Regulations Amending Certain Regulations Made Under the Food and Drugs Act and the Controlled Drugs and Substances Act (Controlled Substances): SOR/2025-246

Canada Gazette, Part II, Volume 159, Number 26

Registration
SOR/2025-246 November 28, 2025

FOOD AND DRUGS ACT
CONTROLLED DRUGS AND SUBSTANCES ACT

P.C. 2025-844 November 28, 2025

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, makes the annexed *Regulations Amending Certain Regulations Made Under the Food and Drugs Act and the Controlled Drugs and Substances Act (Controlled Substances)* under

(a) section 30 [a] of the *Food and Drugs Act* [b]; and

(b) subsection 55(1) [c] of the *Controlled Drugs and Substances Act* [d].

Regulations Amending Certain Regulations Made Under the Food and Drugs Act and the Controlled Drugs and Substances Act (Controlled Substances)

Food and Drugs Act

Food and Drug Regulations

1 The definition *Act* in section A.01.010 of the *Food and Drug Regulations* [1] is replaced by the following:

Act
means the *Food and Drugs Act*; (*Loi*)

2 The definition *nurse practitioner* in subsection B.25.019(2) of the Regulations is replaced by the following:

nurse practitioner
has the same meaning as in subsection 1(1) of the *Controlled Substances Regulations*. (*infirmier praticien*)

3 Subparagraphs C.01.004(1)(b)(i) to (iv) of the Regulations are replaced by the following:

(i) in the case of a prescription drug, the symbol “Pr”, which must not appear on the label of any other drug,

(ii) in the case of a *controlled drug*, as defined in subsection 1(1) of the *Controlled Substances Regulations*, other than one contained in a finished product referred to in section 3 of those Regulations, the following symbol in a clear manner and a conspicuous colour and size,

(iii) in the case of a *narcotic*, as defined in subsection 1(1) of the *Controlled Substances Regulations*, the symbol "N" in a colour contrasting with the rest of the label or in type not less than half the size of any other letter used on the label, and

(iv) in the case of a *targeted substance*, as defined in subsection 1(1) of the *Controlled Substances Regulations*, the following symbol in a colour contrasting with the rest of the label or in type not less than half the size of any other letter used on the principal display panel,

4 Paragraph C.01.028(2)(c) of the Regulations is replaced by the following:

(c) a prescription drug or a *controlled drug*, *narcotic* or *targeted substance*, as those terms are defined in subsection 1(1) of the *Controlled Substances Regulations*, that is required by those Regulations to be sold under a *prescription*, as defined in that subsection.

5 (1) The portion of subsection C.01.031.2(1) of the French version of the Regulations before paragraph (a) is replaced by the following:

C.01.031.2 (1) Les articles C.01.029 à C.01.031 ne s’appliquent pas aux drogues suivantes :

(2) Paragraph C.01.031.2(1)(a) of the Regulations is replaced by the following:

(a) a prescription drug or a *controlled drug*, *narcotic* or *targeted substance*, as those terms are defined in subsection 1(1) of the *Controlled Substances Regulations*, that is required by those Regulations to be sold under a *prescription*, as defined in that subsection;

6 Paragraphs C.01.048(1)(a) to (d) of the Regulations are replaced by the following:

(a) a *controlled drug* or *narcotic*, as those terms are defined in subsection 1(1) of the *Controlled Substances Regulations*; or

(b) a *prescription drug*, as defined in subsection 1(2) of the *Cannabis Regulations*.

7 Paragraph C.01.050(4)(b) of the Regulations is replaced by the following:

(b) *controlled drugs*, *narcotics* or *targeted substances*, as those terms are defined in subsection 1(1) of the *Controlled Substances Regulations*, that are required by those Regulations to be sold under a *prescription*, as defined in that subsection; and

8 (1) Paragraph C.01.061(2)(b) of the English version of the Regulations is replaced by the following:

(b) no package contains less than the number of dosage units shown on the label except as provided in the table to this section; and

(2) Paragraph C.01.061(2)(c) of the Regulations is replaced by the following:

(c) in the case of a *controlled drug* or *narcotic*, as those terms are defined in subsection 1(1) of the *Controlled Substances Regulations*, no package contains more than the number of dosage units shown on the label except as provided in the table to this section.

9 (1) Paragraph (a) of the definition *wholesaler* in subsection C.01A.001(1) of the Regulations is replaced by the following:

(a) a drug in dosage form that is listed in Schedule C or D to the Act or a prescription drug;

(2) Paragraph (c) of the definition *wholesaler* in subsection C.01A.001(1) of the Regulations is replaced by the following:

(c) a *controlled drug* or *narcotic*, as those terms are defined in subsection 1(1) of the *Controlled Substances Regulations*; or

10 Paragraphs C.01A.004(3)(a) to (c) of the Regulations are replaced by the following:

(a) in the case of an activity with respect to a *controlled drug* or *narcotic*, as those terms are defined in subsection 1(1) of the *Controlled Substances Regulations*, a dealer's licence issued under subsection 12(1) of those Regulations; or

(b) in the case of an activity with respect to a drug containing *cannabis*, as defined in subsection 2(1) of the *Cannabis Act*, a licence issued under that Act to conduct that activity in accordance with the *Cannabis Regulations*.

11 Subparagraph C.01A.005(1)(j)(i) of the Regulations is replaced by the following:

(i) for each drug for which the licence is requested that is a *controlled drug* or *narcotic*, as those terms are defined in subsection 1(1) of the *Controlled Substance Regulations*, or a drug containing *cannabis*, as defined in subsection 2(1) of the *Cannabis Act*, and

12 Item 6 of Table II to section C.01A.008 of the Regulations is replaced by the following:

Item	Categories of drugs
6	Prescription drugs, drugs that are *controlled drugs* or *narcotics*, as those terms are defined in subsection 1(1) of the *Controlled Substances Regulations*, and drugs containing *cannabis*, as defined in subsection 2(1) of the *Cannabis Act*

13 (1) The portion of section C.09.001 of the French version of the Regulations before paragraph (a) is replaced by the following:

C.09.001 Le présent titre ne s'applique pas aux drogues suivantes :

(2) Paragraphs C.09.001(a) and (b) of the Regulations are replaced by the following:

(a) a drug that is required by these Regulations to be sold under a prescription;

(b) a drug that is a *narcotic*, as defined in subsection 1(1) of the *Controlled Substances Regulations*, and that is required by those Regulations to be sold under a *prescription*, as defined in that subsection; or

(c) a drug that is intended for use exclusively in animals.

Medical Devices Regulations

14 Subsection 3(2) of the *Medical Devices Regulations* [2] is replaced by the following:

(2) Subsection (1) does not apply to

(a) a drug listed in Schedule E or F to the Act;

(b) a drug listed in any of the schedules to the *Controlled Substances Regulations*; or

(c) a *drug* containing *cannabis*, as those terms are defined in subsection 1(2) of the *Cannabis Regulations* and subsection 2(1) of the *Cannabis Act*, respectively.

Controlled Drugs and Substances Act

Precursor Control Regulations

15 Paragraphs 6.1(a) and (b) of the *Precursor Control Regulations* [3] are replaced by the following:

(a) a dealer's licence issued under subsection 12(1) of the *Controlled Substances Regulations* to *produce*, as defined in subsection 2(1) of the Act, the controlled substance; or

(b) an exemption granted under subsection 56(1) of the Act.

16 (1) Paragraphs 14(4)(b) and (c) of the Regulations are replaced by the following:

(b) for each person referred to in paragraph (a), a document issued by a Canadian police force or by a business that is accredited by the Royal Canadian Mounted Police indicating whether, during the 10 years before the day on which the application is submitted, the person was convicted, as an adult, of an offence mentioned in subparagraphs (a)(i) or (ii);

(c) if any of the persons mentioned in paragraph (a) has ordinarily resided in a country other than Canada during the 10 years before the day on which the application is submitted, a document issued by a police force of that country indicating whether in that period that person was convicted, as an adult, of an offence mentioned in subparagraph (a)(iii); and

(2) Subsection 14(5) of the Regulations is repealed.

17 (1) Subparagraph 20(2)(a)(ii) of the Regulations is replaced by the following:

(ii) the declaration specified in paragraph 14(4)(a) and the documents specified in paragraphs 14(4)(b) and (c); and

(2) Subparagraph 20(2)(b)(ii) of the Regulations is replaced by the following:

(ii) the declaration specified in paragraph 14(4)(a) and the documents specified in paragraphs 14(4)(b) and (c).

18 Subsection 25(1) of the Regulations is amended by adding "and" at the end of paragraph (h), by striking out "and" at the end of paragraph (i) and by repealing paragraph (j).

19 Subsection 32(1) of the Regulations is amended by adding "and" at the end of paragraph (i), by striking out "and" at the end of paragraph (j) and by repealing paragraph (k).

20 Paragraph 60(3)(b) of the Regulations is replaced by the following:

(b) a document issued by a Canadian police force or by a business that is accredited by the Royal Canadian Mounted Police, indicating whether, during the 10 years before the day on which the application is

submitted, the senior person in charge was convicted, as an adult, of an offence mentioned in subparagraph (a)(i) or (ii);

(b.1) if the senior person in charge has ordinarily resided in a country other than Canada during the 10 years before the day on which the application is submitted, a document issued by a police force of that country indicating whether in that period that person was convicted, as an adult, of an offence mentioned in subparagraph (a)(iii); and

21 Subsection 69(1) of the Regulations is amended by adding "and" at the end of paragraph (i), by striking out "and" at the end of paragraph (j) and by repealing paragraph (k).

22 Subsection 85(7) of the Regulations is amended by adding "and" at the end of paragraph (a) and by replacing paragraphs (b) to (d) with the following:

(b) keep any report referred to in section 90 for at least two years after the day on which it is provided.

23 Section 90 of the Regulations is replaced by the following:

90 (1) The holder of a licence, registration or authorization certificate or import or export permit or permit for transit or transhipment issued under these Regulations must take all reasonable measures to ensure the security of any precursor, licence, certificate or permit in the holder's possession.

(2) The holder of a licence, registration or authorization certificate, import or export permit or permit for transit or transhipment issued under these Regulations must provide a written report to the Minister within 72 hours after becoming aware of its loss of theft.

(3) If an agent or mandatary of a licensed dealer or registered dealer becomes aware of a loss or theft of a precursor, the agent or mandatary must notify the dealer immediately.

(4) If a licensed dealer or registered dealer becomes aware of a loss of a precursor that cannot be explained on the basis of normally accepted business activities, or of a theft of a precursor, or that is notified by an agent or mandatary of such a loss or theft, the dealer must

(a) in the case of a loss, provide a written report to the Minister within 72 hours after becoming aware of the loss; or

(b) in the case of a theft, provide

(i) a written report to a police force within 24 hours after becoming aware of the theft, and

(ii) a written report to the Minister within 72 hours after becoming aware of the theft, including a confirmation that the report required under subparagraph (i) has been provided.

(5) A report provided under subsection (2) or (4), or any evidence derived from it, is not to be used or received to incriminate the licensed dealer or registered dealer or the dealer's agent or mandatary in any criminal proceeding against them other than a prosecution under section 132, 136 or 137 of the *Criminal Code*.

24 Section 91.96 of the Regulations is replaced by the following:

91.96 (1) A pharmacist, practitioner or hospital must take all reasonable measures to ensure the security of Class A precursors in their possession.

(2) An agent or mandatary of the pharmacist, practitioner or hospital must notify the pharmacist, practitioner or hospital immediately after becoming aware of

(a) a loss of a Class A precursor; or

(b) a theft of a Class A precursor set out in column 1 of the schedule, if the package that contains the precursor is not intended for retail sale and contains a quantity of the precursor exceeding the maximum set out in column 2.

(3) If a pharmacist, practitioner or hospital becomes aware of a loss or theft of such precursors, or is notified by an agent or mandatary of a such loss or theft, the pharmacist, practitioner or hospital must provide a written report to the Minister within 10 days after the day on which the pharmacist, practitioner or hospital becomes aware of the loss or theft or is notified.

(4) The report, or any evidence derived from it, is not to be used or received to incriminate the pharmacist, practitioner or hospital or the pharmacist's, practitioner's or hospital's agent or mandatary in any criminal proceeding against them other than a prosecution under section 132, 136 or 137 of the *Criminal Code*.

91.97 A pharmacist, practitioner or hospital must make available for examination by the Minister any record required to be kept under this Part and, if requested by the Minister in writing, must provide to the Minister a copy of any such record.

25 The schedule to the Regulations is amended by replacing the references after the heading "SCHEDULE " with the following:

(Paragraph 5(b), section 8, subsections 9(1.1), clause 91.1(1)(d)(iii)(B), subsection 91.3(1), section 91.9, subsection 91.92(1), paragraph 91.96(2)(b) and section 92)

26 The portion of subitem 13(2) of the schedule to the Regulations in column 1 is replaced by the following:

Item	Column 1 Precursor set out in Part 1 of Schedule VI to the Act
13	(2) 3-oxo-2-phenylbutanamide (alpha-phenylacetoacetamide-APAA)

Coming into Force

27 These Regulations come into force on the day on which the *Controlled Substances Regulations* come into force, but if they are registered after that day, they come into force on the day on which they are registered.

N.B. The Regulatory Impact Analysis Statement for these Regulations appears following SOR/2025-242, *Controlled Substances Regulations*.

Footnotes

a S.C. 2024, c. 17, s. 325(2)

b R.S., c. F-27

c S.C. 2024, c. 17, s. 413(1) to (3)

d S.C. 1996, c. 19

1 C.R.C., c. 870

2 SOR/98-282

3 SOR/2002-359