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Legislative Summary

BILL C-28:
AN ACT TO AMEND THE CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999, TO MAKE RELATED AMENDMENTS TO THE FOOD AND DRUGS ACT AND TO REPEAL THE PERFLUOROOCTANE SULFONATE VIRTUAL ELIMINATION ACT

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(Legislative Summary)

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LEGISLATIVE SUMMARY OF BILL C-28: AN ACT TO AMEND THE CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999, TO MAKE RELATED AMENDMENTS TO THE FOOD AND DRUGS ACT AND TO REPEAL THE PERFLUOROOCTANE SULFONATE VIRTUAL ELIMINATION ACT

1 BACKGROUND

Bill C-28, An Act to amend the Canadian Environmental Protection Act, 1999, to make related amendments to the Food and Drugs Act and to repeal the Perfluorooctane Sulfonate Virtual Elimination Act (short title: Strengthening Environmental Protection for a Healthier Canada Act)[1] was introduced in the House of Commons by the Minister of Environment and Climate Change and read for the first time on 13 April 2021. It died on the *Order Paper* upon dissolution of the 43rd Parliament, 2nd Session, on 15 August 2021.

1.1 PURPOSE OF BILL

Bill C-28 amends the *Canadian Environmental Protection Act, 1999*[2] (CEPA). It recognizes Canadians' right to a healthy environment and enshrines the Government of Canada's duty to protect this right. The bill requires the ministers of the Environment and Health (the ministers) to consider vulnerable populations and cumulative effects when assessing a substance's potential to be toxic or to become toxic. The bill creates a two-track prioritization regime for the regulation of toxic substances under CEPA. Toxic substances continue to be listed in Schedule 1, but the single list is divided into Part 1 for substances that pose the highest risk and Part 2 for all others. For toxic substances listed in Part 1 of Schedule 1, the ministers prioritize regulation through total, partial or conditional prohibition of releases of those substances. For toxic substances listed in Part 2 of Schedule 1, the ministers prioritize regulation through pollution prevention actions. The bill amends the *Food and Drugs Act*[3] (FDA) to create an environmental risk assessment and management regime for drugs. The FDA already sets out a framework for assessing and managing health risks to ensure the safety, efficacy and quality of drugs; however, the environmental risks of drug ingredients are currently assessed under CEPA. The amendments establish a single assessment regime under the FDA to assess both the environmental risks and health risks of drugs.

1.2 HISTORY OF THE *CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999*

CEPA is one of the principal federal laws aimed at environmental protection in Canada. Enacted in 1988, the original CEPA consolidated several statutes and parts of statutes related to the environment.[4] This CEPA laid out a framework for

managing toxic substances and gave the ministers authority to regulate sources of pollution.[5] Following a review in 1995, the current version of CEPA came into force in 1999. Since then, CEPA has undergone relatively few and minor amendments.

CEPA has been subject to several parliamentary committee reviews.[6] The most recent review, by the House of Commons Standing Committee on the Environment and Sustainable Development (ENVI), resulted in a June 2017 report containing 87 recommendations that address themes including the following:

- recognizing and implementing a right to a healthy environment;
- recognizing the United Nations *Declaration on the Rights of Indigenous Peoples*;
- consideration of exposures to toxic substances of vulnerable populations;
- consideration of cumulative effects of toxic substances;
- hazard labelling on products containing toxic substances;
- revisiting the virtual elimination regime and implementing a more effective regime;
- prohibiting the highest-risk toxic substances;
- regulating the design and functioning of products that may not contain toxic substances but might release them during their use;
- authority to delete a substance no longer in commerce from the Domestic Substances List;
- authority for the Minister of Health to lead in implementing CEPA for toxic substances where the risks are health-related; and
- increasing transparency and opportunities for public participation.[7]

The response of the Government of Canada to this report was tabled in the House of Commons in June 2018.[8] The Minister of Environment and Climate Change has indicated that some 35 recommendations from the report have been incorporated into Bill C-28.[9]

1.3 PART 5 – CONTROLLING TOXIC SUBSTANCES

CEPA is divided into 12 parts. Parts 1 and 7 of CEPA are not amended by Bill C-28. Many of the provisions in the bill affect Part 5, which regulates the identification and management of toxic substances. The current process under CEPA is described below.

1.3.1 Identifying a Substance as "CEPA Toxic"

Under CEPA, the process for identifying a toxic substance depends on whether the substance existed in Canada when CEPA was first enacted or is either new or subject to a new use. Both existing and new substances must be assessed to determine whether they need to be managed. The test for this, known as the "CEPA toxic" test, is set out in section 64 of CEPA:

> 64 For the purposes of this Part and Part 6, except where the expression "inherently toxic" appears, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that
>
> (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
>
> (b) constitute or may constitute a danger to the environment on which life depends; or
>
> (c) constitute or may constitute a danger in Canada to human life or health.

1.3.1.1 Substances and Activities New to Canada

New substances and significant new activities are typically prohibited until the ministers have assessed whether the substance is toxic or capable of becoming toxic. If the ministers suspect that the substance is toxic or capable of becoming toxic, they may permit use of the substance, subject to any conditions; prohibit the substance; or request more information (section 84(1)). Approximately 400 to 500 new substance notifications are received annually for review.[10]

1.3.1.2 Domestic Substances List

Chemical substances already in commercial use in Canada before 1987 were placed on a list known as the Domestic Substances List.[11] CEPA required that the approximately 23,000 substances on the Domestic Substances List be categorized to determine which ones required further assessment.[12] The Government of Canada completed this "initial priority setting"[13] by the deadline of 2006 as specified in CEPA, seven years after CEPA came into force. Approximately 4,300 substances[14] met the specified criteria to undergo a screening level risk assessment to determine if they were CEPA toxic.

1.3.1.3 Other Mechanisms to Initiate Risk Assessments

In addition to new substance notifications and the results of categorization of the Domestic Substances List, the Government of Canada describes five other mechanisms for identifying candidate substances for risk assessments:

- industry information;
- information exchange and review of decisions of other jurisdictions;
- inclusion on another list referred to as the Priority Substances List;
- emerging science and monitoring; and
- international assessment or data collection.[15]

1.3.2 Adding a Substance to Schedule 1, the List of Toxic Substances

Following a screening assessment of a substance, the ministers propose whether to add the substance to the list of toxic substances in Schedule 1 of CEPA (section 77(2)). Under section 77(3), the ministers are required to recommend that a substance be added to the list of toxic substances if they are satisfied that:

> (a) the substance may have a long-term harmful effect on the environment and is
>
> (i) persistent and bioaccumulative in accordance with the regulations, and
>
> (ii) inherently toxic to human beings or non-human organisms, as determined by laboratory or other studies, and
>
> (b) the presence of the substance in the environment results primarily from human activity[.]

Based on the ministers' recommendation, the Governor in Council issues the order to add the substance to the list of toxic substances (section 90(1)).

1.3.3 Managing Risks of Substances

To manage the risks associated with a new substance or activity, conditions may be placed on the manufacture or import of a substance. Once a substance is added to the list of toxic substances, regulations or instruments may be used to impose such conditions. A pollution prevention plan (Part 4 of CEPA) or objectives, guidelines or codes of practice (Part 3) may also be used to control toxic substances.

1.3.3.1 Virtual Elimination

When the ministers propose to add to the list of toxic substances a substance that is persistent and bioaccumulative, present in the environment primarily due to human activity and not a naturally occurring radionuclide or inorganic substance, they must

propose to use the virtual elimination provisions of CEPA (section 77(4)). To initiate virtual elimination, a substance must be added to the Virtual Elimination List.[16] The level of quantification, defined as "the lowest concentration that can be accurately measured using sensitive but routine sampling and analytical methods" (section 65.1), must be specified for the substance. The release limit of the substance is then set out in regulations and may be reduced over time until the quantity of the substance released into the environment falls below the level specified for that substance. Although the virtual elimination scheme accounts for point sources of toxic substances released into the environment (e.g., wastewater outflow pipes), it does not account for diffuse sources.[17]

2 DESCRIPTION AND ANALYSIS

Bill C-28 contains 69 clauses. Key clauses are discussed in the sections below.

2.1 PREAMBLE, ADMINISTRATIVE DUTIES AND DEFINITIONS (CLAUSES 2 TO 5, 7 AND 8)

Clause 2 amends CEPA's preamble to highlight the government's commitment to implementing the United Nations *Declaration on the Rights of Indigenous Peoples* and to recognize:

- the right of every individual in Canada to a healthy environment;
- the importance of considering vulnerable populations when assessing the toxicity of substances;
- the importance of minimizing the risks posed by exposure to toxic substances, including cumulative effects;
- the role of science in making decisions related to the protection of the environment and human health;
- the importance of reducing, refining or replacing with scientifically justified alternative methods the use of vertebrate animals for testing and assessing substances;
- the importance of encouraging substitution of substances, processes and technologies with alternatives safer for the environment or human health, where economically and technically viable; and
- the importance of Canadians having information on the risks posed by toxic substances to the environment or human health, including through product labelling.

Clause 3 adds protecting the health of vulnerable populations to the duties of the Government of Canada in the administration of CEPA. Protecting the right of every individual in Canada to a healthy environment is also added as a duty, while noting that this right may be balanced with social, economic, health, scientific or other relevant factors (amended section 2(1)).

Clause 4(2) adds a new definition to section 3(1) to state that a vulnerable population is "a group of individuals within the Canadian population who, due to greater susceptibility or greater exposure, may be at an increased risk of experiencing adverse health effects from exposure to substances."

Clause 5 adds new section 5.1, requiring the ministers to develop, within two years after the day of coming into force of this section, an implementation framework on how the right to a healthy environment will be considered in the administration of CEPA. Requirements are laid out for the framework's content, including how principles of environmental justice will be considered and how the right to a healthy environment will be balanced "with relevant factors, including social, economic, health and scientific factors." The ministers are required to consult interested persons during the development of the framework, publish it and report annually on its implementation.

Clause 7 adds protection of the right to a healthy environment to the list of areas in which the ministers shall conduct research, studies or monitoring activities to support the Government of Canada (new section 44(3.1)).

Clause 8 clarifies that the research and studies conducted by the Minister of Health on the role of substances in health problems may include biomonitoring surveys and may relate to vulnerable populations (amended section 45).

2.2 CONTROLLING TOXIC SUBSTANCES

2.2.1 Identifying and Regulating Toxic Substances (Clauses 15 to 17, 19, 22, 49 and 55)

Clause 15 allows the Governor in Council to make regulations respecting the carcinogenicity, mutagenicity and reproductive toxicity of substances as well as the classification of substances as posing the highest risk. This is in addition to the existing power to make regulations respecting, among other things, the persistence and bioaccumulation of substances and the conditions, test procedures and laboratory practices to be followed when analyzing properties (amended section 67).

Clauses 16(2) to 16(5) amend the list of factors in section 68(a) in relation to which the ministers may collect or generate data and conduct investigations when determining whether a substance is toxic and whether and how to control the substance. The following are new factors to consider:

- the potential for cumulative effects when in combination with exposure to other substances;
- whether there is a vulnerable population in relation to the substance;
- delayed or latent carcinogenic, mutagenic or neurotoxic effects over an organism's lifetime;
- the potential to disrupt the endocrine system;
- the existence, development and use of safer or more sustainable alternatives; and
- how the public may be provided with information.

Information continues to be collected or generated to determine if a substance is toxic based on factors including the following:

- whether short-term exposure causes significant effects;
- the potential of organisms in the environment to be widely exposed;
- whether there are multiple ways an organism can be exposed;
- whether the substance can affect an organism's reproduction or survival;
- transgenerational effects or contribution to the population failure of a species;
- quantities, uses and disposal of a substance;
- how the substance is released into the environment;
- the development and use of alternatives to the substance; and
- how to control the presence of the substance in the environment.

Under section 69 of CEPA, either minister or both ministers may issue guidelines on controlling toxic substances after offering to consult provincial governments, representatives of Indigenous governments on the National Advisory Committee (an advisory body that provides guidance to the ministers on environmental matters) and other interested persons. Clause 17 amends section 69 to allow the Minister of Health to issue guidelines on controlling a toxic substance 60 days after offering a consultation; currently, only the Minister of the Environment may issue guidelines independently.

Clause 22 removes the possibility of filing a notice of objection if no regulations have been developed five years after a substance has been listed in Schedule 1. Instead, if the ministers decide to list a substance in Schedule 1 and indicate that regulations or instruments for preventive or control actions regarding the substance will be developed, the Minister of the Environment must publish a statement indicating an estimated time frame for the development of those regulations or instruments. If the ministers change their plan to develop the proposed regulations or instruments, they must publish a statement notifying the public (amended sections 78 and 79).

Clause 49(2) makes it an offence under CEPA to contravene conditions of a permission granted under a regulation with respect to a substance in Schedule 1 or regulations made for the protection of the environment (amended section 272(1)(d)).

Clause 55 repeals sections 330(3) and 330(3.1), which specified that regulations applied throughout Canada except where, to protect the environment or human health, they applied to a part or parts of the country in relation to a toxic substance listed in Schedule 1, fuel standards or releases of substances into air and water. Geographic locations may now be specified in any regulations prescribing "the minimum, average or maximum quantity or concentration of [a] substance" and "the method of determining such a quantity or concentration" (section 330(1)).

2.2.2 Schedule 1
(Clauses 21(1), 29, 58 and 62)

Schedule 1 is reordered into two parts to implement a two-track approach to managing toxic substances. Part 1 lists higher-risk toxic substances and Part 2 lists all other toxic substances, as set out in clauses 21(1) and 29 of the bill.

Part 1 of Schedule 1 lists toxic substances that pose the highest risk: those that are either persistent and bioaccumulative, or inherently toxic. These substances are subject to a more stringent risk management objective in that priority is given to their total, partial or conditional prohibition.

Part 2 of Schedule 1 lists other toxic substances for which priority in risk management measures is given to pollution prevention actions, as is the case for toxic substances listed in Schedule 1 under the current CEPA.

Clause 58 renames Schedule 1 to remove "List of Toxic Substances" from its title. This title change is reflected throughout the amended text. It also categorizes 19 currently listed substances or groups of substances under Part 1 of Schedule 1 and 130 currently listed substances or groups of substances under Part 2 of Schedule 1.

The transitional provisions of the bill allow that substances recommended for addition to Schedule 1 of the current CEPA are deemed recommended for addition to Part 1 if the virtual elimination process is recommended, while substances

recommended for addition to Schedule 1 of the current CEPA with no virtual elimination are deemed recommended for addition to Part 2 (clauses 60 and 61). If a substance is added to Schedule 1 before Bill C-28 receives Royal Assent, it will be listed in Part 1 if virtual elimination is recommended and in Part 2 if virtual elimination is not recommended (clause 62(1)).

2.2.3 Products Containing a Toxic Substance or That May Release the Substance into the Environment (Clauses 9 to 11, 16, 18, 33, 37 and 46 to 48)

Bill C-28 proposes amendments to allow for further regulation of products that contain a toxic substance listed in Schedule 1 or that may release the toxic substance into the environment. For example, the design of products such as portable fuel containers could be targeted since they can release volatile organic compounds listed in Schedule 1.[18]

Clause 9 expands the Minister of the Environment's information-gathering power set out in section 46(1) to include products that contain or may release into the environment a substance that is toxic or capable of becoming toxic as well as activities that may contribute to pollution. The minister may currently gather information including information on substances that are found in low concentrations in the environment but must be monitored; substances released or disposed of at or into the sea; toxic substances; substances that may contribute to polluting fresh water, salt water, or the air; and pollution prevention.

Clauses 10 and 11 amend sections 56(1) and 60(1) to extend the Minister of the Environment's authority to require pollution prevention plans for products that contain or may release into the environment a substance listed in Schedule 1. Currently, pollution prevention plans may be required for substances listed in Schedule 1 and substances causing international air or water pollution.

Clause 16(1) amends section 68 to allow either minister to collect or generate data and conduct investigations to determine whether and how to control a product that contains or may release a substance into the environment. Section 68 currently allows only for the collection and generation of data and the conduct of an investigation to determine whether a substance is toxic or capable of becoming toxic and whether and how to control the substance.

Clause 18 amends section 71 to allow the Minister of the Environment to publish notices in the *Canada Gazette* to require information or samples concerning products that may release a substance into the environment for the purpose of assessing whether a substance is toxic or capable of becoming toxic and whether or how to control the substance. This includes requiring toxicological or other tests. Section 71 currently allows only for the collection of information about activities involving a

substance or products containing the substance. Clause 18 also adds the option to require information on the method used to quantify any such information or the option to specify the method that must be used to quantify the information.

Clauses 33(1) to 33(6) amend section 93(1) to add to the powers to develop regulations respecting a toxic substance listed in Schedule 1. Expanded or new circumstances for which regulations may be developed include:

- the purpose for which a product that may release a substance into the environment may be imported, manufactured, processed or used, offered for sale or sold;
- the manner in and conditions under which a product that may release a substance into the environment may be imported, manufactured, processed or used;
- the purpose for, manner in and conditions under which a substance or a product that contains or may release a substance into the environment may be exported;
- the quantities or concentrations of a substance that may be exported;
- total, partial or conditional prohibition of the manufacture, use, processing, sale, offering for sale, import or export of a product that may release a substance into the environment;
- total, partial or conditional prohibition of the manufacture of a product intended to contain a substance;
- the quantity or concentration that may be released into the environment by a product;
- advertising, packaging and labelling of products that may release a substance into the environment;
- disposal of a product that may release a substance into the environment; and
- the requirement that information, samples, analyses and other elements be submitted to the Minister of the Environment for products containing a substance or that may release a substance into the environment.

Clauses 46(1) to 46(5) amend section 209(2) in the same regard but for federal and Aboriginal land.

Section 99 currently allows the Minister of the Environment to require manufacturers, processors, importers, retailers or distributors of a substance or product containing the substance to inform customers of any danger to the environment or human health or life posed by the product and to replace the substance or product or accept returns. Clause 37 expands these provisions to apply also to products that may release a substance into the environment.

Clause 47 amends section 218 to enable enforcement officers to enter and inspect a location if they suspect it may contain products that may release a substance into the environment. Enforcement officers may currently enter a location if they suspect it contains products containing a substance. Clause 48 amends section 235 to allow enforcement officers to issue environmental protection compliance orders (EPCOs) to persons suspected of committing an offence involving products that may release a substance into the environment. EPCOs may currently be issued to persons suspected of committing an offence involving products containing a substance.

2.2.4 Virtual Elimination List (Clauses 2, 12, 32 and 63)

Clause 12 repeals sections 65 and 65.1 of CEPA, which set out the Virtual Elimination List and associated definitions. Clause 32 repeals a regulation-making power related to virtual elimination (current section 92.1), while clause 2 removes the reference to virtual elimination from the preamble to CEPA. Under clause 63(a), the ministers may repeal the Virtual Elimination List by regulation.

Only two substances have been placed on the Virtual Elimination List to date under CEPA. Environment and Climate Change Canada has characterized the current provisions for virtual elimination as "unworkable,"[19] and ENVI has described them as "non-functional."[20] Instead of virtual elimination, the highest-risk toxic substances will be listed in Part 1 of Schedule 1, and the ministers shall prioritize total, partial or conditional prohibition of these substances (as set out in clauses 21(1) and 29, discussed above).

2.2.5 Domestic Substances List (Clauses 13, 14, 24, 39, 41, 43 and 49)

Clauses 13 and 14 deal with the Domestic Substances List and the Minister of the Environment's authority to add and delete substances from it. Clause 14 gives the minister authority to delete a substance from the Domestic Substances List if it is not being manufactured in or imported into Canada, in Canadian commerce or being used for commercial manufacturing purposes in Canada and to place it on the Non-domestic Substances List. To do so, the minister must publish a notice in the *Canada Gazette* and invite public comments on the intention to delete the substance from the Domestic Substances List (amended section 66 and new section 66.2). Under the current CEPA, the minister may delete a substance from the Domestic Substances List only if they learn that the substance was not manufactured in or imported into Canada in a quantity of at least 100 kg per year or not used in commerce or for manufacturing purposes in Canada between 1 January 1984 and 31 December 1986.

The Minister of the Environment also gains the authority to add to (and, where appropriate, subsequently delete from) the Domestic Substances List substances to which the *Food and Drugs Act* applied between 1 January 1987 and 13 September 2001. The minister is provided with the authority to designate any person or class of persons to exercise these powers and perform these duties and functions (new section 66.2). Clauses 39 and 43 make similar changes regarding the addition to, or deletion from, the Domestic Substances List of living organisms subject to the *Food and Drugs Act*. (In the absence of this authority, such substances had to be listed separately on what is called the In Commerce List.)

Clauses 24 and 41 create "classes of persons" that do not need to be notified, upon being transferred a substance or living organism, of the requirement to provide information to the Minister of the Environment about new activities in relation to a substance or living organism not on the Domestic Substances List (amended sections 85 and 110).

Clause 49(1) makes it an offence under CEPA to fail to notify a person to whom a substance or living organism on the Domestic Substances List is transferred of their responsibility to provide information to the minister about significant new activities involving the substance or living organism (amended section 272(1)(b)).

2.2.6 Priority Substances List (Clauses 19 and 20)

Clause 19 amends sections 73 and 74 to require the ministers to develop and publish a plan specifying which substances should be given priority for assessing whether they are toxic or capable of becoming toxic. This plan may specify the risk management activities that will be undertaken under CEPA or under other acts administered by the ministers. This plan replaces the existing Priority Substances List under CEPA. Two Priority Substances Lists have been established, both prior to 1999.[21]

While developing and implementing the proposed plan, the ministers:

- may consult the National Advisory Committee; government departments or agencies; Indigenous peoples; representatives of industry, labour and municipal authorities; and other interested persons;
- shall consider whether substances should be assessed by class rather than individually; and
- shall consider the various possible impacts of substances.

The proposed plan for priority substances must be published within two years after the bill becomes law and specify the period after which the plan will be reviewed. Progress made in assessing priority substances must be included in the annual report on the administration and enforcement of CEPA tabled in both houses of Parliament.

Clause 20 requires the Minister of the Environment to compile, publish and amend as needed a list of substances that are suspected or have been determined to be capable of becoming toxic. Any person may request that the ministers assess a substance. The ministers have 90 days after receiving a request to inform the requester of how they will deal with the request and why (amended sections 76 and 76.1).

2.2.7 Other Acts of Parliament (Clauses 21, 40, 56 and 57)

If the assessment of a substance indicates that it should be added to either Part 1 or Part 2 of Schedule 1, clause 21 recognizes that instruments or regulations made under another Act of Parliament may provide sufficient protection of the environment and human health in terms of preventive or control actions in relation to the substance. If the ministers deem this to be the case, then the Minister of the Environment and the minister responsible for the Act in question must publish a statement in the *Canada Gazette* describing how the substance will be regulated (amended section 77(1)(b)). Clause 40 applies the same change to living organisms (amended section 109(4)).

Clause 56 allows that any person may submit to the Minister of the Environment comments regarding the statement that another Act of Parliament will be used to regulate a substance or a notice of objection requesting that a board of review be established (amended section 332). Clause 57 allows the Minister of the Environment or the Minister of Health to establish a board of review in response to a notice of objection to a statement (amended section 333). A board of review inquires into the nature and extent of the danger posed by the substance at issue and submits a report with its recommendations and the evidence that was presented to it to the minister or ministers who established the board.

2.3 DISCLOSURE AND CONFIDENTIALITY (CLAUSES 50, 52 TO 54)

Clause 50 amends the process for requesting confidentiality when information is submitted to the Minister of the Environment under CEPA to indicate that a request for confidentiality must now include the reasons for the request (amended section 313). Clause 54 states, however, that a regulation, order or notice may specify that reasons are not required (new section 319(2)).

Clause 52 adds federal boards or agencies to the list of groups with which the Government of Canada may enter into an agreement to disclose information which would otherwise be kept confidential. The board or agency must be involved in the administration or enforcement of a law and must keep the information confidential (amended section 316(1)(c)). The Government of Canada may currently enter into an agreement with other levels of government in Canada, foreign governments and international organizations. The minister may also enter into agreements with other ministers of the Crown.

Clause 53 adds new sections 317.1 and 317.2 to list circumstances under which the Minister of the Environment may disclose the explicit chemical or biological name of a substance or the explicit biological name of a living organism even if a request for confidentiality has been made. These include circumstances where:

- the minister has taken measures to permit or prohibit the manufacture or importation of the substance or living organism;
- the minister has recommended adding the substance or living organism to Part 1 or Part 2 of Schedule 1; or
- 10 years have passed since the request for confidentiality was made.

The explicit names may be published only after the Minister of the Environment has published notice of their intent to do so in the *Canada Gazette*. The requester may submit comments on whether the public interest in the disclosure outweighs any financial loss, impact on the requester's competitive position or damage to privacy or reputation caused by disclosing the information, or whether disclosure is prohibited under the *Access to Information Act*. If the minister decides to disclose the information, they must inform the requester at least 24 hours before doing so, although more rapid disclosure is authorized in an emergency.

2.4 AMENDMENTS TO THE *FOOD AND DRUGS ACT* (CLAUSES 64 TO 69)

Clauses 64 through 67 amend the FDA to create an environmental risk assessment and risk management regime for drugs. The FDA currently sets out a risk assessment and risk management framework for health risks to ensure the safety, efficacy and quality of drugs. The environmental risks of drug ingredients are currently assessed under CEPA.

The amendments aim to consolidate these two separate streams to establish an assessment regime under the FDA in which environmental risk and health risk assessments may be completed concurrently. The federal government asserts that the amendments "would streamline the regulatory process for industry, while strengthening the environmental risk assessment and risk management of drugs."[22]

Clause 64 adds new section 11.1 to the FDA to prohibit the sale and other activities in respect of a drug unless the Minister of Health has assessed its environmental risks in accordance with the regulations made under section 30(1)(l.1).

New sections 21.301, 21.302 and 21.303 in clause 65 set out information, disclosure and labelling requirements for therapeutic products[23] the Minister of Health believes may pose a serious environmental risk as well as the minister's powers in relation to serious environmental risk. These environmental risk provisions correspond to similar measures related to health risks of therapeutic products.

The Minister of Health may require that a person provide information to determine whether a therapeutic product presents a serious environmental risk (new section 21.301(1)).

The Minister of Health may disclose confidential business information to other government departments or other governments for the purpose of managing an environmental risk or to protect the environment. This disclosure may take place without notice to or the consent of the person to whose affairs the information relates (new sections 21.301(2) and (3)).

The Minister of Health may order that the labelling or packaging of a therapeutic product be modified or replaced if the minister believes that doing so is necessary to prevent a serious environmental risk (new section 21.302).

If a serious environmental risk is identified, the Minister of Health may order that the therapeutic product be recalled or sent to a specified place (new section 21.303).

Clause 66 gives the Minister of Health the power to obtain additional information about a therapeutic product's effects on the environment by ordering and requiring the results of information, tests, studies or monitoring of the product. The exercise of this power is subject to regulations (new section 21.33). This corresponds to the current power of the Minister of Health under section 21.32 to order the same information, testing, studies or monitoring of a therapeutic product's effects on health or safety.

2.4.1 Regulation-Making Authority Under the *Food and Drugs Act*

The regulation-making authority of the Minister of Health is amended in clause 67. It gives the minister the power to make regulations declaring that any drug is adulterated if the minister believes that a prescribed substance in that drug presents a serious environmental risk (new section 30(1)(a.01)). Under section 8 of the FDA, adulterated drugs may not be sold. To manage environmental risks, the minister may make regulations respecting the labelling, packaging, offering, exposing or advertising of food, drugs, cosmetics and devices, their sale or conditions of sale, or the use of any

substance as an ingredient in any food, drug, cosmetic or device (new section 30(1)(b.01)).

Clause 67(5) updates section 30(1)(l.1) to reflect the Minister of Health's regulatory authority to manage the risk to the environment or human life or health of the release into the environment of any food, drug, cosmetic or device. It also adds a provision to make regulations to manage environmental risks related to the sale, import, manufacture and other activities in respect of any food, drug, cosmetic or device (new section 30(1)(l.2)). The minister may now also waive any requirement respecting the assessment under the FDA of the environmental risk presented by a food, drug, cosmetic or device (new section 30(1)(l.3)).

Before the Minister of Health recommends regulation of a substance subject to assessment under section 30(1)(l.1), they must consider the degree of uncertainty respecting the environmental risks of using the substance as an ingredient in a drug, including its release into the environment (new section 30(1.01)).

Clause 69 specifies that the amendments made to sections 64, 67(2), 67(5) and 67(6) of the FDA will come into effect on a date specified by the Governor in Council.

2.5 REPEAL OF THE *REGULATIONS ADDING PERFLUOROOCTANE SULFONATE AND ITS SALTS TO THE VIRTUAL ELIMINATION LIST* AND THE *PERFLUOROOCTANE SULFONATE VIRTUAL ELIMINATION ACT* (CLAUSES 63 AND 68)

Clause 63(b) allows the Minister of the Environment and the Minister of Health to repeal the *Regulations Adding Perfluorooctane Sulfonate and Its Salts to the Virtual Elimination List* by regulation.

Clause 68 repeals the *Perfluorooctane Sulfonate Virtual Elimination Act*.[24] Enacted in 2008, this Act mandated the addition of that substance to the Virtual Elimination List maintained under section 65(2) of CEPA. Perfluorooctane sulfonate and its salts, which were added to Schedule 1 of CEPA in 2006, were added to the Virtual Elimination List in 2009.[25] Therefore, the *Perfluorooctane Sulfonate Virtual Elimination Act* is no longer necessary.

NOTES

1. Bill C-28: An Act to amend the Canadian Environmental Protection Act, 1999, to make related amendments to the Food and Drugs Act and to repeal the Perfluorooctane Sulfonate Virtual Elimination Act, 43rd Parliament, 2nd Session.
2. *Canadian Environmental Protection Act, 1999*, S.C. 1999, c. 33.
3. *Food and Drugs Act*, R.S.C. 1985, c. F-27.

4. Robert Milko, *Legislative Summary of Bill C-74: Canadian Environmental Protection Act (CEPA)*, Publication no. LS-9E, Library of Parliament, 31 May 1988.

5. Kristen Douglas and Monique Hébert, *Legislative Summary of Bill C-32: The Canadian Environmental Protection Act, 1999*, Publication no. LS-285E, Library of Parliament, 5 July 1999.

6. House of Commons, Standing Committee on Environment and Sustainable Development (ENVI), *It's About Our Health! Towards Pollution Prevention: CEPA Revisited*, Fifth report, 13 June 1995; ENVI, *The* Canadian Environmental Protection Act, 1999 *– Five-Year Review: Closing The Gaps*, Fifth report, April 2007; and Senate, Standing Committee on Energy, the Environment and Natural Resources, *The* Canadian Environmental Protection Act *(1999, c. 33): Rx: Strengthen and Apply Diligently*, Sixth report, March 2008.

7. House of Commons, ENVI, *Healthy Environment, Healthy Canadians, Healthy Economy: Strengthening the* Canadian Environmental Protection Act, 1999, Eighth report, June 2017.

8. Environment and Climate Change Canada, *Follow-Up Report to the House of Commons Standing Committee on Environment and Sustainable Development on the* Canadian Environmental Protection Act, 1999, 29 June 2018.

9. Stephanie Taylor, The Canadian Press, "Liberals propose enshrining the right to a healthy environment in legislation," *CBC News*, 13 April 2021.

10. Government of Canada, *Identification of chemicals and polymers as risk assessment priorities*.

11. Government of Canada, *Domestic Substances List*.

12. *Canadian Environmental Protection Act, 1999*, S.C. 1999, c. 33, s. 73(1).

13. Environment Canada, *A Guide to Understanding the* Canadian Environmental Protection Act, 1999, 10 December 2004, p. 7.

14. House of Commons, ENVI, *Healthy Environment, Healthy Canadians, Healthy Economy: Strengthening the* Canadian Environmental Protection Act, 1999, Eighth report, June 2017, p. 46.

15. Government of Canada, *Identification of chemicals and polymers as risk assessment priorities*.

16. *Virtual Elimination List*, SOR/2006-298.

17. House of Commons, ENVI, *Healthy Environment, Healthy Canadians, Healthy Economy: Strengthening the* Canadian Environmental Protection Act, 1999, Eighth report, June 2017, p. 78.

18. Government of Canada, "Products that May Release a Toxic Substance," *Bill C-28, Strengthening Environmental Protection for a Healthier Canada Act – Summary of Amendments*.

19. Government of Canada, "Prohibiting Toxic Substances that pose the Highest Risk," *Bill C-28, Strengthening Environmental Protection for a Healthier Canada Act – Summary of Amendments*.

20. House of Commons, ENVI, *Healthy Environment, Healthy Canadians, Healthy Economy: Strengthening the* Canadian Environmental Protection Act, 1999, Eighth report, June 2017, p. 79.

21. Government of Canada, Canadian Environmental Protection Act*: priority substances list*.

22. Environment and Climate Change Canada, *Government of Canada Delivers on Commitment to Strengthen the* Canadian Environmental Protection Act, 1999 *and Recognizes a Right to a Healthy Environment*.

23. For a definition of the term "therapeutic product," see *Food and Drugs Act*, R.S.C. 1985, c. F-27, s. 2.

24. *Perfluorooctane Sulfonate Virtual Elimination Act*, S.C. 2008, c. 13.

25. *Regulations Adding Perfluorooctane Sulfonate and Its Salts to the Virtual Elimination List*, SOR/2009-15.