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CANNABIS ACT

P.C. 2019-780 June 13, 2019

Her Excellency the Governor General in Council,
on the recommendation of the Minister of Border Security and Organized Crime Reduction,
pursuant to subsection 139(1) of the *Cannabis Act*,
makes the annexed *Regulations Amending the Cannabis Regulations (New Classes of Cannabi s)*.

Regulations Amending the Cannabis Regulations (New Classes of Cannabis)

Amendments

1 (1) The definitions *cannabis non-solid concentrates* and *cannabis solid concentrates* in subsection 1(1) of the *Cannabis Regulations* are repealed.

(2) The definition *cannabis oil* in subsection 1(1) of the Regulations is repealed.

(3) The definitions *non-solids containing cannabis and solids containing cannabis* in subsection 1(1) of the Regulations are replaced by the following:

non-solids containing cannabis means substances that are in non-solid form at a temperature of 22 ± 2°C and that have a concentration of 3% w/w or less of THC, taking into account the potential to convert THCA into THC. (*substances qui ne sont pas solides et qui contiennent du cannabis*)

solids containing cannabis means substances that are in solid form at a temperature of 22 ± 2°C and that have a concentration of 3% w/w or less of THC, taking into account the potential to convert THCA into THC. (*solides qui contiennent du cannabis*)

(4) Subsection 1(1) of the Regulations is amended by adding the following definitions in alphabetical order:

cannabis concentrate means a substance that has a concentration of greater than 3% w/w of THC, taking into account the potential to convert THCA into THC. (*cannabis sous forme de concentré*)

cannabis extract means

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

    - **(i)** subjecting anything referred to in item 1 of Schedule 1 to the Act to extraction processing, or
    - **(ii)** synthesizing a substance that is identical to a phytocannabinoid produced by, or found in, a cannabis plant; or
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It does not include a cannabis topical or edible cannabis. (*extrait de cannabis*)

cannabis topical means a substance or mixture of substances that contains or has on it anything referred to in item 1 or 3 of Schedule 1 to the Act and that is intended for use, directly or indirectly, exclusively on external body surfaces, including hair and nails. (*cannabis pour usage topique*)

edible cannabis means a substance or mixture of substances that contains or has on it anything referred to in item 1 or 3 of Schedule 1 to the Act and that is intended to be consumed in the same manner as food. It does not include dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds. (*cannabis comestible*)

(5) The definition *common name* in subsection 1(2) of the Regulations is repealed.

(6) The definition *cannabis product* in subsection 1(2) of the Regulations is replaced by the following:

cannabis product means cannabis of only one of the classes set out in Schedule 4 to the Act — or a cannabis accessory that contains such cannabis — after it has been packaged and labelled for sale to a consumer at the retail level. It does not include

- **(a)** cannabis that is intended for an animal;
- **(b)** a cannabis accessory that contains cannabis that is intended for an animal; or
- **(c)** a drug containing cannabis. (*produit du cannabis*)

(7) Subsection 1(2) of the Regulations is amended by adding the following definitions in alphabetical order:

combination product means a product, consisting of a device and a prescription drug, for which a drug identification number has been assigned under subsection C.01.014.2(1) of the *Food and Drug Regulations*. (*produit mixte*)

constituent means an individual unit of food that is combined as an individual unit of food with one or more other individual units of food to form an ingredient. (*constituant*)

contaminated means, in respect of cannabis, a cannabis accessory or 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 ingredient injurious to human health or unsuitable for human use. (*contaminé*)

durable life means the period, commencing on the day on which a cannabis product is packaged for sale to a consumer at the retail level, during which the product, when it is stored under conditions appropriate to that product, will retain, without any appreciable deterioration, normal palatability and any other qualities claimed for it by the holder of a licence for processing that manufactured the product. (*durée de conservation*)

durable life date means the date on which the durable life of a cannabis product ends. (*date limite de conservation*)

food has the same meaning as in section 2 of the *Food and Drugs Act*. (*aliment*)

food additive means any substance the use of which results, or may reasonably be expected to result, in it or its by-products becoming a part of, or affecting the characteristics of, a food or edible cannabis, but does not include

- **(a)** anything referred to in item 1 or 3 of Schedule 1 to the Act; or
- **(b)** anything that is excluded from the definition *food additive* in subsection B.01.001(1) of the *Food and Drug Regulations*. (*additif alimentaire*)

former Industrial Hemp Regulations means the regulations made by Order in Council P.C. 1998-352 of March 12, 1998 and registered as SOR/98-156. (*ancien Règlement sur le chanvre industriel*)

immediate container means a container that is in direct contact with cannabis or a cannabis accessory that is a cannabis product or, if a wrapper is in direct contact with the cannabis or the cannabis accessory, with the wrapper. (*contenant immédiat*)

ingestion includes absorption in the mouth. (*ingestion*)

ingredient means

- **(a)** in the case of a cannabis 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 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 or cannabis topical; and
- **(b)** in the case of edible cannabis,
    - **(i)** a substance, other than anything referred to in item 1 or 3 of Schedule 1 to the Act,
        - **(A)** that is used to produce the edible cannabis if the use of the substance results, or may reasonably be expected to result, in the substance or its by-products becoming a part of, or affecting the characteristics of, the edible cannabis, or
        - **(B)** that is part of a mixture of substances referred to in item 2 of that Schedule that is used to produce the edible cannabis if the use of the mixture results, or

may reasonably be expected to result, in the substance or its by-products becoming a part of, or affecting the characteristics of, the edible cannabis, or

- **(ii)** a mixture of substances, other than anything referred to in item 1 or 3 of Schedule 1 to the Act,
  - **(A)** that is used to produce the edible cannabis if the use of the mixture results, or may reasonably be expected to result, in the mixture or its by-products becoming a part of, or affecting the characteristics of, the edible cannabis, or
  - **(B)** that is part of a mixture of substances referred to in item 2 of that Schedule that is used to produce the edible cannabis if the use of the latter mixture results, or may reasonably be expected to result, in the former mixture or its by-products becoming a part of, or affecting the characteristics of, the edible cannabis.

(*ingrédient*)

pest control product has the same meaning as in subsection 2(1) of the *Pest Control Products Act*. (*produit antiparasitaire*)

potential to convert CBDA into CBD means the maximum amount of CBD that would be obtained if CBDA was converted into CBD with no further degradation of CBD. (*potentiel de transformation de l'ACBD en CBD*)

potential to convert THCA into THC means the maximum amount of THC that would be obtained if THCA was converted into THC with no further degradation of THC. (*potentiel de transformation de l'ATHC en THC*)

sugars has the same meaning as in subsection B.01.001(1) of the *Food and Drug Regulations*. (*sucres*)

(8) Section 1 of the Regulations is amended by adding the following after subsection (3):

Deeming — immediate container

(4) For the purposes of these Regulations, a cannabis accessory that contains edible cannabis in liquid form at a temperature of 22 ± 2°C and that is a cannabis product is deemed to be an immediate container.

2 (1) The heading to Part 1 of the Regulations is replaced by the following:

General Authorizations and Prohibition

(2) Subsection 4(1) of the Regulations is amended by striking out "and" at the end of paragraph (c) and by replacing paragraph (d) with the following:

- **(d)** to distribute cannabis to other individuals who are involved in the testing of cannabis as a requirement of their duties at a laboratory that is operated by the Government of Canada or the government of a province;
- **(e)** to distribute cannabis to the individuals referred to in subsection (4); and
- **(f)** to distribute cannabis to the holder of a licence for analytical testing.

(3) Subsection 4(4) of the Regulations is replaced by the following:

Authorized activities — accredited laboratory

(4) Individuals who are involved in the testing of cannabis as a requirement of their duties at a laboratory that is designated as an accredited laboratory under section 2.1 of the *Seeds Act* are authorized to conduct the activities referred to in paragraphs (1)(a) and (c) to (f), and to offer to conduct the activity referred to in paragraph (1)(c), to the extent necessary to conduct the testing.

3 The Regulations are amended by adding the following after section 5:

Sale of cannabis containing caffeine

5.1 For the purposes of subsection 34(1) of the Act,

- **(a)** a holder of a licence for processing that authorizes the sale of cannabis may, in accordance with the licence, sell edible cannabis that is not a cannabis product and that contains caffeine if the caffeine has been introduced through the use of ingredients that naturally contain caffeine; and
- **(b)** the following persons may, in accordance with their licence or the provincial authorization, as the case may be, sell edible cannabis that is a cannabis product and that contains caffeine if the caffeine has been introduced through the use of ingredients that naturally contain caffeine and the total amount of caffeine in each immediate container of the cannabis product does not exceed 30 mg:
    - **(i)** a holder of a licence for processing that authorizes the sale of cannabis,
    - **(ii)** a holder of a licence for sale that authorizes the sale of cannabis products, and
    - **(iii)** a person that is authorized under a provincial Act referred to in subsection 69(1) of the Act to sell cannabis.

Sale of cannabis containing ethyl alcohol

5.2 (1) For the purposes of subsection 34(1) of the Act,

- **(a)** a holder of a licence for processing that authorizes the sale of cannabis may, in accordance with the licence, sell a cannabis extract that is not a cannabis product and that contains ethyl alcohol; and
- **(b)** the following persons may, in accordance with their licence or the provincial authorization, as the case may be, sell a cannabis extract that is a cannabis product and that contains ethyl alcohol if the cannabis extract is intended to be ingested and the net

weight of the cannabis extract in each immediate container of the cannabis product does not exceed 7.5 g:

- **(i)** a holder of a licence for processing that authorizes the sale of cannabis,
- **(ii)** a holder of a licence for sale that authorizes the sale of cannabis products, and
- **(iii)** a person that is authorized under a provincial Act referred to in subsection 69(1) of the Act to sell cannabis.

Edible cannabis

(2) For the purposes of subsection 34(1) of the Act,

- **(a)** a holder of a licence for processing that authorizes the sale of cannabis may, in accordance with the licence, sell edible cannabis that is not a cannabis product and that contains ethyl alcohol; and
- **(b)** the following persons may, in accordance with their licence or the provincial authorization, as the case may be, sell edible cannabis that is a cannabis product and that contains ethyl alcohol if the concentration of ethyl alcohol does not exceed 0.5% w/w of the edible cannabis:
  - **(i)** a holder of a licence for processing that authorizes the sale of cannabis,
  - **(ii)** a holder of a licence for sale that authorizes the sale of cannabis products, and
  - **(iii)** a person that is authorized under a provincial Act referred to in subsection 69(1) of the Act to sell cannabis.

Prohibition to sell — voluntary recall

5.3 A person that is authorized under a provincial Act referred to in subsection 69(1) of the Act to sell cannabis must not sell a cannabis product that they know is the subject of a voluntary recall in Canada that has been commenced for reasons respecting

- **(a)** the quality of the cannabis product; or
- **(b)** the applicable requirements of Part 5 or 6 are otherwise not being met.

4 Subsection 10(1) of the Regulations is replaced by the following:

Obtaining cannabis

10 (1) Subject to the other provisions of these Regulations, a holder of a licence that authorizes the possession of cannabis must only possess cannabis that was obtained in accordance with the former *Access to Cannabis for Medical Purposes Regulations*, the former *Industrial Hemp Regulations* or the *Industrial Hemp Regulations* or that is obtained in accordance with these Regulations or from a person that is authorized under a provincial Act referred to in subsection 69(1) of the Act to sell cannabis.

5 (1) Subparagraph 11(5)(c)(ii) of the Regulations is replaced by the following:

- **(ii)** a person that is authorized under a provincial Act referred to in subsection 69(1) of the Act to sell cannabis; and

(2) Subparagraph 11(5)(d)(i) of the Regulations is replaced by the following:

- **(i)** a person that is authorized under a provincial Act referred to in subsection 69(1) of the Act to sell cannabis, or

6 (1) Subparagraph 14(5)(b)(ii) of the Regulations is replaced by the following:

- **(ii)** a person that is authorized under a provincial Act referred to in subsection 69(1) of the Act to sell cannabis; and

(2) Subparagraph 14(5)(c)(i) of the Regulations is replaced by the following:

- **(i)** a person that is authorized under a provincial Act referred to in subsection 69(1) of the Act to sell cannabis, or

7 (1) Subparagraph 17(5)(d)(ii) of the Regulations is replaced by the following:

- **(ii)** a person that is authorized under a provincial Act referred to in subsection 69(1) of the Act to sell cannabis; and

(2) Subparagraph 17(5)(e)(i) of the Regulations is replaced by the following:

- **(i)** a person that is authorized under a provincial Act referred to in subsection 69(1) of the Act to sell cannabis, or

(3) Subsection 17(6) of the English version of the Regulations is replaced by the following:

Client's shipping address

(6) If a holder of a licence for micro-processing or standard processing sends or delivers cannabis products under subparagraph (5)(e)(ii) further to the sale of such products under section 289, the holder must send or deliver the products to the client's shipping address as indicated by the holder of a licence for sale for medical purposes.

8 Paragraph 18(1)(a) of the Regulations is replaced by the following:

- **(a)** the sale or distribution of cannabis products to a person that is authorized under a provincial Act referred to in subsection 69(1) of the Act to sell cannabis; and

9 (1) Subsection 19(1) of the Regulations is replaced by the following:

Quality assurance person

19 (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 the class of cannabis in respect of which activities are conducted under the licence.

Exception — edible cannabis

(1.1) Despite subsection (1), if the quality assurance person does not have the training, experience and technical knowledge related to the requirements of Parts 5 and 6 that are applicable to edible cannabis, the holder of a licence for processing that conducts activities in respect of that class of cannabis must retain the services of another individual who has that training, experience and technical knowledge.

(2) Subsection 19(2) of the Regulations is amended by striking out "and" at the end of paragraph (a) and by replacing paragraph (b) with the following:

- **(b)** investigating every complaint received in respect of the quality of the cannabis and, if necessary, immediately taking measures to mitigate any risk; and
- **(c)** if they suspect, on reasonable grounds, that the cannabis 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.

10 Items 5 and 6 of the table to section 21 of the Regulations are replaced by the following:

Item	Column 1 Class of cannabis	Column 2 Amount that is equivalent to 1 kg of dried cannabis
5	cannabis concentrates	0.25 kg

11 Section 22 of the Regulations is amended by adding the following after subsection (3):

Distribution

(4) A holder of a licence for analytical testing is also authorized, for the purpose of testing, to distribute cannabis to another holder of a licence for analytical testing or the individuals referred to in section 4.

12 Subsection 23(1) of the Regulations is replaced by the following:

Head of laboratory

23 (1) A holder of a licence for 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 to 91.1.

13 Section 25 of the Regulations is replaced by the following:

Destruction

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

Sample not tested

(2) If testing of the sample of a lot or batch of cannabis distributed to the holder of the licence for 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 analytical testing or to the individuals referred to in section 4.

14 Paragraph 28(5)(a) of the Regulations is replaced by the following:

- **(a)** cannabis to any of the following:
    - **(i)** another holder of a licence for research,
    - **(ii)** a holder of a licence for analytical testing,
    - **(iii)** a holder of a cannabis drug licence,
    - **(iv)** the individuals referred to in section 4, or
    - **(v)** the Minister; and

15 Section 29 of the Regulations is amended by striking out "and" at the end of paragraph (i), by adding "and" at the end of paragraph (j) and by adding the following after paragraph (j):

- **(k)** in respect of a licence for 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*.

16 Section 30 of the Regulations is amended by striking out "and" at the end of paragraph (b) and by replacing paragraph (c) with the following:

- **(c)** the holder of a licence does not hold a cannabis licence issued under subsection 14(1.1) of the *Excise Act, 2001*, if it is required; and
- **(d)** the cannabis licence issued to the holder under subsection 14(1.1) of the *Excise Act, 2001* is suspended under subsection 23(2) of that Act.

17 Section 31 of the Regulations is amended by striking out "and" at the end of paragraph (c), by adding "and" at the end of paragraph (d) and by adding the following after paragraph (d):

- **(e)** in the case of a licence for 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*.

18 Section 42 of the Regulations is renumbered as subsection 42(1) and is amended by adding the following after that subsection:

Irradiation of edible cannabis

(2) For greater certainty, in the case of the irradiation of edible cannabis by a holder of a licence for processing, the requirements set out in subsection (1) apply in addition to the conditions set out in paragraphs 102.6(a) and (b).

19 Section 46 of the Regulations is replaced by the following:

Recall

46 (1) A holder of a 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.

Recall simulation

(2) The holder must

- **(a)** at least once every 12 months, conduct a recall simulation based on the system of control;
- **(b)** after completing the recall simulation, prepare a document that sets out the details of how it was conducted and the results; and
- **(c)** retain the document for at least two years after the day on which the recall simulation is completed.

20 The heading "General Provisions" before section 79 of the Regulations and sections 79 and 80 are replaced by the following:

Definitions

Definitions

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 anything that will be used as an ingredient. (*niveau acceptable*)

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 anything that will be used as an ingredient, or to reduce the hazard to an acceptable level. (*mesure de contrôle*)

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 anything that will be used as an ingredient, or to reduce the hazard to an acceptable level. (*point de contrôle critique*)

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 anything that will be used as an ingredient. (*conditions hygiéniques*)

General Requirements

Sale, distribution and exportation — cannabis

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

Non-application — person not holding a licence

79.1 The requirements of this Part do not apply to any activity that a person conducts in respect of anything that will be used as an ingredient unless the activity is conducted by a holder of a licence.

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

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

Standard operating procedures

80 Cannabis 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.

21 Section 81 of the Regulations is renumbered as subsection 81(1) and is amended by adding the following:

Exception — edible cannabis

(2) Despite subsection (1), edible cannabis 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*.

22 Sections 82 to 85 of the Regulations are replaced by the following:

Sanitizers, agronomic inputs and non-food chemical agents

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 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 anything that will be used as an ingredient and that is in accordance with the manufacturer's instructions.

Storage

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

Distribution

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

Building or part of building

84 Any building or part of a building where cannabis 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 or thing that will be used as an ingredient; and
- **(d)** prevents the introduction of an extraneous substance to the cannabis or thing that will be used as an ingredient.

System — filtration and ventilation

85 (1) Any building or part of a building where cannabis or anything that will be used as an ingredient is produced, packaged, labelled, stored or tested must be equipped with a system that

- **(a)** filters air to prevent the escape of odours associated with cannabis plant material to the outdoors;
- **(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 cannabis or thing that will be used as an ingredient;
- **(c)** is accessible and, if necessary for its cleaning, maintenance or inspection, is capable of being disassembled;
- **(d)** is capable of withstanding repeated cleaning; and
- **(e)** functions in accordance with its intended use.

Exception — cultivation, propagation or harvesting of cannabis

(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 cannabis are its cultivation, propagation or harvesting.

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

(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

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

Cross-connection

(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 anything that will be used as an ingredient as a result of the cross-connection.

Lighting

85.2 (1) Any building or part of a building where cannabis 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

(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 thing that will be used as an ingredient, repeated sanitizing; and
- **(b)** not present a risk of contamination of the cannabis or thing that will be used as an ingredient in the event of breakage.

23 (1) The portion of subsection 86(1) of the Regulations before paragraph (a) is replaced by the following:

Equipment

86 (1) Cannabis 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

(2) Paragraphs 86(1)(c) and (d) of the Regulations are replaced by the following:

- **(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 thing that will be used as an ingredient;
- **(d)** prevents the introduction of an extraneous substance to the cannabis or thing that will be used as an ingredient; and
- **(e)** protects the cannabis or thing that will be used as an ingredient against allergen cross-contamination.

(3) Subsection 86(2) of the Regulations is replaced by the following:

Conveyances

(1.1) Cannabis 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

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

24 (1) The portion of subsection 87(1) of the Regulations before paragraph (a) is replaced by the following:

Sanitation program

87 (1) Cannabis 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

(2) Paragraph 87(1)(b) of the Regulations is replaced by the following:

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

(3) Subsection 87(2) of the Regulations is replaced by the following:

Non-application

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

25 Section 88 of the Regulations is replaced by the following:

Hand cleaning and hand sanitizing stations and lavatories

87.1 (1) If necessary to prevent the contamination of cannabis 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

(2) The hand cleaning and hand sanitizing stations must permit the effective cleaning and sanitization of hands.

Lavatories

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

Additional Requirements — Holder of Licence for Processing

Quality assurance

88 A holder of a licence for 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 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 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 is approved by the quality assurance person before it is made available for sale.

Competencies and qualifications

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

Temperature and humidity

88.2 (1) A holder of a licence for processing must ensure that the temperature and humidity of any building or part of a building where cannabis 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 thing that will be used as an ingredient.

Heating, cooling or humidity-control system

(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 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

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

Production of food

(2) A holder of a licence for processing must not produce, package, label or store cannabis at a site set out in the licence if food that is to be sold is also produced, packaged or labelled at that site.

Exception

(3) Despite subsection (2), a holder of a licence for processing may produce, package, label or store cannabis 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 and ingredients from contaminants

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

Ingredients — risk of injury to human health

88.5 A holder of a licence for 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

88.6 (1) A holder of a licence for processing must ensure that any water that might come into contact with a cannabis extract, a cannabis topical, edible cannabis or 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 thing that will be used as an ingredient.

Steam and ice from potable water

(2) A holder of a licence for processing must ensure that any steam or ice that might come into contact with a cannabis extract, a cannabis topical, edible cannabis 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 thing that will be used as an ingredient.

No presence of animals

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

Land — risk of contamination

88.8 If any land that forms part of a site set out in a licence for processing, or any land that is located near such a site, presents a risk of contamination of cannabis 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

88.9 (1) A holder of a licence for processing must ensure that any building or part of a building where cannabis 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 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.

Frequency and manner

(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 thing that will be used as an ingredient and in a manner that does not present a risk of contamination of the cannabis or thing that will be used as an ingredient.

Conveyances and equipment

88.91 A holder of a licence for 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

88.92 A holder of a licence for processing must ensure that any individual who enters or is in any building or part of a building where cannabis 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

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

Prevention, elimination and reduction of hazards

(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

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

Content of preventive control plan

(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,**(c)** supporting documents that show evidence of the information recorded under paragraph (a) and subparagraphs (b)(i) to (vii).
    - **(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 or

anything that will be used as an ingredient in the production of the cannabis extract or edible cannabis,

- **(ii)** a description of the control measures for preventing, eliminating or reducing to an acceptable level the hazards referred to in subparagraph (i) and the evidence that the control measures are effective,
- **(iii)** a description of the critical control points, the related control measures and the evidence that the control measures are effective,
- **(iv)** a description of the critical limits for each critical control point,
- **(v)** the procedures for monitoring the critical control points in relation to their critical limits,
- **(vi)** the corrective action procedures for each critical control point,
- **(vii)** the procedures for verifying that the implementation of the preventive control plan results in compliance with these Regulations, and
- **(viii)** documents that substantiate that the preventive control plan has been implemented with respect to subparagraphs (i) to (vii); and

Retention period

(3) Each document referred to in subparagraph (2)(b)(viii) must be retained for at least two years after the day on which it is prepared.

26 Sections 90 to 92 of the Regulations are replaced by the following:

Testing for phytocannabinoids

90 (1) Testing for the quantity or concentration, as the case may be, of THC, THCA, CBD and CBDA must be conducted on each lot or batch of cannabis, other than cannabis plants or cannabis plant seeds, that

- **(a)** is or will become a cannabis product; or
- **(b)** is or will be contained in a cannabis accessory that is or will become a cannabis product.

Timing of testing

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

Testing for contaminants

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

- **(a)** each lot or batch of cannabis — other than cannabis plants, cannabis plant seeds or edible cannabis — that
  - **(i)** is or will become a cannabis product, or
  - **(ii)** is or will be contained in a cannabis accessory that is or will become a cannabis product; or
- **(b)** each lot or batch of cannabis — other than cannabis plant seeds — that
  - **(i)** is used to produce the cannabis referred to in paragraph (a), or
  - **(ii)** is used to produce edible cannabis that is or will become a cannabis product, or that is or will be contained in a cannabis accessory that is or will become a cannabis product.

Timing of testing

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

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

Tolerance limits

(3) The results of the testing referred to in subsection (1) must enable a determination of whether the contaminants, if any, are or will be within the tolerance limits referred to in subsection 93(3) or 94(2) or section 101.1, as the case may be.

Dissolution and disintegration testing

91.1 (1) If cannabis — or a cannabis accessory that contains cannabis — 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 to determine whether the requirements referred to in that subsection are, or will be, met.

Timing of testing

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

Testing method

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.

Retention period

(2) A portion of the sample referred to in subsection (1) must be retained for at least one year after the date of the last sale of any portion of the lot or batch.

Sufficient quantity

(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.

27 Sections 93 to 98 of the Regulations are replaced by the following:

Interpretation — residues of pest control products

92.1 In this Part, a reference to residues of a pest control product includes the residues of any component or derivative of the pest control product.

Residues of pest control products — cannabis plants and seeds

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 — 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.

Dried and fresh cannabis

93 (1) Dried cannabis or fresh cannabis that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — must not contain or have on it anything other than anything referred to in item 1 of Schedule 1 to the Act.

Residues of pest control products

(2) Despite subsection (1), cannabis that is 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.

Microbial and chemical contaminants

(3) Despite subsection (1), cannabis that is 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 cannabis product.

More stringent limit applies

(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.

Cannabis used in production

94 (1) Cannabis that is referred to in item 1 or 3 of Schedule 1 to the Act and that is used in the production of the following cannabis 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 cannabis extract that will become a cannabis product or that will be contained in a cannabis accessory that will become a cannabis product;
- **(b)** a cannabis topical that will become a cannabis product or that will be contained in a cannabis accessory that will become a cannabis product; and
- **(c)** edible cannabis that will become a cannabis product or that will be contained in a cannabis accessory that will become a cannabis product.

Edible cannabis — microbial and chemical contaminants

(2) Cannabis that is referred to in item 1 or 3 of Schedule 1 to the Act and that is used in the production of edible cannabis must not, if the edible cannabis will become a cannabis product or will be contained in a cannabis accessory that will become a cannabis product, 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

95 (1) Each discrete unit of a cannabis product 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 will perform as intended.

Exception

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

Maximum quantity of THC — discrete unit

96 (1) Subject to subsection 97(1), each discrete unit of a cannabis product that is intended for ingestion or nasal, rectal or vaginal use must not contain a quantity of THC that exceeds 10 mg, taking into account the potential to convert THCA into THC.

Exception

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

Variability limits

97 (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 — must not contain, in respect of any quantity or concentration of THC or CBD that is displayed on the label, less than 85% or more than 115% of that quantity or concentration.

Edible cannabis

(2) Edible cannabis that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — must not contain

- **(a)** if a quantity of THC or CBD that is displayed on the label exceeds 5 mg, less than 85% or more than 115% of that quantity;
- **(b)** if a quantity of THC or CBD that is displayed on the label exceeds 2 mg but does not exceed 5 mg, less than 80% or more than 120% of that quantity; and
- **(c)** if a quantity of THC or CBD that is displayed on the label does not exceed 2 mg, less than 75% or more than 125% of that quantity.

Variability limits — divisible cannabis products

97.1 (1) If a cannabis product that is not in discrete units is represented as being able to be divided into discrete units, each represented unit must not contain

- **(a)** a quantity of THC that is less than 75% or more than 125% of the quantity of THC in each of the other represented units, taking into account the potential to convert THCA into THC; and
- **(b)** a quantity of CBD that is less than 75% or more than 125% of the quantity of CBD in each of the other represented units, taking into account the potential to convert CBDA into CBD.

Divisible units

(2) If a cannabis product is in discrete units that are represented as being able to be divided into discrete sub-units, each represented subunit must not contain

- **(a)** a quantity of THC that is less than 75% or more than 125% of the quantity of THC in each of the other represented subunits, taking into account the potential to convert THCA into THC; and
- **(b)** a quantity of CBD that is less than 75% or more than 125% of the quantity of CBD in each of the other represented subunits, taking into account the potential to convert CBDA into CBD.

Products that must not be sold or distributed

98 The following cannabis products must not be sold or distributed:

- **(a)** a cannabis product that is intended to be used in the area of the human eye bounded by the supraorbital and infraorbital ridges, including the eyebrows, the skin underlying the eyebrows, the eyelids, the eyelashes, the conjunctival sac of the eye, the eyeball and the soft tissue that lies below the eye and within the infraorbital ridge; and
- **(b)** a cannabis product that is intended to be used on damaged or broken skin or to penetrate the skin barrier other than by absorption.

Multiple units

98.1 It is prohibited for a holder of a licence to sell or distribute a cannabis extract, a cannabis topical or edible cannabis that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — if the immediate container contains multiple discrete units, unless the properties of each unit, including size but excluding flavour and colour, as applicable, are consistent.

28 The heading before section 101 of the Regulations and sections 101 and 102 are replaced by the following:

Cannabis Extracts and Cannabis Topicals

Things injurious to health

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 — must not contain or have on it anything that may cause injury to the health of the user when the cannabis product is used as intended or in a reasonably foreseeable way.

Exception

(2) Subsection (1) does not, in respect of a cannabis extract that is intended to be combusted and inhaled, prohibit anything that may cause injury as a result of the intended combustion and inhalation.

Things that do not cause injury

(3) For the purposes of subsection (1), a cannabis extract or a cannabis topical 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)** anything referred to in item 1 or 3 of Schedule 1 to the Act;
- **(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 the cannabis product.

Microbial and chemical contaminants

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 — 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.

Maximum quantity of THC

101.2 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 — must not contain a quantity of THC that exceeds 1000 mg per immediate container, taking into account the potential to convert THCA into THC.

Cannabis extract — content

101.3 (1) A cannabis extract that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — 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.

Prohibited ingredients

(2) The following substances must not be used as ingredients to produce a cannabis 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*.

Exception — vitamins

(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.

Naturally occurring substances

(4) An ingredient that is used to produce the cannabis 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.

Permitted ingredients — inhaled cannabis extract

(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.

Ethyl alcohol — ingested cannabis extract

(6) A cannabis extract 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 does not exceed 7.5 g.

Uniform distribution — cannabinoids and terpenes

101.4 The cannabinoids and terpenes in 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 — must be uniformly distributed throughout the cannabis extract or cannabis topical.

Cannabis extract — external body surfaces

101.5 A cannabis extract that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — must not be represented for use, directly or indirectly, on external body surfaces, including hair and nails.

Edible Cannabis

Ingredients — edible cannabis

102 (1) Edible cannabis that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — must not contain any ingredients other than food and food additives.

Temporarily marketed foods

(2) A food that is described in a Temporary Marketing Authorization Letter issued under subsection B.01.054(1) of the *Food and Drug Regulations* must not be used as an ingredient to produce edible cannabis referred to in subsection (1) and must not be a constituent of such an ingredient.

Meat products, poultry products and fish

(3) A meat product, poultry product or fish, other than a food additive, must not be used as an ingredient to produce edible cannabis referred to in subsection (1) — and must not be a constituent of such an ingredient — unless the meat product, poultry product or fish

- **(a)** has been produced by a person that is authorized to produce it under the laws of a province or the *Safe Food for Canadians Act* or has been imported in accordance with that Act; and
- **(b)** has a water activity that does not exceed 0.85 at a temperature of 22 ± 2°C at the time the meat product, poultry product or fish is obtained by the holder of the licence for processing that is producing the edible cannabis.

Self-produced food

(4) A holder of a licence for processing that produces a food may use it as an ingredient to produce edible cannabis referred to in subsection (1) — or as a constituent of such an ingredient — if

- **(a)** the food is not a meat product, poultry product or fish; and
- **(b)** the sale of the food would not be prohibited under section 4 of the *Food and Drugs Act*.

Food additives

(5) A holder of a licence for processing may use a food additive as an ingredient to produce edible cannabis referred to in subsection (1) only if

- **(a)** the edible cannabis would be a food that is the subject of a marketing authorization if the edible cannabis did not contain or have on it anything referred to in item 1 or 3 of Schedule 1 to the Act;
- **(b)** the marketing authorization permits the food additive to be in or on the food;
- **(c)** the conditions under which the marketing authorization permits the food additive to be in or on the food — including any maximum levels of use — are complied with; and
- **(d)** the food additive is not caffeine or caffeine citrate.

Vitamins and mineral nutrients

(6) A vitamin or mineral nutrient must not be used as an ingredient to produce edible cannabis referred to in subsection (1) unless its use is permitted under subsection (5).

Definitions

(7) The following definitions apply in this section.

fish has the same meaning as in section 1 of the *Safe Food for Canadians Regulations*. (*poisson*)

marketing authorization, except in subsection (2), has the same meaning as in subsection B.01.001(1) of the *Food and Drug Regulations*. (*autorisation de mise en marché*)

meat product has the same meaning as in subsection B.01.001(1) of the *Food and Drug Regulations*. (*produit de viande*)

mineral nutrient has the same meaning as in subsection D.02.001(1) of the *Food and Drug Regulations* except that it does not include sodium, potassium or chloride or compounds that include those elements. (*minéral nutritif*)

poultry product has the same meaning as in subsection B.01.001(1) of the *Food and Drug Regulations*. (*produit de volaille*)

vitamin has the same meaning as in subsection D.01.002(1) of the *Food and Drug Regulations*. (*vitamine*)

water activity means the ratio of the water vapour pressure of a meat product, poultry product or fish to the vapour pressure of pure water, at the same temperature and pressure. (*activité de l'eau*)

Prohibited things

102.1 (1) Edible cannabis that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — must not contain or have on it anything in a quantity that would cause the sale of the edible cannabis to be prohibited under any of paragraphs 4(1)(a) to (d) of the *Food and Drugs Act* if the edible cannabis were a food to which that Act applies.

Not poisonous, harmful or adulterated

(2) Edible cannabis does not have a poisonous or harmful substance in or on it, within the meaning of paragraph 4(1)(a) of the *Food and Drugs Act*, and is not adulterated, within the meaning of paragraph 4(1)(d) of that Act, by reason only that it contains or has on it

- **(a)** anything referred to in item 1 or 3 of Schedule 1 to the Act;
- **(b)** residues of a pest control product that is registered for use on cannabis under the *Pest Control Products Act*, or 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 a product that is to be ingested.

Caffeine

102.2 Edible cannabis that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — must not contain or have on it caffeine unless

- **(a)** the caffeine has been introduced through the use of ingredients that naturally contain caffeine; and
- **(b)** the total amount of caffeine in each immediate container of the cannabis product does not exceed 30 mg.

Ethyl alcohol

102.3 Edible cannabis that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — must not contain or have on it ethyl alcohol unless the concentration of ethyl alcohol does not exceed 0.5% w/w of the edible cannabis.

Cannabis products requiring refrigeration

102.4 It is prohibited for a holder of a licence to sell or distribute edible cannabis that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — if the unopened immediate container must be stored at or below 4°C to prevent the cannabis product from becoming contaminated before its durable life date.

Hermetically sealed containers

102.5 (1) It is prohibited for a holder of a licence to sell or distribute edible cannabis that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — in a hermetically sealed container if any component of the edible cannabis has a pH that exceeds 4.6 and a water activity that exceeds 0.85 at a temperature of 22 ± 2°C.

Definitions

(2) The following definitions apply in subsection (1).

hermetically sealed container means a container that, due to its design, is secure against the entry of micro-organisms, including spores. (*contenant hermétiquement scellé*)

water activity means the ratio of the water vapour pressure of the component to the vapour pressure of pure water, at the same temperature and pressure. (*activité de l'eau*)

Irradiation

102.6 A holder of a licence for processing must not irradiate edible cannabis unless

- **(a)** the edible cannabis would be a food that is listed in item 3 or 4, column 1, of the table to Division 26 of Part B of the *Food and Drug Regulations* if the edible cannabis did not contain or have on it anything that is referred to in item 1 or 3 of Schedule 1 to the Act; and
- **(b)** the holder satisfies the requirements set out in paragraphs B.26.003(2)(a) and (b) and subsection B.26.004(1) of those Regulations in respect of the edible cannabis.

Maximum quantity of THC

102.7 Subject to subsection 97(2), edible cannabis that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — must not contain a quantity of THC that exceeds 10 mg per immediate container, taking into account the potential to convert THCA into THC.

29 Sections 103 and 104 of the Regulations are replaced by the following:

Contamination

103 A cannabis accessory that is a cannabis product, or that is packaged with a cannabis product, must not be contaminated.

Flavour

103.1 A cannabis accessory that is a cannabis product, or that is packaged with a cannabis product, must not impart a characterizing flavour to the cannabis.

Dispensing limit

103.2 Subject to subsection 97(1), each activation of the following cannabis accessories must not dispense a quantity of cannabis extract that contains greater than 10 mg of THC, taking into account the potential to convert THCA into THC:

- **(a)** a cannabis accessory that is a cannabis product and that dispenses a cannabis extract that is intended for ingestion or nasal, rectal or vaginal use; or
- **(b)** a cannabis accessory that is packaged with, and that is intended to dispense, a cannabis extract that is a cannabis product and that is intended for ingestion or nasal, rectal or vaginal use.

Psychological effects, abuse liability and toxicity

104 (1) A component of a cannabis product — other than a component that is anything referred to in item 1 or 3 of Schedule 1 to the Act — and a cannabis accessory that is packaged with a cannabis product must not, through any means other than heating or combustion, and when used as intended or in a reasonably foreseeable way,

- **(a)** alter or enhance the psychological effects derived from the cannabis product in a manner that may cause injury to the health of the user;
- **(b)** increase the potential for abuse liability of the cannabis product; or
- **(c)** increase the toxicity of the cannabis product.

Exceptions

(2) Subsection (1) does not prohibit the presence of

- **(a)** ethyl alcohol in or on a cannabis product referred to in subsection 101.3(6) or section 102.3 if the conditions set out in that subsection or section, as the case may be, are met; and
- **(b)** caffeine in or on a cannabis product referred to in section 102.2 if the conditions set out in that section are met.

PART 6.1

Promotion

Non-application — prescription drug and combination product

104.1 Sections 104.11 to 104.16 do not apply to a prescription drug or a combination product.

Flavours

104.11 It is prohibited to promote a cannabis extract — or a cannabis accessory that contains a cannabis extract — under subsections 17(2) to (6) of the Act in a manner that could cause a person to believe that the cannabis extract or the cannabis accessory has a flavour set out in column 1 of Schedule 3 to the *Tobacco and Vaping Products Act*, other than the flavour of cannabis.

Health and cosmetic benefits

104.12 (1) It is prohibited to promote cannabis, a cannabis accessory or a service related to cannabis under subsections 17(2) to (6) of the Act if there are reasonable grounds to believe that the promotion could create the impression that health or cosmetic benefits may be derived from the service or the use of the cannabis or the cannabis accessory.

Non-application — medical devices

(2) Subsection (1) does not apply with respect to a medical device in respect of which a licence has been issued under subsection 36(1) of the *Medical Devices Regulations*.

Energy value and amount of nutrient

104.13 (1) It is prohibited to promote edible cannabis — or a cannabis accessory that contains edible cannabis — under subsections 17(2) to (6) of the Act by communicating information about 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*.

Exception — nutrition facts table

(2) Despite subsection (1), edible cannabis or a cannabis accessory that contains edible cannabis may be promoted by reproducing the nutrition facts table that is required to be included on the label of any container in which the edible cannabis or the cannabis accessory is packaged in accordance with these Regulations using smaller, larger or identical dimensions and spacing.

Dietary requirements

104.14 It is prohibited to promote edible cannabis — or a cannabis accessory that contains edible cannabis — under subsections 17(2) to (6) of the Act if there are reasonable grounds to believe that the promotion could create the impression that the edible cannabis or accessory is intended

- **(a)** to meet the particular dietary requirements of an individual**(b)** to meet the dietary requirements of young persons.
    - **(i)** who has a physical or physiological condition as a result of a disease, disorder or injury, or
    - **(ii)** for whom a particular effect, including weight loss, is to be obtained by a controlled intake of food; or
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Alcoholic beverages

104.15 It is prohibited to promote cannabis, a cannabis accessory or a service related to cannabis under subsections 17(2) to (6) of the Act if there are reasonable grounds to believe that the promotion could associate the cannabis, the cannabis accessory or the service with an alcoholic beverage.

Tobacco products and vaping products

104.16 It is prohibited to promote cannabis, a cannabis accessory or a service related to cannabis under subsections 17(2) to (6) of the Act if there are reasonable grounds to believe that the promotion could associate the cannabis, the cannabis accessory or the service 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.

Place where young persons are not permitted

104.17 It is prohibited to promote cannabis, a cannabis accessory or a service related to cannabis under paragraphs 17(2)(b) and (3)(b) of the Act in such a manner that the promotion may be audible or visible from outside a place where young persons are not permitted by law.

Number of brand elements

104.18 It is prohibited to promote cannabis, a cannabis accessory or a service related to cannabis under subsection 17(6) of the Act in a manner that results in the same brand element being displayed more than once on a thing referred to in that subsection or in more than one brand element being displayed on the thing.

Public place frequented mainly by young persons

104.19 It is prohibited to promote cannabis, a cannabis accessory or a service related to cannabis under subsection 17(6) of the Act by displaying a brand element of cannabis, of a cannabis accessory or of a service related to cannabis on any thing that is in a school, a public playground, a daycare facility or any other public place frequented mainly by young persons or that is visible from such a place.

Dimensions of brand element

104.2 A brand element referred to in subsection 17(6) of the Act must meet the following requirements:

- **(a)** the surface area must be smaller than or equal to 300 cm^2; and
- **(b)** the height of any letter, character or number must be smaller than or equal to 4 cm.

30 (1) The definition *immediate container* in section 105 of the Regulations is repealed.

(2) Section 105 of the Regulations is amended by adding the following in alphabetical order:

common name, in respect of edible cannabis, has the same meaning as in subsection B.01.001(1) of the *Food and Drug Regulations*. (*nom usuel*)

daily value means

- **(a)** in the case of a nutrient set out in column 1 of Part 1 of the *Table of Daily Values*, as defined in subsection B.01.001(1) of the *Food and Drug Regulations*, the quantity set out in column 3; and
- **(b)** in the case of a nutrient set out in column 1 of Part 2 of the table referred to in paragraph (a), the quantity set out in column 4. (*valeur quotidienne*)

energy value means, in respect of a cannabis product, the amount of energy made available to a person's body when the chemical components of the cannabis product, including protein, fat, carbohydrate and alcohol, are metabolized following ingestion of the cannabis product by the person. (*valeur énergétique*)

exterior display surface means the area on the exterior surface of an immediate container to which a label is applied and that is visible under customary conditions of purchase or use. (*espace extérieur d'affichage*)

fat has the same meaning as in subsection B.01.400(1) of the *Food and Drug Regulations*. (*lipides*)

food allergen has the same meaning as in subsection B.01.010.1(1) of the *Food and Drug Regulations*. (*allergène alimentaire*)

food allergen source, gluten source and added sulphites statement means a statement appearing on the label of any container in which edible cannabis — or a cannabis accessory that contains edible cannabis — that is a cannabis product is packaged that indicates the source of a food allergen or gluten that is present in the cannabis product or the presence in the cannabis product of added sulphites in an amount of 10 p.p.m. or more. (*mention des sources d'allergènes alimentaires ou de gluten et des sulfites ajoutés*)

gluten has the same meaning as in subsection B.01.010.1(1) of the *Food and Drug Regulations*. (*gluten*)

INCI name has the same meaning as in subsection 2(1) of the *Cosmetic Regulations*. (*appellation INCI*)

label does not include a panel referred to in paragraph 132.27(1)(b). (*étiquette*)

p.p.m. means parts per million by weight. (*p.p.m.*)

saturated fatty acids, ***saturated fat***, ***saturates*** or ***saturated*** has the same meaning as in subsection B.01.001(1) of the *Food and Drug Regulations*. (*acides gras saturés, graisses saturées, gras saturés, lipides saturés* ou *saturés*)

sugars-based ingredient has the same meaning as in subsection B.01.001(1) of the *Food and Drug Regulations*. (*ingrédient à base de sucres*)

sulphites means one or more of the following food additives:

- **(a)** potassium bisulphite;
- **(b)** potassium metabisulphite;
- **(c)** sodium bisulphite;
- **(d)** sodium dithionite;
- **(e)** sodium metabisulphite;
- **(f)** sodium sulphite;
- **(g)** sulphur dioxide; and
- **(h)** sulphurous acid. (*sulfites*)

trans fatty acids, ***trans fat*** or ***trans*** has the same meaning as in subsection B.01.001(1) of the *Food and Drug Regulations*. (*acides gras trans*, *graisses trans*, *gras trans*, *lipides trans* ou *trans*)

(3) Section 105 of the Regulations is renumbered as subsection 105(1) and is amended by adding the following after subsection (1):

Definition of *panel*

(2) For the purposes of sections 112 to 117, 121 and 132.13, subsections 132.27(2) to (7) and (9) and sections 132.28 to 132.32, *panel* means a panel referred to in paragraph 132.27(1)(b).

31 Section 112 of the Regulations is replaced by the following:

Image

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 product is packaged must not display any image.

32 (1) Subsection 113(1) of the Regulations is replaced by the following:

Uniform colour

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 product is packaged must be one uniform colour. However, the colour of each surface and the panel may be different.

(2) The portion of subsection 113(2) of the Regulations before paragraph (a) is replaced by the following:

Colour — other requirements

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

(3) Subsection 113(3) of the Regulations is replaced by the following:

Exception

(3) Despite subsection (2),

- **(a)** an interior surface that is made of metal may be the colour of the metal; and
- **(b)** an exterior surface of an immediate container that is made of metal, excluding the label or any image, may be the colour of the metal.

33 Section 114 of the Regulations is repealed.

34 Subsection 115(1) of the Regulations is replaced by the following:

Texture

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 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.

35 Sections 116 and 117 of the Regulations are replaced by the following:

Hidden features

116 (1) The interior surface, exterior surface and panel of any container in which a cannabis 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

(2) Subject to section 132.27, the interior surface and exterior surface of any container in which a cannabis 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

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

36 Section 121 of the Regulations is replaced by the following:

Cut-out window

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

37 The Regulations are amended by adding the following after section 122:

Wrapper

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

- **(a)** it is in direct contact with the cannabis or the cannabis accessory and with one or both of the following:**(b)** it is required to maintain the quality or stability of the cannabis product.
    - **(i)** the immediate container of the cannabis product,
    - **(ii)** a wrapper that is in direct contact with the cannabis or the cannabis accessory; and
-

Packaging requirements — other Regulations

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 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 a cannabis accessory that contains edible cannabis — that is a cannabis product is packaged;
- **(b)** any wrapper that is in direct contact with edible cannabis — or a cannabis accessory that contains edible cannabis — that is a cannabis product; and
- **(c)** any wrapper that is in direct contact with a cannabis extract that is intended for ingestion — or a cannabis accessory that contains cannabis extract intended for ingestion — that is a cannabis product.

Maximum quantity — cannabis extract

122.3 The immediate container of a cannabis extract that is a cannabis product must not contain more than 90 mL of extract that is in non-solid form at a temperature of 22 ± 2°C.

Outermost container

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

- **(a)** food;
- **(b)** more than one class of cannabis set out in Schedule 4 to the Act; or
- **(c)** more than one immediate container.

Exception — multiple immediate containers

(2) Despite paragraph (1)(c), the outermost container may contain more than one immediate container of edible cannabis 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 that is in discrete units, or section 132.19, if they contain edible cannabis 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 in the immediate containers does not exceed the equivalent of 30 g of dried cannabis, as determined in accordance with subsection 2(4) of the Act;
- **(e)** the statement “Contains the equivalent of (the quantity of dried cannabis, in grams, that is equivalent to the total quantity of cannabis, in grams, as determined in accordance with subsection 2(4) 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 in all the immediate containers are consistent.

Interpretation — “unit”

(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

122.5 (1) The immediate container of a cannabis extract that is a cannabis 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, and
    - **(iii)** contains at least 10 mg of THC, taking into account the potential to convert THCA into THC.

Non-application — integrated dispensing mechanism

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

38 (1) The portion of subparagraph 123(1)(c)(v) of the Regulations before clause (A) is replaced by the following:

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

(2) Paragraphs 123(1)(e) and (f) of the Regulations are replaced by the following:

- **(e)** one of the health warning messages set out in the document entitled *Cannabis Health Warning Messages*, as amended from time to time and published by the Government of Canada on its website, that applies to the cannabis product;
- **(f)** in the case of a cannabis product that contains THC in a concentration greater than 10 µg/g, taking into account the potential to convert THCA into THC, the standardized cannabis symbol that must be obtained from the Minister in the form of an electronic file; and
- **(g)** except in the case of dried cannabis or a cannabis plant, the statement "Contains the equivalent of (the quantity of dried cannabis, in grams, that is equivalent to the quantity of cannabis, in grams or seeds, as the case may be, as determined in accordance with subsection 2(4) of the Act, in the container)g of dried cannabis".

(3) Subsection 123(2) of the Regulations is replaced by the following:

Expiry date

(2) The label of a container in which cannabis other than edible cannabis is packaged must not include an expiry date unless the holder of the licence for processing that manufactured the cannabis product has data that establishes the stability period during which,

after the cannabis is packaged in accordance with these Regulations and stored under its recommended storage conditions,

- **(a)** in the case of dried cannabis or fresh cannabis,
    - **(i)** it maintains not less than 80% and not more than 120% of its THC content and CBD content, and
    - **(ii)** the microbial and chemical contaminants it contains or has on it remain within the limits referred to subsection 93(3); and
- **(b)** in the case of a cannabis extract or a cannabis topical,
    - **(i)** it maintains its THC content and CBD content within the variability limits referred to in subsection 97(1), and
    - **(ii)** the microbial and chemical contaminants it contains or has on it remain within the limits referred to in section 101.1.

No expiry date — edible cannabis

(2.1) The label of a container in which edible cannabis is packaged must not include an expiry date.

(4) The Regulations are amended by adding the following after subsection 123(4):

- **Non-application — sections 26 and 27 of Act**
- **(5)** Sections 26 and 27 of the Act do not apply with respect to the name and email address that are included on the label in accordance with paragraph (1)(a).

39 The Regulations are amended by adding the following after section 123:

Wrapper

123.1 (1) The interior and exterior surface of a wrapper must

- **(a)** not display any brand element;
- **(b)** not display any image or information;
- **(c)** be one uniform colour, which may be different for each surface;
- **(d)** not be fluorescent, have fluorescent properties in the ink or have pigments that absorb ultraviolet energy and transmit it as a longer wavelength, such as the Pantone 800 series;
- **(e)** have a smooth texture without any embossing or decorative ridges;
- **(f)** not include any hidden feature that is designed to change the appearance of the wrapper, such as heat-activated ink or a feature that is visible only through technological means; and
- **(g)** not be capable of emitting a scent or sound.

Standardized cannabis symbol

(2) Despite paragraph (1)(b), the standardized cannabis 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.

Requirements

(3) The standardized cannabis 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.

40 (1) The portion of section 124 of the Regulations before paragraph (a) is replaced by the following:

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

124 In the case of dried cannabis or fresh cannabis — 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 product is packaged must also include the following information:

(2) Paragraphs 124(d) to (g) of the French version of the Regulations is replaced by the following:

- **d)** la quantité de THC, en milligrammes, dans chaque unité, précédée de la mention « THC par unité »;
- **e)** la quantité de THC, en milligrammes, que pourrait produire chaque unité, compte tenu du potentiel de transformation de l'ATHC en THC, précédée de la mention « THC total par unité »;
- **f)** la quantité de CBD, en milligrammes, dans chaque unité, précédée de la mention « CBD par unité »;
- **g)** la quantité de CBD, en milligrammes, que pourrait produire chaque unité, compte tenu du potentiel de transformation de l'ACBD en CBD, précédée de la mention « CBD total par unité »;

(3) Section 124 of the Regulations is amended by striking out "and" at the end of paragraph (f), by adding "and" at the end of paragraph (g) and by adding the following after paragraph (g):

- **(h)** the intended use of the cannabis product.

(4) Section 124 of the Regulations is renumbered as subsection 124(1) and amended by adding the following after subsection (1):

Maximum quantity of THC on label

(2) The quantity of THC that is included, in accordance with paragraph (1)(e), on the label of a container in which is packaged dried cannabis or fresh cannabis — or a cannabis accessory that contains dried cannabis or fresh cannabis — that is intended for ingestion or nasal, rectal or vaginal use must not exceed 10 mg.

41 The Regulations are amended by adding the following after section 124:

Dried cannabis or fresh cannabis — discrete units and intended for inhalation

124.1 In the case of dried cannabis or fresh cannabis — or a cannabis accessory that contains dried cannabis or fresh cannabis — that is in discrete units and is intended to be consumed by means of inhalation, the label of any container in which the cannabis product is packaged must also include the following information:

- **(a)** the net weight, in grams, of dried cannabis or fresh cannabis;
- **(b)** the number of units;
- **(c)** the net weight, in grams, of dried cannabis or fresh cannabis in each unit;
- **(d)** the concentration of THC, in milligrams per gram, preceded by “THC”;
- **(e)** the concentration of THC, in milligrams per gram, that the dried cannabis or fresh cannabis could yield, taking into account the potential to convert THCA into THC, preceded by “Total THC”;
- **(f)** the concentration of CBD, in milligrams per gram, preceded by “CBD”;
- **(g)** 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
- **(h)** the intended use of the cannabis product.

42 Paragraphs 125(b) to (e) of the Regulations are replaced by the following:

- **(b)** the concentration of THC, in milligrams per gram, preceded by “THC”;
- **(c)** the concentration of THC, in milligrams per gram, that the dried cannabis or fresh cannabis could yield, taking into account the potential to convert THCA into THC, preceded by “Total THC”;
- **(d)** the concentration of CBD, in milligrams per gram, preceded by “CBD”; and
- **(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”.

43 Sections 126 and 127 of the Regulations are repealed.

44 (1) Subsection 130(1) of the Regulations is replaced by the following:

Presentation of information — general requirement

130 (1) All information that is included on a label must be in English and in French, except for the INCI name and the EU trivial name.

(2) The portion of paragraph 130(3)(e) of the Regulations before subparagraph (i) is replaced by the following:

- **(e)** in the case of the information required under paragraphs 124(1)(d) to (g), 124.1(d) to (g), 125(b) to (e), 132.1(1)(d) to (g), 132.11(d) to (g), 132.12(1)(b) to (e), 132.15(d) to (g), 132.16(b) to (e), 132.18(1)(c) to (j) and 132.19(1)(b) to (e), it must be

(3) Paragraph 130(4)(b) of the French version of the Regulations is replaced by the following:

- **b)** il ne doit pas être d'une couleur comportant du lustre métallique et l'encre ne doit pas avoir de propriétés métalliques, comme le Pantone métallique et le Pantone métallique premium;

(4) Paragraph 130(5)(d) of the Regulations is replaced by the following:

- **(d)** it must be oriented in such a manner that its text is readable from left to right when the container is displayed or visible under the customary conditions of purchase and use; and

(5) Subparagraphs 130(6)(j)(i) to (iii) of the Regulations are replaced by the following:

- **(i)** left-justified without hyphenation, and
- **(ii)** oriented in such a manner that its text is readable from left to right when the container is displayed or visible under the customary conditions of purchase and use; and

(6) Paragraph 130(7)(c) of the French version of the Regulations is replaced by the following:

- **c)** la force du corps des caractères de la mention est d'au moins 6 points et est inférieure à celle des caractères de la mise en garde;

(7) Paragraph 130(8)(b) of the French version of the Regulations is replaced by the following:

- **b)** la force du corps des caractères est inférieure ou égale à celle des caractères utilisés pour les renseignements visés au paragraphe (3).

(8) Paragraph 130(9)(d) of the Regulations is replaced by the following:

- **(d)** if the brand element is an image, its surface area must be
    - **(i)** in the case where the standardized cannabis 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
    - **(ii)** in any other case, smaller than or equal to 25% of the principal display panel and smaller than or equal to the surface area within the border that surrounds the health warning message that is included on the label in accordance with paragraph (6)(h); and

(9) Paragraph 130(9)(e) of the French version of the Regulations is replaced by the following:

- **b)** dans le cas d'un élément de marque consistant uniquement en du texte, la force du corps des caractères est inférieure ou égale à celle des caractères de la mise en garde.

(10) Section 130 of the Regulations is amended by adding the following after subsection (10):

- **Location of information on irradiation — edible cannabis**
- **(11)** Information that is required to be included on a label under paragraph 132.18(1)(p) or 132.19(1)(k) must be displayed on the principal display panel or, if there are separate principal display panels for English and French, on each principal display panel.

45 Section 131 of the French version of the Regulations is replaced by the following:

Représentation ressemblant au symbole normalisé du cannabis

131 Aucune représentation — notamment une illustration, un signe, une marque, un symbole ou un dessin — ressemblant à s'y méprendre au symbole normalisé du cannabis ne peut figurer sur le contenant dans lequel est emballé un produit du cannabis.

46 The Regulations are amended by adding the following after section 132:

Cannabis extract — discrete units and not intended for inhalation

132.1 (1) In the case of a cannabis extract — or a cannabis accessory that contains a cannabis extract — 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 product is packaged must also include the following information:

- **(a)** the net weight, in grams, of the cannabis extract;
- **(b)** the number of units;
- **(c)** the net weight, in grams, of the cannabis extract in each unit;
- **(d)** the quantity of THC, in milligrams, in each unit, preceded by "THC per unit";
- **(e)** the quantity of THC, in milligrams, that each unit could yield, taking into account the potential to convert THCA into THC, preceded by "Total THC per unit";
- **(f)** the quantity of CBD, in milligrams, in each unit, preceded by "CBD per unit";
- **(g)** the quantity of CBD, in milligrams, that each unit could yield, taking into account the potential to convert CBDA into CBD, preceded by "Total CBD per unit";
- **(h)** a list of the ingredients of the cannabis extract;
- **(i)** the name of any food allergen that is present in the cannabis extract, except as a result of cross-contamination;
- **(j)** the identity of the cannabis product in terms of its common name or in terms of its function; and
- **(k)** the intended use of the cannabis product.

Maximum quantity of THC on label

(2) The quantity of THC that is included on the label, in accordance with paragraph (1)(e), of a container in which is packaged a cannabis extract — or in which is packaged a cannabis accessory that contains a cannabis extract — that is intended for ingestion or nasal, rectal or vaginal use must not exceed 10 mg.

Cannabis extract — discrete units and intended for inhalation

132.11 In the case of a cannabis extract — or a cannabis accessory that contains a cannabis extract — that is in discrete units and is intended to be consumed by means of inhalation, the label of any container in which the cannabis product is packaged must also include the following information:

- **(a)** the net weight, in grams, of the cannabis extract;
- **(b)** the number of units;
- **(c)** the net weight, in grams, of the cannabis extract in each unit;
- **(d)** the concentration of THC, in milligrams per gram, in the cannabis extract, preceded by “THC”;
- **(e)** the concentration of THC, in milligrams per gram, that the cannabis extract could yield, taking into account the potential to convert THCA into THC, preceded by “Total THC”;
- **(f)** the concentration of CBD, in milligrams per gram, in the cannabis extract, preceded by “CBD”;
- **(g)** the concentration of CBD, in milligrams per gram, that the cannabis extract could yield, taking into account the potential to convert CBDA into CBD, preceded by “Total CBD”;
- **(h)** a list of the ingredients of the cannabis extract;
- **(i)** the name of any food allergen that is present in the cannabis extract, except as a result of cross-contamination;
- **(j)** the identity of the cannabis product in terms of its common name or in terms of its function; and
- **(k)** the intended use of the cannabis product.

Cannabis extract — not in discrete units

132.12 (1) In the case of a cannabis extract — or a cannabis accessory that contains a cannabis extract — that is not in discrete units, the label of any container in which the cannabis product is packaged must also include the following information:

- **(a)** the net weight, in grams, of the cannabis extract;
- **(b)** the concentration of THC, in milligrams per gram, in the cannabis extract, preceded by “THC”;
- **(c)** the concentration of THC, in milligrams per gram, that the cannabis extract could yield, taking into account the potential to convert THCA into THC, preceded by “Total THC”;
- **(d)** the concentration of CBD, in milligrams per gram, in the cannabis extract, preceded by “CBD”;
- **(e)** the concentration of CBD, in milligrams per gram, that the cannabis extract could yield, taking into account the potential to convert CBDA into CBD, preceded by “Total CBD”;

- **(f)** in the case of a cannabis accessory that contains a cannabis extract intended for ingestion or nasal, rectal or vaginal use or that is packaged with and is intended to dispense the extract,**(g)** a list of the ingredients of the cannabis extract;
    - **(i)** the quantity of THC, in milligrams, that each activation of the accessory dispenses, taking into account the potential to convert THCA into THC, preceded by "Total THC per activation", and
    - **(ii)** the quantity of CBD, in milligrams, that each activation of the accessory dispenses, taking into account the potential to convert CBDA into CBD, preceded by "Total CBD per activation";
-
- **(h)** the name of any food allergen that is present in the cannabis extract, except as a result of cross-contamination;
- **(i)** the identity of the cannabis product in terms of its common name or in terms of its function; and
- **(j)** the intended use of the cannabis product.

Maximum quantity of THC on label

(2) The quantity of THC that is included on the label in accordance with subparagraph (1)(f)(i) must not exceed 10 mg.

Flavours — cannabis extract

132.13 (1) It is prohibited to display on a cannabis extract that is a cannabis product or on a cannabis accessory that contains a cannabis extract and that is a cannabis product — or on the package of such a cannabis product or on the label or panel of a container in which such a cannabis product is packaged — an indication or illustration, including a brand element, that could cause a person to believe that the cannabis product has a flavour set out in column 1 of Schedule 3 to the *Tobacco and Vaping Products Act*, other than the flavour of cannabis.

Non-application — name and email address

(2) Subsection (1) does not apply with respect to the name and email address that are included on the label in accordance with paragraph 123(1)(a).

List of ingredients — cannabis extract

132.14 (1) The list of ingredients of a cannabis extract — or of a cannabis accessory that contains a cannabis extract — must meet the following requirements:

- **(a)** the word "Ingredients" in the English version and the word "Ingrédients" in the French version must appear at the beginning of the list;
- **(b)** no intervening printed, written or graphic material is to appear between the word referred to in paragraph (a) and the first ingredient in the list; and
- **(c)** the ingredients must be

- **(i)** set out in descending order of their proportion of the cannabis extract by weight, determined before the ingredients are combined to form the extract,
- **(ii)** in the case of vitamins referred to in subsection 101.3(3), set out by their chemical name,
- **(iii)** in any other case, set out by their common name or chemical name, and
- **(iv)** separated from other ingredients by a comma.

Ingredients in proportion of 1% or less

(2) Despite subparagraph (1)(c)(i), ingredients that are present in a proportion of 1% or less of the cannabis extract may be listed in any order after the ingredients that are present in a proportion of more than 1% of the cannabis extract.

Exception — flavouring agent

(3) Despite paragraph (1)(c), in the case where the cannabis 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 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".

No individual listing of flavouring agent

(4) If flavouring agents are shown collectively by the name "flavouring agents" under subsection (3), a flavouring agent must not be shown individually in the list of ingredients.

Cannabis topical — discrete units

132.15 In the case of a cannabis topical — or a cannabis accessory that contains a cannabis topical — that is in discrete units, the label of any container in which the cannabis product is packaged must also include the following information:

- **(a)** the net weight, in grams, of the cannabis topical;
- **(b)** the number of units;
- **(c)** the net weight, in grams, of the cannabis topical in each unit;
- **(d)** either the quantity of THC, in milligrams, or the concentration of THC, in milligrams per gram, in each unit, preceded by "THC per unit";
- **(e)** either the quantity of THC, in milligrams, or the concentration of THC, in milligrams per gram, that each unit could yield, taking into account the potential to convert THCA into THC, preceded by "Total THC per unit";
- **(f)** either the quantity of CBD, in milligrams, or the concentration of CBD, in milligrams per gram, in each unit, preceded by "CBD per unit";
- **(g)** either the quantity of CBD, in milligrams, or the concentration of CBD, in milligrams per gram, that each unit could yield, taking into account the potential to convert CBDA into CBD, preceded by "Total CBD per unit";
- **(h)** a list of the ingredients of the cannabis topical;

- **(i)** the identity of the cannabis product in terms of its common name or in terms of its function; and
- **(j)** the intended use of the cannabis product.

Cannabis topical — not in discrete units

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

- **(a)** the net weight, in grams, of the cannabis topical;
- **(b)** either the quantity of THC, in milligrams, or the concentration of THC, in milligrams per gram, in the cannabis topical, preceded by "THC";
- **(c)** either the quantity of THC, in milligrams, or the concentration of THC, in milligrams per gram, that the cannabis topical could yield, taking into account the potential to convert THCA into THC, preceded by "Total THC";
- **(d)** either the quantity of CBD, in milligrams, or the concentration of CBD, in milligrams per gram, in the cannabis topical, preceded by "CBD";
- **(e)** either the quantity of CBD, in milligrams, or the concentration of CBD, in milligrams per gram, that the cannabis topical could yield, taking into account the potential to convert CBDA into CBD, preceded by "Total CBD";
- **(f)** a list of the ingredients of the cannabis topical;
- **(g)** the identity of the cannabis product in terms of its common name or in terms of its function; and
- **(h)** the intended use of the cannabis product.

List of ingredients – cannabis topical

132.17 (1) The list of ingredients of a cannabis topical — or of a cannabis accessory that contains a cannabis topical — must meet the following requirements:

- **(a)** the word "Ingredients" in the English version and the word "Ingrédients" in the French version must appear at the beginning of the list;
- **(b)** no intervening printed, written or graphic material is to appear between the term referred to in paragraph (a) and the first ingredient in the list; and
- **(c)** the ingredients are to be separated from other ingredients by a comma and shown in descending order of their proportion of the cannabis topical by weight, determined before the ingredients are combined to form the cannabis topical, as follows:
    - **(i)** by their INCI name,
    - **(ii)** if an ingredient has no INCI name, by its chemical name,
    - **(iii)** in the case of a botanical, by specifying at least the genus and species portions of its INCI name or, if it has no INCI name, by its chemical name, or
    - **(iv)** if an ingredient is included in the schedule to the *Cosmetic Regulations*, by its EU trivial name set out in column 1 of that schedule or by the appropriate English and French equivalents set out in columns 2 and 3 of that schedule.

Ingredients in proportion of 1% or less

(2) Despite paragraph (1)(c), ingredients that are present in a proportion of 1% or less and all colouring agents of the cannabis topical may be listed in any order after the ingredients that are present in a proportion of more than 1% of the cannabis topical.

Fragrance and flavour

(3) The word “parfum” or “aroma”, respectively, may be inserted at the end of the list of ingredients to indicate that an ingredient has been added to the cannabis topical to produce a fragrance or flavour.

Definition of *botanical*

(4) For the purposes of this section, ***botanical*** means an ingredient that is directly derived from a plant and that has not been chemically modified before it is used in the production of a cannabis topical.

Edible cannabis — discrete units

132.18 (1) In the case of edible cannabis — or a cannabis accessory that contains edible cannabis — that is in discrete units, the label of any container in which the cannabis product is packaged must also include the following information:

- **(a)** if the edible cannabis is in solid form, its net weight, in grams, and in any other case, its net volume, in millilitres;
- **(b)** the number of units;
- **(c)** the quantity of THC, in milligrams, in each unit, preceded by “THC per unit”;
- **(d)** the quantity of THC, in milligrams, that each unit could yield, taking into account the potential to convert THCA into THC, preceded by “Total THC per unit”;
- **(e)** the quantity of THC, in milligrams, in the edible cannabis, preceded by “THC”;
- **(f)** the quantity of THC, in milligrams, that the edible cannabis could yield, taking into account the potential to convert THCA into THC, preceded by “Total THC”;
- **(g)** the quantity of CBD, in milligrams, in each unit, preceded by “CBD per unit”;
- **(h)** the quantity of CBD, in milligrams, that each unit could yield, taking into account the potential to convert CBDA into CBD, preceded by “Total CBD per unit”;
- **(i)** the quantity of CBD, in milligrams, in the edible cannabis, preceded by “CBD”;
- **(j)** the quantity of CBD, in milligrams, that the edible cannabis could yield, taking into account the potential to convert CBDA into CBD, preceded by “Total CBD”;
- **(k)** a list of the ingredients of the edible cannabis, including constituents, if any;
- **(l)** the source of any food allergen or gluten present in the edible cannabis, except as a result of cross-contamination,
    - **(i)** in a food allergen source, gluten source and added sulphites statement, if the food allergen or gluten
        - **(A)** is, or is present in, an ingredient that is not shown in the list of ingredients, but is not a constituent of that ingredient or present in a constituent of that ingredient, or

        - **(B)** is, or is present in, a constituent and neither the constituent nor the ingredient in which it is present is shown in the list of ingredients, or
    - **(ii)** in all other cases, either in the list of ingredients or in a food allergen source, gluten source and added sulphites statement;
- **(m)** the sulphites that are present in the edible cannabis in an amount of 10 p.p.m. or more,**(n)** a nutrition facts table that contains only the information set out in column 1 of the table to section 132.22, expressed using a description set out in column 2, in the unit set out in column 3 and in the manner set out in column 4;
    - **(i)** if at least one sulphite is required to be shown in the list of ingredients under these Regulations, in the list of ingredients, or in the list of ingredients and in a food allergen source, gluten source and added sulphites statement, or
    - **(ii)** in any other case, in the list of ingredients, in a food allergen source, gluten source and added sulphites statement or in both;
-
- **(o)** the common name of the cannabis product;
- **(p)** if the edible cannabis 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 and constitutes 10% or more of the edible cannabis, the statement "irradiated" preceding any mention of the ingredient or constituent on the label.
    - **(i)** "treated with radiation",
    - **(ii)** "treated by irradiation", or
    - **(iii)** "irradiated"; and
-

Maximum quantity of THC on label

(2) The quantity of THC that is included on the label in accordance with paragraph (1)(f) must not exceed 10 mg.

Ingredient not required to be listed

(3) Despite paragraph (1)(k), if one or more constituents of an ingredient are required by these Regulations to be listed in a list of ingredients, the ingredient is not required to be listed if all constituents of the ingredient are shown in the list by their common names and in accordance with subparagraphs 132.21(1)(c)(i) and (ii).

Risk of cross-contamination

(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 may contain the source of a food allergen or gluten.

Edible cannabis — not in discrete units

132.19 (1) In the case of edible cannabis — or a cannabis accessory that contains edible cannabis — that is not in discrete units, the label of any container in which the cannabis product is packaged must also include the following information:

- **(a)** if the edible cannabis is in solid form, its net weight, in grams, and in any other case, its net volume, in millilitres;
- **(b)** the quantity of THC, in milligrams, in the edible cannabis, preceded by "THC";
- **(c)** the quantity of THC, in milligrams, that the edible cannabis could yield, taking into account the potential to convert THCA into THC, preceded by "Total THC";
- **(d)** the quantity of CBD, in milligrams, in the edible cannabis, preceded by "CBD";
- **(e)** the quantity of CBD, in milligrams, that the edible cannabis could yield, taking into account the potential to convert CBDA into CBD, preceded by "Total CBD";
- **(f)** a list of the ingredients of the edible cannabis, including constituents, if any;
- **(g)** the source of any food allergen or gluten present in the edible cannabis, except as a result of cross-contamination,
    - **(i)** in a food allergen source, gluten source and added sulphites statement, if the food allergen or gluten
        - **(A)** is, or is present in, an ingredient that is not shown in the list of ingredients, but is not a constituent of that ingredient or present in a constituent of that ingredient, or
        - **(B)** is, or is present in, a constituent and neither the constituent nor the ingredient in which it is present is shown in the list of ingredients, or
    - **(ii)** in all other cases, either in the list of ingredients or in a food allergen source, gluten source and added sulphites statement;
- **(h)** the sulphites that are present in the edible cannabis in an amount of 10 p.p.m. or more,**(i)** a nutrition facts table that contains only the information set out in column 1 of the table to section 132.22, expressed using a description set out in column 2, in the unit set out in column 3 and in the manner set out in column 4;
    - **(i)** if at least one sulphite is required to be shown in the list of ingredients under these Regulations, in the list of ingredients, or in the list of ingredients and in a food allergen source, gluten source and added sulphites statement, or
    - **(ii)** in any other case, in the list of ingredients, in a food allergen source, gluten source and added sulphites statement or in both;
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- **(j)** the common name of the cannabis product;
- **(k)** if the edible cannabis 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 and constitutes 10% or more of the edible cannabis, the statement "irradiated" preceding any mention of the ingredient or constituent on the label.

    - **(i)** “treated with radiation”,
    - **(ii)** “treated by irradiation”, or
    - **(iii)** “irradiated”; and
-

Maximum quantity of THC on label

(2) The quantity of THC that is included on the label in accordance with paragraph (1)(c) must not exceed 10 mg.

Ingredient not required to be listed

(3) Despite paragraph (1)(f), if one or more constituents of an ingredient are required by these Regulations to be listed in a list of ingredients, the ingredient is not required to be listed if all constituents of the ingredient are shown in the list by their common names and in accordance with subparagraphs 132.21(1)(c)(i) and (ii).

Risk of cross-contamination

(4) Despite paragraph (1)(g), 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 may contain the source of a food allergen or gluten.

Durable life date required

132.2 (1) In the case of edible cannabis 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 is packaged.

Format of durable life date

(2) Any durable life date on the label of any container in which edible cannabis 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

132.21 (1) The list of ingredients of edible cannabis — or of a cannabis accessory that contains edible cannabis — must meet the following requirements:

- **(a)** the word “Ingredients” in the English version and the word “Ingrédients” in the French version must appear at the beginning of the list;
- **(b)** no intervening printed, written or graphic material is to appear between the word referred to in paragraph (a) and the first ingredient in the list;
- **(c)** the ingredients and constituents must be
    - **(i)** set out in descending order of their proportion of the edible cannabis by weight, determined before the ingredients and the constituents are combined to form the edible cannabis,

    - **(ii)** separated from other ingredients or constituents by a comma, and
    - **(iii)** set out by the applicable name in column II of the table to paragraph B.01.010(3)(a) of the *Food and Drug Regulations* or, if none applies, by their common name;
- **(d)** the constituents of an ingredient must be shown
    - **(i)** set out in parentheses, immediately after the ingredient, unless the source of a food allergen or gluten is set out immediately after the ingredient, in which case the constituent of the ingredient must be set out immediately after that source,
    - **(ii)** set out in descending order of their proportion of the ingredient by weight, determined before they are combined to form the edible cannabis, and
    - **(iii)** separated from other constituents by a comma;
- **(e)** the source of a food allergen or gluten must be
    - **(i)** set out in parentheses,
    - **(ii)** set out immediately after an ingredient that is shown in that list, if the food allergen or gluten
        - **(A)** is the ingredient,
        - **(B)** is present in the ingredient, but is not a constituent of or present in a constituent of that ingredient, or
        - **(C)** is, or is present in, a constituent of the ingredient and the constituent is not shown in the list of ingredients,
    - **(iii)** set out immediately after the constituent that is shown in the list, if the food allergen or gluten is that constituent or is present in that constituent, and
    - **(iv)** separated by a comma from other sources of a food allergen or gluten that is shown for the same ingredient or constituent;
- **(f)** sulphites must be shown
    - **(i)** set out by one of the common names “sulfites”, “sulfiting agents”, “sulphites” or “sulphiting agents”, or individually by the applicable name set out in item 21, column I, of the table to paragraph B.01.010(3)(b) of the *Food and Drug Regulations*,
    - **(ii)** in the case of the name “sodium dithionite”, “sulphur dioxide” or “sulphurous acid”, set out by that name, followed by one of the common names “sulfites”, “sulfiting agents”, “sulphites” or “sulphiting agents” in parentheses, unless
        - **(A)** the word “sulfite” or “sulphite” appears in the common name of another sulphite in the list,

        - **(B)** one of the common names “sulfites”, “sulfiting agents”, “sulphites” or “sulphiting agents” is set out in parentheses following another sulphite in the list, or
        - **(C)** one of the common names “sulfites”, “sulfiting agents”, “sulphites” or “sulphiting agents” is shown in a food allergen source, gluten source and added sulphites statement on the label, and
    - **(iii)** set out at the end of the list where they may be shown in any order with the other ingredients that are shown at the end of that list in accordance with subsection (3) or in parentheses immediately after the ingredient of which they are a constituent; and
- **(g)** if the edible cannabis 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 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 by weight, determined before it is combined to form the edible cannabis, and
        - **(C)** separated from other sugars-based ingredients by a comma.

Exception — ingredients and constituents shown collectively

(2) Despite paragraph (1)(c), the ingredients and the constituents set out in column I of an item of the table to paragraph B.01.010(3)(b) of the *Food and Drug Regulations* may be shown collectively in the list of ingredients by the common name set out in column II of that item, unless one of the ingredients or constituents referred to in that table is shown separately in the list of ingredients by its common name.

Exception — ingredients at the end of the list

(3) Despite subparagraph (1)(c)(i), the ingredients referred to in subsection B.01.008.2(4) of the *Food and Drug Regulations*, regardless of their proportion, may be listed at the end of the list of ingredients, in any order.

Exception — source of food allergen or gluten

(4) Despite paragraph (1)(e), the source of the food allergen or gluten is not required to be set out in parentheses immediately after the ingredient or constituent, as the case may be, if the source of the food allergen or gluten appears

- **(a)** in the list of ingredients**(b)** in the food allergen source, gluten source and added sulphites statement.
    - **(i)** as part of the common name of the ingredient or constituent, or
    - **(ii)** in parentheses, in accordance with subparagraph (1)(e)(i), immediately after another ingredient or constituent; or
-

Nutrition facts table

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 is packaged must be established on the basis of the amount, by weight, of the nutrient per immediate container of edible cannabis, rounded off in the applicable manner set out in column 4 of the table to this section.

Not a significant source of a nutrient

(2) Information with respect to a nutrient set out in column 1 of the table to this section that may be expressed as “0” in the nutrition facts table may be omitted from that table if it includes the statement “Not a significant source of (naming each nutrient that is omitted from the nutrition facts table in accordance with this subsection)”.

Presentation

(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.

TABLE

Information to be Included in the Nutrition Facts Table

Item	Column 1 Information	Column 2 Description	Column 3 Unit	Column 4 Manner of expression
1	Immediate container size	"Per container (naming the amount of edible cannabis 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.
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 containe	**(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

			r.	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.
6	The sum of saturated fatty acids and	"Saturated Fat + Trans Fat", "Saturated Fatty Acids + Trans Fatty Acids", "Saturated + Trans"	The sum is expressed as a percentage of th	The percentage is rounded off

	trans fatty acids	or "Saturates + Trans"	e daily value per immediate container.	• **(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 cho lesterol	"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 sod ium	"Sodium"	The amount is expressed • **(a)** in milligram s per immedia te containe r; and • **(b)** as a percenta ge of the daily value per immedia te containe r.	**(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 car bohydrate	"Carbohydrate", "Total Carbohydrate" or "Carbohydrate,	The amount is expressed in	The amount is rounded

		Total"	grams per immediate container.	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.
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 containe	**(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

			r.	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 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 • **(b)** in all other cases, to the nearest multiple of 1%.
14	Amount of calc	"Calcium"	The amount is	**(1)** The amount is

	ium		expressed • **(a)** in milligrams per immediate container; and • **(b)** as a percentage of the daily value per immediate container.	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 • **(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	**(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

			container.	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%.

Presentation of source of food allergen

132.23 (1) The source of a food allergen required to be shown in the list of ingredients or in the food allergen source, gluten source and added sulphites statement under paragraph 132.18(1)(l) or 132.19(1)(g) must be set out

- **(a)** for a food allergen from a food referred to in one of paragraphs (a), (b) and (e) of the definition *food allergen* in subsection B.01.010.1(1) of the *Food and Drug Regulations* or derived from that food, by the name of the food as shown in the applicable paragraph, expressed in the singular or plural;
- **(b)** for a food allergen from the food referred to in paragraph (c) of the definition *food allergen* in subsection B.01.010.1(1) of the *Food and Drug Regulations* or derived from that food, by the name “sesame”, “sesame seed” or “sesame seeds”;
- **(c)** for a food allergen from a food referred to in paragraph (d) or (f) of the definition *food allergen* in subsection B.01.010.1(1) of the *Food and Drug Regulations* or derived from that food, by the name of the food as shown in the applicable paragraph;
- **(d)** for a food allergen from the food referred to in paragraph (g) of the definition *food allergen* in subsection B.01.010.1(1) of the *Food and Drug Regulations* or derived from that food, by the name “soy”, “soya”, “soybean” or “soybeans”;
- **(e)** for a food allergen from a food referred to in one of paragraphs (h) to (j) of the definition *food allergen* in subsection B.01.010.1(1) of the *Food and Drug Regulations* or derived from that food, by the common name of the food referred to in column II of item 6, 23 or 24 of the table to paragraph B.01.010(3)(a) of the *Food and Drug Regulations*, whichever is applicable; and
- **(f)** for a food allergen from the food referred to in paragraph (k) of the definition *food allergen* in subsection B.01.010.1(1) of the *Food and Drug Regulations* or derived from that food, by the name “mustard”, “mustard seed” or “mustard seeds”.

Presentation of source of gluten

(2) The source of gluten required to be shown in the list of ingredients or in the food allergen source, gluten source and added sulphites statement under paragraph 132.18(1)(l) or 132.19(1)(g) must be set out

- **(a)** for gluten from the grain of a cereal referred to in one of subparagraphs (a)(i) to (v) of the definition *gluten* in subsection B.01.010.1(1) of the *Food and Drug Regulations* or derived from that grain, by the name of the cereal as shown in the applicable subparagraph; and
- **(b)** for gluten from the grain of a hybridized strain created from one or more of the cereals referred to in subparagraphs (a)(i) to (v) of the definition *gluten* in subsection B.01.010.1(1) of the *Food and Drug Regulations* or derived from that grain, by the names of the cereals as shown in the applicable subparagraphs.

Declaration on risk of cross-contamination

132.24 If the label of the container in which edible cannabis is packaged includes a declaration alerting consumers that, due to a risk of cross-contamination, the edible cannabis may contain the source of a food allergen or gluten, the declaration must meet the following requirements:

- **(a)** it must be shown immediately after the food allergen source, gluten source and added sulphites statement or, if there is none, immediately after the list of ingredients, and must appear on the same continuous surface as the statement, if any, and the list of ingredients; and
- **(b)** no intervening printed, written or graphic material is to appear between it and the list of ingredients or statement that immediately precedes it.

Presentation of food allergen statement

132.25 (1) A food allergen source, gluten source and added sulphites statement must meet the following requirements:

- **(a)** the word “Contains” in the English version and the word “Contient” in the French version must appear at the beginning of the list;
- **(b)** no intervening printed, written or graphic material is to appear between the word referred to in paragraph (a) and the rest of the statement;
- **(c)** it must appear on the same continuous surface as the list of ingredients; and
- **(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,
    - **(ii)** each source of any gluten that is present in the edible cannabis, 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 is 10 p.p.m. or more.

No duplication

(2) Despite paragraph (1)(d), the following information is not required to be shown in the statement more than once:

- **(a)** the same source of a food allergen;
- **(b)** the same source of gluten; and
- **(c)** one of the common names “sulfites”, “sulfiting agents”, “sulphites” or “sulphiting agents”.

Constituents not required to be shown on label

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 a cannabis accessory that contains edible cannabis — that is a cannabis product is packaged.

Preparation or mixture

(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, 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 a cannabis accessory that contains edible cannabis — that is a cannabis product is packaged.

Common name

(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 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 to which they are added as if they were ingredients of that edible cannabis.

Constituents required to be shown in list of ingredients

(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 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

132.27 (1) In the case of a cannabis product whose immediate container is too small for all the required information to be displayed on its label in accordance with these Regulations,

- **(a)** the label may extend beyond the exterior display surface; or
- **(b)** either a peel-back or accordion panel may be applied to the container.

Label or panel not easily removed

(2) The label that extends beyond the exterior display surface and the panel must be applied in a manner that they cannot be easily removed from the immediate container.

Panel

(3) The panel must

- **(a)** be able to be resealed;
- **(b)** withstand repeated openings and closings without detaching from the immediate container under customary conditions of use; and
- **(c)** include any of the following information that cannot be included on the label because the immediate container of the cannabis product is too small for all the required information to be displayed in accordance with these Regulations:
    - **(i)** the class of cannabis set out in Schedule 4 to the Act to which the cannabis that is in the immediate container belongs,
    - **(ii)** the recommended storage conditions,
    - **(iii)** the packaging date,
    - **(iv)** except in the case of a cannabis plant, cannabis plant seeds or edible cannabis, either
        - **(A)** the expiry date in accordance with subsection 123(2), or
        - **(B)** a statement that no expiry date has been determined,
    - **(v)** except in the case of dried cannabis or a cannabis plant, the statement "Contains the equivalent of (the quantity of dried cannabis, in grams, that is equivalent to the quantity of cannabis, in grams or seeds, as the case may be, as determined in accordance with subsection 2(4) of the Act, in the immediate container)g of dried cannabis",
    - **(vi)** the list of ingredients of the cannabis product, including constituents, if any,
    - **(vii)** in the case of dried cannabis or fresh cannabis, the net weight,
    - **(viii)** in the case of a cannabis extract,
        - **(A)** the net weight, including the net weight of cannabis extract in each unit, if the cannabis extract is in discrete units,
        - **(B)** the quantity of THC and CBD that is dispensed with each activation of any cannabis accessory that is packaged with or contains the cannabis extract, and
        - **(C)** the name of any food allergen that is present in the product,
    - **(ix)** in the case of a cannabis topical, its net weight, including the net weight of cannabis topical in each unit, if the cannabis topical is in discrete units, and
    - **(x)** in the case of edible cannabis,

- **(A)** if the edible cannabis 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, except as a result of cross-contamination,
- **(D)** sulphites that are present in the edible cannabis in an amount of 10 p.p.m. or more, and
- **(E)** the nutrition facts table.

Interpretation — information on panel

(4) The information included on the panel must be shown in accordance with the provisions of these Regulations with respect to a label as if the panel were a label for the purposes of those provisions.

Brand element

(5) The panel must not display any brand element.

Statement on location of information

(6) The label of an immediate container in which a cannabis 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.

Image

(7) The label referred to in subsection (6) may include an image that is printed in black and white and that provides instructions on how to open the panel.

Information on exterior display surface

(8) In addition to the information that is required under these Regulations, the label referred to in subsection (6) may include

- **(a)** a bar code, in accordance with section 122;
- **(b)** a brand element, in accordance with subsection (9); and
- **(c)** an image, in accordance with subsection 130(10).

Exception — brand element

(9) Despite paragraphs 130(9)(d) and (e), a brand element included on a label that extends beyond the exterior display surface or on a label of a container to which a panel is applied must

- **(a)** if the brand element is an image, be 1.27 cm by 1.27 cm in size or smaller; or
- **(b)** if the brand element is text only, be in a type size that is 7 points or smaller.

Prohibited representation — health and cosmetic benefits

132.28 It is prohibited to make an express or implied representation, including by way of a brand element, on a cannabis product — or on the package of a cannabis product or on the label or panel of a container in which such a cannabis 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 product.

Prohibited representation — energy value and amount of nutrient

132.29 (1) It is prohibited to make an express or implied representation, including by way of a brand element, on edible cannabis that is a cannabis product or on a cannabis accessory that contains edible cannabis and that is a cannabis product — or on the package of such a cannabis product or on the label or panel of a container in which such a cannabis 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*.

Interpretation — nutrition facts table

(2) For greater certainty, subsection (1) does not limit the application of paragraphs 132.18(1)(n) and 132.19(1)(i).

Prohibited representation — dietary requirements

132.3 It is prohibited to make an express or implied representation, including by way of a brand element, on edible cannabis that is a cannabis product or on a cannabis accessory that contains edible cannabis and that is a cannabis product — or on the package of such a cannabis product or on the label or panel of a container in which such a cannabis product is packaged — if there are reasonable grounds to believe that the representation could create the impression that the cannabis product is intended

- **(a)** to meet the particular dietary requirements of an individual**(b)** to meet the dietary requirements of young persons.
    - **(i)** who has a physical or physiological condition as a result of a disease, disorder or injury, or
    - **(ii)** for whom a particular effect, including weight loss, is to be obtained by a controlled intake of food; or
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Prohibited representation — alcoholic beverages

132.31 It is prohibited to make an express or implied representation, including by way of a brand element, on a cannabis product — or on the package of a cannabis product or on the label or panel of a container in which such a cannabis product is packaged — if there are reasonable grounds to believe that the representation could associate the cannabis product with an alcoholic beverage.

Prohibited representation — tobacco products and vaping products

132.32 It is prohibited to make an express or implied representation, including by way of a brand element, on a cannabis product — or on the package of a cannabis product or on the label or panel of a container in which such a cannabis product is packaged — if there are reasonable grounds to believe that the representation could associate the cannabis 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.

Non-application — name and email address

132.33 Section 132.28, subsection 132.29(1) and sections 132.3 to 132.32 do not apply with respect to the name and email address that are included on the label in accordance with paragraph 123(1)(a).

Standardized cannabis symbol on cannabis product intended for inhalation

132.34 (1) The standardized cannabis 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 accessory that contains a cannabis extract and that is a cannabis 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.

Requirements

(2) The standardized cannabis 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.

47 Sections 133 and 134 of the Regulations are replaced by the following:

Net weight and volume

133 The net weight and volume that must be included on the label of a cannabis 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.

Number of discrete units

134 The number of discrete units in a container that is labelled in accordance with sections 124, 124.1, 132.1, 132.11, 132.15 and 132.18 must be equal to the number specified on the label.

Number of immediate containers

134.1 The number of immediate containers in an outermost container that is labelled in accordance with paragraph 122.4(2)(a) must be equal to the number of immediate containers specified on the label.

48 Section 138 of the Regulations is renumbered as subsection 138(1) and is amended by adding the following after subsection (1):

Non-application — name and email address

(2) Sections 26 and 27 of the Act do not apply with respect to the name and email address that are included on the label in accordance with paragraph (1)(a).

49 Section 139 of the Regulations is amended by adding the following in alphabetical order:

common name has the same meaning as in subsection C.01.001(1) of the *Food and Drug Regulations*. (*nom usuel*)

50 Section 141 of the Regulations is repealed.

51 Paragraph 155(a) of the Regulations is replaced by the following:

- **(a)** the applicant does not hold an establishment licence that is necessary to authorize them to conduct, at the site proposed in the application or at a building within the site, the activities in relation to drugs containing cannabis that they intend to conduct there;
- **(a.1)** the Minister of Health suspends, in respect of an activity that the applicant intends to conduct in relation to drugs containing cannabis, an establishment licence that is necessary to authorize the applicant to conduct that activity at the site proposed in the application or at a building within the site;

52 Paragraph 156(a) of the Regulations is replaced by the following:

- **(a)** the Minister of Health suspends, in respect of an activity that the holder of the cannabis drug licence is authorized to conduct under the licence, an establishment licence that is necessary to authorize the holder to conduct that activity at the site or at a building within the site;

53 Paragraph 157(c) of the Regulations is replaced by the following:

- **(c)** the holder of the licence no longer holds an establishment licence that is necessary to authorize them to conduct, at the site or at a building within the site, an activity that is authorized under the cannabis drug licence; and

54 (1) The definition “combination product” in section 196 of the Regulations is repealed.

(2) Section 196 of the Regulations is amended by adding the following in alphabetical order:

common name has the same meaning as in subsection C.01.001(1) of the *Food and Drug Regulations*. (*nom usuel*)

55 Subparagraph 205(c)(i) of the English version of the Regulations is replaced by the following:

- **(i)** a description of the cannabis,

56 Subparagraph 209(c)(i) of the English version of the Regulations is replaced by the following:

- **(i)** a description of the cannabis,

57 Subparagraph 214(c)(i) of the English version of the Regulations is replaced by the following:

- **(i)** a description of the cannabis,

58 Subparagraph 218(c)(i) of the English version of the Regulations is replaced by the following:

- **(i)** a description of the cannabis,

59 (1) The portion of subsection 224(1) of the Regulations before paragraph (a) is replaced by the following:

Inventory

224 (1) A holder of a licence must retain, for each lot or batch of cannabis — other than a cannabis extract, a cannabis topical or edible cannabis — that they produce, a document that contains the following information, as applicable:

(2) Subsection 224(1) of the Regulations is amended by striking out "and" at the end of paragraph (e), by adding "and" at the end of paragraph (f) and by adding the following after paragraph (f):

- **(g)** except in the case of cannabis plants or cannabis plant seeds, any information that is obtained through testing and that relates to the phytocannabinoid and terpene content of the cannabis.

(3) The portion of subsection 224(2) of the Regulations before paragraph (a) is replaced by the following:

Packaging

(2) A holder of a licence must retain, for each lot or batch of cannabis — other than a cannabis extract, a cannabis topical or edible cannabis — that they package, a document that contains the following information:

60 Subsections 225(1) and (2) of the Regulations are replaced by the following:

Inventory — cannabis extract, etc.

225 (1) A holder of a licence must retain, for each lot or batch of cannabis extract, cannabis topical or edible cannabis 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 on that date;
- **(b)** if applicable, the date on which the cannabis extract, cannabis topical or edible cannabis 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 cannabis that is used to produce the cannabis extract, cannabis topical or edible cannabis,
    - **(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 cannabis extract, cannabis topical or edible cannabis is or will become a cannabis product or is or will be contained in a cannabis accessory that is or will become a cannabis product,
    - **(i)** the list of ingredients that is required to appear on the label of the cannabis product, and
    - **(ii)** the net weight, net volume or concentration by weight or volume of each of those ingredients;
- **(e)** if the cannabis extract is or will become a cannabis product or is or will be contained in a cannabis accessory that is or will become a cannabis product,**(f)** any information that is obtained through testing and that relates to the phytocannabinoid and terpene content of the cannabis extract, cannabis topical or edible cannabis.
    - **(i)** an indication of whether each ingredient that is required to appear on the label of the cannabis product is a carrier substance, flavouring agent or substance that is necessary to maintain the quality or stability of the cannabis 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 cannabis product; and
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Exception to subparagraph (1)(d)(ii)

(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.

Exception to subparagraph (1)(e)(i)

(1.2) 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 cannabis product, or a combination of any of these.

Packaging

(2) A holder of a licence must retain, for each lot or batch of cannabis extract, cannabis topical or edible cannabis that they package, a document that contains the following information:

- **(a)** a description of the cannabis extract, cannabis topical or edible cannabis, including the brand name, if applicable;
- **(b)** the date on which the cannabis extract, cannabis topical or edible cannabis is packaged and its net weight or volume on that date; and
- **(c)** in the case of a drug containing cannabis, the strength per unit of the drug.

61 Subsection 226(1) of the Regulations is replaced by the following:

Cannabis obtained from another person

226 (1) A holder of a licence must, if they obtain cannabis from another person, retain a document that contains the following information:

- **(a)** the name of the person from which the cannabis is obtained;
- **(b)** the address of the location at which the cannabis is obtained and, if that location is different from the site or sites at which the cannabis was produced, the address of the site or sites, if known;
- **(c)** the date on which the cannabis is obtained;
- **(d)** the quantity of cannabis that is obtained;
- **(e)** a description of the cannabis, including, if applicable, the brand name;
- **(f)** the lot or batch number of the cannabis;
- **(g)** in the case of a drug containing cannabis, 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, the intended use.

62 The Regulations are amended by adding the following after section 226:

Things to be used as ingredients

226.1 (1) A holder of a licence for 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, 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,**(d)** any lot code or other unique identifier that enables the thing to be traced.
    - **(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
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Retention period

(2) The document must be retained for at least two years after the day on which it is prepared.

Definitions

(3) The following definitions apply in paragraph (1)(c).

CAS registry number means the identification number assigned to a chemical by the Chemical Abstracts Service, a division of the American Chemical Society. (*numéro d'enregistrement CAS*)

common name has the same meaning as in subsection B.01.001(1) of the *Food and Drug Regulations*. (*nom usuel*)

INCI name has the same meaning as in subsection 2(1) of the *Cosmetic Regulations*. (*appellation INCI*)

63 Subsection 227(1) of the Regulations is amended by adding the following after paragraph (f):

- **(f.1)** in the case of a cannabis extract, a cannabis topical or edible cannabis that is a cannabis product or that is contained in a cannabis accessory that is a cannabis product, the list of ingredients that appears on the label of the cannabis product;

64 Paragraph 229(1)(b) of the Regulations is replaced by the following:

- **(b)** the date on which the cannabis is destroyed and its pre-destruction net weight or volume on that date;

65 (1) Paragraph 231(1)(a) of the Regulations is replaced by the following:

- **(a)** for each lot or batch of cannabis any portion of which has been sold or exported, retain a document demonstrating that the cannabis 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;

(2) The portion of paragraph 231(1)(d) of the English version of the Regulations before subparagraph (i) is replaced by the following:

- **(d)** in respect of the testing conducted under Part 5 or to meet the requirements set out in Part 6,

(3) Subparagraph 231(1)(e)(ii) of the Regulations is replaced by the following:

- **(ii)** a document that describes every investigation conducted under paragraph 19(2)(b) or (c) and any measures taken under that paragraph; and

(4) Paragraph 231(3)(b) of the English version of the Regulations is replaced by the following:

- **(b)** each version of the document referred to in subparagraph (1)(d)(i), for at least two years after the day on which the validated methods are replaced or, if the methods have not been replaced, two years after the day on which the licence expires or is revoked.

66 Subsection 235(1) of the Regulations is replaced by the following:

System of control

235 (1) A holder of a licence, other than a licence for analytical testing or a cannabis drug licence must retain, for each lot or batch of cannabis 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).

67 Section 242 of the Regulations is replaced by the following:

Form and manner

242 Except as otherwise provided in these Regulations, documents that are required to be provided to the Minister under this Part, Part 8, subsection 241(7) or section 297 must be provided in the form and manner specified in the document entitled *Form and Manner Requirements – Documents Provided to the Minister for the Purposes of the Cannabis Act*, as amended from time to time and published by the Government of Canada on its website.

68 Subparagraph 292(4)(a)(iii) of the Regulations is replaced by the following:

- **(iii)** except in the case of cannabis plants, it prevents the escape of odours associated with cannabis plant material, and

69 Paragraph 312(3)(g) of the Regulations is replaced by the following:

- **(g)** if there is to be any outdoor production, an indication that the site referred to in paragraph (e) is not adjacent to a school, public playground, daycare facility or other public place frequented mainly by young persons.

70 Subparagraph 322(2)(a)(iii) of the Regulations is replaced by the following:

- **(iii)** it prevents the escape of odours associated with cannabis plant material, and

71 Paragraph 326(1)(b) of the Regulations is replaced by the following:

- **(b)** outdoors if the production site is adjacent to a school, public playground, daycare facility or other public place frequented mainly by young persons.

Transitional Provisions

Words and expressions

72 Words and expressions used in sections 73 to 81 have the same meaning as in the *Cannabis Regulations*.

Exemption — cannabis oil

73 (1) A holder of a licence for processing or a licence for sale is — in respect of their activities in relation to cannabis oil, including in respect of an ingredient and anything that will be used as an ingredient — exempt from the application of the *Cannabis Regulations* if

- **(a) the holder was, on the day before the day on which this section comes into force, authorized to conduct the activities; and**
- **(b) the holder conducts the activities in accordance with the *Cannabis Regulations* as they read immediately before the day on which this section comes into force.**

Exemption — sale or distribution

(2) A person, other than a holder of a licence referred to in subsection (1), that is authorized to sell cannabis is — in respect of the sale or distribution of cannabis oil that they obtain, directly or indirectly, from a holder referred to in subsection (1) that meets the conditions set out in that subsection — exempt from the application of the *Cannabis Regulations* if the person complies with those Regulations as they read immediately before the day on which this section comes into force.

Packaging and labelling

(3) A person that is authorized to sell cannabis oil is, in respect of such a sale, exempt from the application of section 25 of the Act if the cannabis oil is packaged and labelled in accordance with the *Cannabis Regulations* as they read immediately before the day on which this section comes into force.

Cessation of effect

(4) This section ceases to have effect on the day that, in the 12th month after the month in which this section comes into force, has the same calendar number as the day on which it comes into force or, if that 12th month has no day with that number, the last day of that 12th month.

Exemption — section 79

74 A holder of a licence that, before the day on which this section comes into force, initiated or completed any activity in relation to the production, packaging, labelling, storing, sampling or testing of dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds in accordance with Part 5 of the *Cannabis Regulations* as they read immediately before the day on which this section comes into force is exempt from the application of section 79 of the *Cannabis Regulations* if

- **(a) the licence holder was, on the day before the day on which this section comes into force, authorized to conduct the activities; and**
- **(b) from the day on which this section comes into force, the licence holder conducts all remaining activities in relation to the production, packaging, labelling, storing, sampling or testing of such cannabis in accordance with Part 5 of the *Cannabis Regulations*.**

Exemption — dried and fresh cannabis

75 (1) Dried cannabis or fresh cannabis is exempt from the application of subsection 93(3) of the *Cannabis Regulations* if the dried cannabi s or fresh cannabis meets the requirements of subsection 94(1) of those Regulations as they read immediately before the day on which this section comes into force.

Cessation of effect

(2) This section ceases to have effect on the day that, in the 12th month after the month in which this section comes into force, has the same calendar number as the day on which it comes into force or, if that 12th month has no day with that number, the last day of that 12th month.

Exemption — more than one immediate container

76 (1) A holder of a licence is — in respect of their activities in relation to dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds that are cannabis products or that are contained in a cannabis accessory that is a cannabis product — exempt from the application of paragraph 122.4(1)(c) of the *Cannabis Regulations* if the holder was, on the day before the day on which this section comes into force, authorized to conduct the activities.

Exemption — holder of licence

(2) A holder of a licence for cultivation or a licence for processing that is authorized to sell dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds that are cannabis products — or that are contained in a cannabis accessory that is a cannabis product — is, in respect of such a sale, exempt from the application of section 25 of the Act if the cannabis product is packaged and labelled in accordance with sections 72 to 81, as applicable, and the *Cannabis Regulations*, other than paragraph 122.4(1)(c).

Exemption — other person

(3) A person, other than a holder of a licence for cultivation or a licence for processing, that is authorized to sell dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds that are cannabis products — or that are contained in a cannabis accessory that is a cannabis product — is, in respect of such a sale, exempt from the application of section 25 of the Act if the cannabis product is packaged and labelled in accordance with sections 72 to 81, as applicable, and the *Cannabis Regulations*, other than paragraph 122.4(1)(c).

Cessation of effect

(4) Subsections (1) and (2) cease to have effect on the day that, in the 12th month after the month in which this section comes into force, has the same calendar number as the day on which it comes into force or, if that 12th month has no day with that number, the last day of that 12th month.

Exemption — health warning messages

77 (1) A holder of a licence is — in respect of their activities in relation to dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds that are cannabis products or that are contained in a cannabis accessory that is a cannabis product — exempt from the application of paragraph 123(1)(e) of the *Cannabis Regulations*, if:

- **(a) the holder was, on the day before the day on which this section comes into force, authorized to conduct the activities;**
- **(b) one of the following health warning messages is included on the label that is applied to any container in which the cannabis product is packaged:(c) the health warning messages referred to in paragraph (b) are displayed in rotation on each type of container of each brand name of the cannabis 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.**
    - **(i) in the case of dried cannabis or a cannabis accessory that contains dried cannabis, one of the health warning messages set out in Part 1 of the document entitled *Cannabis Health Warning Messages*, as it read immediately before the coming into force of this section, or**

- (ii) in any other case, one of the health warning messages set out in Part 2 of that document, as it read immediately before the coming into force of this section; and

Exemption — holder of licence

(2) A holder of a licence for cultivation or a licence for processing that is authorized to sell dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds that are cannabis products — or that are contained in a cannabis accessory that is a cannabis product — is, in respect of such a sale, exempt from the application of section 25 of the Act if the cannabis product is packaged and labelled in accordance with sections 72 to 81, as applicable, and the *Cannabis Regulations*, other than paragraph 123(1)(e).

Exemption — other person

(3) A person, other than a holder of a licence for cultivation or a licence for processing, that is authorized to sell dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds that are cannabis products — or that are contained in a cannabis accessory that is a cannabis product — is, in respect of such a sale, exempt from the application of section 25 of the Act if the cannabis product is packaged and labelled in accordance with sections 72 to 81, as applicable, and the *Cannabis Regulations*, other than paragraph 123(1)(e).

Cessation of effect

(4) Subsections (1) and (2) cease to have effect on the day that, in the 12th month after the month in which this section comes into force, has the same calendar number as the day on which it comes into force or, if that 12th month has no day with that number, the last day of that 12th month.

Exemption — statement on quantity of cannabis

78 (1) A holder of a licence is — in respect of their activities in relation to fresh cannabis or cannabis plant seeds that are cannabis products or that are contained in a cannabis accessory that is a cannabis product — exempt from the application of paragraph 123(1)(g) of the *Cannabis Regulations* if the holder was, on the day before the day on which this section comes into force, authorized to conduct the activities.

Exemption — holder of licence

(2) A holder of a licence for cultivation or a licence for processing that is authorized to sell fresh cannabis or cannabis plant seeds that are cannabis products — or that are contained in a cannabis accessory that is a cannabis product — is, in respect of such a sale, exempt from the application of section 25 of the Act if the cannabis product is packaged and labelled in accordance with sections 72 to 81, as applicable, and the *Cannabis Regulations*, other than paragraph 123(1)(g).

Exemption — other person

(3) A person, other than a holder of a licence for cultivation or a licence for processing, that is authorized to sell fresh cannabis or cannabis plant seeds that are cannabis products — or that are contained in a cannabis accessory that is a cannabis product — is, in respect of such a sale, exempt from the application of section 25 of the Act if the cannabis product is packaged and labelled in accordance with sections 72 to 81, as applicable, and the *Cannabis Regulations*, other than paragraph 123(1)(g).

Cessation of effect

(4) Subsections (1) and (2) cease to have effect on the day that, in the 12th month after the month in which this section comes into force, has the same calendar number as the day on which it comes into force or, if that 12th month has no day with that number, the last day of that 12th month.

Exemption — labelling for dried cannabis and fresh cannabis

79 (1) A holder of a licence is — in respect of their activities in relation to dried cannabis or fresh cannabis that are cannabis products or that are contained in a cannabis accessory that is a cannabis product — exempt from the application of sections 124, 124.1 and 125 of the *Cannabis Regulations* if

- **(a) the holder was, on the day before the day on which this section comes into force, authorized to conduct the activities; and**
- **(b) the holder conducts the activities in accordance with sections 124 and 125 of the *Cannabis Regulations*, as applicable and as they read immediately before the day on which this section comes into force.**

Exemption — holder of licence

(2) A holder of a licence for cultivation or a licence for processing that is authorized to sell dried cannabis or fresh cannabis that are cannabis products — or that are contained in a cannabis accessory that is a cannabis product — is, in respect of such a sale, exempt from the application of section 25 of the Act if the cannabis product is packaged and labelled in accordance with

- **(a) sections 124 and 125 of the *Cannabis Regulations*, as applicable and as they read immediately before the day on which this section comes into force;**
- **(b) sections 72 to 81, as applicable; and**
- **(c) the *Cannabis Regulations*, other than sections 124, 124.1 and 125.**

Exemption — other person

(3) A person, other than a holder of a licence for cultivation or a licence for processing, that is authorized to sell dried cannabis or fresh cannabis that are cannabis products — or that are contained in a cannabis accessory that is a cannabis product — is, in respect of such a sale, exempt from the application of section 25 of the Act if the cannabis product is packaged and labelled in accordance with

- **(a) sections 124 and 125 of the *Cannabis Regulations*, as applicable and as they read immediately before the day on which this section comes into force;**
- **(b) sections 72 to 81, as applicable; and**
- **(c) the *Cannabis Regulations*, other than sections 124, 124.1 and 125.**

Cessation of effect

(4) Subsections (1) and (2) cease to have effect on the day that, in the 12th month after the month in which this section comes into force, has the same calendar number as the day on which it comes into force or, if that 12th month has no day with that number, the last day of that 12th month.

Exemption — size of brand element

80 (1) A holder of a licence is — in respect of their activities in relation to dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds that are cannabis products or that are contained in a cannabis accessory that is a cannabis product — exempt from the application of subparagraph 130(9)(d)(ii) of the *Cannabis Regulations* if the hold er was, on the day before the day on which this section comes into force, authorized to conduct the activities.

Exemption — holder of licence

(2) A holder of a licence for cultivation or a licence for processing that is authorized to sell dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds that are cannabis products — or that are contained in a cannabis accessory that is a cannabis product — is, in respect of such a sale, exempt from the application of section 25 of the Act if the cannabis product is packaged and labelled in accordance with sections 72 to 81, as applicable, and the *Cannabis Regulations*, other than paragraph 130(9)(d)(ii).

Exemption — other person

(3) A person, other than a holder of a licence for cultivation or a licence for processing, that is authorized to sell dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds that are cannabis products — or that are contained in a cannabis accessory that is a cannabis product — is, in respect of such a sale, exempt from the application of section 25 of the Act if the cannabis product is packaged and labelled in accordance with sections 72 to 81, as applicable, and the *Cannabis Regulations*, other than subparagraph 130(9)(d)(ii).

Cessation of effect

(4) Subsections (1) and (2) cease to have effect on the day that, in the 12th month after the month in which this section comes into force, has the same calendar number as the day on which it comes into force or, if that 12th month has no day with that number, the last day of that 12th month.

Activities prior to coming into force

81 (1) It is prohibited for a holder of a licence to sell, distribute or export a cannabis extract, a cannabis topical or edible cannabis — or a cannabis accessory that contains any of these — that was produced, packaged, labelled, stored, sampled or tested before the day on which this section comes into force, unless at the time it was produced, packaged, labelled, stored, sampled or tested

- **(a) the applicable requirements set out in Parts 5, 6 and 11 of the *Cannabis Regulations* were met; and**
- **(b) the requirements set out in subsections 19(1) and (1.1) of the *Cannabis Regulations* were met.**

Application

(2) Subsection (1) applies to the cannabis extract, cannabis topical or edible cannabis — or the cannabis accessory that contains any of these — whether it is a cannabis product or not.

Coming into Force

S.C. 2018, c. 16

82 (1) Subject to subsection (2), these Regulations come into force on the day on which section 193.1 of the *Cannabis Act* comes into force, but if they are registered after that day, they come into force on the day on which they are registered.

First anniversary

(2) Subsection 1(2) comes into force on the first anniversary of the day on which section 2 comes into force.

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations or the Order*.)

Executive summary

Issues: On October 17, 2019, the legal sale of edible cannabis, cannabis extracts, and cannabis topicals will be authorized under the *Cannabis Act*. Amendments to the *Cannabis Regulations* are required to address the public health and public safety risks of these new classes of cannabis, including their appeal to youth and the risks of accidental consumption, overconsumption, and foodborne illness, among other risks.

Description: As per section 193.1 and subsection 226(2) of the *Cannabis Act*, “edibles containing cannabis” and “cannabis concentrates” will be added to Schedule 4 to the Act (*Classes of Cannabis That an Authorized Person May Sell*) on October 17, 2019.

On the same day, the *Order Amending Schedules 3 and 4 to the Cannabis Act* will amend Schedule 4 to delete “edibles containing cannabis” and

“cannabis concentrates” and add “edible cannabis,” “cannabis extracts,” and “cannabis topicals.” Twelve months later (i.e. on October 17, 2020), the Order will delete “cannabis oil” from Schedule 4.

The *Regulations Amending the Cannabis Regulations (New Classes of Cannabis)* establish new regulatory controls to address the public health and public safety risks associated with these new classes of cannabis. These controls include restrictions on product composition and ingredients, tetrahydrocannabinol (THC) limits, and new requirements pertaining to promotion, packaging and labelling, good production practices and record keeping. These amendments will also enable a comprehensive range of product forms within the new classes, consistent with the objective of enabling the legal industry to displace the illegal industry.

Rationale: Proposed regulations for edible cannabis, cannabis extracts, and cannabis topicals were published in the *Canada Gazette*, Part I, on December 22, 2018. These were subject to a 60-day public comment period which ended on February 20, 2019.

During the 60-day public comment period, Health Canada received nearly 6 800 responses to an online questionnaire, and 350 written submissions. Health Canada also held bilateral meetings with all provinces and territories, and targeted consultations with interested parties and partners. All input received during the public consultation was considered in the development of the final regulations.

The amendments to the Regulations are expected to result in a net cost of approximately $41.2 million net present value (PV) over a 10-year period (or $5.9 million annually). These costs will be borne primarily by federal licence holders. The public health and public safety benefits resulting from these amendments are expected to outweigh these costs. As required by the “One-for-One” Rule, the incremental increase in administrative burden for industry resulting from these amendments has been estimated at $352,876 PV over the 10-year period, in 2012 dollars (or $50,242 annually).

Issues

The *Cannabis Act* (the Act) will authorize the legal sale of “edibles containing cannabis” and “cannabis concentrates” on October 17, 2019, by adding these new classes of cannabis to Schedule 4 to the Act (*Classes of Cannabis That an Authorized Person May Sell*).

On that same date, the *Order Amending Schedules 3 and 4 to the Cannabis Act* (the Order) will amend Schedule 4 to the Act to delete “edibles containing cannabis” and “cannabis concentrates,” and add the following three new classes of cannabis:

- **Edible cannabis:** products containing cannabis that are intended to be consumed in the same manner as food (i.e. eaten or drunk);
- **Cannabis extracts:** products that are produced from cannabis using extraction processing methods or by synthesizing phytocannabinoids; and
- **Cannabis topicals:** products that include cannabis and that are intended to be used exclusively on external body surfaces (e.g. skin, hair, and nails).

Consistent with the comprehensive public health approach to the regulation of all cannabis products established by the *Cannabis Regulations* (the Regulations), a

series of targeted amendments to the Regulations are required to address the public health and public safety risks of these new classes of cannabis. The amendments will also enable a comprehensive range of cannabis product forms, consistent with the objective of enabling the legal industry to displace the illegal industry. These amendments will come into force on October 17, 2019.

Background

In the 2015 Speech from the Throne, the Government of Canada committed to legalizing, strictly regulating, and restricting access to cannabis. In June 2016, the Task Force on Cannabis Legalization and Regulation (the Task Force) was established. Composed of nine distinguished experts in public health, substance use, law enforcement and justice, the Task Force was mandated to consult broadly with Canadians and to provide advice on the design of a new legislative and regulatory framework. The Task Force consulted extensively on a detailed discussion paper with provinces and territories, Indigenous governments and organizations and experts in relevant fields, including public health, substance use, criminal justice, law enforcement and industry, as well as with youth.

The Task Force received more than 30 000 responses to its public consultation and more than 300 written submissions from organizations or individuals. It delivered its final report, A Framework for the Legalization and Regulation of Cannabis in Canada, on December 13, 2016. In it, the Task Force made 85 recommendations for the establishment of a comprehensive framework for the legalization and regulation of cannabis across five themes: minimizing harms of use; establishing a safe and responsible supply chain; enforcing public safety and protection; medical access; and implementation.

On April 13, 2017, the Government of Canada introduced Bill C-45 (the Cannabis Act) in the House of Commons. Based in large part on the advice provided by the Task Force, the Act created the foundation for a comprehensive national framework to provide restricted access to regulated cannabis, and to control its production, distribution, sale, importation, exportation, and possession. Following Parliamentary study, the Act received royal assent on June 21, 2018, and was brought into force on October 17, 2018.

As set out in section 7, the purpose of the Act is to protect public health and public safety and in particular to

- protect the health of young persons (i.e. individuals under 18 years of age) by restricting their access to cannabis;
- protect young persons and others from inducements to use cannabis;
- provide for the legal production of cannabis to reduce illegal activities in relation to cannabis;
- deter illegal activities in relation to cannabis through appropriate sanctions and enforcement measures;
- reduce the burden on the criminal justice system in relation to cannabis;
- provide access to a quality-controlled supply of cannabis; and
- enhance public awareness of the health risks associated with cannabis use.

The *Cannabis Regulations*, which also came into force on October 17, 2018, established the rules and standards that apply to the authorized production, distribution, sale, importation and exportation of cannabis (with the exception of industrial hemp), as well as other

related activities respecting the five classes of cannabis (i.e. dried cannabis, fresh cannabis, cannabis oil, cannabis plants, and cannabis plant seeds) that can currently be sold by authorized persons.

The *Cannabis Regulations* set out a comprehensive public health approach to regulating the production, packaging and labelling of all classes of cannabis. More specifically, under the Regulations,

- licences are required in order to cultivate or process cannabis, to sell cannabis for medical purposes, to manufacture prescription drugs containing cannabis, or to conduct analytical testing of or research with cannabis;
- licence holders are subject to strict physical and personnel security requirements;
- the production of cannabis products by licence holders is subject to strict rules and standards, including limits on tetrahydrocannabinol (THC) content and the use of additives, as well as good production practices;
- plain packaging and labelling is required for cannabis products, including strict limits on the use of logos, colours, and branding; and
- continued access to cannabis for medical purposes is provided for patients who need it.

Further information on the Regulations is available in the Regulatory Impact Analysis Statement that was published in the Canada Gazette, Part II, on July 11, 2018.

Objective

The purpose of the *Cannabis Act* is to protect public health and public safety, including by providing access to a quality-controlled supply of cannabis, and by enhancing public awareness of the health risks associated with cannabis use. Amendments to Schedule 4 to the Act will be made to permit a broader diversity of cannabis products to be legally sold in Canada, consistent with the Government of Canada's objective of enabling the legal cannabis industry to displace the illegal market.

Building on the framework established by the current Regulations, a series of targeted amendments to the Regulations will be made to establish new regulatory controls to address the public health and public safety risks associated with edible cannabis, cannabis extracts, and cannabis topicals. In particular, the amendments aim to reduce the

- appeal of such products to youth;
- risk of accidental consumption, especially of edible cannabis, including by youth;
- risk of overconsumption associated with edible cannabis (because of the delay in experiencing the effects of cannabis when it is ingested rather than inhaled) and cannabis products with a higher concentration of THC;
- risk of foodborne illness associated with the production and consumption of edible cannabis;
- risk of dependence and other negative health outcomes associated with cannabis products with a higher concentration of THC or cannabis products that contain ethyl alcohol or caffeine; and
- potential health and, in some cases, safety risks associated with the use of certain solvents, carriers, and diluents.

The amendments focus on those requirements necessary to regulate the new classes of cannabis, and are based on the following policy principles:

- *New classes of cannabis are integrated into the existing cannabis control framework*: Consistent with the Government of Canada's stated public health and public safety objectives, all cannabis products will be strictly regulated under the *Cannabis Act* and its regulations.
- *New requirements are evidence-informed*: New regulatory requirements are based on the best-available public health information on the risks and harms posed by these new classes of cannabis, as well as relevant experience from United States (U.S.) jurisdictions that have legalized and regulated access to cannabis.
- *New requirements are consistent with analogous regulatory frameworks*: To the extent that they support the Government's stated public health and public safety objectives, new regulatory requirements draw from, and are consistent with, other relevant control frameworks, including those for food, vaping products and cosmetics.
- *Amendments will enable a comprehensive range of product forms*: Consistent with the objective of enabling the legal industry to displace the illegal industry as set out in section 7 of the Act, amendments to the Regulations were developed with a view to enabling a comprehensive range of product forms intended for human use within the new classes of cannabis.

Finally, a number of amendments to the Regulations will be made to clarify the original policy intent behind certain provisions of the Act and Regulations, to maintain and improve the overall quality control of legally produced cannabis products (e.g. new requirements pertaining to good production practices that would apply to all licence holders), or to address feedback received during the 60-day public consultation on the proposed amendments to the Regulations.

Description

Schedule 4 to the *Cannabis Act* will be amended by order in council to add three new classes of cannabis that could be sold by authorized persons, namely "edible cannabis," "cannabis extracts," and "cannabis topicals." The Order will delete "cannabis oil" from Schedule 4 one year after the amended Regulations come into force (i.e. on October 17, 2020). While cannabis oil will cease to exist as a standalone class of cannabis on this date, cannabis oil products will continue to exist under the new product classes.

As will be described further below, the most significant amendments to the Regulations will be made to Part 5 (Good Production Practices), Part 6 (Products), Part 7 (Packaging and Labelling), and Part 11 (Record Keeping). In addition, a new Part (Part 6.1) will be added to the Regulations, dealing with Promotion.

Amendments to Schedule 4

Schedule 4 to the Act (*Classes of Cannabis That an Authorized Person May Sell*) sets out the classes of cannabis that can legally be sold by "authorized persons," including federal licence holders and provincially and territorially authorized distributors and sellers. Currently, the following five classes of cannabis are listed on Schedule 4: dried cannabis, cannabis oil, fresh cannabis, cannabis plants, and cannabis plant seeds.

As per section 193.1 and subsection 226(2) of the Act, “edibles containing cannabis” and “cannabis concentrates” will be added to Schedule 4 on October 17, 2019.

On the same day, the *Order Amending Schedules 3 and 4 to the Cannabis Act* will amend Schedule 4 to delete “edibles containing cannabis” and “cannabis concentrates” and add “edible cannabis,” “cannabis extracts,” and “cannabis topicals.” Twelve months later (i.e. on October 17, 2020), the Order will delete “cannabis oil” from Schedule 4.

While the term “cannabis concentrates” will not be one of the new permitted classes of cannabis listed on Schedule 4, the new classes of cannabis will nonetheless permit the legal production and sale of cannabis products with higher concentrations of THC, consistent with the intent of Parliament.

Licensing

Part 2 of the Regulations establishes the classes (e.g. cultivation, processing, sale) and subclasses (e.g. standard and micro-cultivation, standard and micro-processing) of licences that authorize activities with cannabis at the federal level, as well as the rules and requirements that apply to each licence class and subclass.

No major amendments to Part 2 are proposed. As is currently the case for dried cannabis, fresh cannabis and cannabis oil, a processing licence (standard or micro) will be required in order to produce edible cannabis, cannabis extracts and cannabis topicals, and to package and label these types of cannabis products for sale to consumers. In order to sell products within the new classes of cannabis, individual licensed processors will need to apply to Health Canada to amend their licence.

The following amendments to Part 2 will be made:

- A past conviction for an offence under the *Safe Food for Canadians Act* (SFCA) or any of the Acts that were repealed when the SFCA came into force will be added as grounds for the refusal to issue, renew or amend a processing licence, or to revoke a processing licence, if the conviction occurred within the preceding 10 years. Such a conviction will also be grounds to revoke a processing licence should the conviction occur after a licence has been issued.
- Not having a cannabis licence issued under the *Excise Tax Act, 2001*, or having such a licence suspended, will be added as grounds for the suspension of a processing licence, if an excise tax licence is required.
- Section 19 of the Regulations states that a licensed processor must retain the services of one individual with the required training, experience and technical knowledge to act as a quality assurance person (QAP). The Regulations will specify that the QAP will need to have the required qualifications to oversee the quality of cannabis for sale, including training, experience, and technical knowledge of good production practices and product rules applicable to the classes of cannabis being produced. In the event that the QAP does not have the requisite training, experience and technical knowledge with respect to edible cannabis, the licence holder will be required to retain the services of another individual with the required qualifications.

- Section 46 of the Regulations requires licence holders to establish and maintain a system of control to support efficient product recalls. Building on that requirement, licence holders will need to conduct, at least once every 12 months, a recall simulation to evaluate the effectiveness of their recall systems and processes, and prepare a document detailing how the simulation was conducted and the results. This document will need to be kept for at least two years. This is adapted from a requirement under the *Safe Food for Canadians Regulations* (SFCR).
- It will be prohibited for provincially and territorially authorized sellers to sell cannabis products that they know are subject to a voluntary recall in Canada, provided the recall is for reasons of non-compliance with Parts of the Regulations dealing with products and good production practices (i.e. Parts 5 and 6), or for reasons related to the quality of the product (e.g. the product presents a risk of injury to human health). This prohibition will authorize Health Canada to take action against provincially and territorially authorized sellers who do not take necessary actions, including seizing and detaining recalled products.
- Section 4 of the Regulations will be amended to allow for the distribution of cannabis between licensed analytical testers, government laboratories involved in the testing of cannabis, and laboratories designated as accredited laboratories under the *Seeds Act*, to facilitate the testing of cannabis. Research licence holders will also be able to distribute cannabis to government laboratories involved in the testing of cannabis and accredited laboratories under the *Seeds Act*.

Personnel and physical security

Parts 3 and 4 of the Regulations set out requirements pertaining to security clearances and physical security measures, respectively. No amendments are proposed to either part. Licence holders conducting activities with the new classes of cannabis will be subject to the same strict physical and personnel security requirements established under the Regulations.

Good production practices

Part 5 of the Regulations establishes requirements pertaining to the production, distribution and storage of cannabis to control the quality of cannabis produced by federal licence holders (i.e. good production practices). Requirements set out in Part 5 apply to many aspects of the production process, including the equipment being used, the sanitation program, quality assurance, storage and distribution of cannabis products, and standard operating procedures.

Part 5 will be amended to incorporate additional good production practices to prevent contamination of the new classes of cannabis, which must be produced in accordance with the amended Regulations. Many of these new requirements have been adapted from the SFCR, and aim to address the risk of foodborne illness associated with edible cannabis. For example:

- Requirements that pertain to the cleanliness of equipment used with cannabis or ingredients will be expanded to also include conveyances (in this context, the term “conveyance” refers to anything that is used within the licensed facility to transport cannabis or ingredients used in the production of cannabis products; an

example would be a forklift or hand lift), consistent with the SFCR (the requirement would apply to both licensed cultivators and licensed processors).

- Building on existing air filtration requirements (which were designed to prevent the escape of odours associated with cannabis plants), there will be a new requirement to have a ventilation system (whether natural or mechanical) that provides clean air and removes unclean air that may have a negative impact on the cannabis or ingredients. This new requirement will not apply in areas of a building where cannabis is being cultivated under a cultivation licence. This measure is intended to prevent contamination, and is consistent with measures under the SFCR.
- Sanitation program requirements will be expanded to explicitly require hand cleaning and sanitizing stations and lavatories on a licensed site, if necessary, to prevent the contamination of cannabis or ingredients. There will also be a new requirement (that will apply to licensed processors only) pertaining to employee clothing, footwear, and protective coverings. Both new requirements are consistent with the SFCR. While current sanitation program requirements under the Regulations do not explicitly include such requirements, it is anticipated that most, if not all, of the new elements already form part of sanitation programs in place at most licensed sites.
- Existing controls designed to prevent the contamination of cannabis will be expanded to also cover ingredients intended to form part of a cannabis product (licensed processors only).
- Consistent with the SFCR, licensed processors (that produce edible cannabis or cannabis extracts) will be required to prepare, retain, maintain and implement a written preventive control plan (PCP) to identify and address through effective control measures any potential hazards that pose a risk of contamination for these products. The QAP will be required to sign-off on the PCP prior to its implementation. Furthermore, the PCP will need to include documents that show evidence that the requirements of the PCP have been met.
- Employees of licensed processors who conduct activities involving edible cannabis (or ingredients used in the production of edible cannabis) will be required to have the necessary competencies and qualifications to carry out their duties, consistent with the SFCR.
- Currently, the QAP is required to investigate every complaint received in respect of the quality of the cannabis and to take measures to address any identified risk. Under the amended Regulations, the QAP will be required to proactively conduct investigations (or to ensure that such an investigation is conducted on their behalf) if they suspect that cannabis or an ingredient presents a risk of injury to human health or does not meet requirements in Part 5 or Part 6 of the Regulations. If their investigation confirms their suspicions, they must immediately take measures to mitigate any risk. The new requirement, which is adapted from the SFCR, will apply to situations such as where the QAP suspects that an ingredient has been improperly stored, resulting in contamination that presents a risk to human health.
- Licensed processors will need to ensure that steps are taken so that animals are not able to enter into any building or part of a building where cannabis is being produced. While this requirement is taken from the SFCR, it will apply to all licensed processors (not just those processing edible cannabis). Notwithstanding this requirement, if a licensed processor is also a licensed cultivator, the use of beneficial insects (e.g. lady bugs) in cultivation areas within the same building will continue to be permitted.
- There will be a requirement that any water (including ice or steam used in the production of a cannabis product) coming into contact with cannabis or an ingredient be potable, unless the water does not present a risk of contamination,

consistent with the SFCR. This requirement will apply to licensed processors producing the new classes of cannabis.

- The amended Regulations will also clarify that holders of an analytical testing or research licence will not automatically be subject to the good production practice requirements set out in Part 5, given that, in general, cannabis handled by these licence holders is not consumed by human beings. Researchers may be required to comply with good production practice requirements as a condition of their licence, depending on the activity they are conducting. For example, a researcher administering cannabis to a human test subject would need to ensure that the cannabis meets quality-control requirements. Holders of an analytical testing licence will still need to use validated methodologies when conducting testing.

A number of measures will be added to the Regulations to prevent the contamination of cannabis or ingredients. Licensed processors will be required to separate incompatible activities and ensure that contaminated waste is disposed of properly. Licensed processors producing cannabis will also be required to identify and place contaminated ingredients in a designated area within their site, consistent with the SFCR. Furthermore, the requirement (section 80 of the Regulations) to prepare standard operating procedures for the production, packaging, labelling, distribution, storage, sampling, and testing of cannabis will be amended to extend its application to ingredients used in the production of cannabis products. These amendments will require that all such activities must be conducted in accordance with the applicable requirements set out in both Part 5 and Part 6 of the Regulations (currently, section 80 applies only to cannabis, and specifies only that activities must be conducted in accordance with Part 5).

The amendments to the Regulations specify that good production practice requirements will apply only to activities involving ingredients that are conducted by a licence holder, and not to the manufacturers of any such ingredients. For example, a manufacturer of flour that is used as an ingredient in edible cannabis will not be required to follow the good production practices set out in the Regulations when manufacturing the flour, as these activities are already covered by other acts and regulations.

In addition, if a licence holder chooses to process cannabis and food products on the same site, then the production, packaging, labelling, and storage of cannabis and the production, packaging, and labelling of food products will need to be conducted in separate buildings. As will be described further under the “Consultation” section, below, considerable feedback was received on this proposal during the public consultation on the proposed regulations. This provision is a key strategy to mitigate against the food safety and public health concerns associated with multiproduct manufacturing facilities, and in particular to mitigate against the risks of cross-contamination between ingredients and products, and the increased risk of mislabeling and product mix-ups. It is intended to provide Canadians and Canada’s international trade partners and importers of Canadian food products with assurance that all possible measures have been taken to reduce the risk of cross-contamination of Canadian food products with cannabis. To that end, this requirement will apply to all classes of cannabis (not just to edible cannabis) — that is, the amended Regulations will require that any cannabis production occur in a separate building from any food production.

Testing

Part 5 of the Regulations also sets out requirements pertaining to the sampling and testing of cannabis. The current Regulations require that the following testing be conducted on the final form of cannabis products:

- Testing to determine the content of THC, tetrahydrocannabinolic acid (THCA), cannabidiol (CBD), and cannabidiolic acid (CBDA);
- Testing for microbial and chemical contaminants;
- Testing for the residues of solvents used in the production of cannabis oil; and
- Dissolution or disintegration testing (on discrete units intended for ingestion or nasal, rectal, or vaginal use).

The following amendments to the Regulations will be made:

- While the Regulations currently distinguish between testing for solvent residues and chemical contaminants, solvent residues are a form of chemical contaminant. For this reason, the amended Regulations will treat solvent residues in the same way as other chemical contaminants, such as heavy metals. Solvent residue testing will continue to be required any time a solvent is used in the preparation of a cannabis product.
- The licensed processor, when conducting microbial and chemical contaminant testing (including solvent residue testing), will have the option of conducting testing on either the final form of a cannabis product, or at the final step in the production process during which the contaminants could be introduced or concentrated (i.e. on the "input" cannabis). For example, if a cannabis extract is used in the production of a cannabis topical, the licensed processor will have the option of conducting testing on the cannabis extract or on the final form of the cannabis topical. However, for edible cannabis, the amended Regulations will require contaminant testing to be conducted on the "input" cannabis.
- Under the current Regulations, levels of microbial and chemical contaminants must be within the generally established limits for herbal medicines. Under the amended Regulations, microbial and chemical limits will need to be within the limits that are appropriate for the intended use of the product (e.g. ingestion, inhalation).

Product rules for the new classes of cannabis

Part 6 of the Regulations sets out general requirements as well as the rules that apply to the production of cannabis products, by class of cannabis. Given that no rules currently exist with respect to the new classes of cannabis, this Part will be amended to establish rules for edible cannabis, cannabis extracts, and cannabis topicals. These amendments include THC limits per serving (or "discrete unit") and/or per package (i.e. per immediate container), as well as rules pertaining to product composition and ingredients.

THC limits

To reduce the risks associated with overconsumption and accidental consumption, limits will be placed on the quantity of THC that will be permitted in cannabis products in the new classes, both in a discrete unit and in a single immediate container. Specifically:

- For **edible cannabis**, there will be a limit of 10 milligrams of THC per discrete unit and per immediate container. This means, for example, that a container could contain one discrete unit of edible cannabis that contains 10 milligrams of THC; or two discrete units that each contain 5 milligrams of THC.
- For **cannabis extracts**, as is currently the case for cannabis oil, there will be a limit of 10 milligrams of THC per discrete unit that is intended to be ingested or for nasal, rectal, or vaginal use, such as a capsule. In addition, there will be a new limit of 1 000 milligrams (or 1 gram) of THC per immediate container. This means, for example, that a container could contain 100 capsules of an extract that each contain 10 milligrams of THC; or 200 capsules of an extract that each contain 5 milligrams of THC.
- For **cannabis topicals**, there will be a limit of no more than 1 000 milligrams (or 1 gram) of THC in an immediate container.

In addition, a lower possession limit and limit on the quantity of cannabis per package apply to any cannabis product that contains more than 3% THC by weight. Consistent with the Act and current Regulations (paragraph 108(f)), the maximum quantity of cannabis per package and public possession limit of 7.5 grams of cannabis (equivalent to 30 grams of dried cannabis) will apply to cannabis products that are edible cannabis, cannabis extracts, or cannabis topicals that contain more than 3% w/w THC (i.e. products that are considered "cannabis concentrates" for the purposes of Schedule 3 to the Act).

Establishing limits on the quantity of THC that will be allowed in the new classes of cannabis is considered a more effective means of addressing the risks of accidental consumption and overconsumption than establishing a maximum concentration of THC (or "potency") that could be in a product.

The precautionary limit of 10 milligrams of THC per container for edible cannabis aims to address the key public health risks associated with edible cannabis, including the risks of overconsumption and accidental consumption. The limit draws heavily on lessons learned from, and the limits established by, U.S. states that have legalized cannabis. It's important to note that the 10-milligram limit does not represent a safe "dose" or standard "serving size" for THC, particularly for new and novice consumers. Everyone's response to cannabis differs and can vary from one time to the next. For new and novice consumers, Health Canada advises that new consumers should choose an edible cannabis product that contains 2.5 milligrams of THC or less and wait to feel the full effects before consuming more. Health Canada will continue current efforts to develop public education messages and materials for Canadian consumers in collaboration with the provinces, territories, and other partners, to help them lower their risks should they choose to consume cannabis.

Product composition and ingredients

Currently, the Regulations do not permit the addition of anything other than cannabis to cannabis products (with the exception of cannabis oil, which may only contain the carrier oil and any additives necessary to preserve the quality and stability of the product). Consistent with the objective of enabling the legal cannabis industry to displace the illegal market, targeted amendments to the Regulations will permit a broader diversity of product forms for human use.

At the same time, consistent with the comprehensive public health approach to the Regulations, certain limits are important safeguards and will remain in place. For example, product forms that pose a greater risk to human health, such as cannabis products that are intended to be used in the area of the human eye (e.g. eye drops) or cannabis products that are intended to be used on damaged or broken skin or to penetrate the skin barrier by means other than by absorption (e.g. through the use of abrasives or needles) will continue to be prohibited. This does not mean, however, that all transdermal patches will be prohibited — under the amended Regulations, transdermal patches will be considered a cannabis topical.

The amended Regulations will establish the following "variability limits" for the quantity of THC and CBD in a cannabis product in the new classes of cannabis:

- For **edible cannabis**, if the total quantity of THC or CBD that is displayed on the label exceeds 5 mg, the product will be subject to a 15% variability limit (i.e. the container and any discrete units, if applicable, could not contain less than 85% of that amount, or more than 115% of that amount). If the quantity of THC or CBD that is displayed on the label is more than 2 mg but less than 5 mg, the variability limit will be 20%, and if the quantity of THC or CBD is less than 2 mg, the variability limit will be 25%.
- All **cannabis extracts** and **cannabis topicals** will be subject to a variability limit of 15%.

In addition, the amended Regulations will establish new rules for edible cannabis, cannabis extracts, cannabis topicals, and cannabis accessories that are cannabis products as described below.

A. Edible cannabis

All edible cannabis products will need to be shelf-stable (i.e. they must not require refrigeration or freezing).

Only food and food additives will be allowed to be used as ingredients in edible cannabis products, and the use of food additives will need to be in accordance with the limits and purposes that are prescribed for foods in the *Food and Drug Regulations* (FDR). Edible cannabis products will not be allowed to contain poisonous or harmful substances, nor will it be permitted to fortify edible cannabis with vitamins or mineral nutrients. Finally, the edible cannabis product must not contain anything that would be considered unsafe and would cause the sale of the edible cannabis product, if it was a food regulated under the *Food and Drugs Act* (FDA), to be prohibited. It will also be prohibited to use any food described in a Temporary Marketing Authorization Letter issued under the FDR as an ingredient in an edible cannabis product.

The use of meat products, poultry products and fish as ingredients in cannabis products will be generally prohibited. Because dried products pose a lower risk from a food safety perspective than raw products, an exception to this prohibition will be provided for dried meats, poultry or fish, provided they are obtained from a person who is authorized to produce such products under provincial or territorial laws or the SFCA, or has been imported in accordance with the SFCA, and that they have a water activity of 0.85 or less at a temperature of 22°C (plus or minus 2°C) at the time they are obtained. Furthermore, because of the increased risk of botulism associated with low-acid canned foods, the Regulations will prohibit the sale of edible cannabis products in a hermetically sealed container if any

component of the edible cannabis has a pH above 4.6 and a water activity higher than 0.85 when the product is at a temperature of 22°C (plus or minus 2°C).

The use of ingredients containing naturally occurring caffeine will be permitted in edible cannabis products, provided the total amount of caffeine in each immediate container does not exceed 30 milligrams. This amendment will allow for the use of ingredients that contain naturally occurring caffeine, such as chocolate, tea, or coffee. The use of caffeine as a food additive will, however, be prohibited.

Furthermore, the Regulations will allow for a small concentration of ethyl alcohol in edible cannabis products (that does not exceed 0.5% w/w), given that ethyl alcohol is often present as a by-product in fermented ingredients or products (e.g. vinegars).

B. Cannabis extracts

It will be permitted for cannabis extract products to contain flavouring agents in addition to one or more carrier substances and any substance necessary to maintain the quality or stability of the cannabis product. The use of sugars, sweeteners, or sweetening agents as ingredients in cannabis extract products will not be allowed. Furthermore, the use of any ingredient listed in Column 1 of Schedule 2 to the *Tobacco and Vaping Products Act* (which is a list of ingredients that are prohibited in vaping products) would not be permitted in cannabis extract products, except if those ingredients and their level are naturally occurring in an ingredient used to produce the extract. For example, if the carrier oil used in a cannabis extract contains naturally occurring levels of vitamins, this would be permitted. Any ingredient, other than a flavouring agent, used in the preparation of a cannabis extract that is intended to be inhaled will need to comply with a standard set out in one of the publications referred to in Schedule B to the FDA (which is a list of official publications that set out standards, such as the *European Pharmacopoeia*).

The use of ethyl alcohol will be permitted in cannabis extract products that are intended to be ingested (such as tinctures). However, the Regulations will prescribe a maximum net weight per container of 7.5 g for all cannabis extract products that contain ethyl alcohol, and that this limit will apply regardless of the THC content of the product. As will be described under the “Packaging and labelling” section below, other controls will also apply to these products to address the risks associated with the co-use of alcohol and cannabis, as well as the risks associated with accidental consumption and overconsumption.

Cannabis extract products will not be allowed to contain, or have on them, anything that may cause injury to the health of the consumer when the product is used as intended or in a reasonably foreseeable way.

C. Cannabis topicals

Cannabis topical products will not be allowed to contain, or have on them, anything that may cause injury to the health of the consumer when the product is used as intended or in a reasonably foreseeable way. This requirement has been adapted from rules that apply to cosmetics under the *Food and Drugs Act*. Health Canada’s Cosmetic Ingredient Hotlist is an administrative tool that Health Canada uses to communicate that certain substances may be prohibited or restricted for use in cosmetics. Health Canada strongly encourages licensed processors to make use of the Hotlist when looking to determine whether a particular ingredient

could pose a risk of injury to the health of the consumer when used in a cannabis topical product.

D. Cannabis accessories

Targeted amendments to the Regulations will be made to ensure that cannabis accessories that contain or are packaged with cannabis (i.e. a cannabis accessory that is a cannabis product) do not increase the potential for harm associated with cannabis products, and to establish dispensing limits for accessories containing or packaged with certain cannabis extracts.

More specifically:

- A cannabis accessory that is sold containing or packaged with cannabis (e.g. a pre-filled vaping cartridge) must not be contaminated.
- A cannabis accessory must not, through any means other than heating or combustion, alter or enhance the effects of the product, increase the potential for physical dependence on the product, or increase the toxicity of the cannabis product when used as intended or in a reasonably foreseeable way.
- The maximum quantity of THC that could be dispensed per activation of a cannabis accessory containing or packaged with an extract that is intended to be ingested, or for nasal, rectal, or vaginal use (e.g. a spray bottle), will be 10 mg. This provision will operate in concert with the integrated dispensing mechanism, which is described in the “Amendments to packaging requirements” section below.

Promotion

Unless authorized under the Act, it is generally prohibited to promote cannabis, a cannabis accessory, or any service related to cannabis, including by

- communicating information about its price or distribution;
- doing so in a manner that there are reasonable grounds to believe could be appealing to young persons;
- means of a testimonial or endorsement, however displayed or communicated;
- means of the depiction of a person, character or animal, whether real or fictional;
- 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.

Limited promotion of cannabis, cannabis accessories, and services related to cannabis can be permitted under the Act in specific circumstances, subject to all applicable prohibitions. For example, the Act provides for informational promotion and brand-preference promotion, provided the promotion is

- in a communication that is addressed and sent to an individual who is 18 years of age or older and is identified by name;
- in a place where young persons are not permitted by law;
- communicated by means of a telecommunication, where the person responsible for the content of the promotion has taken reasonable steps to ensure the promotion cannot be accessed by a young person;
- in a prescribed place; or

- done in a prescribed manner.

For more information on the promotion prohibitions in the Act, please see: https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/laws-regulations/promotion-prohibitions.html.

A new Part (Part 6.1) will be added to the *Cannabis Regulations* addressing promotion. This new Part will act in concert with the prohibitions on promotion set out in Part 1, Division 2 of the *Cannabis Act*. These new provisions have been added to

- address comments received from public health stakeholders with respect to the proposals to prohibit certain representations and associations on product packages and labels;
- limit the scope of certain exemptions to the general prohibition on the promotion of cannabis, cannabis accessories, and services related to cannabis as set out in the Act; and
- to facilitate compliance.

The draft regulations published in the *Canada Gazette*, Part I, on December 22, 2018, proposed that the amended Regulations would prohibit certain representations and associations on products and their packages and labels (described further under *Packaging and Labelling*, below). In response to comments received during the consultation, the final regulations will extend these prohibitions to promotional activity, so that representations that will not be allowed on a product's packaging and labelling will equally not be allowed in promotions. Namely, this Part of the amended Regulations will prohibit representations in promotional activities pertaining to certain flavours in cannabis extracts; to health or cosmetic benefits; to energy value and amount of certain nutrients; to special dietary requirements; to alcoholic beverages and tobacco and vaping products. These prohibitions and restrictions on representations will not apply with respect to prescription drugs containing cannabis or combination products.

Part 6.1 of the amended Regulations will specify that the limited promotion permitted in a place where young persons are not permitted by law may not be audible or visible from outside the place, as the intent is to ensure that such promotions are not accessible to young persons.

Subsection 17(6) of the *Cannabis Act* includes an exception to the general prohibition on promotion, which permits the promotion of cannabis, a cannabis accessory, or a service related to cannabis by displaying a brand element (e.g. a logo or brand name) on certain "things," subject to the Regulations and any applicable prohibition. This exception permits the display of brand elements on "things" such as t-shirts and hats. The amended Regulations will specify that, in promotion authorized under subsection 17(6) of the Act, only one brand element may appear on the "thing", subject to the applicable restrictions and prohibitions. The amended Regulations will also establish a maximum size limit of 300 cm^2 for that brand element, as well as a maximum height of 4 cm for any text (i.e. letters, characters, or numbers) within the brand element. The intent of these restrictions is to reduce the impact of the promotion authorized under this provision.

The amended Regulations will also clarify that, for the purposes of subsection 17(6), "a thing that is associated with young persons" includes any thing that is in a public place frequented

mainly by young persons (e.g. a public playground) and any thing that is visible from such a place.

Packaging and labelling

Part 7 of the Regulations sets out requirements that apply to cannabis products packaged and labelled for sale at the retail level. These packaging and labelling requirements aim to protect the health of young persons by restricting their access to cannabis and to protect young persons and others from inducements to use cannabis. The requirements also help to promote informed consumer choice and encourage the safe handling and storage of cannabis.

The amended Regulations will maintain the core plain packaging and labelling requirements that currently apply to all cannabis products, such as the standardized cannabis symbol, health warning messages (which will be updated, as will be described further under *Instrument Choice*, below), THC and CBD quantity or concentration, and child-resistant packaging.

Mandatory label information — all classes of cannabis products

Currently, the Regulations require that the concentration of THC and CBD in dried or fresh cannabis (that is not in discrete units) be expressed as a percentage (%), and that the concentration of THC and CBD in cannabis oil be expressed in milligrams per millilitre (mg/ml). The amended Regulations will modify these requirements for all classes of cannabis in order to standardize the display of the amount of THC and CBD. This will allow consumers to better compare across various cannabis products and make more informed decisions. Specifically, the amended Regulations will establish the following requirements:

- For dried or fresh cannabis and cannabis extracts that are in discrete units and intended to be inhaled or for cannabis extracts that are not in discrete units, THC and CBD concentration must be expressed in milligrams per gram (mg/g).
- For cannabis extracts that are in discrete units and not intended to be inhaled and for edible cannabis, the quantity of THC and CBD must be expressed in milligrams. In addition, for any cannabis extract in a container with an integrated dispensing mechanism, the quantity of THC and CBD per activation must be indicated in milligrams (mg).
- For cannabis topicals, the amount of THC and CBD can be expressed as either milligrams per gram (concentration) or milligrams (quantity).

In all cases, the net weight of the product must be represented in grams, with the exception of beverages, where the volume must be represented in millilitres. Nothing would preclude licensed processors from expressing THC and CBD amounts in additional, alternate formats [such as the percentage (%) of THC and CBD], on product labels. However, these alternate formats could not replace the required format, and could only be in addition to the required information.

The amended Regulations will require labels for all cannabis products (except dried cannabis and cannabis plants) to indicate the product's equivalency to grams of dried cannabis. This will provide a new tool for consumers and law enforcement to determine whether an individual is in compliance with the federal public possession limit of 30 grams of dried cannabis "or equivalent" (where equivalency is determined in accordance with subsection 2(4) and Schedule 3 to the Act).

The current Regulations allow for one brand element, other than a brand name, to appear on the label of cannabis products, provided that brand element meets certain requirements. One of those requirements is that the surface area of the brand element must be smaller than or equal to the surface area of the standardized cannabis symbol. However, for products containing 10 ppm THC or less, such as pure CBD oil, there is no requirement for the standardized cannabis symbol to appear on the product label. For products with 10 ppm or less, the amended Regulations will specify that the brand element must be smaller than or equal to 25% of the principal display panel, and must be smaller than or equal to the area within the border of the health warning message that appears on the label.

For the new classes of cannabis, the new labelling requirements will take effect immediately upon coming into force of the amended Regulations. For existing classes of cannabis, the amended Regulations will provide a 12-month transition period within which licensed processors can adjust their packaging and labelling practices to comply with the new requirements. As well, dried cannabis, fresh cannabis, cannabis plants, and cannabis seeds packaged and labelled in accordance with the current Regulations prior to the end of the 12-month transition period may continue to be sold indefinitely by authorized provincial and territorial sellers and federally licensed sellers of cannabis for medical purposes.

Mandatory label information — new classes of cannabis products

Under the amended Regulations, the following label requirements will apply to the new classes of cannabis and to cannabis accessories containing those classes of cannabis.

A. Edible cannabis

Consistent with requirements that apply to food under the FDR, the following will be required on the label of edible cannabis products, in addition to the current labelling requirements, which apply to all cannabis products:

- a list of ingredients;
- the common name of the cannabis product;
- an indication of the source of an allergen or gluten, or that sulphites have been added to the product (alternatively, this information could appear as part of the ingredient list);
- a “durable life date” (more commonly known as a “best-before date”) would need to appear on the label of edible cannabis having a durable life of 90 days or less; and
- a cannabis-specific nutrition facts table (NFT).

The cannabis-specific NFT has been modelled on the standard format NFT for pre-packaged food, incorporating the display of the energy value of the product (i.e. calories) as well as the amounts of the 12 core nutrients and, in some cases, the percent daily value (% DV), on a “per container” basis. The font size, font type, leading and spacing of the cannabis-specific NFT is consistent with other labelling requirements for cannabis products. The requirement will allow consumers to make informed choices based on this information. Specific requirements pertaining to the presentation of the NFT will be set out in the *Directory of Nutrition Facts Table Formats for Edible Cannabis*, published on the Government of Canada’s website.

B. Cannabis extracts

In addition to the current labelling requirements that apply to all cannabis products, a list of ingredients, the identity of the cannabis product in terms of its common name or function, and a list of allergens will be required on the label of cannabis extracts, as well as the intended use of the product (e.g. “for vaping”). For cannabis extracts in a container with an integrated dispensing mechanism, the quantity of THC and CBD per activation (in milligrams) will also be required to appear on the label.

C. Cannabis topicals

In addition to the current labelling requirements that apply to all cannabis products, a list of ingredients, the identity of the cannabis product in terms of its common name or function, as well as the intended use of the product (e.g. “apply to skin”) will need to appear on the label of all cannabis topicals.

D. Standardized cannabis symbol on vaping products and wrappers

Currently, the Regulations require the standardized cannabis symbol to appear on the label of cannabis products that contain more than 10 parts per million (ppm) THC (equivalent to 10 micrograms per gram). The Regulations will be amended to also require the display of the standardized cannabis symbol on any cannabis accessory that contains a cannabis extract product that is intended to be inhaled and that contains more than 10 ppm THC. For example, this will require vaping devices or vaping cartridges that contain a cannabis extract with THC to have the symbol directly on the device or cartridge. In addition, the standardized cannabis symbol will need to be clearly and prominently displayed on the exterior surface of any wrapper that is in direct contact with a cannabis product that contains more than 10 ppm THC.

Reducing inducements to consume cannabis, including consumption of cannabis by young persons

Consistent with the objective, as set out in section 7 of the *Cannabis Act*, to “protect young persons and others from inducements to use cannabis,” the amended Regulations will prohibit the following representations on all product packages and labels:

- Representations regarding health benefits, including those that are currently permitted on food, such as “a healthy diet low in saturated and trans fat may reduce the risk of heart disease,” or “oat fibre helps lower cholesterol” (all classes of cannabis).
- Representations regarding cosmetic benefits, such as “reduces the appearance of wrinkles” or “softens skin” (all classes of cannabis).
- All representations that associate a cannabis product (including its brand element) with an alcoholic beverage or a tobacco product or a vaping product. For example, it will be prohibited to use terms related to alcoholic beverages, such as “beer” or “wine”, on cannabis products. It would similarly be prohibited for the logo of a company that manufactures alcoholic beverages or tobacco or vaping products to be used on a cannabis product if that logo could associate the cannabis with the alcoholic beverage, tobacco product, or vaping product. In addition to reducing inducements to use cannabis, this prohibition is felt to be necessary given the known health risks associated with the concurrent use of alcohol and cannabis, or nicotine/tobacco and cannabis (all classes of cannabis).

- Energy value and nutrient content representations that go beyond those permitted in the list of ingredients and cannabis-specific NFT, including those that are currently permitted on food, such as “high source of fibre” or “low-fat,” or additional information pertaining to the vitamin or mineral content of the product (edible cannabis).
- The representation of edible cannabis as a suitable means of meeting the particular dietary requirements of an individual, or the dietary requirements of young persons. For example, it will be prohibited to say that edible cannabis is suitable for the particular dietary requirements of a person with diabetes, or as part of a low-calorie diet (edible cannabis).
- Representations that could create the impression that a cannabis extract contains certain flavours that are appealing to youth, such as dessert or confectionery flavours, consistent with rules that apply to vaping products under the *Tobacco and Vaping Products Act* (cannabis extracts).

The prohibitions on representations described above will be in addition to prohibitions on the sale of cannabis products or cannabis accessories that have an appearance, shape or other attribute or function that there are reasonable grounds to believe could be appealing to young persons, as well as the promotion, packaging and labelling of cannabis in a manner that could be considered reasonably appealing to young persons. As well, the Act specifically prohibits the package or label of a cannabis product or cannabis accessory to set out a testimonial or endorsement; depict a person, character or animal (whether real or fictional); associate the cannabis, the accessory, or one of the brand elements with a particular lifestyle; or to contain any false, misleading, or deceptive information.

The Regulations require the company name and email address of the licensed cultivator or processor that manufactured the product to appear on the label of that product (subject to specific requirements on size and format, consistent with the plain packaging approach set out in the Regulations). The amended Regulations will contain new provisions which provide that compliance with this provision does not constitute a contravention of the packaging and labelling requirements set out in sections 26 and 27 of the Act. This will provide, for example, that a company named after a person does not contravene the prohibition against depicting a person on a package or label, simply by displaying their company name as required. It is important to note that this provision applies only to packaging and labelling (and not to promotion) and to a company name and email address (and not to other brand elements, such as a company logo).

Amendments to packaging requirements

The current plain packaging requirements for all cannabis products will be maintained, including the requirement for child-resistant packaging, with minor adjustments. First, an exception to the current prohibition on the use of a naturally occurring metallic colour on the external surface of an immediate container that is made of metal will be provided, which will allow for the use of containers such as metal beverage cans. Second, the exterior surface of any container in which a cannabis product is packaged will no longer need to have a matte finish, given that this requirement is incompatible with both the use of metal containers and the allowance for the use of peel-back and accordion labels, which is described further below. Both of these changes will facilitate compliance and provide additional flexibility for regulated parties.

Moreover, the following specific additions and adjustments to the Regulations will be made to account for the new classes of cannabis:

- The immediate container of cannabis extracts that are not in discrete units will need to be designed in such a way that the extract could not easily be poured, or drunk directly from the container (thereby mitigating the risk of accidental consumption). For extracts in liquid form that are not intended to be inhaled and that contain at least 10 mg of THC, the immediate container will need to contain an integrated dispensing mechanism (e.g. a metered spray) that dispenses no more than 10 mg of THC, unless the extract is in the form of discrete units (such as a capsule).
- There will be a new requirement to use "food-grade" packaging (i.e. packaging that meets requirements set out in the FDR and the SFCR for food) for the immediate container of edible cannabis and for any wrappers of edible cannabis and cannabis extracts intended to be ingested.
- The co-packaging of cannabis and food will be prohibited, as will the co-packaging of more than one class of cannabis in the same exterior container.
- Multi-packs of edible cannabis, including beverages, will be permitted, provided the total quantity of THC in the multi-pack does not exceed 10 milligrams, and the total amount of cannabis in the multi-pack does not exceed the public possession limit of 30 grams of dried cannabis or equivalent. This allowance creates consistency within the edible class and is intended to facilitate the availability of edible cannabis products in servings that contain lower quantities of THC (i.e. less than 10 milligrams), consistent with the public health objectives of the Act and Regulations. Notwithstanding the allowance for multi-packs, the amended Regulations will specify that the properties of the edible cannabis in each immediate container must be consistent, thereby precluding the sale of sampler packs.

The use of pressurized containers will be permitted, thereby allowing for carbonated beverages and cannabis accessories such as metered-dose inhalers.

As described under the "THC limits" section above, limits will be placed on the quantity of THC that can be in an immediate container of a cannabis product (e.g. 10 mg of THC per container of edible cannabis, 1 000 mg of THC per container for cannabis extracts and topicals). In addition, the following new maximum weight or volume will apply to cannabis extract products:

- 7.5 g maximum weight for all cannabis extracts that contain ethyl alcohol and are intended to be ingested (irrespective of the quantity of THC in that product); and
- 90 mL for all liquid cannabis extracts.

This is in addition to the maximum package size of 7.5 g that will apply to all "cannabis concentrates," by virtue of paragraph 108(f) of the current Regulations.

Labelling allowances to provide for smaller containers

Currently, the Regulations set out prescriptive display rules and plain packaging requirements that do not allow for the use of expanded panels on containers (such as peel-back and accordion labels), tags, or package inserts. To accommodate smaller containers, and based in part on feedback from regulated parties, the provinces and territories, and consumers, the amended Regulations will enable the use of expanded panels and alternative display formats for certain required information when the immediate container is too small to

otherwise accommodate all required information on the exterior display surface. Tags and package inserts will continue to not be permitted.

The cannabis health warning messages, standardized cannabis symbol and information pertaining to the THC and CBD content of the product will always be required on the exterior display surface, regardless of the size of the container. However, there will be the option for required information such as the packaging date, recommended storage conditions, the list of ingredients, and the NFT, as well as any non-required information that a processor volunteers to display on the label, to be displayed on a panel. Brand elements appearing on the exterior display surface will need to be smaller than or the same size as the minimum size of the standardized cannabis symbol (i.e. 1.27 cm by 1.27 cm), or a type size of 7 points or smaller if the brand element is text only, and no brand elements will be allowed on the panel.

These amendments are considered to be necessary given the restrictions on the package sizes (e.g. the maximum package size of 7.5 g for cannabis extracts containing ethyl alcohol), and also in light of the new labelling requirements that increase the amount of required information (e.g. the NFT for edible cannabis).

Drugs containing cannabis

Part 8 and Part 9 of the Regulations set out rules for drugs containing cannabis and medical devices containing cannabis or that are intended to be used with cannabis. No major changes will be made to these parts of the Regulations.

Minor amendments to Part 8 will be made that will remove the requirement to hold a drug establishment licence (DEL) under the FDR in order to be eligible to apply for a cannabis drug licence. This change will be made because a small number of limited activities with drugs do not require a DEL (e.g. the sale and importation of a drug for use in clinical trials in humans). The grounds for refusal of a cannabis drug licence will be amended to include the applicant not holding a DEL at the proposed site, if one is required under the FDR, and the suspension or cancellation of an applicant's DEL, if one is required under the FDR, at the proposed site. Similarly, the grounds for suspension or revocation of a cannabis drug licence will be amended to clarify that the suspension or revocation of a DEL will only be grounds for suspension or revocation in cases where a DEL is required under the FDR.

Importation and exportation of cannabis

Part 10 of the Regulations deals with the importation and exportation of cannabis. As set out in the *Cannabis Act*, the import and export of cannabis is permitted only for medical or scientific purposes, or in respect of industrial hemp. No major changes will be made to this part of the Regulations. Each importation and exportation of cannabis will continue to require a permit issued by the Minister. The following minor change will be made: whereas import and export permits must currently set out "**the** description of the cannabis," they will now set out "**a** description of the cannabis."

Record keeping

Record-keeping requirements are set out in Part 11 of the Regulations.

Record-keeping requirements that currently apply to cannabis oil (as set out in section 225) will be amended to apply to edible cannabis, cannabis extracts, and cannabis topicals.

Additionally, subsection 231(1) of the Regulations will be amended to clarify that for each lot or batch of cannabis sold or exported, a document must be retained demonstrating that the cannabis meets the requirements set out in both Part 5 and Part 6 of the Regulations (as opposed to just Part 5, as is currently the case).

In addition to current record-keeping requirements, the following new requirements will be made:

- Records will need to be kept pertaining to ingredients used in the production of edible cannabis, cannabis extracts, and cannabis topicals. In particular, the following records pertaining to ingredients will need to be kept by licensed processors:For cannabis extracts, a record must be kept regarding the purpose of each ingredient (e.g. carrier substance, flavouring agent), as well as a description of the flavour of the product, if applicable.
    - the name and business address of the person who supplied the ingredient, if applicable;
    - the date the ingredient was obtained or produced by the licence holder;
    - a description of the ingredient, including its name (or, if applicable, its chemical name, common name, International Nomenclature Cosmetic Ingredient [INCI] name, and Chemical Abstracts Service [CAS] registry number); and
    - a lot code or other unique identifier, if applicable.
-
- A record will need to be kept regarding every investigation undertaken by a QAP, including any proactive investigation of a possible risk of injury to human health or in response to a complaint received in respect of the quality of the cannabis. This record will also need to indicate any measures taken in response.
- Licence holders (all classes of cannabis, except plants and seeds) will be required to keep a record of any information that is obtained through testing that relates to the phytocannabinoid and terpene content of the cannabis product. Currently, licence holders are only required to keep a record of the quantity or concentration of THC, THCA, CBD, and CBDA. However, testing methodologies typically generate a more complete phytocannabinoid and terpene profile. Where this additional information exists, licence holders will be required to keep a record of it.

All of the above records will need to be kept for a period of two years, consistent with the retention periods for most existing record-keeping requirements (adverse reaction reports must be kept for 25 years).

Reporting

Reporting requirements are set out in both Part 12 of the Regulations and the Cannabis Tracking System Order.

No changes will be made to Part 12 of the Regulations. The *Cannabis Tracking System Order* will be replaced with a new Order to include the new classes of cannabis. This new ministerial order will also come into force on October 17, 2019. The Cannabis Tracking and Licensing System, a public-facing web application that enables the submission of monthly tracking reports, as well as new licence applications, requests for licence amendments and renewals, will also be updated.

Test kits

No changes will be made to Part 13 of the Regulations, which deals with test kits.

Access to cannabis for medical purposes

No changes will be made to Part 14 of the Regulations, which enables access to cannabis for medical purposes, aside from minor wording changes to align language in this Part with other Parts of the Regulations. Patients who have the authorization of their health-care practitioner and who are registered with the Minister or a federally licensed seller will benefit from the comprehensive range of new cannabis products that will be enabled through the amendments to the Regulations, including several alternatives to smoking cannabis.

Transitional provisions

A 12-month transition period will be provided for activities in relation to cannabis oil. During this 12-month transition period, cannabis oil can continue to be sold as a class of cannabis (by federal licence holders and provincially and territorially authorized distributors and sellers), subject to the current rules as they apply to cannabis oil. For example, cannabis oil products will continue to be subject to the limit of 10 milligrams of THC per discrete unit, but the new limit of 1 000 milligrams of THC per container will not apply to cannabis oil during this transition period. Twelve months following the coming into force of the amended Regulations, cannabis oil will be deleted as a class of cannabis under Schedule 4 to the Act. The transitional provisions will also necessitate that the document that is currently incorporated by reference as part of the *Cannabis Regulations*, entitled *Limits for Residual Solvents in Cannabis Products*, remain on the Government of Canada's website for a period of 12 months. These solvent limits will continue to apply to cannabis oil during the 12-month transition period.

Additionally, a 12-month transition period for dried or fresh cannabis will be provided in relation to microbial and chemical contaminants (i.e. for a 12-month period, microbial and chemical contaminants could remain within established limits for herbal medicines, rather than within limits appropriate for the intended use of the product, as described under the "Testing" section above).

As noted above, labelling requirements for the new classes of cannabis will take effect immediately upon coming into force of the amended Regulations. This means that products in the new classes would need to be labelled with the new *Cannabis Health Warning Messages*, that the THC and CBD content would need to be expressed in either milligrams per gram (mg/g) or milligrams (mg), and that the product label would need to set out the equivalence of the product to grams of dried cannabis.

For existing classes of cannabis, a 12-month transition period will be provided for licensed cultivators and processors to modify their packaging and labelling practices with respect to the health warning messages, the THC/CBD content, and the equivalence of the product to grams of dried cannabis. That said, the sale to consumers of dried cannabis, fresh cannabis, cannabis plants, and cannabis seeds packaged and labelled under the current Regulations will be allowed indefinitely, to allow for the sale of any products packaged and labelled prior to the end of the transition period.

It is anticipated that licensed processors may wish to begin producing products within the new classes in advance of the coming into force of the amended Regulations (and in advance of their licence being amended to permit them to sell these new products). The transitional provisions clarify that it will be prohibited for a licence holder to sell, distribute, or export products in the new classes that was produced, packaged, labelled, stored, sampled, and tested prior to October 17, 2019, unless, at the time those activities were carried out, the applicable requirements set out in Parts 5 (good production practices), 6 (products) and 11 (record keeping) of the amended Regulations were met. Furthermore, the Quality Assurance Person will need to have the necessary qualifications (i.e. training, experience, and technical knowledge) applicable to the class of cannabis they are producing during this period of time, or in the event that the QAP does not have the requisite training, experience and technical knowledge that are applicable to edible cannabis, the licensed processor would need to retain the services of another individual with the necessary qualifications.

Coming into force

The amended Regulations will come into force on October 17, 2019.

Also on October 17, 2019, “edibles containing cannabis” and “cannabis concentrates” will be added to Schedule 4 to the Act, and Schedule 4 will be further amended to delete “edibles containing cannabis” and “cannabis concentrates” and to add “edible cannabis,” “cannabis extracts,” and “cannabis topicals.”

Amendments to Schedule 3

Schedule 3 to the Act (*Equivalent Amounts*) is used to determine, for example, how many grams of fresh cannabis would be equivalent to 30 grams of dried cannabis, for the purposes of determining the maximum amount of cannabis that an adult can legally possess in a public place.

Currently, both “cannabis solid concentrates” and “cannabis non-solid concentrates” are listed in Schedule 3. In both cases, the quantity that is deemed equivalent to 1 gram of dried cannabis is the same (i.e. 0.25 grams). To simplify Schedule 3, this Order will delete these two categories and add a single category known as “cannabis concentrates.” The term “cannabis concentrates” will be defined in the Regulations as “a substance that has a maximum yield percentage of greater than 3% w/w of THC, taking into account the potential to convert THCA into THC.” This new term will replace the current definitions of “cannabis solid concentrates” and “cannabis non-solid concentrates” in the Regulations.

Regulatory development

Consultations

The development of the amended Regulations, as well as the current Regulations, has been informed by

- 1. the work of the Task Force on Cannabis Legalization and Regulation;
- 2. parliamentary study of Bill C-45, the *Cannabis Act*;
- 3. consultations supporting the development of the current Regulations; and
- 4. a 60-day public consultation on proposed amendments to the Regulations.

In developing these Regulations, Health Canada also considered the experience of U.S. jurisdictions that have legalized and regulated access to cannabis, as well as ongoing feedback received from regulated parties and other stakeholders.

Task Force on Cannabis Legalization and Regulation

The Task Force on Cannabis Legalization and Regulation was formed in June 2016 with a mandate to consult broadly with Canadians and to provide advice on the design of a new legislative and regulatory framework for cannabis in Canada. In its final report, A Framework for the Legalization and Regulation of Cannabis in Canada, the Task Force made 85 recommendations, including a number of recommendations specific to regulating edible cannabis and cannabis extracts, including extracts containing a higher concentration of THC.

Specifically with respect to edible cannabis, the Task Force recommended that

- any product deemed to be appealing to children, including products that resemble or mimic familiar food items, or that are packaged to look like candy, should be prohibited;
- packaging be implemented with standardized, single servings, as well as a standardized cannabis symbol;
- a maximum quantity of THC per serving be established, both on a per-serving and a per-product basis;
- mixed products be prohibited (for example, cannabis-infused alcoholic beverages, or cannabis products with tobacco, nicotine or caffeine); and
- labelling requirements that apply to food and beverage products should also apply to edible cannabis.

With respect to cannabis extracts containing higher concentrations of THC, the Task Force recommended that

- regulatory oversight be provided in order to minimize the risks associated with the illegal production of such products (for example, the use of highly combustible solvents, such as butane, and potentially toxic solvents such as naphtha, which can be used to extract THC);
- strategies be developed to encourage consumption of less potent cannabis;
- all cannabis products be required to include labels identifying levels of THC and CBD;
- a flexible legislative and regulatory framework be enabled at the federal level, that could adapt to new evidence and establish rules for limits on THC or other components; and

- the Government of Canada develop and implement factual public education strategies to inform Canadians about the risks of problematic use and to provide guidance on lower-risk use.

Parliamentary study of Bill C-45

During Parliamentary consideration and debate on Bill C-45, the *Cannabis Act*, the question of whether these new classes of cannabis should be permitted under the legal framework was the subject of considerable debate. Among those who supported their inclusion in the legal framework, there was debate as to whether these products should be legally available immediately upon coming into force of the Act, or whether their legal sale should be enabled within a certain timeframe.
Ultimately, the House of Commons amended the Act to authorize the legal sale of "edibles containing cannabis" and "cannabis concentrates" no later than 12 months following the coming into force of the *Cannabis Act*.

During the debate in the Senate, some Senators expressed concern regarding the inclusion of cannabis products with a higher concentration of THC in the legal framework, given the greater health risks associated with such products. While there was some discussion of imposing a limit on THC, no such amendments were made to the legislation.

Consultations supporting the development of the current Regulations

On November 21, 2017, Health Canada launched a 60-day public consultation to solicit public input and views on a proposed approach to developing regulations to support the coming into force of the *Cannabis Act*. To support the consultation, Health Canada published a detailed consultation paper entitled Proposed Approach to the Regulation of Cannabis. The consultation paper outlined a comprehensive series of regulatory proposals to help achieve the Government's public health and public safety goals of restricting youth access to cannabis, minimizing the harms of cannabis use, and preventing criminals and organized crime from profiting from the illegal production, distribution and sale of cannabis.

During the 60-day public comment period, Health Canada received more than 3 200 responses to an online questionnaire and 450 written submissions. Targeted consultations were also undertaken with interested parties, such as the provinces and territories, Indigenous governments and representative organizations, the cannabis industry (including both existing and prospective licensees), public health organizations, and patients and patient advocates. In total, 192 interested parties participated in the in-person round tables, and 343 interested parties participated in webinars. In addition, Health Canada held both multilateral and bilateral meetings with representatives of all 13 provinces and territories, as well as a series of focused meetings with First Nations, Inuit, and Métis, to seek their feedback on the proposed regulatory approach.

On March 19, 2018, Health Canada published a report entitled Summary of Comments Received During the Public Consultation. In addition to highlighting areas where changes were being considered to the regulatory proposals, this document also provided advance notice of certain regulatory requirements — in particular those pertaining to the plain packaging and labelling of cannabis products.

A majority of those who responded to the November 2017 consultation paper indicated that the industry must be able to offer the same diversity of products that are available in the illegal market in order to be able to successfully displace the illegal market, and suggested that a broader range of products would provide alternatives to smoking cannabis. Many respondents felt that vaping products in particular should have been permitted through the first phase of the *Cannabis Regulations*.

In addition, respondents indicated that additional regulatory provisions would be required to address the unique public health and public safety risks associated with edible cannabis and extracts with a higher concentration of THC, such as provisions on quality control, THC limits, portion sizes, specific packaging and labelling requirements, and the use of highly combustible and/or potentially toxic solvents that are often used in the illegal manufacture of concentrated cannabis extracts. A small number of respondents felt that the regulations should be more restrictive in the types of cannabis products available through the legal system.

60-day public consultation on proposed amendments to the Regulations

On December 20, 2018, Health Canada launched a public consultation to solicit input and views on proposed amendments to the Regulations to address the public health and safety risks of edible cannabis, cannabis extracts, and cannabis topicals. The proposed amendments were published in the *Canada Gazette*, Part I, on December 22, 2018.

During the 60-day public comment period, Health Canada received nearly 6 800 responses to an online questionnaire, and 350 written submissions. Health Canada held bilateral meetings with all provinces and territories. In addition, targeted consultations were undertaken with interested parties and partners, such as the cannabis and food industries and industry associations, provincially and territorially authorized sellers (both public and private), public health organizations, patients, youth, and provincial and territorial ministries of agriculture and food safety. Over 1 500 participants were reached through these targeted engagement sessions, including 162 participants in 7 in-person round tables and 1 297 participants in 8 webinars.

Stakeholders were generally supportive of new classes of cannabis and felt that they would enable the production of a comprehensive range of products, thereby enabling the legal industry to innovate and compete with the illegal market. Additionally, the majority of respondents supported the proposal to delete cannabis oil from Schedule 4 to the Act, and indicated that the new classes would accommodate a variety of oil-based products for various intended uses.

Participants in the consultations also expressed broad support for the proposed amendments to the Regulations. Specifically, stakeholders felt that the proposals would enable the production of a comprehensive range of product forms and would establish reasonable safeguards to protect public health and public safety and to limit the appeal of cannabis products, including to youth.

Notwithstanding this broad support, significant feedback was received on the following three key elements of the proposed amendments to the Regulations:

- 1. the proposed 10-milligram THC per container limit for edible cannabis products;
- 2. the proposed prohibition on manufacturing edible cannabis in the same building as food; and
- 3. packaging and labelling requirements.

A. Proposed 10-milligram THC per container limit for edible cannabis products

The majority of individual respondents and industry stakeholders opposed the proposed 10-milligram THC per container limit for edible cannabis products, indicating that it would impede the ability of the legal cannabis industry to displace the illegal market, where products often claim to contain 100 milligrams of THC or more per package. In contrast, public health stakeholders supported the limit, with some advocating for a more precautionary limit of 5 milligrams per container, to protect consumers from the risks of overconsumption and accidental consumption.

Many stakeholders emphasized the importance of public education to help consumers understand what 10 milligrams of THC represents and how it will affect them. To address feedback received through the consultation, public education efforts will underscore that 10 milligrams should not be confused with a safe “dose” or standard “serving size” for THC, particularly for new and novice consumers. Everyone’s response to cannabis differs and can vary from one time to the next. For new and novice consumers, Health Canada advises that new consumers choose an edible cannabis product that contains 2.5 milligrams of THC or less and wait to feel the full effects before consuming more.

While the feedback received was carefully considered, the 10-milligram THC per container limit for edible cannabis products has been maintained in the final amendments to the Regulations. This is a precautionary limit that aims to address the key public health risks associated with edible cannabis, namely the risks of overconsumption and accidental consumption. The 10-milligram THC limit also draws heavily on lessons learned from, and the limits established by, U.S. jurisdictions that have legalized cannabis. More specifically, some U.S. states started with less restrictive approaches and have had to introduce, over time, new controls (e.g. new labelling requirements) to address public health issues.

To address comments received from industry through the consultation, multi-packs of edible cannabis in both solid and non-solid form (i.e. beverages) will be permitted, provided the total quantity of THC in the multi-pack does not exceed 10 milligrams, and the total size of the multi-pack does not exceed the public possession limit for adults of 30 grams of dried cannabis or equivalent. This adjustment will create consistency within the edible class, as the proposed regulatory amendments would have permitted multi-packs of edible cannabis in solid form.

B. Proposed prohibition on manufacturing edible cannabis in the same building as food

The majority of industry stakeholders, and particularly those in the food industry, suggested that the prohibition on manufacturing edible cannabis and food in the same building was overly burdensome and could pose a barrier for small food businesses who may be interested in producing edible cannabis. Respondents suggested that the Government’s policy objective of protecting the integrity of the food supply system, both domestically and for Canada’s international trading partners, could be met in other ways (e.g. managing risks through preventive control plans, dedicated equipment and physically separated spaces

in the same building, etc.). In contrast, public health stakeholders supported the proposal. Federal government partners also supported the proposal as an effective strategy to help ensure the continued confidence of Canadians in the Canadian food supply system and to protect Canadian food exports.

After carefully weighing the potential costs to the licensed cannabis industry and potential new market entrants against the significant costs that would be associated with any loss of Canadians' confidence in the food supply system and any barriers to the export of Canadian food products, the final regulations will prohibit any class of cannabis from being manufactured in the same building as food products. This measure will help minimize the risks of cross-contamination and reassure Canadians and Canada's international trade partners as to the safety and quality of exported food.

C. Packaging and labelling requirements

The environmental impacts of current packaging and labelling requirements as they apply to cannabis products were a major theme from the public consultation. Many felt that the proposed 10-milligram THC limit for edible cannabis would contribute to further waste. With that being said, a majority of respondents were supportive of the proposed amendments to the Regulations that would allow for the use of peel-back and accordion labels and wrappers as a means of encouraging the use of smaller containers.

Many respondents also suggested that the plain packaging and labelling requirements set out in the current Regulations were too strict, and that they were inconsistent with the objective of enabling the legal industry to displace the illegal market. In many cases, respondents proposed eliminating many of the current requirements and adopting an approach consistent with that for alcohol.

In contrast, public health stakeholders were very supportive of the current plain packaging and labelling approach for all cannabis products, as well the proposed amendments to the Regulations that would prohibit associations with alcoholic beverages on product labels. In fact, many public health stakeholders suggested adding additional restrictions. Most notably, given the proposal to prohibit the cross-branding of cannabis and alcohol, it was suggested that the Regulations should also prohibit the cross-branding of cannabis and tobacco products. The regulatory text has been adjusted to extend the prohibition to tobacco and vaping products.

The proposals to require a Nutrition Facts Table on edible cannabis labels and the standardized cannabis symbol on vaping products and wrappers were widely supported.

D. Other specific adjustments to the Regulations

Stakeholders also proposed a number of specific adjustments to the Regulations that would improve their effectiveness and, in some cases, reduce regulatory burden, without compromising the Government's public health and public safety objectives. More specifically, stakeholders indicated that

- the proposed prohibition on pressurized containers (e.g. metered-dose inhalers) should not form part of the final Regulations, as pressurized containers are subject to controls to regulate their safety under the *Canada Consumer Product Safety Act*;
- requirements for the display of THC and CBD quantity or concentration on product labels should be standardized, thereby enabling consumers to make more informed decisions about consumption;
- it would be easier for consumers, sellers, and law enforcement to determine compliance with the public possession limit of 30 grams of dried cannabis "or equivalent" if the labels on cannabis products indicated the product's equivalency to 30 grams of dried cannabis; and
- the proposed transition period of 6 months for cannabis oil be extended to 12 months, with a view to ensuring continued supply to existing products by registered clients who consume cannabis for medical purposes.

The regulatory text has been adjusted to account for all of the above-noted feedback.

E. Guidance and public education

During the public consultation, industry stakeholders emphasized the need for further guidance related to the amended Regulations, including guidance pertaining to
timing of the licence amendment process
for the new classes of cannabis (see the "Implementation" section below for further details). Provincial and territorial partners as well as industry also requested additional guidance regarding whether a product, package, or label can reasonably be considered "appealing to young persons." To that end, Health Canada will publish guidance that will outline factors that regulated parties should consider (such as a product's shape, colour, ingredients, flavour, packaging, etc.) when assessing whether a product, package or label could be considered reasonably appealing to young persons.

Public health stakeholders similarly emphasized the importance of public education around the new classes of cannabis, as well as updated health warning messages addressing the unique public health risks of edible cannabis and cannabis products with a higher concentration of THC. Comments received during the public consultation were carefully considered when developing the updated *Consumer Information – Cannabis document*, as well as the updated *Cannabis Health Warning Messages*, which are documents that are published on the Government of Canada's website, and that have been incorporated by reference or are referred to as part of the Regulations (see the "Incorporation by reference" section, below).

Modern treaty obligations and Indigenous engagement and consultation

The Government of Canada acknowledges the interests of Indigenous communities and governments in establishing regulatory models and rules for cannabis that meet their unique needs. Broadly speaking, Indigenous regulatory authority derives from different sources, including rights recognized and affirmed in section 35 of the *Constitution Act, 1982*, historic and modern treaties and land claim agreements, self-government agreements, and federal legislation, such as the *Indian Act*.

Some First Nations and Inuit communities have negotiated self-government agreements and land claim agreements with the Government of Canada and provincial and territorial governments, which also contain legislative authority. Although self-government agreements

vary across the country, the powers related to the making of by-laws they contain are generally similar to those found in the *Indian Act*. They allow for the making of by-laws in relation to protecting the health of the community and law and order, as well as in relation to the control or prohibition of "intoxicants." Land claim agreements usually set out limited authorities in relation to the management of settlement lands and resources covered under the agreements. In the context of the *Cannabis Act* and its regulations, Indigenous communities with that authority may therefore choose to review their agreements in order to determine what laws or regulations they may wish to pass within their communities. Such laws could co-exist with the *Cannabis Act* as long as they do not conflict with the Act or frustrate its purpose. Indigenous communities would need to consider any additional restrictions they wish to establish to ensure they are consistent with the objectives of the *Cannabis Act*.

Support for the self-determination of Indigenous peoples is a key objective of the Government of Canada. This must be balanced with the need to ensure that the legal and regulatory framework for cannabis, including criminal prohibitions, is applied consistently across the country. Therefore, similar to the *Criminal Code*, the *Cannabis Act* is a federal law of general application that applies to all people in Canada, including Indigenous peoples.

Indigenous engagement and consultation

The Government of Canada is committed to a renewed, nation-to-nation relationship with Indigenous peoples, based on recognition of rights, respect, co-operation and partnership as the foundation for transformative change. Therefore, Health Canada continues to engage and work closely with Indigenous governments, organizations and communities across the country to help ensure the specific interests of Indigenous peoples are carefully considered.

Engagement with Indigenous peoples has been ongoing throughout the development of the *Cannabis Act* and its regulations, beginning with the work of the Task Force in June 2016. The Government of Canada has engaged extensively with Indigenous leadership, organizations and communities to provide information on the Act and Regulations and to discuss the unique interests of First Nations, Inuit and Métis. As of April 2019, Government of Canada officials have participated in more than 140 engagement sessions with Indigenous leaders, organizations and communities. Through these discussions, First Nations, Inuit and Métis organizations and leaders have expressed a wide range of diverse views and objectives regarding cannabis legalization and regulation. Four themes have arisen consistently:

- public health and public education;
- taxation and revenue generation;
- Indigenous authorities over activities related to cannabis; and
- economic development.

The Government understands that there is significant interest among Indigenous communities in Canada regarding the *Cannabis Act* and its regulations and has taken important steps to address specific interests expressed by Indigenous communities and organizations. The Government will continue to work closely with Indigenous communities and organizations to ensure that their specific needs and interests are carefully considered throughout the implementation of the *Cannabis Act*.

To support the consultation on the proposed regulatory amendments published in the *Canada Gazette*, Part I, on December 22, 2018, Health Canada published a notice in the *First Nations Gazette* on the same date, with the goal of ensuring a robust consultation of Indigenous peoples. Additionally, Health Canada invited the input of Indigenous organizations by directly notifying National Indigenous Organizations, Political-Territorial Organizations and Modern Treaty Holders when the consultation was launched. During the public consultation, just under 5% of respondents self-identified as an Indigenous person, which is proportionate to the Canadian population as a whole. Responses among this group did not significantly differ from the responses of those who did not self-identify.

Instrument choice

Incorporation by reference

A number of documents have been incorporated by reference (IBR) or are referred to as part of the Regulations.

The *Cannabis Health Warning Messages* and *Consumer Information – Cannabis* documents will be updated to address the unique public health risks associated with the new classes of cannabis (in particular, edible cannabis and cannabis products with a higher concentration of THC), and to refresh messaging. The updates to the two documents have been informed by advice from scientific experts, the best available evidence from peer-reviewed scientific publications, the outcomes of public opinion research conducted in May 2018 and February 2019, and feedback received during the public consultation on the proposed amendments to the Regulations. Both documents are considered important tools to help educate Canadians, including both new and experienced consumers, about the health effects and risks of cannabis, and to support informed and responsible use.

The Regulations require that the messages contained in the *Cannabis Health Warning Messages* document be displayed on the label of cannabis products, and that they be rotated, such that each health warning message is displayed, to the extent possible, on equal numbers of containers for each brand name of a cannabis product that is packaged in a year. Whereas currently there are 14 health warning messages for dried cannabis products (13 for all other cannabis products), moving forward, there will be 1 health warning message for cannabis topical products, and 8 health warning messages for all other cannabis products.

The *Consumer Information – Cannabis* document is a key public education tool intended to be distributed at the point of sale. Recognizing that those who are reading this document have already chosen to purchase cannabis, this document will be updated to provide important information on how to minimize the health risks associated with the consumption of cannabis.

One new document, the *Directory of Nutrition Facts Table Formats for Edible Cannabis*, will be incorporated by reference as part of the amended Regulations, and two existing IBR documents have been updated.

The new *Directory of Nutrition Facts Table Formats for Edible Cannabis* will set out technical requirements related to the format of the cannabis-specific NFT that must be displayed on the label of edible cannabis products. The formatting requirements for the NFT are modelled on the approach used for food, with minor adjustments for coherency with other cannabis product labelling requirements, such as font size, font type, and spacing.

The existing *Tolerance Limits for the Net Weight and Volume Declared on Cannabis Product Labelling* sets out an acceptable variance between the weight or volume of dried cannabis, fresh cannabis, and cannabis oil in relation to the amount that appears on the label. The existing tolerance limits for the existing classes of cannabis will not change. The amended document will establish tolerance limits for the new classes of cannabis, which have been modelled on established limits in other regulatory regimes, including the *Consumer Packaging and Labelling Regulations*, which establish tolerance limits for consumer products. The existing IBR document, which includes tolerance limits for cannabis oil, will be maintained during the 12-month transition period for cannabis oil.

In addition, a minor change will be made to the title of the IBR document entitled *Form and Manner Requirements – Documents Provided to the Minister of Health under the Cannabis Act*, to reflect the November 2018 Order in Council appointing the Minister of Border Security and Organized Crime Reduction as the Minister for the purposes of the Act. The new title of this IBR document will be *Form and Manner Requirements – Documents Provided to the Minister for the Purposes of the Cannabis Act*.

While new or updated versions of all of the above-noted documents have been made public, they will not take effect until such time as the amended Regulations come into force on October 17, 2019.

Finally, the current IBR document entitled *Limits for Residual Solvents in Cannabis Products* will no longer be incorporated by reference as part of the amended Regulations. Instead, given the requirement to treat solvent residues in the same way as other chemical contaminants, the limits for residual solvents and other chemical contaminants will be found in any of the publications listed in Schedule B to the FDA (which is a list of official publications that set out standards, such as the *European Pharmacopoeia*). Cannabis oil produced during the 12-month transition period (that is cannabis oil, rather than one of the new classes of cannabis) will continue to be subject to the residual solvent limits set out in the current IBR document.

Baseline scenario

As per section 193.1 and subsection 226(2) of the Act, “edibles containing cannabis” and “cannabis concentrates” will be added to Schedule 4 to the Act on October 17, 2019.

For the purposes of this RIAS and the accompanying cost-benefit analysis (CBA), the baseline scenario assumes that section 193.1 of the Act would come into force on October 17, 2019, but that Schedule 4 would not be subsequently amended to add “edible cannabis,” “cannabis extracts,” and “cannabis topicals,” and that the amended Regulations would not come into force. In the absence of the amending Regulations, it is assumed that the Government would effectively rely on other frameworks (such as those for foods, vaping products, and cosmetics) to regulate these new classes of cannabis.

Even under the baseline scenario, minor regulatory amendments would still be required. This is because certain provisions of the current Regulations, such as restrictions on mixing cannabis with most ingredients, would effectively preclude the production of “edibles containing cannabis” and “cannabis concentrates,” regardless of the fact that their legal sale might be permitted under the *Cannabis Act*. For the purposes of the baseline scenario, it is assumed that amendments would be made to any provisions preventing the production and sale of these classes. In particular, the baseline scenario assumes that the current maximum

yield quantity of 30 mg of THC per millilitre of cannabis oil (equivalent to 3%) would be removed, thereby enabling the production and sale of cannabis oil products with a higher concentration of THC (i.e. "cannabis concentrates"), and that the use of ingredients in "edibles containing cannabis" would be permitted. In the baseline scenario, such amendments would allow for the production of a limited suite of edible and concentrated products, but not the same comprehensive range of cannabis products that will be permitted under the amended Regulations. Under the baseline scenario, it is assumed, for example, that cannabis oil containing higher concentrations of THC would be permitted, but that other cannabis extracts that are not in liquid form at room temperature would not (e.g. wax, hash).

Because edible cannabis meets the definition of "food" under the FDA (and, by extension, the SFCA), the baseline scenario assumes that "edibles containing cannabis" would be subject to both the *Safe Food for Canadians Regulations* (SFCR) and the *Cannabis Regulations*. In this scenario, the FDA and its regulations would not apply; this is because the *Cannabis Exemption (Food and Drugs Act) Regulations* exempt cannabis produced in accordance with the *Cannabis Act* from the application of the *Food and Drugs Act*, subject to certain conditions.

The baseline scenario also assumes that a specific regulatory scheme designed to address the public health and public safety risks posed by edible and concentrated forms of cannabis would not be created, which is clearly inconsistent with the objectives of the Act.

Regulatory scenario

In contrast, under the regulatory scenario, three new classes of cannabis (i.e. edible cannabis, cannabis extracts, and cannabis topicals) will be added to Schedule 4 to the Act. Amendments will be made to the Regulations to address the public health and public safety risks of these new classes of cannabis, resulting in benefits for Canadians. Other amendments to the Regulations will be made to permit a comprehensive range of cannabis products, consistent with the Government's objective of displacing the illegal market.

To reduce the risk of duplication and overlap between regimes and to create clarity and predictability for regulated parties, these new classes of cannabis will be regulated, at the federal level, under the *Cannabis Act* and the *Cannabis Regulations*. More specifically, Health Canada will issue a Notice clarifying that edible cannabis will not be subject to the SFCA and its regulations.

Under the regulatory scenario, relevant requirements of other frameworks, such as those for food, cosmetics, and vaping products under the SFCA, the FDA, and the *Tobacco and Vaping Products Act*, will be incorporated or adapted into the *Cannabis Regulations*, thereby creating consistency between frameworks.

Regulatory analysis

Costs and benefits

It is estimated that the amendments to the Regulations will result in a net cost to Canadians of approximately $41.2 million net present value (PV), in 2017 dollars (or $5.9 million annually). These costs, which will be borne by the regulated industry (in particular, licensed processors), are primarily associated with costs to comply with new regulatory requirements for packaging and labelling, good production practices, testing, record keeping, and understanding the Regulations. Despite the net cost of the amended Regulations, the qualitative benefits are expected to outweigh the net cost to Canadians. These benefits include: (i) helping to displace the illegal market; (ii) providing adult consumers and registered clients of licensed sellers of cannabis for medical purposes with access to quality-controlled edible cannabis, cannabis extracts, and cannabis topicals; and (iii) measures to address the public health risks of the new classes of cannabis.

Market projections

The CBA conducted for the current *Cannabis Regulations* considered total demand for cannabis products, and did not distinguish between classes of cannabis that became legal to sell in Canada by authorized persons on October 17, 2018, and the new classes of cannabis. In other words, the market projections included in the RIAS published in the *Canada Gazette*, Part II, on July 11, 2018, accounted for edible cannabis, cannabis extracts, and cannabis topicals.

According to a recent report, an average of 43% of the total cannabis market in Colorado, California and Oregon between January and July of 2018 was made up of cannabis products other than dried cannabis (based on the top 10 products). Assuming the trend is consistent in Canada, the new classes of cannabis will likely represent over time a significant portion of the total market.

Analytical approach

The *Cabinet Directive on Regulation* requires departments to analyze the costs and benefits of federal regulations. To measure these impacts, the benefits and costs are estimated by comparing the incremental change from the current regulatory framework (i.e. the “baseline scenario”) to what is anticipated to occur under the new regulatory approach (i.e. the “regulatory scenario”).

The baseline scenario, which is described under the “Instrument choice” section above, assumes that edible cannabis would be subject to the *Cannabis Regulations* and the SFCR, but that the FDA and its regulations would not apply. In contrast, under the regulatory scenario, edible cannabis will not be subject to the SFCR. Therefore, for the purposes of this CBA, any of the new regulatory requirements that have been adapted from the SFCR do not represent a cost to industry. However, any of the new requirements adapted from the *Food and Drugs Regulations* in the regulatory scenario do represent a cost to industry. The regulatory scenario represents the most likely outcome of the amendments and additions to the Regulations, based on current information.

The period of analysis for this CBA covers the 10-year period from 2019–2020 to 2028–2029, with each year starting on October 17 and ending on October 16 of the following calendar year. As per Treasury Board of Canada Secretariat guidelines, the CBA only assesses incremental impacts directly related to a regulatory requirement. Any impact that is not associated with a regulatory requirement is considered out of scope for the purposes of the CBA. A 7% discount

rate is used to estimate the present value of the incremental costs and benefits. All values are expressed in 2017 constant dollars and reported for the 10-year period unless otherwise stated.

A summary of the CBA is provided herein. A copy of the full CBA report is available upon request from cannabis@canada.ca.

Assessing regulatory impacts

Regulatory impacts in this analysis have been estimated using two approaches: quantitative analysis, where possible, and qualitative assessments. For the quantitative analysis, Health Canada relied on responses to questionnaires distributed to licence holders in February 2018 and February 2019. Where data was not available from these questionnaires, internal Health Canada data, as well as data from previous cost-benefit analyses (such as the CBA supporting the *Safe Food for Canadians Regulations*) and data from the United States were used as proxies to quantify the impacts of the regulatory changes. When quantification of estimates was not possible, qualitative assessments have been provided.

Affected stakeholders

As discussed above, a cannabis processing licence (either standard or micro) will be required to produce edible cannabis, cannabis extracts, and cannabis topicals and to package and label them for sale to consumers. Licensed processors will be subject to all of the new rules applying to the production of the new classes of cannabis, as well as any new requirements for existing classes of cannabis, as applicable. Therefore, costs to the industry associated with the amended Regulations will be borne primarily by licensed processors. At the same time, these licensed processors also stand to benefit financially from the sale of the new classes of cannabis.

Current consumers of edible cannabis, cannabis extracts and cannabis topicals purchased from the illegal market, as well as current consumers of cannabis products purchased legally (including those who have the authorization of their health-care practitioner to access cannabis for medical purposes) will also be impacted by the amendments to the Regulations. The impacts on consumers are discussed further as part of the analysis below.

Government costs are not described as part of this CBA, as total government costs were included in the CBA conducted for the current *Cannabis Regulations*. As will be described further below, it is expected that the Government of Canada would benefit from a small cost savings in the regulatory versus the baseline scenario.

Key assumptions

The following assumptions were made when developing the CBA:

- As mentioned above, the CBA conducted for the *Cannabis Regulations* considered the total demand for cannabis products (including edible cannabis, cannabis extracts, and cannabis topicals). As a result, this CBA assumes that there would be no new market entrants (i.e. no increase in the total number of federal licence holders) beyond those that were previously forecasted to enter the market.

- Based on projections from the CBA conducted for the *Cannabis Regulations*, it is assumed that there would be 435 licensed processors by the final year of this analysis (2028–2029). This projected number was based on a number of assumptions, including that the rate at which new licences would be granted would be consistent with the rate at which licences were being granted under the former *Access to Cannabis for Medical Purposes Regulations*. These assumptions likely underestimate the number of licences that will be granted, based on improvements and resources that Health Canada has put in place to improve the review of licence applications, as well as potential efficiencies to be gained through the Cannabis Tracking and Licensing System.
- For the purposes of this CBA, an assumption has been made that all licensed processors will manufacture all of the new product classes. This assumption may result in an overestimation of costs to industry. This is not to say that there won't be space in the legal market for licensees who may choose to specialize in the processing of one or more of the new classes of cannabis (e.g. cannabis extracts only, or edible cannabis only).

Assessment of costs and benefits

It is estimated that the amendments to the Regulations will result in a total cost of $54.3 million PV (or $7.7 million annually) and a total benefit of $13.1 million PV (or $1.9 million annually). Taken together, the amendments are estimated to generate a net cost of $41.2 million PV over 10 years (or $5.9 million annually). Total costs are attributed to federal licence holders only (primarily licensed processors), whereas the total benefits are attributed to both industry (including federal licence holders and provincially and territorially authorized distributors and retailers), the Government of Canada, and consumers, with the majority of benefits going to consumers.

The sale of edible cannabis, cannabis extracts and cannabis topicals (with the exception of cannabis oil) is currently illegal in Canada. However, a wide range of products are currently being sold in the illegal market. Once the Regulations have been amended and the new classes of cannabis have been added to Schedule 4 to the *Cannabis Act*, it is expected that products produced by the legal industry will, over time, capture an increasing share of the market. In other words, it is expected that the amended Regulations will help to achieve the Government's objective of displacing the illegal market.

For the purpose of this CBA, the displacement of the illegal market is considered a transfer of revenue from the illegal to the legal market. Although federal licence holders (as well as provincially and territorially authorized retailers) can be expected to benefit from this transfer, as they will accrue profits from the sale of these new cannabis products, the economy-wide impact is neutral; therefore, the benefit has not been quantified as part of this CBA.

While it can be expected that some displacement of the illegal market would occur even under the baseline scenario (given that the baseline scenario assumes that a minimal set of regulatory amendments would be made to allow for the production of edible cannabis and cannabis oil with a higher concentration of THC than is permitted under the current Regulations), the amended Regulations will authorize the production of a much broader suite of new cannabis products than would be allowed under the baseline scenario. Specifically, under the baseline scenario, only concentrated forms of cannabis oil would be permitted (not the broader

category of cannabis extracts), and the vast majority of cannabis topicals would not be permitted.

It should be noted that there are a number of products currently available from the illegal market that will not be permitted under the amended Regulations. This includes products that pose a risk of injury to human health, products that could have serious effects if consumed accidentally, products that do not have restrictions in place to prevent overconsumption (e.g. no THC limits, no integrated dispensing mechanism), and products that are appealing to young persons. While these strict restrictions may be viewed as a "cost" to regulated parties, it is expected that any such costs would be outweighed by the significant, if not quantified, benefits to public health and public safety. Furthermore, it is anticipated that alternatives to many of these riskier products will eventually become available through the legal market.

In order for federal licence holders to produce these new classes of cannabis and benefit financially from their sale, they will need to meet all of the new regulatory requirements and incur the applicable compliance and administrative costs associated with the amended Regulations. These regulatory costs are described in further detail below.

Costs

A. Packaging and labelling requirements

Given that it is currently illegal to sell edible cannabis, cannabis extracts, and cannabis topicals in Canada (with the exception of cannabis oil), it is reasonable to assume that the packages and labels for most of these products have not yet been designed or produced.

In both the baseline and regulatory scenarios, a one-time cost would be incurred to design and produce packages and labels for the new classes of cannabis. This analysis contends that because the design and production costs would be incurred regardless of the regulatory requirements, no incremental costs to regulated parties are associated with the new labelling requirements for the new classes of cannabis. All costs related to the placement of new mandatory information on the package or label (including the list of ingredients, the list of allergens, the durable life date, and the cannabis-specific NFT, as applicable) are not considered to be incremental in comparison with the baseline scenario.

This assumption is consistent with cost-benefit analyses conducted for other packaging and labelling regulations, which have also assumed that companies regularly redesign their packaging and labelling in order to remain competitive and relevant. In a CBA guide to the costs and benefits of nutrition labelling, the United Nations Food and Agriculture Organization (FAO) stated: "If the imposition of mandatory nutrition labelling provides for a transition period, during which time industry can exhaust their existing stock of labels, it is possible to minimize redesigning and reprinting costs. Industry can then include the required nutrition information on future labels as part of routine redesigning/updating of food labels, and thereby minimize the costs arising from complying with mandatory labelling."

The two following new labelling requirements will apply to both existing and new classes of cannabis:

- the new requirement for the label of all cannabis products (except dried cannabis and cannabis plants) to indicate the product's equivalency to grams of dried cannabis for the purpose of complying with federal public possession limits); and
- the new requirement that THC and CBD content on labels be standardized in either milligrams per gram or total milligrams.

Labels for existing classes of cannabis will also need to be updated with the new *Cannabis Health Warning Messages*.

For the new classes of cannabis, any costs related to these new labelling requirements are not considered incremental in comparison with the baseline scenario. However, it is reasonable to assume there will be incremental costs associated with these labelling changes for existing classes. To reduce the impacts of these changes on industry, a 12-month transition period will be provided. During this period, licensed processors will be permitted to reduce or deplete stocks of existing labels. As well, any dried cannabis, fresh cannabis, cannabis plants, or cannabis seeds packaged and labelled in accordance with the existing Regulations, prior to the end of the 12-month transition period, may continue to be sold indefinitely by authorized retailers and licensed sellers of cannabis for medical purposes. For licensed processors who are currently producing existing classes of cannabis, it is anticipated that complying with these new labelling requirements will result in an incremental cost of $9.8 million PV over 10 years (or $1.4 million annually).

One aspect of the new packaging and labelling requirements for the new classes of cannabis that imposes an incremental cost on industry is the Nutrition Facts Table (NFT). While the *placement* of the NFT on the package is not considered an incremental cost, the *development* of the NFT is. Licensed processors will be required to conduct an analysis of the energy value and quantity of fat, carbohydrates, protein, etc., in edible cannabis products, in order to accurately specify these in the cannabis-specific NFT.

This cost will be assumed by licensed processors on an ongoing basis over the 10-year period. The cost is a one-time cost per stock keeping unit (SKU), with new SKUs expected to enter the market on an annual basis. For licensed processors, it is anticipated that complying with this requirement will result in a cost of $15.2 million PV over 10 years (or $2.2 million annually).

B. Good production practices

As mentioned above, for the purposes of this CBA, any of the regulatory requirements that have been adapted from the SFCR are not considered to represent a cost to industry, given the way in which the baseline and regulatory scenarios have been defined. In other words, given that most of the new good production practices (GPP) requirements have been adapted from the SFCR, the incremental costs to industry associated with the new GPP requirements are minimal.

One requirement that was not adapted from the SFCR is the amendment to section 80 of the Regulations, whereby standard operating procedures will apply equally to cannabis (as is currently the case) and to ingredients used in the production of cannabis products. For licensed processors, it is anticipated that complying

with this new requirement will result in a cost of $20.6 million PV over 10 years (or $2.9 million annually).

C. Solvent testing

The current Regulations require that cannabis oil be tested for the residues of solvents used in its production. Similarly, the amended Regulations will require solvent residue testing on edible cannabis, cannabis extracts, and cannabis topicals. As well, minor adjustments to this requirement will be made respecting the timing of testing (e.g. for edible cannabis, solvent residue testing will need to be conducting on the "input" cannabis rather than final form of the product). It is anticipated that licensed processors will assume a cost of $7.9 million PV over 10 years (or $1.1 million annually) to conduct solvent residue testing for the new classes of cannabis.

D. Record keeping

Under the amended Regulations, edible cannabis, cannabis extracts and cannabis topicals will be subject to all of the same record-keeping requirements that currently apply to all cannabis products, as well as to some additional requirements as described under the "Description" section above. The additional time required for the record keeping of these new products (over and above current record-keeping requirements) is assumed to be minimal. The CBA conducted for the *Cannabis Regulations* assumed that the amount of time needed to comply with current record-keeping requirements would be 30 minutes per week. The current CBA assumes that the additional record-keeping requirements described herein would add an additional 10 minutes to the weekly record-keeping time. Records would be kept electronically, following the same procedures being used for the record keeping of products under the current Regulations. It is anticipated that the incremental cost of the new record-keeping requirements for licence holders will be $689,816 PV over 10 years (or $98,214 annually).

E. Understanding the Regulations

When the amended Regulations come into force, certain aspects of the regulatory framework for activities related to cannabis will change. This is especially true in respect of edible cannabis, cannabis extracts and cannabis topicals. In order to comply with any new or amended regulatory requirements, licence holders would spend time reviewing and understanding the requirements that affect their day-to-day business operations. This CBA assumes that it will take the same amount of time, per licence holder, to read and understand the amended Regulations as it did for them to read and understand the current Regulations. It is anticipated that the measures taken to understand the amended Regulations would cost $190,021 PV over 10 years (or $27,055 annually).

Qualitative costs

A. Integrated dispensing mechanism

As noted in the "Description" section above, the immediate container of certain cannabis extracts in liquid form will be required to contain an integrated dispensing mechanism. This requirement is intended to protect adult consumers and youth alike

from the risks associated with overconsumption and accidental consumption. It is anticipated that the requirement to build an integrated dispensing mechanism into immediate containers will impose an incremental cost on licensed processors.

As part of the February 2019 questionnaire sent to licence holders, Health Canada asked licence holders to estimate the cost, per container, of complying with this requirement, as well as the total number of containers to which this requirement would apply (on an annual basis). Approximately one third of respondents to the questionnaire provided an estimated cost; estimates ranged from $0.05 to $1.50 per container. Estimates of the total number of impacted containers were highly variable. On the basis of responses received, Health Canada is unable to reliably assess the incremental costs to licensed processors associated with this new requirement. Of note, there are a number of liquid cannabis oil products for ingestion that are currently available through the legal market and that contain an integrated dispensing mechanism. As a result, for some product lines, the impact is expected to be minimal.

B. Limit of 1 000 milligrams of THC per container for cannabis extracts and cannabis topicals

As noted in the "Description" section above, the maximum amount of THC permitted per container for cannabis extracts and topicals is 1 000 mg. This measure is considered an important safeguard to mitigate the risks of accidental consumption and overconsumption.

As no such limit exists currently for cannabis oil, this requirement will impose an incremental cost on licensed processors who are currently manufacturing cannabis oil products that contain more than 1 000 mg of THC per container. A scan of provincial online sales platforms indicates that a relatively small number of such products are currently being sold and the vast majority of cannabis oil products on the market currently appear to be in compliance with this new THC limit. For those products containing more than 1 000 mg of THC, the amount of THC was typically 1 200 mg per container.

As part of the February 2019 questionnaire, Health Canada asked licence holders to estimate the cost, per container, of this requirement, as well as the total number of containers to which this requirement would apply (on an annual basis). Only 2 licence holders who responded to the questionnaire indicated they would be impacted by this new requirement. Estimates of the resulting cost, per container, ranged from $0.63 to $1.50. On the basis of responses received, Health Canada is unable to reliably assess the incremental costs to licensed processors associated with this new requirement. However, Health Canada acknowledges that this limit may impose additional packaging and labelling costs on those licensed processors who are currently producing cannabis oil products that contain more than 1 000 mg of THC per container.

C. Standardized cannabis symbol on vaping products

As noted in the "Description" section above, the amended Regulations will require the standardized cannabis symbol to be displayed on certain cannabis accessories that contain a cannabis extract, such as a vaping device or a vaping cartridge.

As part of the February 2019 questionnaire sent to licence holders, Health Canada asked licence holders to estimate the cost, per unit, of this requirement, as well as the total number of units to which this requirement would apply (on an annual basis). Approximately 45% of respondents provided an estimated cost. Estimates of the cost, per unit, associated with

this new requirement ranged from $0.05 to $1.50. Estimates of the total number of impacted units were highly variable. On the basis of responses received, Health Canada is unable to reliably assess the incremental costs to licensed processors associated with this new requirement, however, acknowledges that this requirement will impose costs.

D. Prohibition on manufacturing cannabis in the same building as food

As noted in the "Description" section above, under the amended Regulations, the production of cannabis will need to occur in a separate building from food production. This measure will help minimize the risks of cross-contamination of Canadian food products with cannabis and reassure Canadians and Canada's international trade partners as to the safety and quality of Canada's food safety system and Canadian food exports.

During the public consultation on the proposed amendments, a majority of industry stakeholders, and particularly those in the food industry, suggested that this prohibition was overly burdensome and that the costs of building a separate facility could pose a barrier to entry for small food businesses who may be interested in becoming part of the legal cannabis industry.

At the same time, in response to the February 2019 questionnaire, a majority of those licence holders who indicated that they were planning to produce both edible cannabis and food also indicated that this prohibition would have no impact on their planned business model (given that they were intending to produce edible cannabis in a licensed facility where other classes of cannabis are already being processed, rather than utilizing facilities where food is manufactured). Of those who responded to the questionnaire, two licence holders indicated this prohibition would impose costs.

There would be a significant cost to Canadians if cannabis were to end up in food products. In particular, there would be an increased risk of cannabis being accidentally ingested, including by young persons. This could result in having to make warnings on labels of food products, such as school snacks, similar to what is done for peanuts when products are not manufactured in a peanut-free facility (e.g. "may contain traces of nuts").

Health Canada also considered the potential costs to the food industry that would be associated with any barriers to the export of Canadian food products in the event of cross-contamination of foods with cannabis, which would be considerable.

E. Prohibitions and restrictions respecting certain representations and associations (packages, labels, promotions)

As noted in the "Description" section above, the amended Regulations will impose prohibitions and restrictions respecting certain representations and associations on product packages and labels, as well as in certain promotions (e.g. representations regarding health or cosmetic benefits).

It is anticipated that these prohibitions and restrictions will impose an incremental cost on licence holders, in that the prohibitions will limit the type of marketing that will be permitted for persons engaging in activities with cannabis. However, these prohibitions are entirely consistent

with the purpose of the Act, including the objective to “protect young persons and others from inducements to use cannabis.”

F. Promotions: Restrictions on the size and number of brand elements on a “thing”

As noted in the “Description” section above, the amended Regulations will restrict promotion conducted under subsection 17(6) of the Act, which permits the promotion of cannabis, a cannabis accessory, or a service related to cannabis through the display of a brand element (e.g. a logo or brand name) on certain “things” (e.g. t-shirts and hats), subject to the applicable restrictions and prohibitions. The amended Regulations will specify that only one brand element may appear on the “thing,” establish a maximum size limit for the brand element, and specify that such promotions cannot be on things located in places frequented mainly by young persons or visible from such places. These provisions may impose an incremental cost on persons engaging in promotional activities related to cannabis, to the extent that they need to adjust their promotional activities to comply with the new requirements. These restrictions will support achieving the Act’s purpose, including the objective to “protect young persons and others from inducements to use cannabis.”

Benefits

A. No SFCR licence

Under the baseline scenario, licensed processors would be subject to the *Cannabis Act* and the SFCA, and would therefore be required to obtain licences under both the *Cannabis Regulations* and the SFCR. Under the regulatory scenario, licensed processors will not be required to obtain a licence under the SFCR, resulting in a reduction in administrative burden. It is anticipated that licensed processors will benefit in the amount of $49,755 PV over the 10-year period (or $7,084 annually) in administrative costs savings as a result. Furthermore, licensed processors will not be required to pay the $250 fee to apply for a licence under the SFCR. It is anticipated that licensed processors will benefit in the amount of $401,088 PV over the 10-year period (or $57,106 annually) as a result of this fee savings.

Finally, the Government will benefit by saving the costs related to providing the service of administering and processing licences under the SFCR, which are not fully cost-recovered. In 2017, the Canadian Food Inspection Agency (CFIA), which administers the SFCR, conducted consultations on a proposed restructuring of its cost recovery regime. During these consultations, it was noted that CFIA fees are currently well below the cost to deliver services. The CFIA is continuing to examine its cost recovery structure and will consult stakeholders again before any restructuring takes place. For the purposes of this CBA, it is assumed that the fees charged to the industry reflect 10% of the government costs of providing the service to the industry. Therefore, it is estimated that the amended Regulations will result in savings to government of $2,250 per licence, or a total benefit of $3.6 million PV over the 10-year period (or $513,953 annually).

B. Labelling allowances to provide for smaller containers

As noted under the “Description” section above, the amended Regulations will permit the use of expanded panels on containers (i.e. peel-back and accordion labels) for the display of certain mandatory information. This allowance will apply equally to existing

and new classes of cannabis, thereby allowing for smaller containers than under the current Regulations. This allowance for smaller containers is expected to result in environmental benefits, as described below in the “Strategic Environmental Assessment” section.

This allowance is also expected to result in cost savings for licensed processors who package existing classes of cannabis. This is supported by the February 2019 questionnaire, in which 82% of respondents estimated this change would result in savings; the reduction in packaging costs was estimated, on average, to be 2.5%. Based on these responses, it is estimated that permitting the use of expanded panels on containers will result in an incremental cost savings of $9.0 million PV over 10 years (or $1.3 million annually).

Qualitative benefits

A. Public health

A number of provisions in the amended Regulations address the public health and public safety risks posed by the new classes of cannabis. The provisions are intended to protect public health by reducing the appeal of such products to youth, and the risks of overconsumption and accidental consumption. Furthermore, the amended Regulations contain a number of provisions designed to reduce the risk of foodborne illness associated with edible cannabis, including a number of provisions adapted from the SFCR (e.g. good production practices) and the FDR (e.g. food-grade packaging).

There is currently no legal commercial source of supply for consumers who may wish to purchase edible cannabis, cannabis extracts, and cannabis topicals in Canada (with the exception of cannabis oil). However, such products are readily available from the illegal market. Enabling the legal production and sale of these new classes of cannabis will provide adult Canadians with access to a legal, quality-controlled and strictly regulated supply of products in these classes. This represents a benefit for those who are currently purchasing such products from the illegal market.

Under the amended Regulations, current consumers of legal cannabis products (including registered clients of licensed sellers of cannabis for medical purposes) will be able to choose from among a much broader suite of legal products. Some products in the new classes represent a reduced health risk, such as alternatives to smoking cannabis. However, some of the new products that will be allowed under the amended Regulations represent a greater health risk, such as products with a higher concentration of THC. Public education efforts will be a critical component of mitigating the health risks of such products.

Canadians will also benefit from the prohibitions on representations and associations on products, packages, and labels, and in promotions, which are intended to protect young persons and others from inducements to use cannabis.

B. Public safety

The amendments to the Regulations will enable a broader suite of products than would be permitted under the baseline scenario. It is therefore anticipated

that the amended Regulations will prove more effective in terms of meeting the Government's objective of displacing the illegal market than would be expected under the baseline scenario.

Summary: Net impacts of amendments to the *Cannabis Regulations*

In summary, the amendments to the Regulations are estimated to generate a net cost to federal licence holders of $41.2 million PV over the 10-year period (or $5.9 million annually). In contrast, the potential public health and public safety benefits resulting from the amended Regulations are considerable, even if they cannot be quantified. It is expected that these benefits will outweigh the costs. The following table provides a detailed cost-benefit statement.

Table 1: Cost-benefit statement

	Base Year 2019–2020	**Year 4 2022–2023**	**Year 7 2025–2026**	**Year 10 2028–2029**	**Total (PV)**	**Annualized Average**
A. Quantified impacts (2017 constant dollars, CAN$)						
Benefits						
Benefits to federal licence holders						
No SFCR licence — Fee and administrative savings	77,927	24,706	98,242	24,706	450,843	64,190
Labelling allowances to provide for smaller containers	413,465	1,272,250	1,491,504	1,726,602	9,020,315	1,284,290
Benefits to government						
SFCR licence — Application processing savings	623,939	197,818	786,598	197,818	3,609,790	513,953
Total benefits of the amended Regulations	1,115,330	1,494,775	2,376,344	1,949,127	13,080,948	1,862,433
Costs						
Costs to federal licence holders						
Packaging and labelling requirements	5,387,664	1,500,733	1,480,064	1,478,476	24,946,437	3,551,811
Good production practices	13,503,725	33,009	0	0	20,575,896	2,929,545
Solvent testing	587,832	1,044,808	1,209,495	1,400,142	7,874,022	1,121,084
Record-keeping	62,697	98,919	98,421	98,315	689,816	98,214
Understanding the Regulations	124,709	305	0	0	190,021	27,055
Total costs of the amended Regulations	**19,666,625**	**2,677,773**	**2,787,980**	**2,976,933**	**54,276,192**	**7,727,709**
Net impact of the amended Regulations	**−18,551,295**	**−1,182,999**	**−411,636**	**−1,027,806**	**−41,195,244**	**−5,865,276**

Small business impact (cost)	***17,699,963***	***2,409,996***	***2,509,182***	***2,679,240***	***48,848,573***	***6,954,938***

B. Qualitative impacts

Benefits

Public health

- Reducing health risks for adult consumers of edible cannabis, cannabis extracts and cannabis topicals and registered clients of licensed sellers of cannabis for medical purposes
- Reducing risk of accidental consumption and overconsumption of cannabis, as well as foodborne illness
- Promoting informed consumer choice (e.g. nutrition facts table, list of ingredients, list of allergens)
- Reducing inducements for young persons and others to consume cannabis
- Minimizing the risk of cross-contamination of food with cannabis
- Reassuring Canadians and Canada's international trade partners as to the safety and quality of Canadian food

Public safety

- Displacing the illegal market (broader range of product forms)
- *Environmental benefits*
- Reducing, over time, the overall volume of packaging waste and a shift toward more environmentally friendly packaging materials

Costs

- Complying with the new requirement to package liquid extracts that are ingested in a container that includes an integrated dispensing mechanism
- Reducing the amount of THC per container, to comply with the new 1 000 milligram THC per container limit (applies only to those cannabis oil products that contain more than 1 000 mg THC per container)
- Ensuring that vaping products are labelled with the standardized cannabis symbol
- Increasing costs for small food businesses to become part of the legal cannabis industry (i.e. prohibition on manufacturing cannabis in a food facility)
- Reducing the ability for licence holders to differentiate their products from other products on the market (i.e. prohibitions on representations and associations on products, packages, labels, new promotions provisions)

Sensitivity analysis

A sensitivity analysis was conducted to show the estimated net impacts of the amendments to the Regulations at a 3%, 7% and 10% discount rate (7% was used in this analysis). At a 3% discount rate, the net impact would be a $43.2 million PV cost over 10 years, while a 10% discount rate would result in a $37.9 million PV cost over the 10-year period. As seen in Table 1, the 7% discount rate results in a net cost of $41.2 million PV over 10 years.

Small business lens

The cannabis industry is currently comprised mostly of small businesses. Based on internal Health Canada data and input from responses to questionnaires that were distributed to industry stakeholders in February 2018 and February 2019, it is assumed that 90% of licence holders will meet the definition of small business throughout the period from 2019–2020 to 2028–2029.

The *Cannabis Regulations* and the current amendments to the Regulations were both developed with small businesses in mind, which addresses the requirement to consider approaches that address small business needs. The requirements described herein are designed to address the public health and public safety risks associated with the new classes of cannabis. As such, it is considered important that all licence holders who opt to produce the new classes of cannabis comply with the new requirements pertaining to those classes. However, the licensing framework provides alternative compliance approaches for smaller producers. First, it will be possible for holders of a micro-processing licence (as opposed to a standard processing licence) to produce, package and label the new classes of cannabis. Micro licence holders are subject to somewhat reduced physical security requirements as compared with standard licence holders, reflecting differences in the risk of diversion related to the scale of the operation, which reduces upfront capital costs and facilitates compliance. Second, given that a number of the new requirements are specific to one or more of the new classes of cannabis, small businesses could opt to specialize in, for example, only the production of cannabis extracts, and would not need to comply with requirements pertaining to edible cannabis.

Of the $54.3 million PV cost to industry over the 10-year period, roughly $48.8 million PV (2017 base year) will be assumed by small businesses ($7.0 million annually). The cost per small business decreases from roughly $71,000 in Year 1 of the analysis, to just $6,800 in the final year.

As noted in the “Consultation” section above, based on feedback received a majority of industry stakeholders, and particularly those in the food industry, suggested that the prohibition on manufacturing cannabis in the same building as food may pose a barrier to entry for small food businesses who may be interested in becoming part of the legal cannabis industry. After carefully weighing the potential costs to the licensed cannabis industry and potential new market entrants against the significant costs that would be associated with any barriers to the export of Canadian food products, the final regulations will prohibit any class of cannabis from being manufactured in the same building as food products. This measure will help minimize the risks of cross-contamination and help ensure the continued confidence of Canadians in the Canadian food supply system and reassure Canada’s international trade partners as to the safety and quality of exported food.

Small Business Lens Summary		
Number of small businesses impacted	392 (final year)	
Number of years	10 years (2019–2020 to 2028–2029)	
Base year for costing	2017	
Compliance costs	**Annualized Value**	**Present Value**
Packaging and labelling	$3,196,630	$22,451,793
Good production practices	$2,636,590	$18,518,307
Testing	$1,008,975	$7,086,620

Understanding the Regulations	$21,914	$153,917
Total	**$6,864,110**	**$48,210,637**
Administrative costs	**Annualized Value**	**Present Value**
Record keeping	$88,393	$620,834
Understanding the Regulations	$2,435	$17,102
Total	**$90,828**	**$637,936**
Total cost (all impacted small businesses)	**$6,954,938**	**$48,848,573**

“One-for-One” Rule

As per the requirements of the *Red Tape Reduction Act* and the *Red Tape Reduction Regulations*, the increase in administrative burden costs on all affected industry stakeholders has been estimated over a 10-year period (2019–2020 to 2028–2029) and discounted to 2012 using a 7% real discount rate. The “One-for-One” Rule applies since there is an incremental increase in administrative burden on business, and the amended Regulations are considered an “IN” under the Rule. Given that this is an amendment to an existing regulation (the *Cannabis Regulations*), there is no net increase or decrease in regulatory titles.

The total net incremental increase in administrative burden for industry resulting from the amendments to the Regulations has been estimated at $352,876 PV over the 10-year period, in 2012 dollars. The annualized incremental net cost is estimated to be $50,242, or $122 per business. This estimate is based on consultations with licence holders conducted as part of the CBA for the *Cannabis Regulations*, as well as departmental expertise and analysis.

The anticipated increase in administrative burden is mostly related to the additional record-keeping requirements to which licensed processors will be subject (i.e. 10 additional minutes per week per licence holder on an ongoing basis, as described above). There is also an increase in administrative burden related to the cost associated with understanding the amended Regulations, which is a one-time cost incurred by every licence holder. These increases are partially offset by not needing to apply for or renew a licence under the SFCR, which is estimated to result in savings of one hour every two years per licence holder.

Regulatory cooperation and alignment

International

The *Cannabis Regulations* are part of a new and unique approach to controlling the public health and public safety risks associated with cannabis on a national scale. Canada has actively engaged international partners to promote understanding of the overarching objectives of the *Cannabis Act*. As the non-medical use of cannabis is currently illegal at the national level in other Organisation for Economic Co-operation and Development (OECD) member states, opportunities for regulatory alignment are limited. Nevertheless, given the scope of this national initiative, the regulatory framework has been informed by best practices and lessons learned from other jurisdictions, including a number of U.S. states that have legalized and regulated cannabis for non-medical purposes. Health Canada will continue to engage with these jurisdictions in order to collect and share public health information and best practices in this field.

Canada is a party to three United Nations drug control conventions: the *Single Convention on Narcotic Drugs, 1961* as amended by the 1972 Protocol; the *Convention on Psychotropic Substances, 1971*; and the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988*. General international trade in cannabis is prohibited by the drug conventions of the United Nations. Therefore, under the *Cannabis Act* and its regulations, the import and export of cannabis is permitted only for scientific or medical purposes, or in respect of industrial hemp. A permit is required from the Minister in order to import or export cannabis. No changes will be made to the import and export provisions of the Regulations.

Provinces and territories

Building on the advice provided by the Task Force, Health Canada has maintained regular and ongoing contact with the provinces and territories throughout the development of the legislative and regulatory frameworks at the federal level and in each jurisdiction. Given the provincial and territorial responsibility for distribution and retail sale of cannabis, provincial and territorial partners were engaged extensively throughout the development of both the current and amended Regulations. Federal, provincial and territorial officials have worked closely together to design and implement the new legal and regulatory frameworks and are expected to continue to do so.

During the public consultation on the proposed amended Regulations, Health Canada held multilateral and bilateral meetings with officials from all 13 provinces and territories, to ensure their perspectives and feedback were carefully considered in the development of the final amended Regulations. This is in addition to ongoing meetings with senior officials from all provinces and territories. Dedicated webinars were also held with both public and private provincial and territorial sellers, to ensure they understood the regulatory proposals and answer any questions they might have.

Overall, the provinces and territories were supportive of the proposed amendments to the Regulations, noting that some of the proposed restrictions (e.g. the 10-milligram per container THC limit for edible cannabis products) were not consistent with the objective of displacing the illegal market. They emphasized the importance of public education and guidance to support implementation.

Strategic environmental assessment

As noted above, the environmental impacts of packaging for cannabis products was a major theme during the public consultation on the proposed amendments to the Regulations. Respondents felt that current packaging and labelling requirements for cannabis products contributes to excessive waste, and that the 10 mg limit proposed for edible cannabis would further exacerbate this issue. The current plain packaging and labelling requirements, including the requirements for child-resistant packaging and for certain mandatory information to appear on the label, as well as the limit of 10 mg of THC per container for edible cannabis products, are important aspects of the Government's overall strategy to protect public health and to reduce inducements to consume cannabis, and are specifically targeted at protecting young persons.

Amendments to labelling requirements under the amended Regulations that allow for the use of peel-back or accordion labels are expected to enable smaller package sizes

for cannabis products without compromising the overall public health objectives of current packaging and labelling requirements. The amended Regulations will also allow for the use of wrappers to maintain the quality and stability of the cannabis product. It is expected that enabling the use of wrappers will allow licensed processors to move toward the use of materials other than plastics (e.g. cardboard) for cannabis product packaging.

The Regulations do not require the use of plastic for cannabis product packaging, however, they do require that packages be child-resistant, consistent with rules for pharmaceutical drugs in Canada. Based on the experience of U.S. jurisdictions that have legalized and regulated cannabis, child-resistant packages are available in more environmentally friendly materials, such as cardboard and recycled materials. Over time, we expect innovations by the licensed industry and programs to address waste from cannabis product packaging to emerge. For example, PEI Cannabis Corp. has implemented a program in stores across the province, where consumers can bring in cannabis packaging to be recycled. Some private cannabis sellers across the country have taken it upon themselves to do the same.

It is anticipated that the amended Regulations will have a positive impact on the environment, in that they may, over time, result in a reduction in the overall volume of packaging waste and a shift toward more environmentally friendly packaging materials. Reducing plastic waste is one of the environmental sustainability priorities set out in the *Federal Sustainable Development Strategy 2019-2022*.

Gender-based analysis plus (GBA+)

Prevalence of cannabis use according to age and sex

Canadian surveys of cannabis use suggest there are differences in the prevalence of cannabis use according to age (with youth and young adults having higher rates of use than adults over the age of 25) and sex (with males having higher rates of use than females). There is also evidence to suggest that males are more likely than females to use cannabis on a daily or almost daily basis.

According to the 2017 Canadian Tobacco, Alcohol and Drugs Survey (CTADS), a biennial general population survey of tobacco, alcohol and drug use among Canadians aged 15 years and older, 19% of youth (i.e. individuals aged 15 to 19) and 33% of young adults (i.e. individuals aged 20 to 24) reported past-year cannabis use. This prevalence is markedly higher than that of adults aged 25 and older, only 13% of whom reported past-year cannabis use. The prevalence of past-year cannabis use among males 15 years and older (19%) was higher than among females (11%). Additionally, the prevalence of cannabis use among males was reported to be higher in 2017 (19%), as compared with a past-year use rate of 15% among males in 2015, suggesting that the prevalence of use among males might be on the rise.

Nonetheless, the age of initiation to cannabis use did not differ significantly by sex, at 18 years for males and 19 years for females. The average age of initiation is highly dependent on the age range of the respondents in the survey, as well as the distribution of respondents within predetermined age groups. Adults aged 25 years and older were on average 19 years old when they first tried cannabis, compared to 17 years among individuals aged 20 to 24 and 16 years among individuals aged 15 to 19.

The 2016-2017 Canadian Student Tobacco, Alcohol and Drugs Survey (CSTADS) found that 17% of respondents in grades 7 to 12 reported using cannabis in the last 12 months. Of those surveyed, 18% of males reported using cannabis, compared with 16% of females. Females were slightly older than males when they first used cannabis, at 14.4 years for females, compared to 14.1 years for males.

The 2018 Canadian Cannabis Survey (CCS) found that 25% of people who used cannabis in the past 12 months reported daily or almost daily use. A greater percentage of males (28%) reported daily or almost daily use compared to females (21%), whereas a greater percentage of females (43%) reported less than monthly use compared to males (30%).

Impacts of cannabis use according to sex and age

The current state of the evidence suggests sex-dependent differences with respect to a number of cannabis outcomes. For example, studies suggest a greater prevalence of problematic cannabis use (i.e. cannabis use disorder) among males. Other studies suggest females are more sensitive to the effects of THC, need less THC to achieve intoxication, and are more likely to experience adverse effects related to acute cannabis consumption. Evidence also suggests that female cannabis consumers progress more quickly to dependence/addiction. More research is needed to explain the fundamental sex-dependent differences relating to cannabis use.

Regardless of sex, the risks of experiencing adverse effects from cannabis appear to be greater if using cannabis products with a higher concentration of THC.

Studies suggest that cannabis use during pregnancy is associated with a number of different negative outcomes for children, including low birth weight and poorer longer-term developmental outcomes. Youth are particularly vulnerable to the effects of cannabis. This is because THC affects the same components in the brain that direct brain development, and research has shown that adolescence is a critical time for brain development. Cannabis use that begins early in adolescence, that is frequent and that continues over time has been associated with an increased risk of harms, some of which may not be fully reversible. At any age, cannabis use affects the way the brain functions, which includes impacts on attention, memory and learning.

The studies above suggest that public education efforts should take sex- and age-specific factors into consideration when developing key messages on effects and risks.

Patterns of cannabis use according to product class — Sex

Findings from the 2018 Canadian Cannabis Survey (CCS) suggest the most common method of cannabis consumption is smoking (89%), followed by eating cannabis in food (42%), vaporizing using a vape pen (26%), and vaporizing using a vaporizer (14%). Smoking was more common among males than females (90% of males reported smoking cannabis, versus 86% of females). A similar pattern was observed for vaping (with 16% of males reporting using a vaporizer, versus 12% of females, and 28% of males reporting use of a vape pen, versus 22% of females). There was no significant difference reported in the consumption of edible cannabis between males (40%) and females (44%).

In the 2017 CCS, smoking rates were reported at 94% (96% among males and 91% among females), the consumption of edible cannabis was reported at 34% (33% among males and 34% among females), and vaping using a vape pen was reported at 20% (23% among males and 17% among females). These results suggest that smoking rates of cannabis are decreasing, and that consuming edible cannabis and vaping cannabis with a vape pen are becoming increasingly popular methods of consumption.

Findings from the 2018 CCS suggest the most common type of cannabis product used is dried flower/leaf (82%), followed by edible cannabis (41%), hashish/kief (26%), solid concentrates (19%), liquid concentrates (17%), cannabis oil cartridges or disposable vape pens (16%), beverages (4%), and other products (4%). Use of hashish/kief was more common among males than females (31% among males, versus 19% among females). A similar pattern was observed for dried flower/leaf (83% of males, versus 80% of females), liquid concentrates (20% of males, versus 14% of females), solid concentrates (20% of males, versus 17% of females), and cannabis oil cartridges or disposable vape pens (18% of males, versus 14% of females). For edible cannabis, there was no significant difference in consumption between males (40%) and females (43%).

Patterns of cannabis use according to product class — Age

According to the 2018 CCS, respondents under the age of 25 reported greater use of dried cannabis, cannabis concentrates and extracts, and edible cannabis than those aged 25 years and older. Specifically, the use of

- dried leaf/flower was reported by 85% of those aged 16 to 19 years and 86% of those aged 20 to 24, versus 81% of those aged 25 and older;
- hashish/kief was reported by 47% of those aged 16 to 19 years and 34% of those aged 20 to 24 years, versus 22% of those aged 25 and older;
- liquid concentrates was reported by 22% of those aged 20 to 24, versus 17% of those aged 25 and above; and was unreportable for those aged 16 to 19 years;
- solid concentrates was reported by 32% of those aged 16 to 19 years and 28% of those aged 20 to 24 years, versus 15% of those aged 25 and older; and
- edible cannabis was reported by 43% of those aged 16 to 19 years and 50% of those aged 20 to 24 years, versus 39% of those aged 25 years and older.

Compared to the 2017 CCS results, the use of dried flower appears to be decreasing (previously reported by 93% of those aged 16–19 years, 91% of those aged 20–24 and 87% of those aged 25 and above), while the use of edible cannabis appears to be increasing across all age groups (previously reported by 35% of those aged 16–19 years, 33% of those aged 20–24 and 28% of those aged 25 years and above). The use of solid concentrates and hashish / kief seems to be increasing most among those aged 16–19 years: in 2017, the use of these cannabis products among those aged 16–19 years was reported at 23% and 38% respectively.

Similar patterns of use were observed among students in grades 7 to 12 as part of the 2016–17 CSTADS. Among students in grades 7 to 12 who used cannabis, 80% reported smoking cannabis, 34% reported consuming edible forms of cannabis, 30% reported vaping, 22% reported dabbing cannabis, and 14% reported drinking cannabis. Approximately 25% of students who reported using cannabis reported using more than one method of consumption.

Health Canada will continue to use national surveys such as the CCS, CTADS and CSTADS to monitor trends in cannabis use in Canada.

Indigenous considerations

Evidence suggests that Indigenous peoples are at a greater risk of experiencing complex mental health and substance-use issues due to a variety of factors, including the intergenerational impacts of Indian Residential Schools and colonialism, which have had lasting effects on many communities and families, as well as social, economic, and cultural inequities that persist today. In addition, those living in rural and remote areas have an increased vulnerability to mental wellness challenges due to their isolation. The Regional Health Survey (RHS) is a cross-sectional survey of First Nations living on-reserve and in northern communities across Canada. According to Phase 3 of the RHS, past-year cannabis use among First Nations adults 18 years of age and older is 30%; approximately 12% of adults reported daily or almost daily use. Past-year use among youth aged 12–17 decreased from 36% in Phase 2 to 27% in Phase 3.

Recognizing the unique context, interests and priorities of First Nations, Inuit and Métis across Canada, Health Canada will continue to engage and collaborate with Indigenous leadership, organizations, and communities over the long term as the cannabis regulatory framework is implemented and evolves. This will include sharing information about legalization and regulation, ensuring public education and awareness activities are effective, and ensuring that their interests are being fully considered. Health Canada will also continue to work together with government partners such as Indigenous Services Canada and Crown-Indigenous Relations and Northern Affairs Canada to support Indigenous organizations with expertise in mental wellness and substance use to lead key engagement and public education activities, and to support those interested in economic development and partnerships in the legal cannabis industry.

Implementation, compliance and enforcement, and service standards

Implementation

Licence amendments and new product notifications

A processing licence (either micro or standard) under the Regulations will be required in order to produce, package, label, and sell the new classes of cannabis. Health Canada has adopted a graduated licensing approach, whereby processing licence holders may first be authorized to conduct an initial set of activities, and must obtain approval from Health Canada in order to conduct new activities (or the same activity in respect of another class of cannabis). For example, a processing licence holder may be authorized to sell certain classes of cannabis (e.g. dried, fresh) to provincially or territorially authorized distributors or sellers or to federally licensed sellers of cannabis for medical purposes, but not other classes (e.g. oil). This has been operationalized through conditions of licence, which specify any restrictions pertaining to the authorized activities. As part of this graduated licensing approach, licensed processors will need to apply to Health Canada to amend their licence in order to sell these new classes of products.

In addition, as per section 244 of the Regulations, at least 60 days before making a new cannabis product available for sale, holders of a processing licence will need to provide

Health Canada with a written notice that states the class of cannabis to which the product belongs (as per Schedule 4 to the Act), a description of the product (including the brand name), and the date on which the product is expected to be made available for sale. As is currently the case, notification of a new product will not constitute “approval” for sale by Health Canada. Licence holders will continue to be responsible for making sure the new product meets all of the requirements set out in the Act and Regulations.

Health Canada will begin accepting applications to amend existing processing licences to permit the sale of the new classes of cannabis by mid-September 2019. For licensed processors that already have the authority to sell cannabis oil, it is expected that the licence amendment process will be completed within the 60-day new product notification period outlined above.

October 17, 2019, the date that the new classes of cannabis will be added to Schedule 4, is the earliest date that licensed processors will be able to provide notice to Health Canada of any products in the new classes that they are intending to sell. Accordingly, December 16, 2019, is the earliest date that notified products in the new classes could be made available for sale to provincially or territorially authorized distributors and sellers. It is also the earliest date that a licensed seller of cannabis for medical purposes could begin selling notified products in the new classes to registered clients. The availability of different products within the new classes of cannabis will depend on decisions taken by the industry as well as provinces and territories. Furthermore, it will likely take time before the licensed industry makes a full suite of products available.

Cannabis oil

One of the key changes resulting from the amended Regulations and the Order is that cannabis oil will be deleted from Schedule 4. The amended Regulations will include transitional provisions to allow current regulated parties and provincially and territorially authorized distributors and sellers to continue conducting activities with respect to cannabis oil while they put in place measures to meet the new regulatory requirements. For example, there will be a 12-month transition period following the coming into force of the amended Regulations for requirements pertaining to cannabis oil. During this transition period, authorized activities with cannabis oil could continue, provided that they are conducted in accordance with the applicable requirements under the Regulations as they read before the amended Regulations come into force. This transition period is intended to allow sufficient time for industry to make the necessary updates to its products, packages and labels to meet the new requirements.

Communications and guidance

Health Canada is committed to continuing to provide industry, the provinces and territories, and other stakeholders with relevant and timely information. External guidance will be developed and updated to facilitate transition. Key information to enable a smooth transition will be provided to industry as early as possible.

Consistency with other regulatory frameworks

The rules for edible cannabis, cannabis extracts, and cannabis topicals have been developed taking into consideration existing regulatory frameworks for food, vaping products, and

cosmetics. Health Canada will continue to work with the Canadian Food Inspection Agency and regulatory programs within Health Canada in order to ensure that the product rules are consistent with those under other frameworks, as appropriate, and remain consistent over time.

Compliance and enforcement

Health Canada will continue to provide oversight to verify that regulated parties are aware of and adhere to the proposed new regulatory requirements. Health Canada will take timely actions respecting individuals and businesses whose cannabis products or activities with cannabis pose an unacceptable risk to public health and/or public safety or do not comply with the applicable requirements. Health Canada's national compliance and enforcement approach would continue to apply, including promoting and verifying compliance with the Act and its regulations through inspections and other means, and working toward preventing non-compliance. In alignment with the Health Canada Compliance and enforcement policy framework and the Health Canada *Compliance and Enforcement Policy for the Cannabis Act*, and informed by the circumstances of each case, Health Canada takes a risk-based approach to its enforcement actions and will choose the most appropriate tool to achieve compliance and mitigate risks as circumstances warrant. The enforcement measures under the *Cannabis Act* and the *Cannabis Regulations* will continue to be available to Health Canada. These measures will maintain the same delivery approach, which ranges from activities intended to educate and prevent non-compliance through compliance promotion, to measures intended to bring a regulated party back into compliance or address a risk to public health or public safety. Enforcement measures could include, but are not limited to, warnings, product recall, product seizure, placing conditions on a federal licence, suspending or revoking a federal licence or permit, issuing administrative monetary penalties of up to $1 million, ministerial orders, or prosecution. To support its compliance objectives, Health Canada will also continue to collaborate with other partners, including the provinces and territories, law enforcement, the Canada Border Services Agency, the Canada Revenue Agency, the Canadian Food Inspection Agency and the Public Health Agency of Canada. Supported by the provisions in the *Cannabis Act* related to information disclosure, Health Canada may also disclose relevant information obtained under the Act where the disclosure is necessary to protect public health or public safety.

Service standards

A non-binding, 30-business day administrative standard has been established for application screening and import/export permit applications. Health Canada is committed to monitoring the administration of the cannabis regulatory program closely, as the requirements on this program normalize over the next year or so, with a view to establishing defined service standards in a variety of areas, such as the processing of licence amendments. Health Canada will also establish a forum with industry representatives to discuss the administration of the cost recovery regime and the development of service standards.

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