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Regulations Amending the Narcotic Control Regulations and the Precursor Control Regulations (Fentanyl and Amphetamines): SOR/2019-120

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Registration

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CONTROLLED DRUGS AND SUBSTANCES ACT

P.C. 2019-420 May 3, 2019

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 55(1) ^a of the *Controlled Drugs and Substances Act* ^b, makes the annexed *Regulations Amending the Narcotic Control Regulations and the Precursor Control Regulations (Fentanyl and Amphetamines)*.

Regulations Amending the Narcotic Control Regulations and the Precursor Control Regulations (Fentanyl and Amphetamines)

Narcotic Control Regulations

1 Item 15 of the schedule to the *Narcotic Control Regulations* ¹ is amended by adding the following after subitem 13:

- (14) 4-Anilino-N-phenethylpiperidine (ANPP) (N-phenyl-1-(2-phenylethyl)piperidine-4-amine), its derivatives and analogues and salts of derivatives and analogues

Precursor Control Regulations

2 The portion of item 10 of the schedule to the *Precursor Control Regulations* ² in column 1 is replaced by the following:

| Item | Column 1 |
|------|--|
| | Precursor set out in Part 1 of Schedule VI to the Act |
| 10 | 3,4-Methylenedioxyphenyl-2-propanone (1-(1,3-benzodioxole)-2-propanone), its derivatives and analogues and salts of derivatives and analogues, including: (1) methyl 3-(1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (MMDMG) |

3 The portion of item 13 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 | 1-Phenyl-2-propanone, its derivatives and analogues and salts of derivatives and analogues, including: (1) methyl 2-methyl-3-phenyloxirane-2-carboxylate (BMK methyl glycidate) (2) 3-oxo-2-phenylbutanamide (α -phenylacetoacetamide-APAA) |

4 The portion of item 29 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 |
| 29 | Norfentanyl (N-phenyl-N-piperidin-4-ylpropanamide), its salts, derivatives and analogues and salts of derivatives and analogues |

5 The schedule to the Regulations is amended by adding the following after item 32:

| Item | Column 1 | Column 2 |
|------|---|--|
| | Precursor set out in Part 1 of Schedule VI to the Act | Maximum Quantity (expressed as an absolute amount or per package) |
| 33 | Benzylfentanyl (N-(1-benzylpiperidin-4-yl)-N-phenylpropionamide), its salts, derivatives and analogues and salts of derivatives and analogues | 0 |

Coming into Force

6 These Regulations come into force on the day on which they are published in the *Canada Gazette*, Part II.

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

Issues

The Government of Canada is committed to protecting the health and safety of Canadians by minimizing the risks caused by diversion and problematic use of controlled substances. Precursor chemicals that can be used in the illegal production of controlled substances are controlled under the *Controlled Drugs and Substances Act* (CDSA) and its regulations. In recent years, certain novel chemicals that can be used in the illegal production of fentanyl and amphetamines have been identified by law enforcement agencies. These chemicals are not currently controlled under the CDSA and, therefore, activities with these substances, including importation into Canada, can occur legally. This means law enforcement officials can only take action once illegal substances are produced using these chemicals or if they have evidence that these chemicals will be used to produce an illegal substance. In order to protect public health and safety, it is necessary to control these chemicals under the CDSA and its regulations as part of the Government's efforts to address the opioid crisis and respond to problematic substance use. This will allow Canada Border Services Agency (CBSA) officers and law enforcement officers to take actions to stop illegal trafficking and production of fentanyl and amphetamines.

Background

Precursors are chemicals that are either used as the core chemical structures or as essential reagents or solvents in the synthesis of controlled substances. Currently, 37 chemicals are listed as precursors in Schedule VI to the CDSA and regulated under the *Precursor Control Regulations* (PCR).

Fentanyl, a synthetic opioid, is a controlled substance and the fentanyl group (fentanyl and their derivatives and analogues) is listed as item 16 in Schedule I to the CDSA and regulated under the *Narcotic Control Regulations* (NCR). Therapeutic products containing fentanyl are approved in Canada as analgesics for the treatment of severe pain. As an opioid, fentanyl's euphoric effects and addictive properties make it prone to problematic use. Six chemicals that can be used to manufacture fentanyl are currently listed in Schedule VI to the CDSA and regulated under the PCR.

Amphetamines, a group of chemically related substances including amphetamine, methamphetamine and MDMA (ecstasy), are central nerve system stimulants. While some amphetamines have medical applications, many amphetamines, in particular methamphetamine and MDMA, have been illegally produced and trafficked for problematic use for decades. Amphetamines are listed in Schedule I to the CDSA and regulated under part G or J of the *Food and Drug Regulations* (FDR-G or FDR-J). Major amphetamine precursors such as ephedrine, pseudoephedrine, phenylacetic acid, and red and white phosphorus are currently listed in Schedule VI to the CDSA and regulated under the PCR.

Legislative framework for controlled substances and precursors

The CDSA provides for the control of substances that can alter mental processes and that may produce harm to public health and safety when diverted to an illegal market or used problematically. It also provides for the control of precursors that can be used in the production of controlled substances. Certain activities with controlled substances and precursors are prohibited under the CDSA, unless authorized under the regulations or exempted in accordance with the CDSA. The CDSA specifies the offences and penalties associated with the conduct of illegal activities with controlled substances and precursors. Furthermore, the CDSA authorizes the Governor in Council to make regulations as required and to amend the schedules to the CDSA by order. Substances listed in Schedules I to V to the CDSA are defined as controlled substances, while substances listed in Schedule VI to the CDSA are defined as precursors.

The NCR describe the circumstances and requirements in which persons (including businesses), pharmacists, practitioners and hospitals may conduct regulated activities including possession, sale, distribution, importation and exportation, and production of narcotics. Prior to engaging in an activity with narcotics controlled under the CDSA, persons, including businesses, may be required to submit an application to Health Canada. Authorizations may be provided in the form of a dealer's licence and, for importation and exportation activities, of a permit. There are also requirements related to storage, security, and record keeping.

The PCR set out a framework within which activities with precursors are regulated. Under the PCR, a licence is required for any person to produce, package, sell, provide, import, export, and possess for the purpose of export Class A precursors, and a registration is required for any person to produce for the purpose of sale, import and export Class B precursors. The PCR also specify record keeping, security and reporting requirements for licensed or registered dealers.

The Schedule to the PCR includes specified thresholds, in absolute quantities or package size, for each Class A precursor. These thresholds apply to provisions regarding (1) exempted sale or provision by a specified person; and (2) particular record keeping and transport documentation requirements. The PCR allow retailers who meet the criteria specified in section 5 to sell or provide Class A precursors without a licence if a transaction does not exceed the maximum quantity set out in the Schedule. In addition, particular record-keeping requirements must be met if a licensed dealer, a pharmacist, a practitioner or a person in charge of a hospital sells or provides a Class A precursor above the maximum quantity set out in the Schedule. Furthermore, a specified document must be attached to any shipment of Class A precursors that exceeds the maximum quantity set out in the Schedule.

Fentanyl and its problematic use in Canada

Fentanyl is very toxic and dangerous when used for non-medical purposes due to its potency. Since 2009, there has been a significant increase in opioid-related overdoses and deaths (often characterized as an "opioid crisis") in Canada. Illegally produced fentanyl poses significant risks to public health as it is often mixed in an unknown quantity with other drugs, such as oxycodone and heroin. Users are not always aware that they are taking fentanyl. The problematic use of opioids is now one of the leading public health and safety concerns in Canada. According to a report issued by Health Canada in December 2018, entitled *National report: Apparent opioid-related deaths in Canada*, there were 3 987 apparent opioid-related deaths in 2017, 92% of which were accidental. Furthermore, 72% of accidental, apparent opioid-related deaths involved fentanyl or its analogues in 2017, compared to 55% in 2016.

According to the Royal Canadian Mounted Police (RCMP), fentanyl is finding its way into the Canadian illegal drug market in three ways: diversion of pharmaceutical fentanyl products (mainly skin patches); smuggling from abroad, notably China; and, more recently, production in clandestine laboratories in Canada using precursor chemicals. Canadian-based organized crime uses the smuggled or Canadian-made illegal fentanyl to prepare products for distribution and sale.

Illegal fentanyls are either imported or produced in Canada. Law enforcement agencies have intercepted numerous unauthorized shipments of fentanyls into Canada and dismantled clandestine laboratories. However, shipments to Canada of chemicals that are not controlled under the CDSA, such as benzylfentanyl, derivatives and analogues of 4-anilino-N-phenethylpiperidine (ANPP) and norfentanyl have been identified by the CBSA.

Benzylfentanyl is currently controlled in the United States as a precursor under the *Controlled Substances Act*.

Amphetamines and their problematic use in Canada

Recently available information has indicated that there has been a rise in the problematic use of methamphetamine in the past few years. There were 35 methamphetamine-related deaths in 2017 in Manitoba. As well, a 600% increase in the use of methamphetamine has been observed in Vancouver's supervised injection site since 2006. Along with the increase of problematic use of amphetamines, law enforcement agencies have experienced more frequent interceptions of amphetamines. In addition, the CBSA has identified shipments of MMDMG to Canada in the past few years. While many of these shipments were in small quantities, some shipments involve large quantities of the chemical, which can be used in the illegal production of methamphetamine.

Objective

The objective of these amendments is to minimize the risk to the health and safety of Canadians caused by diversion of controlled substances by placing legislative controls on newly identified chemicals that can be used in the illegal production of fentanyls and amphetamines. Such amendments would provide law enforcement agencies with the power to take actions against any unauthorized activities with these substances and allow Health Canada to regulate legitimate activities with these substances, if needed.

Description

Section 60 of the CDSA authorizes the Governor in Council to make an order to amend schedules to the Act. This regulatory initiative amends Schedules I and VI to the CDSA as follows:

- “(14) 4-Anilino-N-phenethylpiperidine (ANPP) (N-phenyl-1-(2-phenylethyl)piperidine-4-amine), its derivatives and analogues and salts of derivatives and analogues” is added as a new subitem under item 16 (fentanyls, etc.) in Schedule I;
- Item 9 in Part 1 of Schedule VI (3,4-methylenedioxyphenyl-2-propanone) is expanded to include “its derivatives and analogues and salts of derivatives and analogues, including:
 - (1) methyl 3-(1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (MMDMG)”;

- Item 11 in Part 1 of Schedule VI (1-phenyl-2-propanone) is expanded to include “its derivatives and analogues and salts of derivatives and analogues, including:
 - (1) methyl 2-methyl-3-phenyloxirane-2-carboxylate (BMK methyl glycidate)
 - (2) 3-oxo-2-phenylbutanamide (α -phenylacetoacetamide-APAA);
- Item 28 in Part 1 of Schedule VI (norfentanyl) is expanded to include “its salts, derivatives and analogues and salts of derivatives and analogues”;
- “Benzylfentanyl (N-(1-benzylpiperidin-4-yl)-N-phenylpropionamide), its salts, derivatives and analogues and salts of derivatives and analogues” is added as a new item in Part 1 of Schedule VI.

Subsection 55(1) of the CDSA authorizes the Governor in Council to amend regulations made under the Act. This regulatory initiative amends the schedules to the NCR and the PCR as follows:

NCR

- “(14) 4-Anilino-N-phenethylpiperidine (ANPP) (N-phenyl-1-(2-phenylethyl)piperidine-4-amine), its derivatives and analogues and salts of derivatives and analogues” is added as a new subitem under item 15 (fentanyls, etc.).

PCR

- Item 10 [3,4-methylenedioxyphenyl-2-propanone (1-(1,3-benzodioxole)-2-propanone)] in column 1 is expanded to include “its derivatives and analogues and salts of derivatives and analogues, including:
 - (1) methyl 3-(1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (MMDMG);
- Item 13 (1-phenyl-2-propanone) in column 1 is expanded to include “its derivatives and analogues and salts of derivatives and analogues, including:
 - (1) methyl 2-methyl-3-phenyloxirane-2-carboxylate (BMK methyl glycidate)
 - (2) 3-oxo-2-phenylbutanamide (α -phenylacetoacetamide-APAA);
- Item 29 (norfentanyl) in column 1 is expanded to include “its salts, derivatives and analogues and salts of derivatives and analogues”;
- “Benzylfentanyl (N-(1-benzylpiperidin-4-yl)-N-phenylpropionamide), its salts, derivatives and analogues and salts of derivatives and analogues” is added as a new item in column 1 and its corresponding quantity in column 2 is indicated “0.”

Regulatory development

Consultation

In order to inform the public of the Government’s intent and provide an opportunity for comment, Health Canada published a [notice to interested parties](http://rp-pr/p1/2018/2018-12-15/pdf/g1-15250.pdf) ([/rp-pr/p1/2018/2018-12-15/pdf/g1-15250.pdf](http://rp-pr/p1/2018/2018-12-15/pdf/g1-15250.pdf)) in the *Canada Gazette*, Part I, on December 15, 2018, for a 30-day comment period. In addition to the *Canada*

Gazette publication, Health Canada posted the link to the notice on the Consulting with Canadians web page on the Government of Canada website, and notified targeted stakeholders of the notice by email, particularly those regulated under the above-mentioned regulations.

The comment period ended on January 14, 2019, and 11 comments were submitted to Health Canada. Two comments were received from organizations representing the health care sector and eight comments were submitted by private citizens. While four private citizens and one organization indicated support for the proposed scheduling, others expressed their views on the overarching policy framework for controlling drugs. Examples of the comments received are as follows:

- **Comment:** Fentanyl should be controlled more stringently (e.g. as a weapon instead of a drug) given its ability to cause death.
Health Canada response: This issue is outside the scope of this regulatory initiative. Although Health Canada is concerned with the health risks associated with fentanyl, it is a drug; therefore, the CDSA is the appropriate legislative framework for its control. As stated above, Health Canada has developed comprehensive approaches to tackle the opioid crisis in order to minimize the risk to public health and safety caused by the problematic use of opioids, primarily fentanyl.
- **Comment:** Health Canada should focus on the provision of treatment for substance use rather than drug prohibition.
Health Canada response: While enforcing the CDSA is necessary to tackle illegal activities with controlled substances, Health Canada recognizes that there is a public health crisis related to problematic substance use and that past approaches to drug policy have not been effective. The [Canadian drugs and substances strategy \(https://www.canada.ca/en/health-canada/services/substance-use/canadian-drugs-substances-strategy.html\)](https://www.canada.ca/en/health-canada/services/substance-use/canadian-drugs-substances-strategy.html) takes a public health approach to drug use and restores harm reduction as a key pillar, alongside prevention, treatment and enforcement.
- **Comment:** Scheduling one substance may lead to criminals developing other substances.
Health Canada response: Health Canada is aware of the trend of illegal manufacture of controlled substances and makes efforts to take proactive approaches in scheduling substances under the CDSA, one of which is to include derivatives and analogues of a controlled substance in the schedules to the Act. That way, possible or likely chemicals that share a similar chemical structure with a currently controlled substance will be subject to the control of the CDSA and its regulations.
- **Comment:** The inclusion of derivatives and analogues may pose challenges in determining the scope of control under the CDSA as these terms may implicate numerous chemicals.
Health Canada response: Health Canada recognizes the scientific complexities of determining the control status of chemicals that are considered derivatives and analogues of a controlled substance. Over the course of the administration of the CDSA and its regulations, Health Canada has established a solid knowledge base in chemistry and pharmacology and effective procedures to identify the chemical and pharmacological properties of substances in the context of the Act.

No comments specifically opposing this regulatory initiative were received.

As scheduling the chemicals in question under the CDSA and its regulations may affect international trade in the future, the Government of Canada notified members of the World Trade Organization of this proposal (a link to the notice to interested parties was provided) on December 21, 2018, for a 30-day comment period. No objection has been received from the notified parties.

Given that this regulatory initiative was published in the *Canada Gazette*, Part I, for comment through a notice to interested parties and that the chemicals in question have no legitimate commercial use, this initiative was not prepublished.

Instrument choice

Scheduling the chemicals in question provides law enforcement agencies with the authority to take legal action in relation to activities with these chemicals that are not in accordance with the CDSA. Furthermore, scheduling these chemicals under the CDSA and its regulations allows Health Canada to place regulatory control on the legitimate production, sale, import and export of these chemicals, in the event that they do have a legitimate industrial or commercial use in the future.

Given that these chemicals have no known legitimate industrial or commercial use in Canada, and the only known use of these chemicals is in the illegal production of fentanyl and amphetamines, placing legislative controls on them is the recommended option.

Regulatory analysis

Costs and benefits

The amendments are expected to help mitigate the risks to health and safety associated with the chemicals in question.

Benefits

The precursor substances that are subject to the amendments could be used by clandestine laboratories to produce fentanyl or amphetamines (e.g. methamphetamine or MDMA) for the illegal market. According to the *Canadian Drug Summary: Methamphetamine* (<http://www.ccsa.ca/Resource%20Library/CCSA-Canadian-Drug-Summary-Methamphetamine-2018-en.pdf#search=methamphetamine>), in 2017, law enforcement agencies reported 47 cases of illegal methamphetamine production in Canada, and 7 cases of illegal manufacturing of MDMA were reported in 2016. Problematic use of illegal fentanyl and amphetamines has resulted in significant harm to public health and safety in Canada. Though there are no statistics at the national level on the incidence of negative health outcomes associated with problematic use of fentanyl and amphetamines, in British Columbia, the coroner's report shows that of the 1 380 cases of illegal drug overdose deaths that occurred in the first nine months of 2018, approximately 85% were associated with illegal fentanyl.³ In Manitoba, there were 35 deaths that occurred in 2017 where methamphetamine was identified as contributing to or causing these deaths.⁴ Controlling substances, including precursor substances that can be used in the illegal production of fentanyl and amphetamines, will ultimately help protect the health and safety of Canadians and is consistent with the whole-of-government approach being taken to help address the opioid crisis.

Costs

Since no legitimate activities have been identified, and no establishments have expressed interest in conducting activities with these substances, no stakeholders would be affected by these amendments and they would not incur any incremental costs.

The Government of Canada is not expected to incur any incremental costs. Compliance and enforcement activities conducted by Health Canada and other government agencies will continue to be conducted as per current practice with respect to the family of these substances and no additional resources would be required.

Small business lens

The small business lens does not apply, as there are no associated impacts on businesses.

“One-for-One” Rule

The “One-for-One” Rule does not apply, as there is no impact on businesses.

Strategic environmental assessment

In accordance with *The Cabinet Directive on the Environmental Assessment of Policy, Plan and Program Proposals*, a preliminary scan concluded that a strategic environmental assessment is not required for this initiative.

Gender-based analysis plus

A gender-based analysis plus (GBA+) was undertaken for this initiative. Controlling these substances is expected to protect the health and safety of Canadians by reducing the risks associated with the availability of these chemicals and their subsequent use in the illegal production of fentanyl and amphetamines (e.g. methamphetamine or MDMA). Though there are sex/gender differences in the problematic use of illicit fentanyls and amphetamines and the resulting adverse outcomes, the GBA+ conducted for these amendments did not uncover any potential gender-based impacts on any subgroups based on gender or any other socioeconomic characteristics.

There is only limited information available that differentiates the cases of reported negative health events associated with fentanyls or amphetamines between men and women. However, research has found that men are at greater risk of harm by illegal fentanyl than women. In Alberta and British Columbia, men accounted for approximately 80% of fentanyl-associated unintentional deaths. In 2017, among Canadians aged 15 or above, the prevalence of lifetime methamphetamine use among males (54.4%) was significantly higher than among females (2.2%). Also, research shows that women seem to be more sensitive to the effects of MDMA when they use the same amount as men; women also reported having more long-term effects (e.g. paranoia, mood swings, anxiety, and depression).

In addition to gender differences, there was uneven distribution of deaths across age groups and provinces:

- In 2017 in British Columbia, 28.9% of accidental apparent fentanyl-related deaths occurred among individuals between the ages of 30 and 39 years.
- In Alberta, among males who died due to a fentanyl overdose, the highest number of deaths occurred among individuals aged between 30 and 34 years, while for females, the highest number of deaths occurred among individuals aged 25 to 29 years.

The potential health benefits associated with these amendments would be experienced by every sub-group of Canadians who use illegal fentanyls and amphetamines. There is no evidence indicating that the existing gender differences in the use patterns of fentanyls and amphetamines and adverse outcomes linked to

these substances among different subgroups would be disproportionately affected as a result of the amendments. Therefore, no GBA+ impacts have been identified for this proposal.

Implementation, compliance and enforcement, and service standards

Due to the urgent health and safety risks caused by the problematic use of fentanyl and amphetamines, these regulatory amendments come into force on the day of publication in the *Canada Gazette*, Part II. As part of the implementation of these amendments, Health Canada will notify stakeholders of the changes and provide additional information on the Department's website.

Health Canada is responsible for authorizing activities (through licences, permits, and exemptions) with substances scheduled under the CDSA and its regulations and for monitoring compliance with regulatory requirements. Law enforcement agencies and CBSA officials are responsible for taking enforcement action in response to contraventions of the CDSA. Under the CDSA, a range of penalties applies to the offences associated with the precursor chemicals covered by these regulatory amendments. The maximum penalty for indictable offences with respect to substances in Schedule VI to the CDSA is imprisonment for a term not exceeding 10 years.

There are no additional service standards other than those that already exist for issuing licences and permits under the CDSA.

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Footnotes

^a S.C. 2017, c. 7, ss. 40(1) to (11)

^b S.C. 1996, c. 19

¹ C.R.C., c. 1041

² SOR/2002-359

- 3 More details can be found in British Columbia's [Statistical Reports](https://www2.gov.bc.ca/gov/content/life-events/death/coroners-service/statistical-reports) (<https://www2.gov.bc.ca/gov/content/life-events/death/coroners-service/statistical-reports>).
 - 4 See "[Meth overdose deaths double in Manitoba in 2 years](https://www.cbc.ca/news/canada/manitoba/meth-overdose-deaths-double-in-manitoba-in-2-years-1.4801236)" (<https://www.cbc.ca/news/canada/manitoba/meth-overdose-deaths-double-in-manitoba-in-2-years-1.4801236>)."
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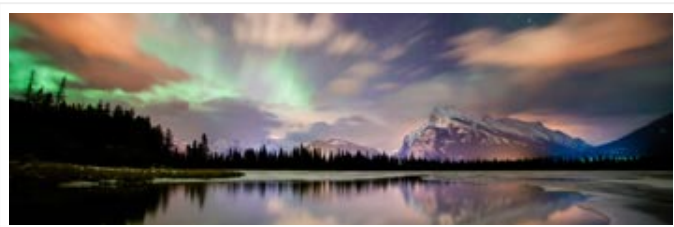
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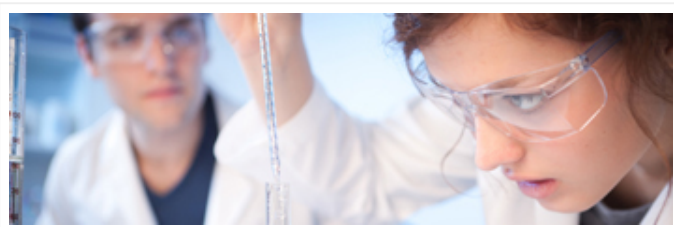
(https://www.budget.gc.ca/2018/docs/themes/advancement-advancement-en.html?utm_source=CanCa&utm_medium=Activities_e&utm_content=Advancement&utm_campaign=CAbdgt18)
Advancing our shared values

#YourBudget2018 – Reconciliation



(https://www.budget.gc.ca/2018/docs/themes/reconciliation-reconciliation-en.html?utm_source=CanCa&utm_medium=%20Activities_e&utm_content=Reconciliation&utm_campaign=CAbdgt18)
Advancing reconciliation with Indigenous Peoples

#YourBudget2018 – Progress



(https://www.budget.gc.ca/2018/docs/themes/progress-progres-en.html?utm_source=CanCa&utm_medium=Activities_e&utm_content=Progress&utm_campaign=CAbdgt18)
Supporting Canada's researchers to build a more innovative economy