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Order 2025-112-11-01 Amending the Domestic Substances List: SOR/2025-254

Canada Gazette, Part II, Volume 159, Number 27

Registration

SOR/2025-254 December 9, 2025

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 2025-112-11-01 Amending the Domestic Substances List* under subsection 112(1) of the *Canadian Environmental Protection Act, 1999* ^c.

Ottawa, December 4, 2025

Julie Dabrusin

Minister of the Environment

Order 2025-112-11-01 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 and non-replicative adeno-associated virus serotype 4D-R100 carrying a miRNA targeting VEGF-C and expressing the aflibercept protein (4D-150) N

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

19802-0 N	Saccharomyces cerevisiae strain containing genes 1 to 5 (originating, respectively, from foreign organisms A to E), over-expressing native genes 1 and 2 and adapted for elevated temperature tolerance
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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 seven substances (five chemicals and polymers and two 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 seven substances to the *Domestic Substances List*. Also, under the authority of section 66 of the Act, the Minister is updating the identifiers of 227 polymers on the *Domestic Substances List* with the addition of the letter "P." These substances were added to the *Domestic Substances List* while meeting the reduced regulatory requirements (RRR) polymer criteria.²

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* (SOR/94-311) provides an inventory of substances in the Canadian marketplace. It was originally published in the *Canada Gazette*, Part II, in 1994 and its current structure was established in 2001 (*Order 2001-87-04-01 Amending the Domestic Substances List* (PDF, 2.11MB) [SOR/2001-214]). The *Domestic Substances List* 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 seven substances to the Domestic Substances List and updating 227 substances on the Domestic Substances List

The ministers assessed information on seven substances new to Canada (five chemicals and polymers and two living organisms) and determined that they meet the criteria for addition to the *Domestic Substances List*, under subsection 87(5) or 112(1) of the Act. These seven 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)*.

The Government identified substances assessed as RRR polymers and added to the *Domestic Substances List* prior to the introduction of the RRR criteria and the letter “P” in 2003. Therefore, a *Notice of intent to amend the Domestic Substances List, adding the letter “P” to the identifiers of 254 reduced regulatory requirement polymers* was published on January 18, 2025. The letter “P” after a substance identifier indicates that the substance is a polymer that meets the RRR polymer criteria set out in the *New Substances Notification Regulations (Chemicals and Polymers)*. Any form of the polymer

that does not meet the RRR polymer criteria is subject to notification under the regulations prior to import or manufacture. After taking into consideration responses to the notice of intent, the Minister adds the letter “P” to the identifiers of 227 polymers under subsection 66(1) of the Act.

Objective

The objective of *Order 2025-66-11-01 Amending the Domestic Substances List* (Order 2025-66-11-01) is to add the letter “P” to the identifiers of 227 polymers on the *Domestic Substances List*.

Order 2025-66-11-01 specifies that 227 polymers on the *Domestic Substance List* are RRR polymers. Any form of these polymers that does not meet the RRR polymer criteria is subject to notification under the regulations prior to import or manufacture.

The objective of *Order 2025-87-11-01 Amending the Domestic Substances List* (Order 2025-87-11-01) is to add five chemicals and polymers to the *Domestic Substances List*.

The objective of *Order 2025-112-11-01 Amending the Domestic Substances List* (Order 2025-112-11-01) is to add two living organisms to the *Domestic Substances List*

Order 2025-66-11-01, Order 2025-87-11-01 and Order 2025-112-11-01 (the orders) are expected to facilitate access to seven substances for businesses, as the substances are no longer subject to requirements under subsection 81(1) or 106(1) of the Act.

Description

Order 2025-66-11-01 is made under subsection 66(1) of the Act to update the identifiers of 227 polymers on the *Domestic Substances List*:

- the letter “P” is added following the Chemical Abstracts Service (CAS) Registry Numbers³ of 117 polymers on Part 1 of the *Domestic Substances List*; and
- the letter “P” is added following the Confidential Accession Numbers (CANs) of 110 polymers on Part 3 of the *Domestic Substances List*.

Order 2025-87-11-01 is made under subsection 87(5) of the Act to add five chemicals and polymers to the *Domestic Substances List*:

- one substance identified by its CAS Registry Number is added to Part 1 of the *Domestic Substances List*; and
- four substances identified by their masked names⁴ and their CANs are added to Part 3 of the *Domestic Substances List*.

Order 2025-112-11-01 is made pursuant to subsection 112(1) of the Act to add two living organisms to the *Domestic Substances List*:

- one living organism identified by its specific substance name is added to Part 5 of the *Domestic Substances List*; and
- one living organism identified by its masked name and its CAN is 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 2025-87-11-01 and Order 2025-112-11-01 was deemed necessary.

In January 2025, a *Notice of intent to amend the Domestic Substances List, adding the letter “P” to the identifiers of 254 reduced regulatory requirement polymers* was published in Part I of the *Canada Gazette* followed by a 120-

day comment period. After taking into consideration responses to the notice of intent, it was determined that 27 of these polymers are potentially commercialized in Canada in a form that may not meet the RRR polymer criteria, and as such, the letter “P” is added to 227 polymers in Order 2025-66-11-01.

Modern treaty obligations and Indigenous engagement and consultation

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 their identifiers on 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 federal obligation under section 87 or 112 of the Act that is triggered once a substance meets the criteria for addition.

Small business lens

Since the orders do not impose any regulatory requirements (see “Benefits and costs” section), they do not have impacts on 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” section), they do not impose new administrative burden on business 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 preliminary scan of additions to the *Domestic Substances List* concluded that a strategic environmental and economic assessment is not required for the orders.

Right to a healthy environment

In the administration of the Act, the Government of Canada has a duty, to protect the right to a healthy environment as provided for under the Act, subject to reasonable limits. An implementation framework published in accordance with subsection 5.1(1) of the Act sets out considerations to protect this right and uphold the principles described in the framework.

Work to inform the orders began before the implementation framework was published on July 19, 2025. Recognizing that decisions made under the Act are informed by analyses and consultations that are often the result of years of work, a transition period is in place to allow the Department of the

Environment and the Department of Health to support continued protection of the environment and human health. The objective of the transition period is to continue to advance timely decisions under the Act and actions while consideration of the right to a healthy environment and relevant principles are being fully integrated into the administration of the Act. The orders are proceeding under the transition period referenced in the framework.

Although the implementation framework was not available to be applied from the beginning of the work undertaken to inform the orders, many of the elements included in the framework were considered. The addition of new substances to the *Domestic Substances List* aligns with the framework by conducting an initial screening and review of the information submitted for new substances under the Act, prior to their use in Canada, to determine whether the new substances may pose a risk to the environment and human health and warrant further assessment under the Act.

Gender-based analysis plus

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

Implementation, compliance and enforcement

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 Reduced regulatory requirement (RRR) polymers are considered of low human health and environmental concern, allowing for a reduced set of information to be submitted to the government compared to other new polymers (see section 3.3.1.5 of the Guidance document for the New Substances Notification Regulations (Chemicals and Polymers). RRR polymers are identified by a “P” flag on Canada’s *Domestic Substances List*.

3 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.

4 Masked names are regulated under the Masked Name Regulations and are created to protect confidential business information.

- 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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