a private residence, the type and name of the establishment;

(e) if cannabis is being shipped, an indication of whether the shipping address is to be

(i) the address referred to in subparagraph (b)(i),

(ii) the mailing address of the place referred to in subparagraph (b)(i), or

(iii) if the health care practitioner who provided the medical document has consented to receive cannabis products on behalf of the applicant, the address of the health care practitioner;

(e.1) if psilocybin is being shipped and the health care practitioner has consented to receiving the psilocybin, the address of the health care practitioner;

(f) if applicable, the given name, surname and date of birth of one or more adults who are responsible for the applicant; and

(g) a statement signed and dated by the applicant, or an adult who is named under paragraph (f), confirming that

(i) the applicant ordinarily resides in Canada,

(ii) the information in the application is correct and complete,

(iii) the medical document that forms the basis for the application has not, to the knowledge of the individual signing the statement, been altered,

(iv) the medical document is not being used to seek or obtain cannabis or psilocybin products from another source,

(iv.1) if the medical document relates to psilocybin, the applicant has advised their health care practitioner whether they are also seeking psilocybin from a licensed dealer under the *Narcotic Control Regulations*,

(v) in the case where the applicant is signing the statement and they do not intend to use psilocybin for experiential training, they intend to use any cannabis or psilocybin product that is supplied to them on the basis of the application only for their own medical purposes,

(vi) in the case where an adult who is named under paragraph (f) is signing the statement, they are responsible for the applicant; and

(vii) the applicant agrees to consume the psilocybin at a health care practitioner-approved clinic and be supervised by a therapeutic regulated professional while experiencing the effects of psilocybin

Health care practitioner's consent

The health care practitioner would have to consent to receiving the psilocybin and would be able to withdraw consent.

CRs – Amend section 280.

280(1) If an application referred to in section 279 includes, as a shipping address, the address of the health care practitioner who provided the applicant with the medical document, the application must include a statement, signed and dated by the health care practitioner, consenting to receive cannabis products other than cannabis plants and cannabis plant seeds, or if applicable, psilocybin, on the applicant's behalf.

(2) If the applicant becomes a client of a holder of a licence for sale under this Division and the health care practitioner ceases to consent to receive cannabis

products or psilocybin on the behalf of the client, the health care practitioner must send a written notice to that effect to the client and the holder.

Registration of client

The holder of a licence for sale would register a psilocybin client with certain information.

CRs – Amend section 282.

282(1) A holder of a licence for sale may, subject to section 284, register an applicant as a client.

(2) A holder that registers an applicant as a client must provide them with

(a) a registration document that contains the following information:

(vi.1) the amount of psilocybin expressed in grams indicated in the medical document and the class of psilocybin;

(vii) in the case of a registration that is based on a medical document, the shipping address indicated in the application under paragraph 279(2)(e) or 279(2)(e.1),

(b) information that will permit them to use a unique identifier for the purpose of ordering cannabis or psilocybin; and

Return of Products

Psilocybin would be permitted to be returned under certain circumstances.

CRs – Amend section 292 and add subsection 292(6).

292(1) An individual to whom cannabis or psilocybin products are sold under section 289 — or a designated person to whom cannabis plants or cannabis plant seeds are sent or delivered under section 291 — may return the cannabis or psilocybin products if the holder of the licence for sale accepts the return.

(2) The individual who is returning the cannabis or psilocybin products must, subject to subsection (3), send them or have them delivered to the holder of the licence for sale or the holder of a licence for processing or psilocybin processing or cultivation or the holder for the licence for psilocybin cultivation, as indicated by the holder of the licence for sale.

(3) In the case of cannabis or psilocybin products that were transferred to the

individual, clinic or therapeutic regulated professional by a health care practitioner who had consented under subsection 280(1) to receive them, the individual, clinic or therapeutic regulated professional who is returning the cannabis or psilocybin products may, with the consent of the health care practitioner, give them, send them or have them delivered to the health care practitioner.

(4) The individual, clinic or therapeutic regulated professional who is returning the cannabis or psilocybin products must, if they are sending or having delivered cannabis plants — or other cannabis or psilocybin products in respect of which the total quantity of cannabis or psilocybin exceeds the equivalent of 100 g of dried cannabis or psilocybin,

(5) A health care practitioner must ensure that the requirements set out in paragraphs (4)(a) and (b) are met if they are sending or having delivered cannabis or psilocybin products referred to in subsection (4) that have been returned to them under subsection (3) or (6).

(6) A clinic or therapeutic regulated professional to whom psilocybin products were provided by a health care practitioner under s. 354.1 may, with the consent of the health care practitioner, give them, send them or have them delivered to the health care practitioner.

Replacement of returned cannabis or psilocybin

Psilocybin would be permitted to be replaced under certain circumstances.

*CR*s - Amend section 293.

293(1) A holder of a licence for sale to which cannabis or psilocybin products, other than cannabis plants or cannabis plant seeds, are returned in accordance with section 292 may replace them with cannabis or psilocybin products, other than cannabis plants or cannabis plant seeds, in respect of which the total quantity of cannabis or psilocybin does not exceed the equivalent of 150 g of dried cannabis or psilocybin.

(2) A holder of a licence for sale to which cannabis plants or cannabis plant seeds are returned in accordance with section 292 may replace them with a quantity of cannabis plants or cannabis plant seeds, or both, that does not exceed, taking into account the seed-to-plant ratio specified in subsection 290(2), the maximum number of plants, determined in accordance with section 325, that are authorized to be under production under the client's registration with the Minister.

(3) A holder of a licence for processing or psilocybin processing may replace cannabis or psilocybin products that have been returned in accordance with

section 292 with cannabis or psilocybin products in respect of which the total quantity of cannabis or psilocybin, according to information provided by the holder of the licence for sale, does not exceed the applicable quantity of cannabis or psilocybin referred to in subsection (1) or (2).

(4) A holder of a licence for cultivation may replace cannabis plants or cannabis plant seeds that have been returned in accordance with section 292 with a quantity of cannabis plants or cannabis plant seeds, or both, that, according to information provided by the holder of the licence for sale, does not exceed the quantity of cannabis plants or cannabis plant seeds that could be replaced by the holder of the licence for sale under subsection (2).

Sale, display and promotion of cannabis and psilocybin — young persons

The sale, display and promotion of psilocybin and accessories to young persons would be limited.

CRs – Amend section 294.

294 A holder of a licence for sale is authorized to sell a cannabis or psilocybin accessory — other than a cannabis or psilocybin accessory referred to in section 31 of the Act or a device referred to in subsection 202(2) — to a young person if the holder takes reasonable steps to ensure that the young person is authorized to possess cannabis or psilocybin under section 267.

Packaging and labeling products — limiting access to young persons

Packaging and labeling would limit access to young persons.

*CR*s - Amend section 295.

295(1) A holder of a licence for sale is authorized to display a cannabis or psilocybin product, or a package or label of a cannabis or psilocybin product, in a manner that may result in the cannabis or psilocybin product, package or label being seen by a young person if the holder takes reasonable steps to ensure that any such young person is authorized to possess cannabis or psilocybin under section 267.

(2) A holder of a licence for sale that sells a cannabis or psilocybin accessory is authorized to display it, or its package or label, in a manner that may result in the cannabis or psilocybin accessory, package or label being seen by a young person if the holder takes reasonable steps to ensure that any such young person is authorized to possess cannabis or psilocybin under section 267.

Promotion of cannabis or psilocybin products and accessories— young persons

Promotion of psilocybin products and accessories would be limited to young persons.

CRs - Amend section 296.

296(1) A holder of a licence for sale that promotes a cannabis or psilocybin product by means of informational promotion or brand-preference promotion that is communicated by means of a telecommunication is exempt from the condition set out in paragraph 17(2)(c) of the Act if they have taken reasonable steps to ensure that the promotion cannot be accessed by a young person other than a young person who is authorized to possess cannabis or psilocybin under section 267.

(2) A holder of a licence for sale that promotes a cannabis or psilocybin accessory by means of informational promotion or brand-preference promotion that is communicated by means of a telecommunication is exempt from the condition set out in paragraph 17(3)(c) of the Act if they have taken reasonable steps to ensure that the promotion cannot be accessed by a young person other than a young person who is authorized to possess cannabis or psilocybin under section 267.

Reports to Minister

Information that would be provided on a monthly basis to the Minister

CRs - Amend section 297.

297(1) A holder of a licence for sale must, on or before the 15th day of each month, provide the Minister with a report that contains the following information:

(a) the number of clients who had a valid registration on the last day of the previous month;

(b) the number of clients who, in the previous month, had their medical document transferred to another holder of a licence for sale or returned to them at their request or at the request of a named responsible adult;

(c) in respect of the medical documents that formed the basis for registrations that were valid on the last day of the previous month,

(i) the average daily quantity of dried cannabis or psilocybin, expressed in grams,

(ii) the median daily quantity of dried cannabis or psilocybin, expressed in grams, and

(iii) the highest daily quantity of dried cannabis or psilocybin, expressed in grams;

(e) the number of purchase orders referred to in subsection 289(1) that the holder refused to fill during the previous month, including the number of them that were refused for each of the following reasons:

(iii) the purchase order specified cannabis or psilocybin products, other than cannabis plants or cannabis plant seeds, in respect of which the quantities of cannabis or psilocybin exceeded the equivalent of 100 g of dried cannabis or psilocybin, and

(iv) the cannabis or psilocybin product specified in the purchase order was unavailable;

(2) In this section, health care practitioner means an individual who is, or was, a medical practitioner or nurse practitioner.

Disclosure to Third Parties

Information that would be provided to third parties

*CR*s - Amend section 298.

298 (1) A holder of a licence for sale must, if they are provided with an individual's given name, surname, and date of birth by a member of a Canadian police force who requests information in the course of an investigation under the Act, disclose the following information to the police force as soon as feasible and no later than 72 hours after receiving the request:

(b) in the case where the individual is an individual referred to in paragraph (a),

(i) an indication of whether the client is a registered person and, if so, the classes of cannabis or psilocybin that the client is permitted to obtain by virtue of their registration with the holder, and

(ii) the daily quantity of dried cannabis or psilocybin that is specified in the client's registration document in accordance with subparagraph 282(2)(a)(vi) or, as applicable, subparagraph 282(2)(vi.1).

(2) Information provided under this section must be used only for the purposes of the investigation or the administration or enforcement of the Act or these Regulations.

Disclosure to licensing authority

Information would be provided to the licensing authority.

CRs - Amend section 299.

299(1) A holder of a licence for sale must disclose, in writing and as soon as feasible, factual information about a health care practitioner or a therapeutic regulated professional — in relation to cannabis or psilocybin — that they have obtained under the Act or the *Controlled Drugs and Substances Act* to

(a) the provincial professional licensing authority for a province in which the health care practitioner or therapeutic regulated professional is, or was, entitled to practise if the licensing authority submits to the holder a written request that sets out the health care practitioner's or therapeutic regulated professional's name and address, a description of the information being requested and a statement that the information is required for the purpose of assisting an investigation by the authority; or

(b) the provincial professional licensing authority for a province in which the health care practitioner or the therapeutic regulated professional is not entitled to practise if the licensing

(i) a written request that sets out the health care practitioner's or therapeutic regulated professional's name and address and a description of the information being requested, and

(ii) a document that shows that

(A) the health care practitioner or therapeutic regulated professional has applied to the licensing authority to practise in that province, or

(B) the licensing authority has reasonable grounds to believe that the health care practitioner or therapeutic regulated professional is practising in that province without being authorized to do so.

(2) The factual information that may be requested includes information — including patient information — contained in, or in respect of, any medical document that was signed by the health care practitioner or therapeutic regulated professional.

(5) In this section, health care practitioner, clinic or therapeutic regulated professional means an individual who is, or was, a medical practitioner or nurse practitioner or is or was a clinic.

Quarterly reports

Information would be requested from a holder of a licence on a quarterly basis regarding receipt of psilocybin.

*CR*s - Amend section 300.

300(1) A provincial professional licensing authority may submit a written request to a holder of a licence for sale to obtain information, on a quarterly basis, in respect of each client who is registered with the holder on the basis of a medical document that was signed by a health care practitioner, clinic or therapeutic regulated professional who

(d) the daily quantity of dried cannabis or psilocybin specified in the medical document;

(g) for each shipment of cannabis or psilocybin products that was sent or delivered during the quarter,

(ii) the quantity of cannabis or psilocybin that was sent or delivered, expressed in grams, and

(iii) the class of cannabis or psilocybin set out in Schedule 4 or 7 to the Act to which the cannabis or psilocybin products belong.

Purchase orders

Information that would be retained on purchase orders.

*CR*s - Amend section 304.

304(1) A holder of a licence for sale must retain, in respect of each purchase order referred to in section 289 that they fill or cause to be filled, a document that contains the following information:

(d) the names they have assigned to the cannabis or psilocybin products that are sent or delivered and the brand names;

(e) the quantity of cannabis or psilocybin that is sent or delivered;

(f) the date on which the cannabis or psilocybin products are sent or delivered; and

(g) the address to which the cannabis or psilocybin products are sent or delivered.

(2) The holder must retain the document — together with the relevant written purchase order or, in the case of a verbal purchase order, the record referred to in subsection 289(3) — for at least two years after the day on which the document is prepared.

Health Care Practitioners – Security of Products

Health care practitioners would take steps to ensure the security of psilocybin.

CRs – Amend section 330.

330 A health care practitioner must, in respect of cannabis or psilocybin products that they possess for the practice of their profession,

(a) take reasonable steps to protect them from theft or loss; and

(b) report any theft or loss to the Minister within 10 days after becoming aware of the theft or loss.

Clinics and therapeutic regulated professionals – Security of Products

Clinics and therapeutic regulated professionals would take steps to ensure the security of psilocybin.

CRs – New section 330.1.

330.1 Clinics and therapeutic regulated professionals must, in respect of psilocybin products that they possess in the course of their work,

(a) take reasonable steps to protect them from theft or loss; and

(b) report any theft or loss to the Minister within 10 days after becoming aware of the theft or loss.

Returned products

Health care practitioners would document returned products.

CRs – Amend section 331.

331(1) A health care practitioner must, if they accept cannabis or psilocybin products that are returned under subsection 292(3) or (6), retain a document that contains the following information:

(a) the name of the individual who is returning the cannabis or psilocybin

products;

(b) the address of the location at which the cannabis or psilocybin products are received;

(c) the date on which they are received;

(d) the quantity of cannabis or psilocybin that is received; and

(e) a description of the cannabis or psilocybin products, including their brand names.

(2) The health care practitioner is not required to include the information referred to in paragraphs (1)(d) and (e) if

(a) they are unable to ascertain the information without unsealing a parcel that meets the requirements of paragraph 292(4)(a) and the parcel is subsequently sent or delivered to the holder of the licence that originally sold or distributed the cannabis or psilocybin products to or for the client; or

(b) in the case of a cannabis accessory that contains cannabis or a psilocybin accessory that contains psilocybin, they are unable to ascertain the information.

Disclosure to licensing authority

The Minister would disclose misconduct with respect to a health practitioner or and a therapeutic regulated professional to their regulator.

CRs – Amend section 333.

333 The Minister must disclose, in writing, factual information about a health care practitioner or a therapeutic regulated professional — in relation to cannabis or to psilocybin — that has been obtained under the Act or the *Controlled Drugs and Substances Act* to

(a) the provincial professional licensing authority for a province in which the health care practitioner or therapeutic regulated professional is, or was, entitled to practise if

(i) the licensing authority submits to the Minister a written request that sets out the health care practitioner's or the therapeutic regulated professional's name and address, a description of the information being requested and a statement that the information is required for the purpose of assisting an investigation by the authority,

(ii) the Minister has reasonable grounds to believe that the health care practitioner or the therapeutic regulated professional has contravened, in relation to cannabis or to psilocybin, a rule of conduct established by the licensing authority,

(iii) the Minister becomes aware that the health care practitioner or therapeutic regulated professional has been convicted of

(A) a designated offence,

(B) a controlled substance offence in relation to cannabis or to psilocybin,

(C) a contravention of the former *Access to Cannabis for Medical Purposes Regulations* or the former *Marihuana for Medical Purposes Regulations*, or

(D) a contravention of the *Narcotic Control Regulations* in relation to cannabis or to psilocybin, or

(iv) the Minister has reasonable grounds to believe that the health care practitioner or the therapeutic regulated professional has contravened this Part or the former *Access to Cannabis for Medical Purposes Regulations*, the former *Marihuana for Medical Purposes Regulations* or — in relation to cannabis or psilocybin — the *Narcotic Control Regulations*; and

(b) the provincial professional licensing authority for a province in which the health care practitioner or therapeutic regulated professional is not entitled to practise if the licensing authority submits to the Minister

(i) a written request that sets out the health care practitioner's or therapeutic regulated professional's name and address and a description of the information being requested, and

(ii) a document that shows that

(A) the health care practitioner or the therapeutic regulated professional has applied to the licensing authority to practise in that province, or

(B) the licensing authority has reasonable grounds to believe that the health care practitioner or the therapeutic regulated professional is practising in that province without being authorized to do so.

Notice from Minister

Minister would notify relevant parties if a health care practitioner cannot sign medical documents.

CRs – Amend subsections 335(1), (2) and (5).

335(1) The Minister must, in the circumstances set out in subsection (2), issue a notice to the persons and pharmacies specified in subsection (3) advising them, as applicable, that

(a) the holders of a licence for sale and the holders of a licence for processing that receive the notice must not send cannabis <u>or psilocybin</u> products to the health care practitioner who is named in the notice;

(b) any medical document that is signed by the health care practitioner who is named in the notice must not form the basis for registering a client if the medical document is signed after the day on which the notice is issued; and

(c) pharmacists practising in the notified pharmacies must not distribute or sell cannabis products <u>or psilocybin products</u> on the basis of a medical document signed by, or a written order issued by, the health care practitioner who is named in the notice if the medical document is signed, or the written order is issued, after the day on which the notice is issued.

(2) The notice must be issued if

(a) the health care practitioner who is named in the notice has asked the Minister, in writing, to issue it;

(b) the health care practitioner who is named in the notice has contravened, in relation to cannabis <u>or to psilocybin</u>, a rule of conduct established by the provincial professional licensing authority for the province in which the health care practitioner is practising and the licensing authority has asked the Minister, in writing, to issue the notice;

(c) the health care practitioner who is named in the notice has been convicted of

(i) a designated offence,

(ii) a contravention of these Regulations,

(iii) a controlled substance offence in relation to cannabis <u>or psilocybin</u>,

(iv) a contravention of the former *Access to Cannabis for Medical Purposes Regulations* or the former *Marihuana for Medical Purposes Regulations*, or

(v) a contravention of the *Narcotic Control Regulations* in relation to cannabis <u>or psilocybin</u>; or

(3) A notice that is issued under this section must be issued to

(a) the health care practitioner who is named in the notice;

(b) all holders of a licence for sale, holders of a licence for processing, all holders of a licence for psilocybin sale, holders of a licence for psilocybin processing;

(c) all hospital pharmacies in the province in which the health care practitioner who is named in the notice is entitled to practise and is practising;

(d) the provincial professional licensing authority for the province in which the health care practitioner who is named in the notice is entitled to practise; and

(e) on request, the provincial professional licensing authority for any province other than the province referred to in paragraph (d).

(4) The Minister may issue a notice referred to in subsection (1) if he or she has reasonable grounds to believe that the health care practitioner who is named in the notice

(a) has conducted an activity referred to in section 272 other than in accordance with that section;

(b) has provided a medical document, or issued a written order, or a psilocybin prescription under *the Narcotic Control Regulations* that contains false or misleading information;

(c) has, on more than one occasion, provided themselves with a medical document or issued a written order or a psilocybin prescription under the *Narcotic Control Regulations* for themselves, contrary to accepted medical practice;

(d) has, on more than one occasion, conducted an activity referred to in section 272 in respect of their spouse, common-law partner, parent or child, including a child adopted in fact, contrary to accepted medical practice; or

(e) is unable to account for a quantity of cannabis or psilocybin for which they were responsible under this Part, the *Narcotic Control Regulations* or the former *Access to Cannabis for Medical Purposes Regulations*.

(5) Before issuing a notice under subsection (4), the Minister must

(c) consider

(iii) whether the actions of the health care practitioner pose a significant risk to public health or public safety, including the risk of cannabis or psilocybin being diverted to an illicit market or activity.

Prohibition — notified pharmacies

Pharmacists would be required to limit the amount of psilocybin that may be dispensed.

CRs – Amend section 337.

337 (1) A pharmacist who is practising in a pharmacy that has received a notice issued under section 335 must not distribute or sell cannabis or psilocybin products on the basis of a medical document signed, or a written order issued, by the health care practitioner who is named in the notice unless the medical document is signed, or the written order is issued, before the day on which the notice is issued.

(2) A pharmacist who is practising in a pharmacy that has received a notice issued under section 344 must not distribute or sell cannabis or psilocybin products to the pharmacist who is named in the notice.

(3) The prohibitions referred to in subsections (1) and (2) cease to apply if the notice is retracted.

Prohibition — dispensing

Pharmacists would be required to limit the amount of psilocybin that may be dispensed.

CRs – Amend section 338.

338 A pharmacist must not use an order — including a written order — to dispense a cannabis or psilocybin product if the quantity of cannabis or psilocybin that would be dispensed, when added to the quantity of cannabis or psilocybin that has already been dispensed under the order, would exceed the quantity of cannabis or psilocybin specified in the order.

Hospital pharmacists

Hospital pharmacists would have the same authority with psilocybin as they have with cannabis.

CRs – Amend section 339.

339(1) Subject to section 337, a pharmacist who is practising in a hospital may, if authorized by the individual in charge of the hospital,

(a) distribute, sell or return, in accordance with paragraph 348(2)(b) or subsection 348(4) or (7), cannabis or psilocybin products, other than cannabis plants or cannabis plant seeds, that have been received from a holder of a licence for sale or a holder of a licence for processing or psilocybin processing; or

(b) distribute — but not send — or sell cannabis or psilocybin products, other than cannabis plants or cannabis plant seeds, to an employee of the hospital or a health care practitioner practising in the hospital, on receipt of an order, in writing, that has been signed and dated by

(i) the pharmacist in charge of the hospital's pharmacy, or

(ii) a health care practitioner who is authorized by the individual in charge of the hospital to sign the order.

(2) Before distributing or selling cannabis or psilocybin products under paragraph (1)(b), the pharmacist receiving the order must verify the signature on the order, if it is unknown to them.

(3) A pharmacist must not conduct the activities referred to in subsection (1) if the pharmacist has been named in a notice that has been issued under section 344 and that has not been retracted.

(4) In this section, *distribute* does not include administering.

Hospital pharmacists' retention of documents

Hospital pharmacists would have to retain the same documents regarding psilocybin as with cannabis.

CRs – Amend section 340.

340(1) A pharmacist who receives cannabis or psilocybin products from a person must retain a document that contains the following information:

(a) the quantity of cannabis or psilocybin that is received;

(b) a description of the cannabis or psilocybin products, including their brand names;

(c) the date on which the cannabis or psilocybin products are received; and

(d) the name and mailing address of the person from which the cannabis or psilocybin products are received.

(2) A pharmacist who distributes or sells cannabis or psilocybin products on the basis of a medical document or written order must retain a document that contains the following information:

(a) the pharmacist's name or initials;

(b) the name, initials and address of the health care practitioner who provided the medical document or issued the written order;

(c) the name and mailing address of the individual for whom the cannabis or psilocybin products are distributed or sold;

(d) the quantity of cannabis or psilocybin that is distributed or sold;

(e) a description of the cannabis or psilocybin products, including their brand names;

(f) the date on which the cannabis or psilocybin products are distributed or sold; and

(g) the number that the pharmacist has assigned to the medical document or written order.

(3) A pharmacist who distributes or sells cannabis or psilocybin products for emergency purposes on the basis of an order made in accordance with subsection 348(4) must retain a document that contains the following information:

(a) the name and address of the pharmacist or health care practitioner who signed the order;

(b) the name and address of the individual to whom the cannabis or psilocybin products are distributed or sold;

(c) the quantity of cannabis or psilocybin that is distributed or sold;

(d) a description of the cannabis or psilocybin products, including their brand names; and

(4) A pharmacist who returns cannabis or psilocybin products must retain a document that contains the following information:

(a) the name and address of the person to which the cannabis or psilocybin products are returned;

(b) the quantity of cannabis or psilocybin that is returned;

(c) a description of the cannabis products, including their brand names; and

(d) the date on which the cannabis or psilocybin products are returned.

(5) The documents must be retained for at least two years after the day on which they are prepared.

Security of cannabis and psilocybin products

Hospital pharmacist would keep secure and report loss or theft for psilocybin, as required for cannabis.

CRs – Amend section 342.

342 The pharmacist in charge of a hospital's pharmacy must, in respect of cannabis and psilocybin products that are on the pharmacy premises or for which the pharmacist is responsible,

(a) take reasonable steps to protect them from theft or loss; and

(b) report any theft or loss to the Minister within 10 days after becoming aware of the theft or loss.

Disclosure to licensing authority

Minister would notify pharmacist regulator if reasonable grounds to believe the pharmacist has contravened relevant rules for psilocybin.

CRs – Amend section 343.

343 The Minister must disclose, in writing, factual information about a pharmacist — in relation to cannabis or psilocybin — that has been obtained under the Act or the *Controlled Drugs and Substances Act* to

(a) the provincial professional licensing authority for a province in which the pharmacist is, or was, entitled to practise if

(i) the licensing authority submits to the Minister a written request that sets out the pharmacist's name and address, a description of the information being requested and a statement that the information is required for the purpose of assisting an investigation by the authority,

(ii) the Minister has reasonable grounds to believe that the pharmacist has contravened, in relation to cannabis or psilocybin, a rule of conduct established by the licensing authority,

(iii) the Minister becomes aware that the pharmacist has been convicted of

(A) a designated offence,

(B) a controlled substance offence in relation to cannabis or psilocybin,

(C) a contravention of the former *Access to Cannabis for Medical Purposes Regulations*, or

(D) a contravention of the *Narcotic Control Regulations* in relation to cannabis or psilocybin, or

(iv) the Minister has reasonable grounds to believe that the pharmacist has contravened these Regulations, the former *Access to Cannabis for Medical Purposes Regulations* or — in relation to cannabis — the *Narcotic Control Regulations*; and

(b) the provincial professional licensing authority for a province in which the pharmacist is not entitled to practise if the licensing authority submits to the Minister

(i) a written request that sets out the pharmacist's name and address and a description of the information being requested, and

(ii) a document that shows that

(A) the pharmacist has applied to the licensing authority to practise in that province, or

(B) the licensing authority has reasonable grounds to believe that the pharmacist is practising in that province without being authorized to do so.

Notice from Minister

The Minister would issue a Notice in certain circumstances.

CRs – Amend section 344.

344(1) The Minister must, in the circumstances set out in subsection (2), issue a notice to the following persons and pharmacies advising them that holders of a

licence for sale, holders of a licence for processing or psilocybin processing and pharmacists practising in the notified pharmacies must not distribute or sell cannabis or psilocybin products to the pharmacist who is named in the notice:

(a) the pharmacist who is named in the notice;

(b) all holders of a licence for sale and all holders of a licence for processing;

(c) all hospital pharmacies in the province in which the pharmacist who is named in the notice is entitled to practise and is practising;

(d) the provincial professional licensing authority for the province in which the pharmacist who is named in the notice is entitled to practise; and

(e) on request, the provincial professional licensing authority for any province other than the province referred to in paragraph (d).

(2) The notice must be issued if

(a) the pharmacist who is named in the notice asks the Minister, in writing, to issue the notice;

(b) the pharmacist who is named in the notice has contravened, in relation to cannabis or psilocybin, a rule of conduct established by the provincial professional licensing authority for the province in which the pharmacist is practising and the licensing authority has asked the Minister, in writing, to issue the notice;

(c) the pharmacist who is named in the notice has been convicted of an offence referred to in subparagraph 343(a)(iii); or

(d) the pharmacist who is named in the notice has been named in a notice issued under subsection 181(2) or (4).

(3) The Minister may issue a notice referred to in subsection (1) if he or she has reasonable grounds to believe that the pharmacist who is named in the notice

(a) has conducted an activity referred to in section 339 other than in accordance with that section;

(b) has, on more than one occasion, distributed or sold a cannabis or psilocybin product to their spouse, common-law partner, parent or child, including a child adopted in fact, contrary to accepted pharmaceutical practice; or

(c) is unable to account for a quantity of cannabis products for which they were responsible under this Part, the *Narcotic Control Regulations* or the former *Access to Cannabis for Medical Purposes Regulations*.

(4) Before issuing a notice under subsection (3), the Minister must

(a) consult with the provincial professional licensing authority for the province in which the pharmacist to whom the notice relates is entitled to practise;

(b) send to the pharmacist a written notice that sets out the reasons why a notice is being considered and give him or her an opportunity to present reasons why the notice should not be issued; and

(c) consider

(i) any reasons that have been presented by the pharmacist under paragraph (b),

(ii) the compliance history of the pharmacist in respect of the Act, the *Controlled Drugs and Substances Act* and the regulations made or continued under either Act, and

(iii) whether the actions of the pharmacist pose a significant risk to public health or public safety, including the risk of cannabis <u>or psilocybin</u> being diverted to an illicit market or activity.

<u>Hospital security of cannabis and psilocybin products</u>

Hospitals would keep secure and report loss or theft for psilocybin, as required for cannabis.

CRs – Amend section 347.

347 An individual in charge of a hospital must, in respect of cannabis <u>or psilocybin</u> products that they permit to be administered, distributed or sold,

(a) take reasonable steps to protect them from theft or loss; and

(b) report any theft or loss to the Minister within 10 days after becoming aware of the theft or loss.

<u>Administration, distribution and sale</u>

Hospital would have the ability to order and receive psilocybin pursuant to the same rules as cannabis.

CRs – Amend section 348.

348(1) An individual in charge of a hospital must not permit cannabis or psilocybin products to be administered, distributed or sold, except in accordance with this section.

(2) An individual in charge of a hospital may permit cannabis or psilocybin products, other than cannabis plants and cannabis plant seeds, received from a holder of a licence for sale or a holder of a licence for processing or a holder of a licence for psilocybin processing to be

(a) administered, on receipt of a medical document or written order, to an inpatient or outpatient of the hospital; or

(b) distributed — but not sent — or sold, on receipt of a medical document or written order, to an individual referred to in paragraph (a) or an adult who is responsible for them.

(c) if the hospital permits psilocybin to be administered or distributed then the hospital employee, hospital pharmacist or health care practitioner may only administer or distribute psilocybin to a person authorized to receive psilocybin in accordance with Part 14.1.

(3) An individual in charge of a hospital must, if they permit cannabis or psilocybin products to be distributed or sold under paragraph (2)(b), ensure that

(a) the quantity of cannabis that is distributed or sold does not exceed the equivalent of the lesser of

(i) 30 times the daily quantity of dried cannabis that is specified in the medical document or written order, and

(ii) 150 g of dried cannabis;

(a.1) the quantity of psilocybin that is distributed or sold does not exceed the equivalent of the lesser of

(i) 30 times the daily quantity of dried psilocybin that is specified in the medical document or written order, and

(ii) 100 g of dried psilocybin;

(b) the cannabis or psilocybin products are distributed or sold in the container in which they were received from the holder of the licence for sale or the holder of the licence for processing or psilocybin processing;

(c) a label is applied to the container in which the cannabis or psilocybin products were received indicating

(i) the given name, surname and profession of the health care practitioner who signed the medical document or written order,

(ii) the given name and surname of the patient,

(iii) the daily quantity of dried cannabis or dried psilocybin that is specified in the medical document or written order, and

(iv) the date on which the cannabis or psilocybin products are distributed or sold;

(d) the patient or responsible adult is provided with the current version of the document entitled *Consumer Information — Cannabis*, published by the Government of Canada on its website, if the cannabis is being sought; and

(e) the patient or responsible adult is provided with a separate document containing the information referred to in paragraph (c).

(4) An individual in charge of a hospital may permit cannabis or psilocybin products, other than cannabis plants and cannabis plant seeds, received from a holder of a licence for sale or a holder of a licence for processing or a holder of a licence for psilocybin processing to be distributed or sold for emergency purposes to an employee of or a health care practitioner in another hospital on receipt of an order, in writing, that has been signed and dated by a pharmacist in the other hospital or a health care practitioner who is authorized by the individual in charge of the other hospital to order cannabis or psilocybin products.

(5) An individual in charge of a hospital must not permit cannabis or psilocybin products to be distributed or sold under subsection (4) unless the signature on the order has been verified by the individual who distributes or sells the cannabis or psilocybin products, if it is unknown to them.

(6) An individual in charge of a hospital may permit cannabis or psilocybin products, other than cannabis plants and cannabis plant seeds, to be distributed for research purposes to an individual who is employed in a research laboratory in the hospital and who holds a licence for those purposes.

(7) An individual in charge of a hospital may permit cannabis or psilocybin products to be

(a) returned to the holder of the licence for sale or the holder of the licence for processing or a holder of a licence for psilocybin processing from which the

cannabis or psilocybin products were received, on receipt of a written request for the cannabis or psilocybin products that has been signed and dated by, or on behalf of, the holder; or

(b) distributed or sold, for destruction, to a holder of a licence for sale, or a holder of a licence for processing or a holder of a licence for psilocybin processing, that is authorized to destroy cannabis or psilocybin that they did not produce, sell or distribute, on receipt of a written request for the cannabis or psilocybin products that has been signed and dated by, or on behalf of, the holder.

Possession — hospital employees

Hospital employees would be able to possess psilocybin if obtained in accordance with the Regulations.

CRs – Amend section 349.

349 A hospital employee is authorized to possess cannabis or psilocybin products, other than cannabis plants or cannabis plant seeds, if

(a) the cannabis or psilocybin products have been obtained in accordance with section 348 or 350; and

(b) the employee requires the cannabis or psilocybin products for the purposes of, and in connection with, their employment.

Return and replacement

The rules regarding returning cannabis to hospital employees would apply to psilocybin.

CRs – Amend section 350.

350(1) An individual to whom cannabis or psilocybin products are distributed or sold under paragraph 348(2)(b) may return them to a hospital employee who is authorized to distribute or sell cannabis or psilocybin products if the employee accepts the return.

(2) The individual returning the cannabis or psilocybin products must comply with the requirements set out in subsection 292(4) if they are returning more than the equivalent of 30 g of dried cannabis or 100 g of dried psilocybin and are sending the cannabis or psilocybin products or having them delivered to the hospital.

(3) The individual in charge of the hospital may, subject to the limit referred to in

paragraph 348(3)(a), permit cannabis or psilocybin products that have been returned to be replaced.

Retention of documents

The hospital would have to maintain certain records in relation to psilocybin.

CRs – Amend section 351.

351(1) An individual who is in charge of a hospital must ensure that documents that contain the following information are retained:

(a) in respect of cannabis or psilocybin products that are received at the hospital,

(i) the class of cannabis or psilocybin set out in Schedule 4 or 7 to the Act to which the cannabis or psilocybin products belong and their brand names,

(ii) the quantity of cannabis or psilocybin that is received,

(iii) the name and address of the person from which the cannabis or psilocybin products are received, and

(iv) the date on which the cannabis or psilocybin products are received;

(b) in respect of cannabis or psilocybin products that are distributed or sold for a patient,

(i) the given name and surname of the patient,

(ii) the given name, surname and profession of the health care practitioner who signed the relevant medical document or written order, together with the date on which it was signed,

(iii) the daily quantity of dried cannabis or psilocybin that is specified in the medical document or written order referred to in subparagraph (ii) and, if applicable, the period of use that is specified,

(iv) the class of cannabis or psilocybin set out in Schedule 4 or 7 to the Act to which the cannabis or psilocybin products belong,

(v) the quantity of cannabis or psilocybin that is distributed or sold, and

(vi) the date on which the cannabis or psilocybin products are distributed or sold; and

(c) in respect of cannabis or psilocybin products that are distributed or sold to a person that is authorized to sell or distribute such products — other than an adult referred to in paragraph 266(1)(d) or (e) — or that are returned under subsection 348(7),

(i) the name of the person to which the cannabis or psilocybin products are distributed, sold or returned,

(ii) the date on which the cannabis or psilocybin products are distributed, sold or returned,

(iii) the quantity of cannabis or psilocybin that is distributed, sold or returned,

(iv) the brand names of the cannabis or psilocybin products, and

(v) in the case of cannabis or psilocybin products that are distributed, sold or returned under subsection 348(7), the address of the person to which they are distributed, sold or returned.

(2) The individual in charge of the hospital must ensure that the documents are retained for at least two years after the day on which they are prepared.

Disclosure to nursing statutory body

Minister would notify nurse regulator if reasonable grounds to believe the nurse has contravened relevant rules for psilocybin.

CRs – Amend section 353.

353(1) The Minister must disclose, in writing, factual information about a nurse — in relation to cannabis or psilocybin — that has been obtained under the Act or the *Controlled Drugs and Substances Act* to

(a) the nursing statutory body for a province in which the nurse is, or was, entitled to practise if

(i) the nursing statutory body submits to the Minister a written request that sets out the nurse's name and address, a description of the information being requested and a statement that the information is required for the purpose of assisting an investigation by the body,

(ii) the Minister has reasonable grounds to believe that the nurse has contravened, in relation to cannabis or psilocybin, a rule of conduct established by the nursing statutory body,

(iii) the Minister becomes aware that the nurse has been convicted of

(A) a designated offence,

(B) a controlled substance offence in relation to cannabis <u>or psilocybin</u>,

(C) a contravention of the former *Access to Cannabis for Medical Purposes Regulations* or the former *Marihuana for Medical Purposes Regulations*, or

(D) a contravention of the *Narcotic Control Regulations* in relation to cannabis <u>or psilocybin</u>, or

(iv) the Minister has reasonable grounds to believe that the nurse has contravened this Part, the former *Access to Cannabis for Medical Purposes Regulations*, the former *Marihuana for Medical Purposes Regulations* or — in relation to cannabis <u>or psilocybin</u> — the *Narcotic Control Regulations*; and

(b) the nursing statutory body for a province in which the nurse is not entitled to practise if the nursing statutory body submits to the Minister

(i) a written request that sets out the nurse's name and address and a description of the information being requested, and

(ii) a document that shows that

(A) the nurse has applied to the nursing statutory body to practise in that province, or

(B) the nursing statutory body has reasonable grounds to believe that the nurse is practising in that province without being authorized to do so.

Part 14.1 – Psilocybin for Medical Purposes

<u>Health care practitioner can send psilocybin to a clinic or a therapeutic regulated professional</u>

The health care practitioner would send psilocybin to a clinic or to a therapeutic regulated professional at a clinic.

CRs – New section 353.1

<u>353.1 A health care practitioner is authorized, in respect of an individual who is under their professional treatment and if psilocybin is required for the condition for which the individual is receiving treatment, to sell or distribute psilocybin to the individual, to a clinic approved of by the health care professional or to a</u>

therapeutic regulated practitioner at a health care practitioner-approved clinic provided,

(1) the individual has agreed to consume the psilocybin at the health care practitioner-approved clinic and the health care practitioner-approved clinic has agreed to have the individual attend at the clinic for the purposes of consuming psilocybin,

(2) the individual has agreed to consume only the psilocybin provided by the health care practitioner and comply with any other conditions requested by the health care practitioner,

(3) the individual has agreed to be supervised by a therapeutic regulated professional while experiencing the effects of psilocybin and the health care practitioner-approved clinic has agreed to have a therapeutic regulated professional supervise the individual while the individual is experiencing the effects of psilocybin,
(4) the health care practitioner-approved clinic and, if applicable, a therapeutic regulated professional have agreed to receive the psilocybin; and
(5) the clinic and, if applicable, a therapeutic regulated professional have received the health care practitioner's written approval as set out in s. 355.1 of the Regulations.

The health care practitioner approval

The health care practitioner would approve a clinic in writing.

CRs – New section 353.2.

353.2(1) The health care practitioner shall provide their approval of a clinic in writing to the clinic, to the individual and to, if known at the time of signing the approval, the therapeutic regulated professional.

(2) the approval shall include the following information:

(i) the name of the individual,

(ii) the date,

(iii) the name of the health care practitioner,

(iv) the name and address of the clinic,

(v) the name of the therapeutic regulated professional, if known at the time of signing the approval,

(vi) the amount and class of psilocybin; and

(vii) to whom the psilocybin was provided.

(3) the health care practitioner shall add any other conditions to the approval as deemed appropriate; and

(4) this approval is required before psilocybin can be consumed at a clinic whether psilocybin is sent to the clinic, sent to the therapeutic regulated professional or brought to the clinic by the individual.

Records

The health care practitioner, the clinic, and the therapeutic regulated professional would keep records regarding the psilocybin.

CRs – New section 353.3.

353.3 The health care practitioner, the clinic, and the therapeutic regulated professional at the clinic, whether or not the practitioner charges for the psilocybin, shall keep a record showing the name and quantity of the psilocybin sold, provided or received, the person to whom it was sold or provided or from whom it was received, the date on which it was sold, provided or received, and a copy of the approval set out at section 353.2.

The clinic and the therapeutic regulated professional

The clinic and the therapeutic regulated health care professional would be authorized to conduct certain activities with psilocybin.

CRs – New section 353.4.

353.4(1) If named on an approval under section 353.2, a clinic or a therapeutic regulated professional is authorized to possess psilocybin if provided by a health care practitioner, a hospital pharmacist, or a hospital employee in accordance with these regulations,

(2) If named on an approval under section 353.2, a clinic or a therapeutic regulated professional is authorized to administer, sell or provide psilocybin to an individual named on a health care practitioner's approval,

(3) If named on an approval under section 353.2, a clinic and a therapeutic regulated professional acting under this Part shall take reasonable steps to ensure psilocybin received under section 353.1(1) is stored securely and in refrigerated conditions at or about 19 C;

(4) If named on an approval under section 353.2, a clinic and a therapeutic regulated professional acting under this Part shall ensure the individual is supervised by the therapeutic regulated professional while the individual is experiencing the effects of psilocybin;

(5) If named on an approval under section 353.2, a clinic and a therapeutic regulated professional shall require that the individual consume only the psilocybin provided by the health care practitioner and shall comply with any other terms set out in the of the approval under s. 353.2; and

(6) If not named on an approval under section 353.2, a therapeutic regulated professional is authorized as if named on the approval if the clinic has asked the therapeutic regulated professional to supervise the individual as required by section 353.4(4), the therapeutic regulated professional has agreed to supervise and the therapeutic regulated professional has seen and obtained a copy of the approval confirming the clinic's legal authority with respect to psilocybin under section 353.4.

Non-compliance

There would be monitoring and reporting of individual non-compliance.

CRs – New section 353.5

353.5(1) In the event the individual fails to comply with the Regulations or the health care practitioner's approval, the clinic and the therapeutic regulated professional shall notify the health care practitioner.

(2) In the event, the health care practitioner becomes aware that the individual has failed to comply with these Regulations, the Act, the *Controlled Drugs and Substances Act*, or the *Narcotic Control Regulations* then the health care practitioner shall notify the holder of the psilocybin sales licence if applicable, the licensed dealer if applicable and the Minister.

The *Narcotic Control Regulations*, C.R.C., c. 1041 (the "*NCRs*")

Schedule

In order to make the *NCRs* applicable to psilocybin, the definition of narcotic would be changed to include psilocybin and psilocin.

NCRs – New additions to the Schedule listing narcotics:

19. Psilocin (3–[2–(dimethylamino)ethyl]–4–hydroxyindole) and any salt thereof.

20. Psilocybin (3–[2–(dimethylamino)ethyl]–4–phosphoryloxyindole) and any salt thereof.

Definitions

NCRs – New definition added to section 2(1).

approval **means a practitioner's approval of a clinic under section 53.2**

clinic **means a facility where psilocybin is used in accordance with these Regulations and is supervised by a therapeutic regulated professional**

dried psilocybin **means any part of a psilocybin mushroom that has been subjected to a drying process**

holder of a psilocybin licence for sale **means the holder of a psilocybin licence for sale under the *Cannabis Regulations*.**

licenced practical nurse **(LPN) means a person who is registered and entitled under the laws of the Province to practice in that Province as a licenced practical nurse.**

occupational therapist **means an individual who is registered and entitled under the laws of the Province to practice in that Province as an occupational therapist.**

physiotherapist **means an individual who is registered and entitled under the laws of the Province to practice in that Province as an physiotherapist.**

practitioner-approved clinic **means a clinic that has been approved by an individual's practitioner, under section 53.2, as a place where the individual will consume psilocybin in accordance with the Regulations**

Psilocybin **means:**
Psilocybin mushrooms,
Psilocybin extracts,
Synthetic psilocybin,
Psilocybin (3–[2–(dimethylamino)ethyl]–4–phosphoryloxyindole) and any salt thereof.
Psilocin (3–[2–(dimethylamino)ethyl]–4–hydroxyindole) and any salt thereof,
It does not include psilocybin mushroom spores.

psilocybin extract **means**

(a) a substance produced by subjecting psilocybin mushrooms to extraction processing, or
(b) a substance or mixture of substances that contains or has on it a substance

produced in a manner referred to in paragraph (a).

psilocybin mushrooms **are any species of fungi which produce psilocybin**

psychologist **means a person who is registered and entitled under the laws of the Province to practice in that Province as a psychologist**

psychotherapist **means a person who is registered and entitled under the laws of the Province to practice in that Province as a psychotherapist.**

registered practical nurse **(RPN) means a person who is registered and entitled under the laws of the Province to practice in that Province as a registered practical nurse.**

registered nurse **(RN) means a person who is registered and entitled under the laws of the Province to practice in the Province as a registered nurse.**

social worker **means a person who is registered and entitled under the laws of the Province to practice in that Province as a social worker.**
synthetic psilocybin **means psilocybin and psilocybin salts produced without fungi that naturally produce psilocybin.**

therapeutic regulated professional **means**

(a) ***a practitioner*****, but excluding a practitioner of veterinary medicine;**

(b) ***a nurse practitioner*****;**

(c) ***a psychologist*****;**

(d) ***a psychotherapist*****;**

(e) ***a registered nurse*****;**

(f) a ***registered practical nurse*****;**

(g) ***a licenced practical nurse;***

(h) a social worker;

(i) an occupational therapist;

(j) a physiotherapist; and

(k) a pharmacist,

Authorized activities

NCRs – New section 3.1.

Any person is deemed to be in compliance with the *Narcotic Control Regulations* with respect to psilocybin if the person is in compliance with the *Cannabis Act* and the *Cannabis Regulations*.

Sale to pharmacist

A licensed dealer would not sell psilocybin to a pharmacist.

NCRs – Amend section 25.1.

25.1(1) Subject to subsection (2), a licensed dealer may sell or provide a narcotic, other than psilocybin, to a pharmacist.

Provision to hospital employee

A licensed dealer would not sell psilocybin to a hospital employee.

NCRs – Amend section 25.3.

25.3(1) Subject to subsection (2), a licensed dealer may provide a narcotic, other than psilocybin, to a hospital employee.

(2) A licensed dealer may provide diacetylmorphine (heroin) to a hospital employee only if that hospital provides care or treatment to persons.

Sale to exempted person

A licensed dealer would not sell psilocybin to an exempted person.

NCRs – Amend section 25.4.

25.4 A licensed dealer may sell or provide a narcotic, other than psilocybin, to a person who is exempted under section 56 of the Act with respect to the possession of that narcotic.

Practitioner prescriptions

Practitioners would be permitted to prescribe psilocybin.

NCRs – Amend section 53.

53(1) No practitioner shall administer a narcotic to a person or animal, or prescribe, sell or provide a narcotic for a person or animal, except as authorized under this section.

(2) Subject to subsection (4), a practitioner may administer a narcotic to a person or animal, or prescribe, sell or provide it for a person or animal, if

(a) the person or animal is a patient under their professional treatment,

(b) the narcotic is required for the condition for which the person or animal is receiving treatment; and

(c) the narcotic is psilocybin and the practitioner is in compliance with sections 53.1 to 53.5 or the *Cannabis Regulations*.

Practitioners send psilocybin to a clinic or a therapeutic regulated professional

A practitioner would send psilocybin to a clinic or to a therapeutic regulated professional at a clinic.

CRs – New section 53.1

53.1 A practitioner is authorized, in respect of an individual who is under their professional treatment and if psilocybin is required for the condition for which the individual is receiving treatment, to sell or distribute psilocybin to the individual, to a clinic approved of by the practitioner or to a therapeutic regulated practitioner at a practitioner-approved clinic provided,

(1) the individual has agreed to consume the psilocybin at the practitioner-approved clinic and the health care practitioner-approved clinic has agreed to have the individual attend at the clinic for the purposes of consuming psilocybin,

(2) the individual has agreed to consume only the psilocybin provided by the practitioner and comply with any other conditions requested by the practitioner,

(3) the individual has agreed to be supervised by a therapeutic regulated professional while experiencing the effects of psilocybin and the practitioner-approved clinic has agreed to have a therapeutic regulated professional supervise the individual while the individual is experiencing the effects of psilocybin,

(4) the practitioner-approved clinic and, if applicable, a therapeutic regulated professional have agreed to receive the psilocybin; and

(5) the clinic and, if applicable, a therapeutic regulated professional have received the health care practitioner's written approval as set out in s under section 53.2 of

the Regulations.

The practitioner approval

The practitioner would approve a clinic in writing.

CRs – New section 53.2.

53.2(1) The practitioner shall provide their approval of a clinic in writing to the clinic, to the individual and to, if known at the time of signing the approval, the therapeutic regulated professional.

(2) the approval shall include the following information:

(i) the name of the individual,
(ii) the date,

(iii) the name of the practitioner,

(iv) the name and address of the clinic,

(v) the name of the therapeutic regulated professional, if known at the time of signing the approval,

(vi) the amount and class of psilocybin; and

(vii) to whom the psilocybin was provided.

(3) the practitioner shall add any other conditions to the approval as deemed appropriate; and

(4) this approval is required before psilocybin can be consumed at a clinic whether psilocybin is sent to the clinic, sent to the therapeutic regulated professional or brought to the clinic by the individual.

Records

The practitioner, the clinic, and the therapeutic regulated professional would keep records regarding the psilocybin.

NCRs – New section 53.3.

53.3 The practitioner, the clinic, and the therapeutic regulated professional at the clinic, whether or not the practitioner charges for the psilocybin, shall keep a record showing the name and quantity of the psilocybin sold, provided or received,

the person to whom it was sold or provided or from whom it was received, the date on which it was sold, provided or received, and a copy of the approval under section 53.2.

The clinic and the therapeutic regulated health care professional

The clinic and the therapeutic regulated health care professional would be authorized to conduct certain activities with psilocybin.

NCRs – New section 53.4.

53.4(1) If named on an approval under section 53.2, a clinic or a therapeutic regulated professional is authorized to possess psilocybin if provided by a practitioner in accordance with these regulations,

(2) If named on an approval under section 53.2, a clinic or a therapeutic regulated professional is authorized to administer, sell or provide psilocybin to an individual named on a practitioner's approval,

(3) If named on an approval under section 53.2, a clinic and a therapeutic regulated professional acting under this Part shall take reasonable steps to ensure psilocybin received pursuant to section 53.1(1) is stored securely and in refrigerated conditions at or about 19 C;

(4) If named on an approval under section 53.2, a clinic and a therapeutic regulated professional acting under this Part shall ensure the individual is supervised by the therapeutic regulated professional while the individual is experiencing the effects of psilocybin;

(5) If named on an approval under section 53.2, a clinic and a therapeutic regulated professional shall require that the individual consume only the psilocybin provided by the practitioner and shall comply with any other terms set out in the of the approval under section 53.2; and

(6) If not named on an approval under section 53.2, a therapeutic regulated professional is authorized as if named on the approval if the clinic has asked the therapeutic regulated professional to supervise the individual as required by section 53.4(4), the therapeutic regulated professional has agreed to supervise and the therapeutic regulated professional has seen and obtained a copy of the approval confirming the clinic's legal authority with respect to psilocybin under section 53.4.

Non-compliance

53.5(1) In the event the individual fails to comply with the Regulations or the

practitioner's approval, the clinic and the therapeutic regulated professional shall notify the health care practitioner.

(2) In the event, the practitioner becomes aware that the individual has failed to comply with these Regulations, the Act, the *Controlled Drugs and Substances Act*, or the *Narcotic Control Regulations* then the practitioner shall notify the holder of the psilocybin sales licence if applicable, the licensed dealer if applicable and the Minister.

General Obligations of the Clinic and the Therapeutic Regulated Professional

Just as the practitioner has general obligations to the Minister so shall the clinic and the therapeutic regulated professional have similar obligations.

NCRs – New section 55.1.

55.1 A clinic and a therapeutic regulated professional shall

(a) furnish to the Minister any information that the Minister may require respecting the use by the clinic and the therapeutic regulated professional at the clinic of psilocybin received – including the administering, selling or providing of them to a person,

(b) produce to an inspector on request any records that these Regulations require the clinic and the therapeutic regulated professional to keep;

(c) permit an inspector to make copies of such records or to take extracts therefrom;

(d) permit an inspector to check all stocks of psilocybin on the clinic's premises;

(e) retain in the clinic's possession and the therapeutic regulated professional's possession for at least two years any record that these Regulations require to keep;

(f) take adequate steps to protect psilocybin in clinic and the therapeutic regulated professional's possession from loss or theft; and

(g) report to the Minister any loss or theft of psilocybin within 10 days of the clinic's or the therapeutic regulated professional's discovery of the loss or theft.

Communication of Information by Minister to Licensing Authority

Just as the Minister must report certain information about a practitioner to the provincial professional licensing authority, similar rules must apply to the therapeutic regulated

professionals.

NCRs - Amend section 57.

57 The Minister must provide in writing any factual information about a practitioner or a therapeutic regulated professional that has been obtained under the Act or these Regulations to the provincial professional licensing authority that is responsible for the registration and authorization of the person to practised their profession

(a) in the province in which the practitioner or the therapeutic regulated professional is or was registered and entitled to practise if

(i) the authority submits to the Minister a written request that sets out the practitioner's or the therapeutic regulated professional's name and address, a description of the information being requested and a statement that the information is required for the purpose of assisting a lawful investigation by the authority, or

(ii) the Minister has reasonable grounds to believe that the practitioner or the therapeutic regulated professional has

(A) contravened a rule of conduct established by the authority,

(B) been convicted of a designated substance offence, or

(C) contravened these Regulations.

(b) in a province in which the practitioner or the therapeutic regulated professional is not registered and entitled to practise, if the authority submits to the Minister

(i) a written request that sets out the practitioner's or the therapeutic regulated professional's name and address and a description of the information being requested, and

(ii) a document that shows that

(A) the practitioner or the therapeutic regulated professional has applied to that authority to practise in that province, or

(B) the authority has reasonable grounds to believe that the practitioner is practising in that province without being authorized to do so.

Transition provision

Psilocybin would no longer be regulated as a restricted drug under the *Food and Drug Regulations*. Licensed dealers under the *Narcotic Control Regulations* would have the authority to conduct activities with psilocybin. Licensed dealers under the *Food and Drug Regulations* who already have the authority to conduct activities with psilocybin under their dealer's licence would be transitioned to the *Narcotic Control Regulations* with respect to psilocybin.

NCRs – New section 75.

75 Every licence that was issued in relation to psilocybin under Part J of the *Food and Drug Regulations* that was in force immediately before the commencement day is deemed in relation to its application to psilocybin to have been issued under section 10.1 of the *Narcotic Control Regulations* and continues in force until it is revoked or, if it is expressed to expire on a particular date, it continues in force until it expires, unless it is revoked before that date and is subject to the conditions set out in *Narcotic Control Regulations*.

Controlled Drugs and Substances Act **(S.C. 1996, c. 19)**

Some amendments would be necessary to ensure that parties complying with the *Cannabis Regulations* are not in contravention of the *CDSA.* This would only concern activities with psilocybin under the *Cannabis Regulations* (the "*CRs*"). The *CDSA* already protects activities authorized by *CDSA* regulations. Psilocybin activities authorized under the *Narcotic Control Regulations* possession by patients or dispensing by practitioners or clinics are accordingly protected. The *CRs* are under the *Cannabis Act*.

CDSA – Amend the definition of traffic in section 1.

traffic **means, in respect of a substance included in any of Schedules I to V,**

(a) to sell, administer, give, transfer, transport, send or deliver the substance,

(b) to sell an authorization to obtain the substance, or

(c) to offer to do anything mentioned in paragraph (a) or (b),
otherwise than under the authority of the regulations or the *Cannabis Regulations*.

Possession

CDSA – Amend subsection 4(1).

4(1) Except as authorized under the regulations or the *Cannabis Regulations*, no person shall possess a substance included in Schedule I, II or III.

Importing and exporting

CDSA – Amend subsection 6(1) and (2).

6(1) Except as authorized under the regulations or the *Cannabis Regulations*, no person shall import into Canada or export from Canada a substance included in Schedule I, II, III, IV, V or VI.

(2) Except as authorized under the regulations or the *Cannabis Regulations*, no person shall possess a substance included in Schedule I, II, III, IV, V or VI for the purpose of exporting it from Canada.

Production of substance

CDSA – Amend subsection 7(1)

7(1) Except as authorized under the regulations or the *Cannabis Regulations*, no person shall produce a substance included in Schedule I, II, III, IV or V.

***Cannabis Exemption (Food and Drugs Act) Regulations* (SOR/2016-231)**

The Cannabis Exemption (Food and Drugs Act) Regulations (the "*CERs*") exempt medical cannabis from the *Food and Drugs Act*. The medical cannabis must be produced and sold in accordance with the *Cannabis Regulations*. The exempted party must also not make any medical representations about the cannabis. There would be similar regulations for psilocybin.

CERs – New section 1.1.

1.1 *Psilocybin*, as defined in subsection 1(1) of the *Cannabis Regulations* and in relation to which an activity is conducted in accordance with the *Cannabis Regulations*, is exempt from the application of the *Food and Drugs Act*, unless the psilocybin

(a) is manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, or in restoring or correcting organic functions, in human beings or animals;

(b) is represented for use in modifying organic functions in human beings or animals;

(c) is manufactured, sold or represented for use in disinfection in premises in which food is manufactured, prepared or kept;

(d) is an *active pharmaceutical ingredient* as defined in subsection C.01A.001(1) of the *Food and Drug Regulations*; or

(e) is sold to be used for the purpose of a *clinical trial*, as defined in section C.05.001 of the *Food and Drug Regulations*, or an *experimental study*, as defined in section C.08.013 of those Regulations.

2 Despite paragraph 1(a), psilocybin that is produced, manufactured or sold in accordance with the *Cannabis Regulations* is exempt from the application of the *Food and Drugs Act* from the time it is produced, manufactured or sold by any of the following persons, unless it is represented for a use referred to in that paragraph:

(a) a person to which a psilocybin-related licence as defined in the *Cannabis Regulations*, other than a cannabis drug licence, was issued under subsection 62(1) of the *Cannabis Act*; and

(b) a person authorized to administer, sell, or provide psilocybin under the *Cannabis Regulations*.

(b) a person authorized to administer, sell, or provide psilocybin under the *Narcotic Control Regulations*.

***Food and Drug Regulations* C.R.C., c. 870 (the "*FDRs*")**

Psilocybin would be removed from the restricted drug list at the *Food and Drug Regulations'* Part J Schedule.

The Schedule to Part J of the *Food and Drug Regulations* shall be amended by deleting lines

8 Psilocin (3-[2-(dimethylamino)ethyl]-4-hydroxyindole) and any salt thereof

9 Psilocybin (3-[2-(dimethylamino)ethyl]-4-phosphoryloxyindole) and any salt thereof