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Order 2025-112-06-01 Amending the Domestic Substances List: SOR/2025-171

Canada Gazette, Part II, Volume 159, Number 19

Registration

SOR/2025-171 August 29, 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* ^a in respect of each living organism referred to in the annexed Order;

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

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 those living organisms are in effect;

Therefore, the Minister of the Environment makes the annexed *Order 2025-112-06-01 Amending the Domestic Substances List* under subsection 112(1) of the *Canadian Environmental Protection Act, 1999* ^a.

Ottawa, August 27, 2025

Julie Dabrusin

Minister of the Environment

Order 2025-112-06-01 Amending the Domestic Substances List

Amendment

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 SLB101 expressing a genetically modified human microdystrophin gene (SGT-003) N

Recombinant human T-cells expressing an anti-CD19/anti-CD20 chimeric antigen receptor transgene (JNJ-90014496) 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 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*.

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.

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 Numbers² 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 names³ 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

A substance 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

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)*.

Objectives

The objective of *Order 2025-87-06-01 Amending the Domestic Substances List* is to add five chemicals and polymers to the *Domestic Substances List*.

The objective of *Order 2025-112-06-01 Amending the Domestic Substances List* is to add two living organisms to the *Domestic Substances List*.

Order 2025-87-06-01 and Order 2025-112-06-01 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 2025-87-06-01 is made under subsection 87(5) of the Act to add five chemicals and polymers to the *Domestic Substances List*:

- three substances identified by their CAS Registry Numbers are added to Part 1 of the *Domestic Substances List*; and
- two substances identified by their masked names and their CANs are added to Part 3 of the *Domestic Substances List*.

Order 2025-112-06-01 is made pursuant to subsection 112(1) of the Act to add two living organisms to the *Domestic Substances List*:

- two living organisms identified by their specific name are added to Part 5 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 2025-87-06-01 and Order 2025-112-06-01 was deemed necessary.

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 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 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.

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.

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 (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)

Fax: 819-938-5212

Email: substances@ec.gc.ca

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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