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Order 2025-87-05-01 Amending the Domestic Substances List: SOR/2025-169

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CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

Whereas the Minister of the Environment has been provided with information under paragraph 87(5)(a) of the *Canadian Environmental Protection Act, 1999* ^a in respect of the substance referred to in the annexed Order;

Whereas the period for assessing the information under section 83 of that Act has expired;

And whereas no conditions specified under paragraph 84(1)(a) of that Act in respect of the substance are in effect;

Therefore, the Minister of the Environment makes the annexed *Order 2025-87-05-01 Amending the Domestic Substances List* under subsections 87(3) ^b and (5) of the *Canadian Environmental Protection Act, 1999* ^a.

Ottawa, August 27, 2025

Julie Dabrusin

Minister of the Environment

Order 2025-87-05-01 Amending the Domestic Substances List

Amendment

1 Part 2 of the *Domestic Substances List* ¹ is amended by adding the following in numerical order:

Column 1	Column 2
Substance	Significant New Activity for which substance is subject to subsection 81(3) of the Act

12022-41-2
N-S

- 1 Any activity involving the substance iron potassium oxide, other than as a catalyst, in a quantity that, in a calendar year,
 - (a) exceeds 100 kg but is equal to or less than 1 000 kg;
 - (b) exceeds 1 000 kg but is equal to or less than 10 000 kg; or
 - (c) exceeds 10 000 kg.
- 2 Despite section 1, an activity is a significant new activity only if the primary particle size distribution of the substance possesses at least one of the following characteristics:
 - (a) at least 10% of the substance's particles, by number, have a dimension within the range of 1 to 100 nm;
 - (b) at least 1% of the substance's particles, by mass, have a dimension within the range of 1 to 100 nm.
- 3 Despite section 1, an activity is not a significant new activity if
 - (a) the substance is a *research and development substance* or a *site-limited intermediate substance*, as those terms are defined in subsection 1(1) of the *New Substances Notification Regulations (Chemicals and Polymers)*; or
 - (b) the substance, or the product that contains the substance, is intended only for export.
- 4 For each proposed significant new activity in relation to the substance, the following information must be provided to the Minister at least 90 days before the day on which the significant new activity begins:
 - (a) a description of the significant new activity;
 - (b) the quantity of the substance that is anticipated to be used in a calendar year;
 - (c) the particle size and particle size distribution of the substance — determined in accordance with a methodology that is consistent with the conditions and procedures described in the Organisation for Economic Co-operation and Development (OECD) Guidelines for the Testing of Chemicals, *Test No. 125: Nanomaterial Particle Size and Size Distribution of*

Nanomaterials — and the analytical data that is necessary to determine those characteristics;

(d) the agglomeration state, aggregation state, shape, surface area, surface chemistry and surface charge of the substance and the analytical data that is necessary to determine those properties;

(e) all other information and test data in respect of the substance that are in the possession of the person who is proposing the significant new activity, or to which they may reasonably be expected to have access, and that permit the identification of the adverse effects that the substance may have on the environment and human health and the degree of environmental and public exposure to the substance;

(f) the name of every government department or agency, either outside or within Canada, to which the person who is proposing the significant new activity has provided information regarding the use of the substance — as well as the department's or agency's file number, if known — and, if any, the outcome of the department's or agency's assessment and the risk management actions that the department or agency has imposed in relation to the substance;

(g) the name, civic and postal addresses, telephone number and, if any, fax number and email address of the person who is proposing the significant new activity and, if they are not resident in Canada, of a person resident in Canada who is authorized to act on their behalf;

(h) a certification that the information is accurate and complete, dated and signed by the person who is proposing the significant new activity or, if they are not resident in Canada, by a person resident in Canada who is authorized to act on their behalf;

(i) in the case of a significant new activity described in paragraph 1(a), the information referred to in items 3 to 7 of Schedule 4 to the *New Substances Notification Regulations (Chemicals and Polymers)*;

(j) in the case of a significant new activity described in paragraph 1(b),

(i) the information referred to in paragraph (i) or, if that information has been previously provided, the date of the submission of that information and, if they are known, the new substances pre-notification consultation number, if it has been assigned, and the significant new activity notification number,

(ii) the information referred to in items 2 to 6 and 8 of Schedule 5 to the *New Substances Notification Regulations (Chemicals and Polymers)*, and

(iii) the mutagenicity data and a report from an *in vitro* mammalian cell genotoxicity study in respect of the substance, with and without metabolic activation, for gene mutations; and

(k) in the case of a significant new activity described in paragraph 1(c),

(i) the information referred to in paragraph (j) or, if that information has been previously provided, the date of the submission of that information and, if they are known, the new substances pre-notification consultation number, if it has been assigned, and the significant new activity notification number, and

(ii) the information referred to in items 2 to 11 of Schedule 6 to the *New Substances Notification Regulations (Chemicals and Polymers)*.

5 The following information must be determined based on the data and a report from a study in respect of the substance, conducted in accordance with a methodology that is described in the OECD Series on the Safety of Manufactured Nanomaterials and other Advanced Materials, Publication No. 36, *Guidance on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials*, that is current at the time the study is conducted:

(a) the information referred to in paragraphs 4(c) and (d);

(b) the information referred to in subparagraph 4(j)(ii) in respect of items 4 to 6 of Schedule 5 to the *New Substances Notification Regulations (Chemicals and Polymers)*;

(c) the information referred to in subparagraph 4(j)(iii); and

(d) the information referred to in subparagraph 4(k)(ii) in respect of items 3 to 7, 9 and 10 of Schedule 6 to the *New Substances Notification Regulations (Chemicals and Polymers)*.

6 The following information must be determined based on the data and a report from a study in respect of the substance, conducted in accordance with a methodology that is described in the OECD Series on Testing and Assessment, Publication No. 317, *Guidance Document on Aquatic and Sediment Toxicological Testing of Nanomaterials*, that is current at the time the study is conducted:

(a) the information referred to in subparagraph 4(j)(ii) in respect of items 4 and 5 of Schedule 5 to the *New Substances Notification Regulations (Chemicals and Polymers)*; and

(b) the information referred to in subparagraph 4(k)(ii) in respect of item 3 of Schedule 6 to the *New Substances Notification Regulations (Chemicals and Polymers)*.

7 The following information must be determined based on the data and a report from a study in respect of the substance, conducted in accordance with the Principles of Good Laboratory Practice set out in Annex II of the *Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals*, adopted by the OECD on May 12, 1981, that are current at the time the study is conducted:

(a) the information referred to in subparagraph 4(j)(ii) in respect of items 4 to 6 of Schedule 5 to the *New Substances Notification Regulations (Chemicals and Polymers)*;

(b) the information referred to in subparagraph 4(j)(iii); and

(c) the information referred to in subparagraph 4(k)(ii) in respect of items 3 to 7, 9 and 10 of Schedule 6 to the *New Substances Notification Regulations (Chemicals and Polymers)*.

8 The information provided under section 4 is to be assessed within 90 days after the day on which it is received by the Minister.

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 Order.)

Issues

The Minister of the Environment and the Minister of Health (the ministers) assessed information on one chemical, iron potassium oxide (Chemical Abstracts Service (CAS) Registry Number ² 12022-41-2), and determined that it meets 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 section 87 of the Act, the Minister of the Environment (the Minister) is adding this substance to the *Domestic Substances List*.

The ministers identified potential human health or environmental concerns if this substance was to be used in certain new activities. In order to continue addressing these potential human health or environmental concerns, the Minister is maintaining the existing requirements under the significant new activity (SNAC) provisions of the Act applied to this substance.

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, 14 times per year to add, update or delete substances.

The *Domestic Substances List* includes eight parts defined as follows:

Part 1

Sets out chemicals and polymers, except those referred to in Part 2, 3 or 4 that are identified by their CAS Registry Numbers, 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 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 and their 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 new 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 pursuant to 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.

Criteria for adding, varying or rescinding SNAc requirements for substances on the Domestic Substances List

The Minister may amend the *Domestic Substances List* to add, vary or rescind reporting obligations imposed under the SNAc provisions of the Act. If the ministers assess a substance and available information suggests that certain new activities related to that substance may pose a risk to human health or the environment, the Minister may add that substance to the

Domestic Substances List with reporting obligations under the SNAc provisions of the Act (subsection 87(3) or 112(3)). The SNAc provisions of the Act establish a requirement for any person considering undertaking a significant new activity in relation to the substance to submit a Significant New Activity Notification (SNAN) to the Minister containing certain required information. Upon receipt of the complete information, the ministers would conduct further assessment of the substance, and, if necessary, implement risk management measures before the activity is undertaken. To see the substances subject to SNAc provisions of the Act, please visit the [Canada.ca Open Data Portal](https://open.canada.ca/data/en/open/dataset/12022-41-2).

Adding one substance to the Domestic Substances List

The Minister assessed information on one substance new to Canada (CAS Registry Number 12022-41-2) and determined that it meets the criteria for addition to the *Domestic Substances List*, under subsection 87(5) of the Act. This substance is therefore being added to the *Domestic Substances List* and, as a result, is no longer subject to the [*New Substances Notification Regulations \(Chemicals and Polymers\)*](#).

The assessment of the substance identified potential toxicity concerns associated with exposure where the substance is a nanomaterial. Therefore, the SNAc provisions of the Act were applied to this substance prior to its addition to the *Domestic Substances List*, pursuant to the [*Significant New Activity Notice No. 21849*](#), published in November 2024.

To continue addressing the potential human health or environmental concerns, the SNAc requirements on the substance are being maintained, and thus, are being added with the substance to the *Domestic Substances List*.

Objective

The objective of *Order 2025-87-05-01 Amending the Domestic Substances List* (the Order) is to add one chemical (CAS Registry Number 12022-41-2) to the *Domestic Substances List* and to continue contributing to the protection of human health and of the environment by maintaining the SNAC requirements applied to this substance. The requirement to notify any significant new activity, as defined in the Order, is maintained so that further assessment of the substance is conducted and, if necessary, risk management measures are implemented before the activity is undertaken.

The Order is expected to facilitate access to the substance identified by the CAS Registry Number 12022-41-2 for businesses, as this substance is no longer subject to requirements under subsection 81(1) of the Act.

Description

The Order is made under subsections 87(3) and 87(5) of the Act to add one chemical identified by its CAS Registry Number along with SNAC requirements to Part 2 of the *Domestic Substances List*.

SNAC applicability and reporting requirements

The SNAC provisions of the Act apply to the substance identified by the CAS Registry Number 12022-41-2. It is therefore mandatory to meet the requirements of subsection 81(3) of the Act before manufacturing, importing or using this substance for a significant new activity as defined in the Order.

Under the Order, any person wishing to engage in a significant new activity in relation to the substance identified by the CAS Registry Number 12022-41-2 is required to submit a SNAN to the Minister. The SNAN must contain all the information prescribed in the Order and must be submitted at least

90 days prior to the manufacture, import or use of the substance for the proposed significant new activity. For guidance on preparing a SNAN, please see section 1.3 and section 4 of the Guidance document for the *New Substances Notification Regulations (Chemicals and Polymers)*. If the substance falls under the definition of a nanomaterial, the notifier can refer to Appendix 10 of this document for further guidance specific to nanomaterials.

When determining the applicability of the SNAN requirements, it is recommended to use methods specified in the Organisation for Economic Co-operation and Development (OECD) Guidelines for the Testing of Chemicals, Test No. 125 or, in either OECD Series on the Safety of Manufactured Nanomaterials, No. 36 or No. 41 to verify whether the primary particle size distribution of the substance meets any of the criteria under section 1 of the Order. The ministers will use the information submitted to conduct a further assessment of the substance, and, if necessary, implement risk management measures before the activity is undertaken.

Activities not subject to notification requirements

The notification requirements do not apply to uses of the substance identified by the CAS Registry Number 12022-41-2 that are regulated under any act of Parliament listed in Schedule 2 of the Act, including the *Pest Control Products Act*, the *Fertilizers Act* and the *Feeds Act*. Also, the notification requirements do not apply to any transient reaction intermediate, impurity, contaminant, partially unreacted material, or incidental reaction product, and under certain circumstances, to mixtures, manufactured items, wastes or substances carried through Canada. For more information on these terms, including definitions, please see section 3.2 of the Guidance document for the *New Substances Notification*

Regulations (Chemicals and Polymers). Please note that individual components of a mixture may be subject to the notification requirements under certain circumstances.

Activities involving the use of the substance identified by the CAS Registry Number 12022-41-2 as a research and development substance, site-limited intermediate substances or in the manufacture of an export-only product are also excluded from notification requirements. For more information on these terms, including definitions, please see section 3.4 of the Guidance document for the New Substances Notification Regulations (Chemicals and Polymers).

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 Order 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; therefore, they 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 instrument that allows the Minister to comply with these obligations.

Applying the SNAC provisions of the Act to substances is considered when there is suspicion that new activities may pose a risk to human health or the environment. For more information, please consult the Policy on the Use of Significant New Activity Provisions of the *Canadian Environmental Protection Act, 1999*.

Regulatory analysis

Benefits and costs

Adding one substance to the *Domestic Substances List* is administrative in nature. The Order does not impose any regulatory requirements on businesses; therefore, it does 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 of the Act that is triggered once a substance meets the criteria for addition.

Maintaining the SNAC requirements for the substance identified by the CAS Registry Number 12022-41-2 continues contributing to the protection of human health and the environment by requiring that potential significant new activities involving the substance undergo further assessment, and that, if necessary, risk management measures are implemented before the activity is undertaken. The Order does not impose any regulatory requirements (and therefore, any administrative or compliance costs) on businesses related to current activities. The Order would continue to only target significant new activities involving the substance identified by the CAS Registry Number 12022-41-2, should any person choose to pursue such an activity. In the event that any person wishes to use, import, or

manufacture the substance for a significant new activity, they would be required to submit a SNAN to the Minister containing the complete information referred to in the Order.

While there is no notification fee associated with submitting a SNAN to the Minister in response to the Order, the notifier may incur costs associated with generating data and supplying the required information. Similarly, in the event that a SNAN is received, the Department of the Environment and the Department of Health would incur costs for processing the information and conducting further assessment of the substance to which the SNAN relates. The Department of the Environment will incur negligible costs for conducting compliance promotion and enforcement activities associated with the Order.

Small business lens

The assessment of the small business lens concluded that the Order has no impact on small businesses, as it does not impose any administrative or compliance costs on businesses related to current activities.

One-for-one rule

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

Regulatory cooperation and alignment

There are no agreements or obligations directly associated with the Order.

International obligations

There are no agreements or obligations directly associated with the Order.

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 Order.

Gender-based analysis plus

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

Implementation, compliance and enforcement, and service standards

Implementation

The Order is now in force. Developing an implementation plan is not required when adding substances to the *Domestic Substances List*. The Order does not constitute an endorsement from the Government of Canada of the substance to which it relates, nor an exemption from any other laws or regulations that are in force in Canada and that may apply to this substance or to activities involving it.

Compliance and enforcement

When assessing whether or not a substance is subject to the SNAC provisions of the Act, a person is expected to make use of information in their possession, or to which they may reasonably be expected to have access. This means information in any of the notifier's offices worldwide or other locations where the notifier can reasonably have access to the information. For example, manufacturers are expected to have access to their formulations, while importers or users of a substance are expected to have access to import records, usage information and the relevant Safety Data Sheet (SDS).

Although an SDS is an important source of information on the composition of a purchased product, it should be noted that the goal of the SDS is to protect the health of workers in the workplace from specific hazards of chemical products, and may not include all the information on these hazards. Therefore, an SDS may not list all product ingredients or substances that may be subject to the SNAC provisions of the Act. Any person requiring more detailed information on product composition is encouraged to contact their supplier.

If any information becomes available that reasonably supports the conclusion that a substance added to the *Domestic Substances List* through any order is toxic or capable of becoming toxic under section 64 of the Act, the person who obtains the information and is involved in activities with the substance is obligated, under section 70 of the Act, to provide that information to the Minister without delay.

A company can submit a SNAN on behalf of its clients. In cases where a person receives possession or control of a substance from another person, they may not be required to submit a SNAN, under certain conditions, if their activities were covered by an original SNAN.

Any person who transfers the physical possession or control of a substance subject to an order to another shall notify that person of their obligation to comply with that order, including the obligation to notify the Minister of any significant new activity and to provide all the required information specified in that order.

A pre-notification consultation (PNC) is recommended for notifiers who wish to consult during the planning or preparation of a SNAN to discuss any questions or concerns they have about the prescribed information and test plans.

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 PNC, 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 Order is 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.

Service standards

In the event that a SNAN is submitted to the Minister in relation to the substance identified by the CAS Registry Number 12022-41-2, the ministers will assess the information after the complete information is received, within the prescribed timelines set out in the Order.

Contact

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819-938-3232 (outside of Canada)

Fax: 819-938-5212

Email: substances@ec.gc.ca

Footnotes

a S.C. 1999, c. 33

b S.C. 2023, c. 12, s. 26

1 SOR/94-311

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