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# Order 2025-112-03-01 Amending the Domestic Substances List: SOR/2025-58

Canada Gazette, Part II, Volume 159, Number 6

Registration

SOR/2025-58 February 28, 2025

CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

Whereas the Minister of the Environment has been provided with information under paragraph 112(1)(a) of the *Canadian Environmental Protection Act, 1999* <sup>a</sup> in respect of the living organism referred to in the annexed Order;

Whereas the Minister of the Environment and the Minister of Health are satisfied that the living organism has been manufactured in or imported into Canada by the person who provided the information prescribed under the *New Substances Notification Regulations (Organisms)* <sup>b</sup>;

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 organism are in effect;

Therefore, the Minister of the Environment makes the annexed *Order 2025-112-03-01 Amending the Domestic Substances List* under subsection 112(1) of the *Canadian Environmental Protection Act, 1999* <sup>a</sup>.

Ottawa, February 25, 2025

Steven Guilbeault

Minister of the Environment

# Order 2025-112-03-01 Amending the Domestic Substances List

## Amendment

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

Recombinant and non-replicating adeno-associated virus serotype 5 (AAV5) vector containing the codon-optimized coding DNA sequence for the human coagulation factor IX variant R338L (FIX-Padua) N

## Coming into Force

**2 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 19 substances (17 chemicals and polymers, the version of one polymer not meeting the Reduced Regulatory Requirements criteria and one living organism) 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 19 substances to the *Domestic Substances List*.

Also, after communicating with the persons responsible for the requests for confidentiality and obtaining their written consent, the Minister is disclosing the explicit chemical identity of 12 substances by moving them from Part 3 to Part 1 of the *Domestic Substances List* under the authority of section 66 of CEPA. The Minister is also updating the masked names of 21 substances on Part 3 under the authority of section 66 of CEPA, as well as updating the identifier of one polymer on Part 3.

## 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* [SOR/2001-214]). The *Domestic Substances List* is amended, on average, 14 times per year to add, update or delete substances.

The *Domestic Substances List* includes eight parts:

### **Part 1**

Sets out chemicals and polymers, except those referred to in Part 2, 3 or 4, that are identified by their Chemical Abstracts Service (CAS) Registry Numbers<sup>2</sup> or their Substance Identity Numbers assigned by the Department of the Environment and the names of the substances.

### **Part 2**

Sets out chemicals and polymers subject to Significant New Activity (SNAc) requirements that are identified by their CAS Registry Numbers.

### **Part 3**

Sets out chemicals and polymers, except those referred to in Part 4, that are identified by their masked names<sup>3</sup> and their Confidential Substance Identity Numbers (also referred to as Confidential Accession Numbers [CANs]) assigned by the Department of the Environment.

### **Part 4**

Sets out chemicals and polymers subject to SNAc requirements that are identified by their masked names and their CANs.

## **Part 5**

Sets out inanimate biotechnology products and living organisms, except those referred to in Part 6, 7 or 8, that are identified by their American Type Culture Collection (ATCC) numbers, International Union of Biochemistry and Molecular Biology (IUBMB) numbers or specific substance names.

## **Part 6**

Sets out inanimate biotechnology products and living organisms subject to SNAc requirements that are identified by their ATCC numbers, IUBMB numbers or specific substance names.

## **Part 7**

Sets out inanimate biotechnology products and living organisms, except those referred to in Part 8, that are identified by their masked names and their CANs.

## **Part 8**

Sets out inanimate biotechnology products and living organisms subject to SNAc requirements that are identified by their masked names and their CANs.

## ***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.

### ***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 concern. 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 19 substances on the Domestic Substances List***

The ministers assessed information on 18 substances new to Canada (17 chemicals and polymers and one living organism) and determined that they meet the criteria for addition to the *Domestic Substances List*, under subsection 87(5) or 112(1) of the Act. The ministers also assessed information on the non-RRR version of one polymer (CAS Registry Number 1232651-32-9) already on Part 1 of the *Domestic Substances List* with a P flag and determined that the non-RRR version of the polymer meets the criteria

for addition under subsection 87(5) of the Act. These 19 substances (17 chemicals and polymers, the non-RRR version of CAS Registry Number 1232651-32-9 and one living organism) 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).

### ***Disclosing the identity of 12 substances and updating the masked name of 21 substances***

The Minister contacted persons responsible for confidentiality requests concerning substance identity that were made prior to the year 2004. In response, written consent to disclose the information was provided for 12 substances. Therefore, the Minister is updating the identifier of these 12 substances on the *Domestic Substances List* under subsection 66(1) of the Act. These substances are now identified by their CAS Registry Numbers on the *Domestic Substances List*.

Responses also included confirmation of the initial request for confidentiality concerning the identity of 21 substances. The masked name for these substances are updated on the *Domestic Substances List* to improve compliance with the requirements set out in the *Masked Name Regulations*. The Minister is updating the masked name of these 21 substances on the *Domestic Substances List* under subsection 66(1) of the Act.

### ***Updating the identifier of one polymer on the Domestic Substances List***

An administrative correction is made to the identifier of one polymer (CAN 13809-3) on Part 3 of the *Domestic Substances List* by removing the P flag. The polymer assessed under subsection 81(1) of the Act did not meet the

RRR polymer criteria, and as such, the P flag should not have been added. Therefore, under subsection 66(1), the Minister is updating the identifier of this polymer on the *Domestic Substances List*.

## Objective

The objective of *Order 2025-66-03-01 Amending the Domestic Substances List* is to move 12 substances from Part 3 of the *Domestic Substances List* to Part 1, update the masked names of 21 substances listed on Part 3 of the *Domestic Substances List*, and make a correction to the identifier of one polymer on Part 3 of the *Domestic Substances List*.

Order 2025-66-03-01 will increase transparency for 12 substances, increase compliance with the *Masked Name Regulations* for 21 substances, and correct the identifier of one polymer.

The objective of *Order 2025-87-03-01 Amending the Domestic Substances List* is to add 17 substances and the non-RRR version of one polymer to the *Domestic Substances List*.

The objective of *Order 2025-112-03-01 Amending the Domestic Substances List* is to add one living organism to the *Domestic Substances List*.

Order 2025-66-03-01, Order 2025-87-03-01 and Order 2025-112-03-01 are expected to facilitate or continue to facilitate access to 32 substances for businesses, as the substances are no longer masked or no longer subject to requirements under subsection 81(1) or 106(1) of the Act.

## Description

Order 2025-66-03-01 is made under subsection 66(1) of the Act to update 34 substances on the *Domestic Substances List*:



- 12 substances identified by their CAS Registry Numbers are added to Part 1 of the *Domestic Substances List*; and the corresponding masked names and CANs are deleted from Part 3 of the *Domestic Substances List*;
- the masked names of 21 substances on Part 3 of the *Domestic Substances List* are updated; and
- the CAN of one polymer on Part 3 of the *Domestic Substances List* is corrected the by deleting the P flag.
- Order 2025-87-03-01 is made under subsection 87(5) of the Act to add 17 chemicals and polymers to the *Domestic Substances List* as well as the non-RRR version of one polymer:
- four substances identified by their CAS Registry Numbers are added to Part 1 of the *Domestic Substances List*;
- the CAS Registry Number of one polymer is added on Part 1 of the *Domestic Substances List* without the P flag; and
- 13 substances identified by their masked names and their CANs are added to Part 3 of the *Domestic Substances List*.

Order 2025-112-03-01 is made pursuant to subsection 112(1) of the Act to add one living organism to the *Domestic Substances List*:

- one living organism identified by its specific name is added to Part 5 of the *Domestic Substances List*.

## Regulatory development

### Consultation

As CEPA does not prescribe any public comment period before adding a substance to the *Domestic Substances List*, no consultation period for Order 2025-87-03-01 and Order 2025-112-03-01 was deemed necessary.

Disclosing the identity of substances and updates to masked names in Order 2025-66-03-01 are made after obtaining written consent from the persons responsible for the request for confidentiality, and therefore no consultation period was deemed necessary.

Updating the identifier for one polymer is administrative in nature and was therefore not subject to consultation.

### ***Modern treaty obligations and Indigenous engagement and consultation***

The assessment of modern treaty implications made in accordance with the *Cabinet Directive on the Federal Approach to Modern Treaty Implementation* concluded that 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.

### ***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***

The assessment of the small business lens concluded that the orders have no impact on small businesses, as they do not impose any administrative or compliance costs on businesses.

### ***One-for-one rule***

The assessment of the one-for-one rule concluded that the rule does not apply to the orders, as there is no impact on industry.

### ***Regulatory cooperation and alignment***

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 assessment is not required for the orders.

### ***Gender-based analysis plus***

No gender-based analysis plus (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](mailto: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](mailto:enviroinfo@ec.gc.ca).

## Contact

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Fax: 819-938-5212

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## Footnotes

a S.C. 1999, c. 33

b 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.
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