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Order Amending Schedule V to the Controlled Drugs and Substances Act (Fentanyl Precursors and Carisoprodol): SOR/2025-64

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CONTROLLED DRUGS AND SUBSTANCES ACT

Whereas, in accordance with paragraph 60.1(1)(a) \underline{a} of the *Controlled Drugs and Substances Act* \underline{b} , the Minister of Mental Health and Addictions and Associate Minister of Health has reasonable grounds to believe that the substances referred to in the annexed Order pose a significant risk to public health or safety;

Therefore, the Minister of Mental Health and Addictions and Associate Minister of Health makes the annexed *Order Amending Schedule V to the Controlled Drugs and Substances Act (Fentanyl Precursors and Carisoprodol)* under paragraph 60.1(1)(a) $^{\underline{a}}$ and subsection 60.1(2) $^{\underline{a}}$ of the *Controlled Drugs and Substances Act* $^{\underline{b}}$.

Ottawa, February 28, 2025

Ya'ara Saks

Minister of Mental Health and Addictions and Associate Minister of Health

Order Amending Schedule V to the Controlled Drugs and Substances Act (Fentanyl Precursors and Carisoprodol)

Amendments

1 Schedule V to the Controlled Drugs and Substances Act $\,^{\,\underline{b}}$ is amended by adding the following:

Item	Column 1	Column 2
	Substance	Period
1	Carisoprodol (2-((carbamoyloxy)methyl)-2-methylpentyl isopropylcarbamate)	April 14, 2025 to April 13, 2026
2	Phenethyl bromide ((2-bromoethyl)benzene)	April 14, 2025 to April 13, 2026
3	Propionic anhydride (propanoic anhydride)	May 29, 2025 to May 28, 2026
4	Benzyl chloride ((chloromethyl)benzene)	May 29, 2025 to May 28, 2026

- 2 Item 1 of Schedule V to the Act is deleted.
- 3 Item 2 of Schedule V to the Act is deleted.
- 4 Item 3 of Schedule V to the Act is deleted.
- 5 Item 4 of Schedule V to the Act is deleted.

Coming into Force

- 6 (1) Subject to subsections (2) to (5), this Order comes into force on April 14, 2025.
- (2) Section 2 comes into force on the earlier of, but no earlier than April 15, 2025,
 - (a) the day on which a provision of an order made under section 60 of the *Controlled Drugs and Substances Act* comes into force, if that provision adds carisoprodol (2-((carbamoyloxy)methyl)-2-methylpentyl isopropylcarbamate) to any of Schedules I, II, III, IV or VI to that Act, and
 - (b) April 14, 2026.
- (3) Section 3 comes into force on the earlier of, but no earlier than April 15, 2025,
 - (a) the day on which a provision of an order made under section 60 of the *Controlled Drugs and Substances Act* comes into force, if that provision adds phenethyl bromide ((2-bromoethyl)benzene) to any of Schedules I, II, III, IV or VI to that Act, and
 - (b) April 14, 2026.
- (4) Section 4 comes into force on the earlier of, but no earlier than May 30, 2025,
 - (a) the day on which a provision of an order made under section 60 of the *Controlled Drugs and Substances Act* comes into force, if that provision adds propionic anhydride (propanoic anhydride) to any of Schedules I, II, III, IV or VI to that Act, and
 - (b) May 29, 2026.
- (5) Section 5 comes into force on the earlier of, but no earlier than May 30, 2025,
 - (a) the day on which a provision of an order made under section 60 of the *Controlled Drugs and Substances Act* comes into force, if that provision adds benzyl chloride ((chloromethyl)benzene) to any of Schedules I, II, III, IV or VI to that Act, and
 - (b) May 29, 2026.

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

Issues

The overdose crisis and the threat posed by illegal synthetic drugs such as fentanyl has had a tragic impact on people across the country. As part of <u>Canada's Border Plan</u>, the Government of Canada is taking concrete action to further strengthen border security, including by increasing support to law enforcement

agencies to detect, intercept, and curb the illegal trade of fentanyl and precursor chemicals. While all known essential fentanyl precursors are already controlled in Canada, other chemicals can also be used in the illegal production of fentanyl. There is evidence that phenethyl bromide is being imported into Canada for the purpose of illegal fentanyl production, and that propionic anhydride and benzyl chloride can also be used to illegally produce fentanyl. Additionally, the drug carisoprodol has been recommended for scheduling under the United Nations' *Convention on Psychotropic Substances (1971)*, one of the three international drug conventions to which Canada is a party. Scheduling these substances under the *Controlled Drugs and Substances Act* (CDSA) will provide additional tools for the Canada Border Services Agency and law enforcement agencies to prevent their importation, distribution and use.

Background

Fentanyl and fentanyl precursors

Between January 2016 and June 2024, there were a total of 49 105 apparent opioid toxicity deaths reported in Canada. Fentanyl and fentanyl analogues continue to be major drivers of the overdose crisis, with 79% of all accidental apparent opioid toxicity deaths from January to June 2024 involving fentanyl. ¹ In addition to the devastating public health and social harms associated with the consumption of illegal synthetic opioids such as fentanyl, Canada is also extremely concerned with their impact on public safety, including security challenges associated with their illegal production, diversion, trafficking, and related crimes.

Fentanyl and its analogues are highly potent synthetic opioids that are controlled in Canada under Schedule I of the CDSA. The CDSA is the federal statute that provides a framework for the control of substances that can alter mental processes and may produce harm to health or society when diverted to an illegal market or misused. Substances listed in Schedules I to V of the CDSA are defined as controlled substances, while substances listed under Schedule VI are defined as precursors. Precursors are chemicals that are essential to the production of a controlled substance. While some precursor chemicals have legitimate uses, they can also be used in the illegal production of controlled substances, like fentanyl and fentanyl analogues.

All known essential building blocks that can be used to produce fentanyl are already controlled in Canada. While it is not possible to produce fentanyl without using one of these already controlled building blocks, other chemicals can also be used in the illegal production of fentanyl. Three of these fentanyl precursor chemicals are

- phenethyl bromide;
- propionic anhydride (also known as propanoyl propanoate); and
- benzyl chloride.

Phenethyl bromide

A Health Canada assessment of available information concluded that phenethyl bromide (Chemical Abstracts Service Registry Number 103-63-9) can be used to produce fentanyl and that it is being used in clandestine laboratories in Canada. Significant quantities of phenethyl bromide are being imported into

Canada, but there is insufficient information to conclude whether it is being imported for legitimate or illegal purposes. However, there is evidence that imported phenethyl bromide (source region: Asia) was present in a clandestine laboratory in Canada.

Additionally, at the international level, phenethyl bromide is on the United States' Drug Enforcement Agency's Special Surveillance List, $\frac{2}{2}$ and the United States has recently proposed to make it a List I chemical. $\frac{3}{2}$ Data from the International Narcotics Board (INCB) Precursor Incident Communication System (PICS) and Project Ionics indicated that between 2020 and 2023, approximately 4 300 kg of phenethyl bromide has been intercepted (originating in Asia with North America being the destination), often with other known fentanyl precursors. $\frac{4}{2}$

Phenethyl bromide can be used for legitimate purposes, such as in the manufacture of pharmaceuticals, fragrances, industrial chemicals, and research chemicals; however, the extent of its use by Canadian industry is unknown. While it is expected that this scheduling action will have impacts on legitimate industry, given that there is information to show that phenethyl bromide is being used in clandestine laboratories in Canada, urgent action is needed to control this substance.

Propionic anhydride and benzyl chloride

Research has shown that propionic anhydride (also known as propanoyl propanoate; Chemical Abstracts Service Registry Number 123-62-6) and benzyl chloride (Chemical Abstracts Service Registry Number 100-44-7) can be used to synthesize illegal fentanyl. These chemicals are classified as List I and List II chemicals, respectively, under the United States' Controlled Substances Act.

Both of these precursor chemicals have legitimate uses. Propionic anhydride is known to be used in other countries to manufacture perfumes, oils, resins, dyes, and pharmaceuticals, although the extent of its use in Canada is unknown. Benzyl chloride is used in Canada in the production of industrial cleaners, household cleaning products, lubricants and corrosion inhibitors (including those used in the oil and gas industry) and personal care products, among other known uses.

While there is currently limited to no evidence that either of these precursor chemicals are being imported and used in illegal drug production in Canada, urgent action is needed to control these substances, given evidence they can be used in illegal fentanyl production and the significant risk that illegally produced fentanyl poses to public health and safety.

Carisoprodol

Carisoprodol is a sedative drug used in some countries as a muscle relaxant indicated for the relief of acute, painful musculoskeletal conditions. It produces effects similar to central nervous system depressants such as barbiturates and benzodiazepines. Although there is strong evidence of the drug's potential for misuse, including a recent <u>Critical review report</u> published by the World Health Organization Expert Committee on Drug Dependence, currently there is limited evidence of its non-medical use in Canada.

The Director General of the World Health Organization recently recommended that carisoprodol be added to Schedule IV of the *Convention on Psychotropic Substances (1971)*. ⁵ This recommendation will be voted on at the United Nations' Commission on Narcotic Drugs meeting in March 2025. In anticipation of this possible scheduling action, Health Canada completed a scientific assessment of carisoprodol. Based on

available information, there are currently no known medical, commercial, or industrial uses of carisoprodol in Canada. Since 2021, carisoprodol has not been identified in seized samples from Canadian law enforcement agencies or the Canada Border Services Agency. While carisoprodol is sold as a prescription drug in the United States (US) and in several other countries, it is no longer authorized for sale in Canada.

Temporary scheduling of substances under Schedule V

In May 2017, the CDSA and Part J of the *Food and Drug Regulations* (FDR) were amended to include a mechanism to quickly and temporarily schedule new substances as controlled substances in Canada.

Subsection 60.1(1) of the CDSA grants the Minister the authority to temporarily add a substance to Schedule V of the CDSA through a ministerial order, if the Minister has reasonable grounds to believe that the substance

- (a) poses a significant risk to public health or safety;
- (b) may pose a risk to public health or safety; and
 - (i) is being imported into Canada with no legitimate purpose, or
 - (ii) is being distributed in Canada with no legitimate purpose.

Once a substance is added to Schedule V of the CDSA, its importation, exportation, possession for the purposes of exportation, production, trafficking (including sale), and possession for the purpose of trafficking are all prohibited (note that the prohibition on possession in subsection 4(1) of the CDSA does not apply to substances included in Schedule V). Anyone needing to import and use a substance listed on Schedule V requires appropriate authorizations from Health Canada. Anyone who fails to comply with the law would be subject to the offences and penalties set out in the CDSA.

For temporarily controlled substances listed in Schedule V to the CDSA, the Minister can, by order, also add those substances to the schedule to Part J of the FDR. This provides a mechanism for researchers to legally conduct otherwise prohibited activities with drugs that have been placed under temporary control in Schedule V.

Objective

The objective of this scheduling action is to rapidly control phenethyl bromide, propionic anhydride, benzyl chloride and carisoprodol under the CDSA to prevent harms to public health and public safety arising from the potential use of these substances.

Given the prevalence of fentanyl in the toxic illegal drug supply in Canada and because Canada has observed an increase in illegal fentanyl production by organized crime groups, there is a need to disrupt the supply of precursor chemicals used in illegal fentanyl production to protect public health and safety. Actions to disrupt the illegal drug market include controlling activities with precursor chemicals that can be used in the production of illegal fentanyl, and controlling drugs, like carisoprodol, with the potential for misuse and diversion.

This scheduling action provides the Canada Border Services Agency and law enforcement with additional tools to take action against any illegal importation, distribution, and use of these substances. The Order adding carisoprodol to Part J of the *Food and Drug Regulations* facilitates research and clinical testing with the drug while it is temporarily controlled.

Description

Phenethyl bromide, propionic anhydride and benzyl chloride are known to be used in the illegal synthesis of fentanyl and fentanyl analogues, and the drug carisoprodol has significant potential for misuse. As a result, the Minister of Mental Health and Addictions and Associate Minister of Health has reasonable grounds to believe these substances pose a significant risk to public health and safety. This Order adds three fentanyl precursors, phenethyl bromide, propionic anhydride and benzyl chloride, as well as the drug carisoprodol to Schedule V of the CDSA, pursuant to the Minister's authority under paragraph 60.1(1)(a) of the CDSA.

As a result of this Order, anyone found importing, exporting, possessing for the purpose of exporting, producing, trafficking (including sale), and possessing for the purpose of trafficking phenethyl bromide, propionic anhydride, benzyl chloride or carisoprodol without appropriate authorizations is subject to criminal prohibitions under the CDSA. As a result, law enforcement and border services officers can take action (e.g. seize) to stop the illegal importation, distribution and use of these four substances.

Pursuant to subsection 60.1(1), a substance may be temporarily added to Schedule V for a period of up to one year, with the possibility of extending the scheduling for an additional year. During this time, Health Canada intends to advance a regulatory package that would control the three fentanyl precursors under Schedule VI of the CDSA and the *Precursor Control Regulations* (PCR) and that would control carisoprodol under Schedule IV of the CDSA and the Schedule to the *Benzodiazepines and Other Targeted Substances Regulations* (BOTSR).

Actions to mitigate the impact of the scheduling action on Canadian industry and researchers

As part of this scheduling action, the Minister is also amending Part J of the *Food and Drug Regulations* under subsections J.01.002(1) and (2) to add carisoprodol to Part III of its schedule to facilitate its use in clinical testing and laboratory research. A licence or research authorization is required to conduct most activities with substances scheduled under Part J. Anyone needing to conduct activities with this drug for any other activities not authorized under Part J would need to apply to Health Canada for an exemption.

Health Canada will also consider requests for exemptions under subsection 56(1) of the CDSA for organizations and individuals who need to conduct activities with benzyl chloride, phenethyl bromide and/or propionic anhydride for legitimate purposes during the period of temporary control. This is intended to minimize the impact of the scheduling action on Canadian industry and researchers. A class exemption will be issued for persons importing or exporting preparations or mixtures containing benzyl chloride, phenethyl bromide and/or propionic anhydride if those substances together make up no more than 30% of the total weight (for solids) or volume (for liquids), including when combined with other Class B precursors. Anyone not covered by the class exemption who needs to use these substances for legitimate purposes will need to apply to Health Canada for an individual exemption.

Regulatory development

Consultation

The objective of the scheduling action is to rapidly mitigate the risks to public health and safety associated with activities such as the importation and distribution of phenethyl bromide, propionic anhydride, benzyl chloride and carisoprodol. On February 14, 2025, Health Canada published a Notice of Intent (NOI) to inform the public and Canadian industry of the proposal to temporarily control these substances. Comments were accepted for 10 days. Targeted emails were sent to key stakeholders who might be impacted, including controlled substance licensed dealers, precursor licensed and registered dealers, drug establishment licence holders, as well as industry associations, including:

- Oil and gas associations;
- Cosmetics and perfume associations;
- Chemical associations;
- Vehicle manufacturing associations;
- · Consumer product associations; and
- Mining association.

Over the course of the 10-day consultation period, Health Canada received 30 written responses to the NOI, including:

- Fifteen (15) industry members;
- Six (6) industry associations;
- Seven (7) members of the public; and
- One (1) researcher.

In addition to the NOI, Health Canada also held a technical briefing on the proposal that was attended by representatives from the oil and gas, mining, consumer products, forestry products, paint and coatings, and food and beverage associations.

Stakeholders who participated in the consultations indicated they use phenethyl bromide, propionic anhydride or benzyl chloride in the following ways:

- Benzyl chloride, and to a much lesser extent, propionic anhydride are used in the pharmaceutical, chemical and research industries for research, manufacturing active pharmaceutical ingredients and as analytical standards, among other things. One respondent mentioned using phenethyl bromide to manufacture active pharmaceutical ingredients.
 - The majority of respondents from these industries indicated that they expect the controls would have low or no impacts on their operations, providing certain activities involving preparations or mixtures are exempt from regulatory requirements if the precursor and other Class B precursors constitute 30% or less of the total weight or volume.
 - However, one pharmaceutical company indicated that they use propionic anhydride to manufacture a sleep aid, and that its control would significantly impact their business due to the

increased costs required to store the material on site or to find another chemical to replace it.

- Similarly, two more companies using large quantities of benzyl chloride in their manufacturing
 process stated that the control of this substance would require them to build new storage vaults at
 considerable expense or require them to decrease other stock in their existing vaults to be able to
 store benzyl chloride.
- Carisoprodol is manufactured and sold in Canada by one company that responded to the NOI.
 - This company stated that they expect demand for their product to increase as a result of its control, and that the scheduling action may impact turnaround times to process orders due to additional regulatory requirements being imposed.
- Benzyl chloride is also involved in manufacturing lubricants and other chemicals for use in the oil, gas and mining industries.
 - One company replied that they import large volumes of benzyl chloride on a monthly basis and are concerned that its control may initially disrupt manufacturing at their facility.
 - One fuel industry association stated that they support the accelerated control of benzyl chloride, provided exemptions for preparations and mixtures are put in place, consistent with the regulation of Class B precursors.
- Benzyl chloride is heavily used as an intermediate in the production of paints, adhesives, coatings and resins, and as raw material for plasticizers and certain other additive functions in these products.
 - However, representatives from this industry noted that benzyl chloride is usually found at trace levels as an impurity in the final products.
 - Their industry association stated that they support the accelerated control of benzyl chloride, provided exemptions for preparations and mixtures are put in place, consistent with the regulation of Class B precursors.
- Benzyl chloride is also frequently found as an impurity in disinfectants, hard surface sanitizers, corrosion inhibitors, industrial and institutional cleaners, skin antiseptics, food packaging, cosmetics, fragrances and personal care products.
 - This precursor is usually found at trace levels in the final products.
 - One industry association stated that they support the accelerated control of benzyl chloride provided exemptions for preparations and mixtures are put in place, consistent with the regulation of Class B precursors.
 - A consumer products association noted that while none of their members appear to be manufacturing disinfectants in Canada at present, they have done so in the past and may do so again in future. This would require the importation of large quantities of benzyl chloride as starting material.
- Propionic anhydride may have potential uses in the forest products industry to make pulp fibre stronger and more water-resistant.

With regards to comments from the public, one comment was received against controlling carisoprodol, another individual was supportive of taking action against illegal fentanyl production, and the other responses were out of scope. These consisted of general questions and comments on regulation, public safety and animal testing.

Modern treaty obligations and Indigenous engagement and consultation

Health Canada examined the geographical scope and subject matter of the initiative in relation to modern treaties in effect and did not identify any potential modern treaty implications.

Instrument choice

Scheduling these substances provides the Canada Border Services Agency and law enforcement with additional tools to take legal action in relation to activities with phenethyl bromide, propionic anhydride, benzyl chloride and carisoprodol that contravene the CDSA.

Health Canada considered whether these substances should be scheduled using the Governor in Council's authority to schedule substances under the CDSA following the standard regulatory development process. It was determined that, given the significant risk these substances pose to public health and safety, the accelerated scheduling pathway provided for under s. 60.1(1) of the CDSA was the most appropriate mechanism for the Minister to use in the short term, as it allowed for rapid action to be taken to control these substances.

Regulatory analysis

Benefits and costs

Benefits

Once in force, these scheduling actions will help reduce the negative public health and safety outcomes associated with illegal fentanyl production and consumption, and from the potential misuse and diversion of carisoprodol. The accelerated scheduling of these substances enables the Canada Border Services Agency and law enforcement to take action against any illegal activities, such as importation and distribution of these substances. Adding carisoprodol to Part J of the *Food and Drug Regulations* helps mitigate any impacts on potential clinical trials or other research activities involving this substance.

Persons (e.g. business, researcher) conducting legitimate activities with these substances are expected to benefit from the class exemption and delayed coming-into-force date of the scheduling action as it provides them with time to seek appropriate authorization from Health Canada in order to continue their activities and avoid any potential economic costs or disruptions to their activities.

Costs

Industry

Benzyl chloride has numerous applications and is used broadly in various industrial and commercial activities in Canada. Phenethyl bromide and propionic anhydride are also used in industrial and commercial activities, albeit to a lesser extent. All three substances are considered to be in use in Canada despite a lack of information available to quantify their prevalence.

It is assumed that many businesses conducting activities associated with the precursors in preparations and mixtures that contain less than 30% of some combination of Class B and the temporarily controlled precursors will benefit from the class exemption. Those that are not captured by the class exemption will need to apply for an individual subsection 56(1) exemption, which also involves obtaining a criminal record check, to continue their activities and they will incur the associated costs. Additionally, all impacted businesses will incur costs to provide import and export notifications to Health Canada and keep records. It is anticipated that an average of 3 hours and 15 minutes, respectively, would be spent to prepare and submit an exemption request and to provide an import notification to Health Canada. The costs associated with this administrative effort can be estimated using an average wage rate of \$34.40 per hour. Health Canada was unable to estimate the potential costs to all impacted businesses and to provide a sense of the magnitude of the potential impacts as the data needed on the number of potentially affected businesses was not available at the time of conducting the assessment.

Finally, given that there is limited evidence of legitimate activity involving carisoprodol in Canada, scheduling this substance under Schedule V to the CDSA is not expected to have any significant impacts on businesses. However, a few licensed dealers may need to amend their licences to add carisoprodol and, if necessary, apply for an import or export permit, should they choose to supply this substance to researchers.

Researchers and laboratories

As benzyl chloride, phenethyl bromide, and propionic anhydride are expected to be used in Canada as analytical reference materials by forensic laboratories or for research, laboratories and researchers may be impacted by the Order. If the activities they need to conduct are not captured by the class exemption, laboratories and researchers who want to continue their activities with these precursors will need to apply for subsection 56(1) exemption and incur the related administrative costs. Further, while researchers would not require an exemption to possess carisoprodol while it is controlled under Schedule V, researchers would incur costs associated with meeting the requirements of Part J of the *Food and Drugs Regulations* if they intend to use carisoprodol for clinical trials or laboratory research. It is anticipated that an average of 45 minutes would be spent to prepare and submit an authorization request to Health Canada. Where applicable, an additional 15 minutes may be spent to provide import notification to Health Canada. Although it is not possible to estimate the costs to all impacted laboratories and researchers due to lack of data, given the limited administrative efforts per impacted stakeholder, the overall costs for this group of stakeholders are not expected to be significant.

Individual travellers

Individuals travelling with a prescription drug containing carisoprodol will also need to apply for an individual subsection 56(1) exemption prior to entering Canada. A few minutes would be spent to prepare and submit an exemption request. As such, the cost to individual applicants is expected to be negligible.

Government

Costs associated with compliance promotion and enforcement activities will be incurred by Health Canada to ensure that only activities duly authorized are conducted with the three fentanyl precursors. Limited costs will be incurred for conducting activities to support the implementation of the scheduling action, such

as developing and publishing web promotional materials to raise awareness about the temporary scheduling of these precursors and responding to stakeholders' enquiries.

Health Canada will also incur additional costs to process individual subsection 56(1) exemption requests, licence amendments and Part J authorization requests as well as import permits and import notification. Given that it is not possible to reliably estimate the number of potential requests that will be received, estimating the related processing costs to Health Canada is not possible but may be significant.

A small number of federal government organizations, including Health Canada, that possess a dealer's licence under Part J of the *Food and Drug Regulations* may incur costs associated with submitting requests to amend their dealer's licences and/or apply for a permit to import or export carisoprodol. In addition, they will also need to apply for an exemption in order to conduct activities with the fentanyl precursors and to provide import and export notifications to Health Canada. The overall cost to these affected entities is expected to be negligible.

Small business lens

Analysis under the small business lens concluded that the scheduling action will impact small businesses.

Small businesses will benefit from the subsection 56(1) class exemption and the delayed coming into force of the scheduling action. As a result, economic costs to small businesses will largely be mitigated.

The costs to impacted small businesses will be related to the administrative burden described in the Cost-Benefit Analysis section. It was not possible to estimate the administrative costs to impacted small businesses at the time of preparing this Regulatory Impact Analysis Statement as information regarding the number of potentially affected small businesses was not available. Nevertheless, it is anticipated that the costs to small businesses will not be disproportionate compared to other businesses. Providing any flexibility to small businesses is not necessary.

One-for-one rule

The one-for-one rule applies since there is an incremental increase in administrative burden on business, and the scheduling action is considered burden in under the rule.

While it is expected that businesses will face administrative burden, as described in the Cost-Benefit Analysis section, it was not possible to estimate the related costs for the purpose of the one-for-one due to a lack of information regarding the number of potentially affected business. The incremental administrative costs may not be significant and would be incurred only over the period the scheduling action is in force (up to one year).

Regulatory cooperation and alignment

Fentanyl precursors

The 1988 *United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*, to which Canada is a party, does not control phenethyl bromide, propionic anhydride or benzyl chloride. However, other fentanyl precursors are controlled under the 1988 Convention including 4-piperidone, 1-boc-4-piperidone, *N*-phenyl-4-piperidinamine (4-AP), tert-butyl 4-(phenylamino)piperidine-1-carboxylate (1-boc-4-AP), norfentanyl, 4-anilino-N-phenethylpipieridine (4-ANPP) and N-phenylethyl-4-piperidone (NPP).

While this Order has not been developed specifically in cooperation or to align with other jurisdictions, concerns relating to the illegal production, distribution and use of illegal fentanyl are global. As a result, the control of substances used in the illegal production of fentanyl and fentanyl analogues helps address domestic and international illegal drug trafficking concerns.

Controlling these fentanyl precursors is in line with Canada's plan to detect and disrupt the fentanyl trade to strengthen border security as part of Canada's <u>Border Plan</u>. It also aligns with Canada's commitment to strengthen the coordinated global response to the international public health and public safety challenges posed by synthetic drugs, as outlined in the <u>Ministerial Declaration on Accelerating and Strengthening the Global Response to Synthetic Drugs</u>.

Carisoprodol

The Director General of the World Health Organization recently recommended that carisoprodol be added to Schedule IV of the *Convention on Psychotropic Substances (1971)*, which will be voted on at the United Nations' Commission on Narcotic Drugs meeting in March 2025.

If member parties to the Convention decide to vote in favour of this recommendation, Canada, as a party to the convention, would be expected to take action to control carisoprodol domestically. Other countries, including the United States, have already taken action to Schedule this substance. ⁶ Proactively controlling carisoprodol allows Canada to meet its expected international obligations and aligns with the actions taken by other countries to schedule this substance.

Effects on the environment

In accordance with the *Cabinet Directive on Strategic Environmental and Economic Assessment* (SEEA Directive), a preliminary scan concluded that a SEEA is not required.

Gender-based analysis plus

Canada continues to face an unprecedented overdose crisis affecting individuals of all walks of life regardless of sex/gender, geography or socioeconomic status. Opioid-related harms are distributed unevenly among subgroups of affected Canadians based on sex/gender or other factors. For example:

- There were a total of 49 105 apparent opioid toxicity deaths between January 2016 and June 2024. 1
- Of all apparent opioid toxicity deaths between January 2024 and June 2024, 79% involved fentanyl.
- About 84% of the accidental apparent opioid toxicity deaths which occurred from January 2024 to June 2024 were in British Columbia (BC), Alberta, and Ontario.
- Males accounted for about three quarters (72%) of the deaths associated with opioids in the same period.
- Across all genders, individuals aged between 30 and 39 years old represented the majority of deaths associated with opioids from January 2024 to June 2024, and during the same period, the majority of accidental opioid-related poisoning hospitalizations occurred among individuals of 60 or more years.
- Indigenous people have been and continue to be disproportionately impacted by the opioid overdose crisis. For example, First Nations people in BC died of an overdose at six times the rate of other BC

residents from January 2023 to June 2023, ⁷ and in Alberta, First Nations people died of an accidental opioid overdose at seven times the rate of other residents between January 2020 and December 2020. ⁸

Actions to disrupt the illegal importation of fentanyl precursor chemicals into Canada are expected to benefit groups affected by the overdose crisis. These benefits are expected to be experienced by all potentially impacted groups or subgroups. Although there are sex/gender differences in adverse health outcomes associated with the consumption of opioids, there is no evidence indicating that the scheduling action will result in any potential for disproportionate impacts to any affected groups or subgroups based on sex/gender, socioeconomic, or any other such characteristics.

As carisoprodol is no longer authorized for sale as a prescription drug in Canada, control of this substance is unlikely to have any impacts on any groups or subgroups based on sex/gender, socioeconomic, or any other such characteristics.

Implementation, compliance and enforcement, and service standards

Implementation

The Order controlling phenethyl bromide and carisoprodol comes into force on April 14, 2025, which is 45 days after the making of the Order. The Order controlling propionic anhydride and benzyl chloride comes into force on May 29, 2025, which is 90 days after the making of the Order. The delayed coming into force period gives anyone wanting to conduct legitimate activities with these substances time to apply to Health Canada for authorization, as needed.

This scheduling action is in effect for one year and will end as set out in the Order on April 14, 2026, for phenethyl bromide and carisoprodol, and May 29, 2026, for propionic anhydride and benzyl chloride, or the day on which an Order is made adding these substances to another Schedule to the CDSA.

Once these scheduling actions are taken, Health Canada will send notification emails to potentially impacted stakeholders to ensure they are aware of this Order and its implications. This notification will also include contact information, guidance material related to the class exemption, and instructions on how to apply for an individual subsection 56(1) exemption to allow stakeholders to legally conduct activities with these substances while they are temporarily controlled. Travellers wanting to visit Canada with a prescription for carisoprodol for therapeutic use should contact Health Canada to obtain the appropriate authorizations.

Questions about how to access propionic anhydride, benzyl chloride, and phenethyl bromide for legitimate use should be directed to <u>precursors-precurseurs@hc-sc.gc.ca</u>. Questions about how to access carisoprodol for legitimate use should be directed to <u>exemption@hc-sc.gc.ca</u>.

Compliance and enforcement

Health Canada is responsible for authorizing (through licences, permits, and exemptions) legitimate activities with substances scheduled under the CDSA and its regulations and for monitoring compliance with regulatory requirements.

The Canada Border Services Agency supports compliance monitoring for controlled substances and precursors at the border. Federal, provincial and local law enforcement are responsible for taking enforcement action in response to contraventions of the CDSA and its regulations. Under the CDSA, a range of penalties apply to the offences associated with the substances covered by these amendments. For certain offences involving Schedule V substances (trafficking, possession for the purpose of trafficking, importing, exporting, possession for the purpose of exporting, production), there is a maximum penalty of up to 10 years of imprisonment if the offence is prosecuted by indictment or of up to 18 months of imprisonment if the offence is prosecuted by summary conviction.

The criminal prohibition on possession of controlled substances under subsection 4(1) of the CDSA does not apply to substances listed in Schedule V.

Contact

For enquiries or for more information, please contact the Office of Legislative and Regulatory Affairs in Health Canada's Controlled Substances and Overdose Response Directorate at <u>csd.regulatory.policy-politique.reglementaire.dsc@hc-sc.gc.ca</u>.

Footnotes

- <u>a</u> S.C. 2017, c. 7, s. 45
- <u>b</u> S.C. 1996, c. 19
- <u>https://health-infobase.canada.ca/substance-related-harms/opioids-stimulants/</u>
- <u>https://www.federalregister.gov/documents/2023/10/24/2023-23478/special-surveillance-list-of-chemicals-products-materials-and-equipment-used-in-the-manufacture-of</u>
- <u>https://www.federalregister.gov/documents/2024/10/28/2024-24616/possible-control-of-phenethyl-bromide-as-a-list-i-chemical</u>
- <u>4 https://www.incb.org/incb/en/precursors/pics.html</u>
- <u>5 https://www.unodc.org/unodc/en/commissions/CND/session/68 Session 2025/documentation.html</u>
- <u>6 https://www.deadiversion.usdoj.gov/drug_chem_info/carisoprodol/carisoprodol.pdf (PDF)</u>
- 7 <u>https://www.fnha.ca/Documents/FNHA-First-Nations-and-the-Toxic-Drug-Poisoning-Crisis-in-BC-Jan-June-2023.pdf</u>
- <u>https://open.alberta.ca/dataset/ef2d3579-499d-4fac-8cc5-94da088e3b73/resource/8f1214fc-4db2-4e73-a297-1303293c4e90/download/health-alberta-opioid-response-surveillance-report-first-nations-people-2021-12.pdf</u>