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Order 2026-112-05-01 Amending the Domestic Substances List: SOR/2026-85

Canada Gazette, Part II, Volume 160, Number 11

Registration

SOR/2026-85 May 13, 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 2026-112-05-01 Amending the Domestic Substances List* under subsection 112(1) of the *Canadian Environmental Protection Act, 1999* ^c.

Ottawa, May 11, 2026

Julie Dabrusin

Minister of the Environment

Order 2026-112-05-01 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”:

Adeno-associated virus 2 vector encoding human aquaporin 1 (rAAV2-hAQP1) AAV2hAQP1 N

Carnobacterium divergens M35 N

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

19817-5 N	<i>Saccharomyces</i> species YS223-F7
19821-9 N	Unmodified <i>Pseudomonas</i> bacteriophage 1 for treating infections in humans
19822-0 N	Unmodified <i>Pseudomonas</i> bacteriophage 2 for treating infections in humans
19823-1 N	Unmodified <i>Morganella morganii</i> bacteriophage 1 for treating infections in humans
19824-2 N	Phage QP-STA-003 targeting <i>Staphylococcus aureus</i>

19825-3 N	Phage QP-STA-005 targeting <i>Staphylococcus aureus</i>
19826-4 N	Phage QP-ECO-022 targeting <i>Escherichia coli</i>
19827-5 N	<i>Pseudomonas</i> species bacteriophage QP-PSA-006
19828-6 N	<i>Pseudomonas</i> species bacteriophage QP-PSA-007
19829-7 N	<i>Pseudomonas</i> species bacteriophage QP-PSA-009
19830-8 N	Phage QP-PSA-001 targeting <i>Pseudomonas aeruginosa</i>
19831-9 N	Phage QP-PSA-002 targeting <i>Pseudomonas aeruginosa</i>
19832-0 N	Phage QP-PSA-017 targeting <i>Pseudomonas aeruginosa</i>
19833-1 N	Phage QP-PSA-018 targeting <i>Pseudomonas aeruginosa</i>

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 22 substances (6 chemicals and polymers and 16 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 22 substances to the *Domestic Substances List*.

Also, the Minister is updating the identifier of one polymer on Part 1 under the authority of section 66 of the Act.

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, polymers, inanimate products of biotechnology, or living organisms;
- confidentiality: whether the substance's identity is confidential; and
- whether the significant new activity provisions of the Act apply to the substance.

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 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.

Reduced regulatory requirement polymers

Polymers that meet the reduced regulatory requirement (RRR) criteria set out in the *New Substances Notification Regulations (Chemicals and Polymers)* are considered to pose low concerns. However, the same polymers may be synthesized in forms that do not meet the RRR criteria, and in such cases, their toxicological properties are unknown. RRR polymers are added to the *Domestic Substances List* with a “P” flag. This flag signals that any form of the polymer not meeting the RRR polymer criteria is subject to notification under the regulations prior to import or manufacture.

Adding 22 substances to the Domestic Substances List

The ministers assessed information on 22 substances new to Canada (6 chemicals and polymers and 16 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 22 substances (6 chemicals and polymers and 16 living organisms) 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)*.

Updating the identifier of one polymer on the Domestic Substances List

An administrative correction is made to the identifier of one polymer (Chemical Abstracts Service [CAS] Registry Number ² 351498-70-9) on Part 1 of the *Domestic Substances List* by removing the P flag. The polymer assessed under the Act did not meet the RRR polymer criteria, and as such, the P flag does not apply. Therefore, under subsection 66(1) of the Act, the Minister is updating the identifier of this polymer on the *Domestic Substances List*.

Objective

The objective of *Order 2026-66-05-01 Amending the Domestic Substances List* (Order 2026-66-05-01) is to make a correction to the identifier of one polymer on Part 1 of the *Domestic Substances List*.

The objective of *Order 2026-87-05-01 Amending the Domestic Substances List* (Order 2026-87-05-01) is to add six chemicals and polymers to the *Domestic Substances List*.

The objective of *Order 2026-112-05-01 Amending the Domestic Substances List* (Order 2026-112-05-01) is to add 16 living organisms to the *Domestic Substances List*.

Order 2026-87-05-01 and Order 2026-112-05-01 are expected to facilitate or continue to facilitate access to 22 substances for businesses, as the substances are no longer subject to requirements under subsection 81(1) or 106(1) of the Act.

Description

Order 2026-66-05-01 is made under subsection 66(1) of the Act to update one substance on the *Domestic Substances List*:

- The identifier of one polymer (CAS Registry Number 351498-70-9) on Part 1 of the *Domestic Substances List* is corrected by deleting the P flag.

Order 2026-87-05-01 is made under subsections 87(1) and 87(5) of the Act to add six chemicals and polymers to the *Domestic Substances List*:

- Three substances identified by their CAS Registry Number are added to Part 1 of the *Domestic Substances List*; and
- Three substances identified by their masked name³ and their confidential accession number⁴ (CAN) are added to Part 3 of the *Domestic Substances List*.

Order 2026-112-05-01 is made pursuant to subsection 112(1) of the Act to add 16 living organisms to the *Domestic Substances List*:

- Two living organisms identified by their specific substance name are added to Part 5 of the *Domestic Substances List*; and
- Fourteen living organisms identified by their masked name and their CAN 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 Order 2026-87-05-01 and Order 2026-112-05-01 was deemed necessary.

Updating the identifier for one polymer is administrative in nature, and no consultation period 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. Therefore, 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 and updating substance identifiers on the *Domestic Substances List* are 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. Therefore, they 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 the “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* (SEEA), a 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 or update substance identifiers 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 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.

Other relevant factors that were considered include the statutory framework and regulatory timelines for assessing new substances.

Gender-based analysis plus

No gender-based analysis plus ⁶ (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 prenotification consultation, they are encouraged to contact the Substances Management Information Line by email at substances@ec.gc.ca or by phone at 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 (GBA+) 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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