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Order 2026-112-03-01 Amending the Domestic Substances List: SOR/2026-52

Canada Gazette, Part II, Volume 160, Number 7

Registration

SOR/2026-52 March 18, 2026

CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

Whereas the Minister of the Environment has been provided with information under section 106 ^a or 107 ^b of the *Canadian Environmental Protection Act, 1999* ^c, and any additional information or test results required under subsection 109(1) of that Act, in respect of each of the living organisms referred to in the annexed Order;

Whereas the Minister of the Environment and the Minister of Health are satisfied that the living organisms have been manufactured in or imported into Canada by the person who provided the information prescribed by the *New Substances Notification Regulations (Organisms)* ^d;

Whereas the period for assessing the information under section 108 of that Act has expired;

And whereas no conditions specified under paragraph 109(1)(a) of that Act in respect of the living organisms are in effect;

Therefore, the Minister of the Environment makes the annexed *Order 2026-112-03-01 Amending the Domestic Substances List* under subsection 112(1) of the *Canadian Environmental Protection Act, 1999* ^c.

Ottawa, March 17, 2026

Julie Dabrusin

Minister of the Environment

Order 2026-112-03-01 Amending the Domestic Substances List

Amendments

1 Part 5 of the *Domestic Substances List* ¹ is amended by adding the following in alphabetical order under the heading “Organisms/Organismes”:

Recombinant replication-incompetent adeno-associated viral vector serotype 9 expressing β -hexosaminidase genes (ssAAV9-CAG-HEXBP2AHEXA) N

Unmodified UM171-expanded human hematopoietic stem cells N

2 Part 7 of the List is amended by adding the following in numerical order:

19815-3 N	Unmodified staphylococcal bacteriophage 1 for treating infections in humans
19816-4 N	Unmodified staphylococcal bacteriophage 2 for treating infections in humans

Coming into Force

3 This Order comes into force on the day on which it is registered.

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the orders.)

Issues

The Minister of the Environment and the Minister of Health (the ministers) assessed information on eight substances (four chemicals and polymers and four living organisms) and determined that they meet the criteria for addition to the *Domestic Substances List*, as set out in the *Canadian Environmental Protection Act, 1999* (the Act). Therefore, under the authority of sections 87 and 112 of the Act, the Minister of the Environment (the Minister) is adding these eight substances to the *Domestic Substances List*.

Background

Assessment of substances new to Canada

Substances that are not on the *Domestic Substances List* are considered new to Canada and are subject to notification and assessment requirements set out in sections 81, 83, 106 and 108 of the Act, as well as in the *New Substances Notification Regulations (Chemicals and Polymers)* and the *New Substances Notification Regulations (Organisms)*. The Act and these regulations ensure that new substances introduced to the Canadian marketplace are assessed to identify potential risks to the environment and human health, and that appropriate control measures are taken, if deemed necessary.

For more information on the thresholds and scope of these regulations, please see section 1 in the *Guidance document for the New Substances Notification Regulations (Chemicals and Polymers)* and section 2 of the

Guidelines for the Notification and Testing of New Substances: Organisms.

Domestic Substances List

The Domestic Substances List provides an inventory of substances in the Canadian marketplace. It was originally published in the *Canada Gazette*, Part II, in 1994 and is amended, on average, 12 times per year to add, update or delete substances.

The *Domestic Substances List* includes eight parts, in which substances are divided based on

- substance type (chemicals and polymers or inanimate products of biotechnology and living organisms);
- confidentiality; and
- whether the significant new activity provisions of the Act have been applied.

Adding substances to the Domestic Substances List

New substances must be added to the *Domestic Substances List* under subsection 87(1), 87(5) or 112(1) of the Act within 120 days after the following criteria have been met:

- the Minister has been provided with the regulatory information regarding the substance. The information to be provided is set out in the *New Substances Notification Regulations (Chemicals and Polymers)* and the *New Substances Notification Regulations (Organisms)*;
- the period prescribed under section 83 or 108 of the Act for the assessment of the information submitted for the substance has expired;

- the substance is not subject to any conditions imposed under paragraph 84(1)(a) or 109(1)(a) of the Act on its import or manufacture; and
- for additions under subsection 87(1), the ministers are satisfied that the substance has already been manufactured in, or imported into Canada in excess of the prescribed quantity by the person who provided the information; for additions under subsection 112(1), the ministers are satisfied that the substance has already been manufactured in, or imported into Canada by the person who provided the information.

Adding eight substances to the Domestic Substances List

The ministers assessed information on eight substances new to Canada (four chemicals and polymers and four living organisms) and determined that they meet the criteria for addition to the *Domestic Substances List*, under subsection 87(1), 87(5) or 112(1) of the Act. These eight substances are therefore being added to the *Domestic Substances List* and, as a result, are no longer subject to the *New Substances Notification Regulations (Chemicals and Polymers)*, nor to the *New Substances Notification Regulations (Organisms)*.

Objective

The objective of *Order 2026-87-03-01 Amending the Domestic Substances List* (Order 2026-87-03-01) is to add four chemicals and polymers to the *Domestic Substances List*.

The objective of *Order 2026-112-03-01 Amending the Domestic Substances List* (Order 2026-112-03-01) is to add four living organisms to the *Domestic Substances List*.

Order 2026-87-03-01 and Order 2026-112-03-01 (the orders) are expected to facilitate access to eight substances for businesses, as the substances are no longer subject to requirements under subsection 81(1) or 106(1) of the Act.

Description

Order 2026-87-03-01 is made under subsections 87(1) and 87(5) of the Act to add four chemicals and polymers to the *Domestic Substances List*:

- two substances identified by their Chemical Abstracts Service (CAS) Registry Numbers ² are added to Part 1 of the *Domestic Substances List*; and
- two substances identified by their masked names ³ and their confidential accession number ⁴ (CANs) are added to Part 3 of the *Domestic Substances List*;

Order 2026-112-03-01 is made pursuant to subsection 112(1) of the Act to add four living organisms to the *Domestic Substances List*:

- two living organisms identified by their specific substance names are added to Part 5 of the *Domestic Substances List*; and
- two living organisms identified by their masked names and their CANs are added to Part 7 of the *Domestic Substances List*.

Regulatory development

Consultation

As the Act does not prescribe any public comment period before adding a substance to the *Domestic Substances List*, no consultation period for the orders was deemed necessary.

Indigenous engagement, consultation and modern treaty obligations

Orders amending the *Domestic Substances List* do not introduce any new regulatory requirements and, therefore, do not result in any impact on modern treaty rights or obligations. As a result, specific engagement and consultations with Indigenous peoples were not undertaken.

Instrument choice

Under the Act, the Minister is required to add a substance to the *Domestic Substances List* when it is determined to meet the criteria for addition. Orders amending the *Domestic Substances List* are the only regulatory instruments that allow the Minister to comply with these obligations.

Regulatory analysis

Benefits and costs

Adding substances to the *Domestic Substances List* is administrative in nature. The orders do not impose any regulatory requirements on businesses and, therefore, do not result in any incremental compliance costs for stakeholders or enforcement costs for the Government of Canada. Adding substances to the *Domestic Substances List* is a statutory obligation under sections 87 and 112 of the Act that is triggered once a substance meets the criteria for addition.

Small business lens

As described in the “Benefits and costs” subsection, the orders will not result in any incremental impacts. As a result, the orders will not impact Canadian small businesses and the small business lens⁵ was not applied.

One-for-one rule

Since the orders do not impose any regulatory requirements (see “Benefits and costs” subsection), they do not impose new administrative burden on businesses and the one-for-one rule does not apply.

Regulatory cooperation and alignment, and international obligations

There are no international agreements or obligations directly associated with the orders.

Effects on the environment

In accordance with the Cabinet Directive on Strategic Environmental and Economic Assessment, a strategic environmental and economic assessment (SEEA) is required for proposals that are expected to have important effects (positive or negative, direct or indirect) on the environment and economy. Since orders amending the *Domestic Substances List* to add substances do not result in incremental impacts (benefits and costs), a SEEA is not required.

Right to a healthy environment

The Government of Canada has a duty, in the administration of the Act, to protect the right to a healthy environment as provided for under the Act, subject to reasonable limits. An implementation framework sets out considerations to protect this right and uphold the principles described in the framework.

Many of the elements included in the framework were considered to inform the orders. In line with the framework, an initial screening and review of the best available science submitted for new substances under the new substances regulations prior to their importation or manufacture into Canada was conducted to determine whether these substances may pose a risk to the environment and human health. Furthermore, the addition of

substances to the *Domestic Substances List* aligns with the framework's non-regression principle, as this is not expected to lead to a decrease in environmental and/or human health protection, since the assessment of the substances concluded they are not suspected of being toxic or capable of becoming toxic.

Gender-based analysis plus

No gender-based analysis plus⁶ (GBA+) impacts have been identified for the orders.

Implementation, compliance and enforcement, and service standards

Implementation

The orders are now in force. Developing an implementation plan is not required when adding substances to the *Domestic Substances List*. The orders do not constitute an endorsement from the Government of Canada of the substances to which they relate, nor an exemption from any other laws or regulations that are in force in Canada and that may apply to these substances or to activities involving them.

Compliance and enforcement

Where a person has questions concerning their obligation to comply with an order, believes that they may be out of compliance, or would like to request a pre-notification consultation, they are encouraged to contact the Substances Management Information Line at substances@ec.gc.ca (email), 1-800-567-1999 (toll-free in Canada), or 819-938-3232 (outside of Canada).

The orders are made under the authority of the Act, which is enforced in accordance with the *Canadian Environmental Protection Act: compliance and enforcement policy*. In instances of non-compliance, consideration is given

to factors such as the nature of the alleged violation, effectiveness in achieving compliance with the Act and its regulations, and consistency in enforcement when deciding which enforcement measures to take. Suspected violations can be reported to the Enforcement Branch of the Department of the Environment by email at enviroinfo@ec.gc.ca.

Contact

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Substances Management Information Line:

1-800-567-1999 (toll-free in Canada)

819-938-3232 (outside of Canada)

Email: substances@ec.gc.ca

Footnotes

^a S.C. 2023, c. 12, s. 39.01

^b S.C. 2017, c. 26, s. 27

^c S.C. 1999, c. 33

^d SOR/2005-248

¹ SOR/94-311

- 2 The Chemical Abstracts Service Registry Number is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.
- 3 Masked names are regulated under the *Masked Name Regulations* and are created to protect confidential business information.
- 4 The confidential accession number (CAN) is a unique confidential substance identity number assigned by the Department of the Environment.
- 5 The assessment of the small business lens has the objective of reducing regulatory costs on small businesses without compromising the health, safety, security and environment of people in Canada.
- 6 Gender-based analysis plus is an analytical process that provides a rigorous method for the assessment of systemic inequalities, as well as a means to assess how diverse groups of women, men and gender diverse people may experience the incremental impact of policies, programs and initiatives.
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