Government of Canada
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BILL C-28

Strengthening Environmental Protection for a Healthier Canada Act: Summary of Amendments

Canada

Bill C-28, *Strengthening Environmental Protection for a Healthier Canada Act*

Summary of Amendments

The following is intended to provide a plain language summary of key amendments put forward in Bill C-28, *Strengthening Environmental Protection for a Healthier Canada Act*. For the comprehensive and detailed list of amendments, please refer to the Bill.

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April 13, 2021

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Environmental Rights

Right to a Healthy Environment under CEPA

- The preamble to the Act will recognize that every individual in Canada has a **right to a healthy environment** as provided under CEPA, and section 2 of the Act (respecting administrative duties) will require that the Government protect that right *[clause 2(1), clause 3(2)]*.
    - Within two years, the Ministers must develop an **implementation framework to set out how that right will be considered in the administration of the Act** *[clause 5]*.
        - Interested persons (e.g., stakeholders, partners) will have an opportunity to participate in the development of the implementation framework.
        - The Minister of Environment and Climate Change must publish the framework and annually report on its implementation.
    - The Ministers must **conduct research, studies or monitoring activities** to support the Government in protecting a right to a healthy environment *[clause 7]*.
- In addition, the preamble to the Act will include related statements:
    - confirming the Government's commitment to implement the **United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP)** *[clause 2(3)]*;
    - recognizing the importance of considering **vulnerable populations** in risk assessments and of minimizing the risks posed by the **cumulative effects** of toxic substances *[clause 2(4)]*;
    - endeavouring to reduce, refine or replace the use of **animal testing** *[clause 2(5)]*; and
    - recognizing the importance of **Canadians having information** regarding the risks of toxic substances, including by **labelling products** *[clause 2(6)]*.

Strengthening Chemicals Management: Existing Substances

Risk Assessment

Plan of Chemicals Management Priorities and Public Request Mechanism

- Within two years, the Ministers must develop, consult on, and publish a **Plan of Chemicals Management Priorities**, which will set out a multi-year, integrated plan for the assessment of substances as well as the activities and initiatives that support chemicals management, such as information-gathering, risk management, risk communications, research and monitoring *[clause 19]*.
    - The Ministers are empowered **to consult with interested stakeholders and partners**, such as Indigenous peoples, representatives of industry, labour and municipal authorities, or other interested persons, in the development and implementation of the Plan of Chemicals Management Priorities. The public can also influence these priorities through the draft publication framework, which provides for a public comment period.
    - The Plan of Chemicals Management Priorities must specify the term of the plan, after which time the Ministers will be **required to review the Plan**.
    - Stakeholder engagement and public consultation requirements will also apply to any updates to the Plan following the Ministers' review of it.

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- In developing and implementing the Plan, the Government will continue to set priorities, and assess and manage substances by taking a risk-based approach that accounts for the properties of a substance as well as exposure to the substance, and must consider a number of factors of importance to Canadians, including:
    - vulnerable populations and cumulative effects;
    - particular properties and characteristics of substances, such as carcinogenicity, mutagenicity or neurotoxicity;
    - the capacity of substances to disrupt reproduction or endocrine systems;
    - the advantages of class-based assessments (e.g., as a means of avoiding regrettable substitutions);
    - safer or more sustainable alternatives; and
    - means of providing information to the public, such as through labeling and other risk communication strategies *[clause 16]*.

- The Ministers must **report annually to Parliament**, as part of the CEPA annual report, on their progress in implementing the Plan of Chemicals Management Priorities *[clause 19]*.

- The spent **categorization provisions** and dated **Priority Substances List (PSL) provisions will be repealed** *[various clauses]*.

- In addition, a **new provision will allow any person to request that the Ministers assess a substance** to determine whether it is toxic or capable of becoming toxic. The Ministers must reply within 90 days indicating how they intend to deal with the request and the reasons for dealing with it in that manner *[clause 20]*.

Vulnerable Populations and Cumulative Effects

- The Ministers must consider available information regarding **vulnerable populations** and **cumulative effects** when conducting and interpreting the results of certain risk assessments under CEPA (i.e. all assessments other than assessments of new substances and significant new activities) *[clause 20]*.

- These amendments complement the recognition of a right to a healthy environment and support the Government's duty to protect it *[clause 2(1), clause 3(2)]*.

    - The preamble to the Act will include new language recognizing the importance of considering **vulnerable populations** in risk assessments and of minimizing the risks posed by the **cumulative effects** of toxic substances *[clause 2(4)]*.

    - The Act will define a "vulnerable population" in a manner that captures **biological susceptibility** (e.g. infants, pregnant women) and **potential exposure** (e.g. Indigenous communities eating traditional foods, areas where pollution standards may be exceeded) *[clause 4(2)]*.

    - Explicit recognition that the **Government's duty** (under section 2) to exercise its powers in a manner that protects the environment and human health **includes the health of vulnerable populations** *[clause 3(1)]*.

    - The Act will provide that the **Minister of Health's obligation to conduct biomonitoring surveys,** as part of the obligation to conduct research and studies in relation to the health effects of substances, may include vulnerable populations *[clause 8]*.

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- Ensuring **vulnerable populations and cumulative effects** are reflected under the list of **matters** that must be considered when developing and implementing the **Plan of Chemicals Management Priorities** *[clause 16(2)]*.

- In addition, amendments will facilitate the making of **geographically targeted regulations** that could, for example, be used to help address pollution **"hot spots"** *[clause 54]*.

Public Accountability Framework (Sections 77 and 91-92)

Transparency, Participation and Accountability in Assessment and Management of Risks

- The public accountability framework under section 77 and the CEPA "time-clock" in sections 91 and 92 **will now apply to all risk assessments of substances to determine whether they are "toxic" under CEPA**, except for assessments of new substances and significant new activities *[clause 21(1)]*.

  - This broadens the scope of section 77, which previously only applied to certain risk assessments of substances, and will have the resulting effect of broadening the scope of the CEPA time-clock obligation as well.

- Following an assessment of whether a substance is toxic or capable of becoming toxic, the Ministers must propose one of four measures under section 77:
  a) taking no further action – e.g. if the substance is not toxic.
  b) adding the substance to the Watch List – e.g. if the substance is of potential concern and requires monitoring *(see "Watch List" section below)*.
  c) recommending that the substance be added to Part 1 of Schedule 1 *(see "Prohibiting Toxic Substances that pose the Highest Risk" section below).*
  d) recommending that the substance be added to Part 2 of Schedule 1 *[clause 21(1)]*.

- If the proposed measure is a recommendation that the substance be added to Schedule 1 (i.e. either (c) or (d) as per above), then the CEPA time-clock obligation is triggered and the Ministers must develop a risk management instrument in relation to the substance *[clause 21(2)]*.

  - The particular risk management approach will differ depending on whether the toxic substance is added to Part 1 (priority to prohibition) or Part 2 (priority to pollution prevention) of Schedule 1 (*see "Prohibiting Toxic Substances that pose the Highest Risk" section below).*

Timelines for Additional Planned Risk Management

- Where the Ministers propose to develop more than one risk management instrument in respect of a substance, the Ministers must **communicate the timelines for making the additional planned instruments** when publishing the first finalized instrument *[clause 22]*.

Risk Management

Watch List

- The Ministers must publish and maintain a **list of substances of potential concern**, due to their hazardous properties for example *[clause 20]*.

- The decision to declare that a substance is "capable of becoming toxic" and add it to the **Watch List** will be one of the four options under section 77 that the Minister may take following a risk

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assessment (*see "Transparency, Participation and Accountability in Assessment and Management of Risks" section above*) *[clause 21(1)]*.

Prohibiting Toxic Substances that pose the Highest Risk

- **Generally**
  The unworkable provisions for **virtual elimination (VE)** of toxic substances that are persistent and bioaccumulative (PBTs) **will be repealed and replaced** with a new regime that remains risk-based but provides that toxic substances of highest risk should be managed by giving priority to prohibition *[various clauses]*.

    - Recall that substances that are found "toxic" under section 64 of CEPA have been assessed as such according to a risk-based process that looks at both hazard and exposure.

  The list of toxic substances in Schedule 1 will be split into two parts to implement a two-track approach for managing toxic substances under CEPA *[clause 57]*.

    - Toxic substances that are either persistent and bioaccumulative (PBTs), or inherently toxic and found to pose the highest risk will be added to **Part 1** and subject to a more stringent risk management objective (i.e. **priority given to prohibition**) *[clause 21(1), clause 29]*.

        - Initially, toxic substances on Part 1 will be those that have been found to meet the criteria in the existing *Persistence and Bioaccumulation Regulations.*

        - It is anticipated that those regulations would be amended or new regulations made to define "highest risk" by reference not only to persistence and bioaccumulation but also to prescribed thresholds for **carcinogenicity, mutagenicity and reproductive toxicity (CMR)**, and any other relevant circumstances or conditions (see proposed regulatory authorities under subsection 67(1)) *[clause 15]*.

        - The Government will engage interested stakeholders in the development of the new regulatory criteria to define toxic substances that pose the highest risk.

    - Other toxic substances will be added to **Part 2** and continue to be subject to regular risk management actions (i.e. **priority given to pollution prevention**) *[clause 21(1), clause 29]*.

- **Prohibiting PBTs and Toxic Substances that Pose the Highest Risk**
  Under the amendments, the Ministers must recommend that toxic substances of highest risk, as defined by regulations made under section 67, be added to the **new Part 1 of Schedule 1** *[clause 15, clause 21(1)]*.

  When developing risk management instruments in respect of these toxic substances, the **Ministers must give priority to the total, partial or conditional prohibition** of activities in relation to these substances *[clause 29]*.

    - **total prohibition** could be implemented as a complete ban or phase out of all activities involving the substance (e.g. for persistent and bioaccumulative toxic substances in accordance with Canada's international commitments).

    - **partial prohibition** could be implemented as a ban or phase out of activities of concern involving the substance, which may be most uses in some cases, with exemptions for critical or essential uses for which there are no feasible alternatives (e.g. prohibition of all uses except for essential medical uses or other similarly essential uses).

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- **conditional prohibition** could be implemented such that all new activities involving the substance are prohibited unless the Ministers have specifically authorized the use (e.g. through a permit) on the basis that the activity can be undertaken in a manner that minimizes or eliminates any harmful effect on human health or the environment, and there are no feasible alternatives.

In summary, the amendments provide that prohibition would be the starting point for risk management of toxic substances added to Part 1 of Schedule 1, while recognizing that, as the list of toxic substances on Part 1 grows to include toxic substances with properties or characteristics beyond persistence and bioaccumulation, more tailored approaches to managing the risks may be needed. As noted above, partial or conditional prohibitions may be more appropriate in some cases, and indeed necessary in other cases.

- **Supporting Powers**
  In support of this new priority to be given to prohibition, amendments will add a new provision to section 93 (i.e. the main regulation-making authority for toxic substances) that explicitly enables ministerial permitting regimes *[clause 33(7)]*.

  - This **permitting power** will allow the Minister to require that proponents first demonstrate that a prohibited activity can be **undertaken safely** and that there are **no feasible alternatives** before deciding whether to issue a permit authorizing the proponent to undertake the activity according to specific conditions or control measures.

  - Permitting decisions by the Minister could also be discretionary under this new authority (this can be contrasted with existing regulatory permitting regimes that require the Minister to issue a permit if prescribed conditions are met).

- **Other Toxic Substances**
  As noted above, for toxic substances that do not meet the regulatory persistent and bioaccumulative or inherently toxic and of "highest risk" criteria, the Ministers will continue to recommend that these other toxic substances be added to **Part 2 of Schedule 1**, and they will continue to be required to **give priority to pollution prevention actions** (which may include prohibition) when managing the risks posed by those substances *[clause 21(1), clause 29]*.

- **Application**
  The amendments to CEPA will not affect products, such as pesticides, which are specifically regulated under other federal Acts, such as the *Pest Control Products Act* (PCPA). This is consistent with certain frameworks and provisions under CEPA and the best-placed act approach to chemicals management.

  The amendments do not require that the Government of Canada's Toxic Substances Management Policy (TSMP) be updated; the new proposed regime and the TSMP can stand together. Any future decision to update the TSMP would be done in consultation with the relevant departments, agencies and stakeholders in order to ensure that it is updated in a manner that accommodates the particularities posed by pesticides, for example.

Products that May Release a Toxic Substance

- Information-gathering and regulatory authorities may be exercised in respect of **products that may release a toxic substance** (even though the products themselves do not contain the toxic substance) *[various clauses]*.

  - New powers will allow control measures that target the design and functioning of products such as portable fuel containers (vis-à-vis the release of volatile organic compounds listed on Schedule 1).

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Best-Placed Act / Best-Placed Minister

- The Ministers may "operationalize" and **rely on an existing federal measure** under another Act or regulation by clarifying how that measure addresses the risks of a toxic substance that were identified during the risk assessment *[clause 21, clause 23, clause 30, clause 40]*.

    - Examples of existing federal measures include the following general prohibitions:
        - subsection 36(3) of the *Fisheries Act* (prohibition on the deposit of deleterious substances);
        - section 16 of the *Food and Drugs Act* (prohibition on the sale of cosmetics containing substances that may cause injury); and
        - sections 7 and 8 of the *Canada Consumer Product Safety Act* (prohibitions on the manufacture, import, advertisement and sale of consumer products that are a danger to human health).

    - Where the Ministers decide to rely on an existing federal measure that addresses the risks identified for a toxic substance, they must make a statement to that effect and outline additional administrative measures that will be taken to ensure it is effective and, in which case, they do not need to develop a new risk management instrument.

- In cases where **another federal Act or minister is best placed** to manage the risks identified for a toxic substance, a **new** regulation or instrument can be made under that other federal Act in order to formally fulfill the legal obligation under CEPA to develop a risk management instrument *[clause 30, clause 31]*.

- Similarly, the **Minister of Health will be responsible** for fulfilling the risk management obligation under CEPA where the Minister of Health will be leading the development and implementation of the new risk management instrument(s) in relation to substances that pose health concerns *[clause 30, clause 31]*.

Renaming Schedule 1

- The title of Schedule 1 (i.e. "List of Toxic Substances") will be removed so that the title will simply be "**Schedule 1**" *[various clauses]*.

Domestic Substances List (DSL)

Power to Add In-Commerce List (ICL) Substances to the DSL

- The Minister will be able to **add substances on Health Canada's "In-Commerce List"** (ICL) to the Domestic Substances List (DSL) under CEPA to reflect the fact that they are in Canadian commerce *[clause 4(1), clause 14, clause 26, clause 28, clause 38, clause 55]*.

    - The In-Commerce List is comprised of substances used in products regulated under the *Food and Drugs Act* and that were in Canadian commerce between January 1, 1987 and September 13, 2001.

Power to Remove Substances No Longer in Commerce from the DSL

- The Minister will be able to **remove substances from the Domestic Substances List (DSL)** to reflect the fact that they are no longer in Canadian commerce *[clause 4(1), clause 13, clause 14, clause 28, clause 38, clause 55]*.

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- In the interests of transparency and fairness, the Minister will publish a notice of the proposed removal in the *Canada Gazette* and provide for a **60-day comment period** *[clause 14, clause 38]*.

New Substances and Significant New Activities

Varying Significant New Activity (SNAc) Information

- The Minister will be able to **vary elements of a significant activity notice or order** beyond the significant new activity itself, such as the data or information that needs to be submitted for evaluation prior to undertaking the activity, as well as the timelines for submitting that information *[clause 24, clause 26, clause 41, clause 43]*.

Downstream Communication of Significant New Activities (SNAc)

- The transferor of a new substance must notify transferees of any obligation to comply with the significant new activity provisions in respect of the new substance. This obligation will be extended so that it also applies vis-à-vis any obligation to comply with the **significant new activity provisions in respect of *existing* substances** *[clause 24, clause 25, clause 26, clause 27, clause 41, clause 42, clause 43, clause 44]*.

- The Minister will be able to **tailor the scope of that obligation** by specifying, in the SNAc notice or order itself, the class of persons who are not required to be so notified.

    - For example, the Minister may specify that persons downstream of product formulators, such as retailers of finished products, do not need to be notified of the obligation to comply with the SNAc.

Amendments to the *Food and Drugs Act* (FDA)

- Amendments to the *Food and Drugs Act* (FDA) will enable the creation of an environmental risk assessment and risk management regime for drugs under the *Food and Drug Regulations* (currently limited to health risk) *[clause 64, clause 65, clause 66, clause 67]*.

- This will enable the Government of Canada to move towards creating an environmental notification, risk assessment and risk management framework for drugs under the FDA that the Minister of Health could recommend to the Governor in Council for addition to CEPA's Schedules 2 and 4 (e.g. a regime that provides CEPA-equivalent pre-market notification and assessment for certain new substances).

    - If the environmental notification, risk assessment and risk management framework for drugs under the FDA is found to meet the requirements necessary to be added to Schedules 2 and 4, this regime would be treated in the same manner as the *Pest Control Products Act*, the *Fertilizers Act* and the other scheduled federal statutes and regulations—that is, new substances that are manufactured or imported for use in drugs would no longer be notifiable or assessed under CEPA, as this would happen entirely under the FDA.

    - This regime would strengthen the environmental risk assessment and risk management of drugs, and remove the duplicate notification process between the FDA and CEPA (for safety, efficacy and quality and environmental assessments), creating a more streamlined regulatory approach for industry with respect to the assessment and approval of drugs in Canada.

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Information-Gathering

Powers to Compel Information

- Amendments will strengthen the Minister's primary information-gathering authority under **section 71** by ensuring that it can be used to specify the **methods for quantifying** the required information as well as the **test procedures or laboratory practices to be followed** in performing any required tests *[clause 18]*.

- Amendments will also allow the Minister to **require supplementary information** (e.g. models or methods used) as well as to **require that samples be provided** along with test results *[clause 18]*.

Confidential Business Information (CBI)

- Unless otherwise specified, amendments provide that **confidentiality requests** made under section 313 must be **accompanied by reasons** (e.g. explaining the basis upon which confidentiality is claimed) *[clause 49, clause 53]*.

- Amendments will authorize the Minister to **disclose the explicit name** of a masked substance when **risk management instruments** have been put in place for the substance (e.g. when the significant new activity provisions have been applied to the substance) *[clause 50, clause 52]*.

- Amendments will also authorize the Minister to **disclose explicit names after ten years** have passed from the date the name was masked, but will give proponents the opportunity to demonstrate that it should nevertheless remain confidential *[clause 50, clause 52]*.

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