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Order 2024-87-21-01 Amending the **Domestic Substances List: SOR/2025-17**

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CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

The Minister of the Environment makes the annexed Order 2024-87-21-01 Amending the Domestic Substances List under subsection 87(3) ^a of the Canadian Environmental Protection Act, 1999 b.

Ottawa, February 4, 2025

Steven Guilbeault Minister of the Environment

Order 2024-87-21-01 Amending the **Domestic Substances List**

Amendments

1 Part 1 of the *Domestic Substances List* $\frac{1}{2}$ is amended by deleting the following:

111-41-1

2 Part 2 of the List 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

111-41-1 S'	 1 The use of the substance ethanol, 2-[(2-aminoethyl)amino]- in the manufacture of any of the following products if the product contains the substance at a concentration equal to or greater than 0.1% by weight: (a) a consumer product to which the <i>Canada Consumer Product Safety Act</i> applies and that is to be sold in a container larger than 250 mL; or
	(b) a <i>cosmetic</i> as defined in section 2 of the <i>Food and Drugs Act</i> .
	 2 The importation of the substance ethanol, 2-[(2-aminoethyl)amino]- in any of the following products that contains the substance at a concentration equal to or greater than 0.1% by weight if the total quantity imported in all such products in a calendar year is greater than 10 kg: (a) a consumer product to which the <i>Canada Consumer Product Safety Act</i> applies and that is to be sold in a container larger than 250 mL; or
	(b) a <i>cosmetic</i> as defined in section 2 of the <i>Food and Drugs Act</i> .
	3 Despite sections 1 and 2, an activity is not a significant new activity if (a) the substance is a <i>research and development substance</i> or <i>a site-limited intermediate substance</i> as those terms are defined in subsection 1(1) of the <i>New Substances Notification Regulations (Chemicals and Polymers)</i> ; or
	(b) the substance, or the product that contains the substance, is intended only for export.
	 4 For each proposed significant new activity, the following information must be provided to the Minister at least 90 days before the day on which the activity begins: (a) a description of the significant new activity in relation to the substance;
	(b) the anticipated annual quantity of the substance to be used or imported;
	(c) the information specified in items 3 to 7 of Schedule 4 to the <i>New Substances Notification Regulations (Chemicals and Polymers)</i> ;

(d) the information specified in paragraphs 2(d) to (f) and 8(f) and (g) of Schedule 5 to those Regulations;

(e) a description of the consumer product or cosmetic that contains the substance, the intended use and method of application of that consumer product or cosmetic and the function of the substance in that consumer product or cosmetic;

(f) the total quantity of the consumer product or cosmetic expected to be sold in Canada in a calendar year by the person proposing the significant new activity;

(g) all other information and test data in respect of the substance that are in the possession of the person 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;

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

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

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

5 The information referred to in section 4 is to be assessed within 90 days after the day on which it is received by the Minister. **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 Order.)

Issues

The <u>Chemicals Management Plan</u> (CMP) is a Government of Canada initiative through which the risks of exposure of Canadians and the environment to substances ² are assessed and managed. As part of the CMP, the Minister of the Environment (the Minister) may apply the <u>significant new activity (SNAc) provisions</u> of the <u>Canadian Environmental</u> <u>Protection Act, 1999</u> (CEPA) to certain substances to request information to assess the potential for environmental and human health risks when the substance is used in a significant new activity. A significant new activity is an activity that results in the entry of a substance in the environment in a different quantity or concentration, or in different circumstances, than those in which the substance previously entered into the environment, which could affect the environmental or human exposure to that substance in Canada. If risks are identified, the Government of Canada may recommend risk management measures to mitigate them.

In accordance with subsection 87(3) of CEPA, the Minister is issuing *Order* 2024-87-21-01 Amending the <u>Domestic Substances List</u> (DSL) ³ to apply the SNAc provisions of CEPA to ethanol, 2-[(2-aminoethyl)amino]- (CAS RN ⁴ 111-41-1), also known as "AEEA."

Background

Chemicals Management Plan

In 2006, the Government of Canada launched the CMP, a federal program with the objective of reducing the risks posed by certain substances to Canadians and the environment from exposure to activities that involve them (e.g. industrial releases from manufacturing) or products that contain them (e.g. consumer products use and disposal). As part of the CMP, government officials from the Department of the Environment and the Department of Health (the departments) conduct assessments under the authority of CEPA to analyze the available information on substances (e.g. hazardous properties and uses) in order to identify existing and potential environmental and human health risks posed by exposure to these substances. The Minister of the Environment and the Minister of Health (the ministers) may recommend the development of risk management measures to mitigate these risks wherever identified, under the authority of a broad suite of federal laws, including CEPA, the *Canada Consumer Product Safety Act*, the *Food and* Drugs Act, the Pest Control Products Act, and the Fisheries Act.

The SNAc provisions of CEPA

Following the assessments of substances, the Minister may apply the SNAc provisions of CEPA to certain substances that are determined to have properties of concern, to request information to assess the environmental and human health risks of increased exposure to these substances when used in a significant new activity in Canada. The SNAc provisions establish a requirement for any person (individual or corporation) considering manufacturing, importing or using a substance for a significant new activity to submit a Significant New Activity Notification (SNAN) to the Minister containing the prescribed information for that substance. Upon receipt of the complete information, government officials would conduct further assessment of that substance before the activity is undertaken, to determine whether exposure to that substance from that activity could pose a risk to the environment or human health and whether further risk management considerations may be required to mitigate those risks.

To see the substances subject to the SNAc provisions of CEPA, please visit the <u>Canada.ca Open Data Portal</u>.

Description, uses, and sources of exposure

AEEA does not occur naturally in the environment. The Minister issued a mandatory survey under section 71 of CEPA ⁵ that included the substance. Information received from industry for the reporting year 2008 indicated that a lesser quantity than the reporting threshold of 100 kilograms (kg) of AEEA was manufactured in Canada, and more than 500 000 kg of AEEA were imported into Canada. In 2011, AEEA was not manufactured in Canada, and between 100 000 kg and 500 000 kg of AEEA was imported into Canada in the same year.

In Canada, AEEA is present as a component in food-packaging adhesives and inks with no direct contact with food, and as a component of an agent used in the paper manufacturing process. AEEA is also a component in additives for closed recirculating cooling systems where the treated water will not come into direct contact with food. AEEA may also be present in some epoxy adhesives, or super glues, used for smallscale repairs or hobbies. AEEA can also be found as a component of corrosion inhibitors, lubricant additives, and as a component of pigments used in fibres (e.g. carpets).

However, most of the AEEA imported into Canada is used as a chemical intermediate, a curing agent for epoxy resins, in commercial building products, and a component of adhesives and sealants used in asphalt paving or patching. AEEA can also be a minor constituent of solid products in building materials, with very limited potential for release. Internationally, in the United States, AEEA has been used as a reactant in the production of an organic flotation agent used to process ground marble ore. In Europe, AEEA is used in the production of polyurethane and hardeners for epoxy resins. Specifically, in Switzerland, AEEA is reported as a constituent of soldering flux. In Japan, AEEA is primarily used as a chemical intermediate to produce surfactants and waxes for application in consumer uses. Other international uses of the substance have been identified which could be of concern for human health, including use in cosmetics and personal care products marketed in Europe.

Summary of the assessment

As part of the CMP, in May 2016, the ministers published a *Final Screening Assessment for Ethanol, 2-[(2-aminoethyl)amino]-(AEEA)*, part of the Internationally Classified Substance Grouping, on the Canada.ca (Chemical Substances) website. The screening assessment concluded that the substance does not meet the environmental or health criteria for a toxic substance as set out in paragraph 64(a), (b) or (c) of CEPA. ⁶ The screening assessment also determined that the substance has properties of concern that could pose a risk to the environment or human health if exposure levels to AEEA were to increase from its use in a significant new activity in Canada. As a result, the Minister decided to apply the SNAc provisions of CEPA to AEEA.

Objective

The objective of *Order 2024-87-21-01 Amending the Domestic Substances List* (the Order) is to apply the SNAc provisions of CEPA to AEEA in accordance with subsection 87(3) of CEPA. As part of the CMP, the Order contributes to the protection of the environment and human health by reducing the risks associated with increased exposure of Canadians and the environment to AEEA in the event of its use in a significant new activity in Canada.

Description

Pursuant to subsection 87(3) of CEPA, the Order applies the SNAc provisions under subsection 81(3) of CEPA to AEEA. For a description of the significant new activities associated with this substance, please see the regulatory text in the Order.

Applicability

The Order does not impose any regulatory requirements on existing activities involving the substance in Canada, which have been determined to present no or limited risk, or are adequately managed.

The SNAc provisions of CEPA target potential significant new activities involving a substance that could result in a new or increased exposure to that substance in Canada. A significant new activity is an activity that results in the entry of the substance in the environment in a different quantity or concentration, or in different circumstances, than those in which the substance previously entered into the environment. ^Z For details on the significant new activities associated with AEEA, please see the regulatory text in the Order.

Should a person (individual or corporation) choose to engage with a substance, they would be required to comply with any regulations associated with that substance. In the same manner, if a person chooses to engage in a significant new activity in relation to a substance subject to the SNAc provisions of CEPA, they would be required to submit a SNAN to the Minister. The SNAN must contain all of the information prescribed in an order and must be submitted in the prescribed period before the day on which the significant new activity begins. The prescribed information to complete a SNAN is specific to each substance and is

described in the order that applied the SNAc provisions of CEPA to a substance. ⁸ For details on the information that would be required to be submitted in a SNAN for AEEA, please see the regulatory text in the Order.

Notification requirements

Below is a summary of the notification requirements for AEEA. For specific details, please see the regulatory text in the Order.

Activities subject to notification requirements

The notification requirements apply to

- the use of the substance in the manufacture of a consumer product to which the <u>Canada Consumer Product Safety Act</u> applies that is to be sold in a container larger than 250 mL, or in the manufacture of a *cosmetic* as defined in section 2 of the <u>Food and Drugs Act</u>, if the product or cosmetic contains the substance at a concentration equal to or greater than 0.1% by weight; and
- the importation of the substance in any consumer product to which the <u>Canada Consumer Product Safety Act</u> applies that is to be sold in a container larger than 250 mL, or in any cosmetic as defined in section 2 of the <u>Food and Drugs Act</u>, that contains the substance at a concentration equal to or greater than 0.1% by weight if the total quantity imported in all such products or cosmetics in a calendar year is greater than 10 kg.

Activities not subject to notification requirements

The notification requirements do not apply

- if the substance is a research and development substance, sitelimited intermediate substance, or export-only substance; ⁹
- to any use of the substance that is regulated under the Acts of Parliament listed in Schedule 2 of CEPA, including the <u>Pest Control</u>

Products Act, the Fertilizers Act, and the Feeds Act; and

 if the substance is exempt or excluded from notification requirements under CEPA (i.e. as a transient reaction intermediate, impurity, contaminant, partially unreacted material, or incidental reaction product, and, under certain circumstances, in mixtures, manufactured items, or wastes). ¹⁰

Information requirements

Below is a summary of the information requirements for the notification of a proposed significant new activity in relation to AEEA. For specific details, please see the regulatory text in the Order.

The Order requires the submission of

- a description of the proposed significant new activity;
- relevant information in Schedules 4 and 5 of the <u>New Substances</u> <u>Notification Regulations (Chemicals and Polymers)</u> (SOR/2005-247);
- a description of the product or cosmetic that contains the substance, the intended use and method of application of that product, and the function of the substance within that product; and
- other information in respect of the substance, including additional details surrounding use, and exposure information.

Regulatory development

Consultation

As part of the CMP, on June 25, 2016, the Minister published a <u>Notice of</u> <u>Intent</u> (NOI) to apply the SNAc provisions of CEPA to AEEA in the *Canada Gazette*, Part I, for a 60-day public comment period. During the public comment period, a stakeholder submitted information identifying a use of AEEA that had not previously been identified. As a result, revisions to the definition of the significant new activities relating to this substance were made. On September 12, 2020, an amended <u>NOI</u> was published in the *Canada Gazette*, Part I, for a 60-day public comment period. During this period, the Department received one comment stating no objection to the publication.

The departments informed the provincial and territorial governments about the Order through the CEPA National Advisory Committee (CEPA NAC) 11 via a letter and provided them with an opportunity to comment. No comments were received from the Committee.

Modern treaty obligations and Indigenous engagement and consultation

An assessment of modern treaty implications conducted in accordance with the <u>Cabinet Directive on the Federal Approach to Modern Treaty</u> <u>Implementation</u> concluded that orders amending the DSL to apply the SNAc provisions of CEPA to certain substances do not result in any impact on modern treaty rights or obligations, as they do not impose regulatory requirements (see "Applicability" section) that could result in incremental impacts (see "Benefits and costs" section) that would warrant specific engagement and consultation with Indigenous Peoples separate from the 60-day public comment period that followed publication of the NOI.

Instrument choice

The decision to use the SNAc provisions of CEPA is risk-based. The SNAc provisions will be considered for use where there is reasonable suspicion that certain new activities with respect to a substance may result in new or increased risks to the environment or human health. That suspicion could be based on factors such as the specific properties of that substance, the function of that substance and the presence of that substance in markets in other jurisdictions. $\frac{12}{12}$

As part of the CMP, the assessment informed the determination that applying the SNAc provisions of CEPA to AEEA is the most appropriate instrument to mitigate the risks of increased exposure of Canadians and the environment to the substance in the event of use in a significant new activity in Canada.

Regulatory analysis

Benefits and costs

Orders amending the DSL to apply the SNAc provisions of CEPA to certain substances do not result in incremental impacts (benefits and costs). The SNAc provisions aid in the protection of the environment and human health through their contribution to the main objective of the CMP. These orders usually do not apply to current activities identified at the time of the analysis involving those substances, as they are not considered to pose an environmental or human health risk, or their risk is adequately managed. These orders apply to the potential use of those substances in a significant new activity that could result in a new or increased exposure to those substances. Should a person (individual or corporation) choose to engage in a significant new activity involving a substance subject to the SNAc provisions of CEPA, they would be required to comply with all the regulations in place associated with that activity and that substance, including the requirement to submit a SNAN to the Minister. Therefore, the costs associated with a submission of a SNAN are not considered incremental to the SNAc provisions for a substance, but rather costs of conducting business and/or complying with federal laws and regulations in Canada.

Small business lens

Since orders amending the DSL to apply the SNAc provisions of CEPA to certain substances do not result in incremental impacts (benefits and costs), the assessment of the <u>small business lens</u> concluded that these

orders do not have impacts on small businesses. 13

One-for-one rule

Since orders amending the DSL to apply the SNAc provisions of CEPA to certain substances do not result in incremental impacts (benefits and costs), the assessment of the <u>one-for-one rule</u> concluded that these orders do not have impacts on businesses that would need to be addressed under the rule. ¹⁴

Regulatory cooperation and alignment

Canada cooperates with other international organizations and regulatory agencies for the management of chemicals (e.g. the United States Environmental Protection Agency, the European Chemicals Agency, and the Organisation for Economic Co-operation and Development), and is party to several international multilateral environmental agreements in the area of chemicals and waste. ¹⁵ The CMP is administered in cooperation and alignment with these agreements.

Effects on the environment

In accordance with the <u>Cabinet Directive on Strategic Environmental and</u> <u>Economic Assessment</u>, a <u>Strategic Environmental and Economic</u> <u>Assessment</u> was completed for the CMP, which includes orders amending the DSL to apply the SNAc provisions of CEPA to certain substances. The assessment concluded that the CMP is expected to have a positive impact on the environment and human health.

Gender-based analysis plus

Since orders amending the DSL to apply the SNAc provisions of CEPA to certain substances do not result in incremental impacts (benefits and costs), <u>Gender-based analysis plus</u> (GBA+) does not apply. ¹⁶

Implementation, compliance and enforcement, and service standards

Implementation

Orders amending the DSL are in force on the day that they are registered. Compliance promotion activities conducted as part of the implementation of those orders will include developing and distributing promotional material, responding to inquiries from stakeholders and undertaking activities to raise industry stakeholders' awareness of the requirements in those orders in the event a substance subject to the SNAc provisions of CEPA is used in a significant new activity in Canada.

Compliance

When assessing whether or not a substance is subject to SNAc provisions of CEPA, a person (individual or corporation) 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, mixture, or product are expected to have access to import records, usage information, and the relevant <u>Safety Data Sheet</u>. ¹⁷

Where a person involved in activities with a substance obtains information that reasonably supports the conclusion that that substance is toxic or is capable of becoming toxic, the person is obligated, under section 70 of CEPA, to provide that information to the Minister without delay.

Under section 87.1 of CEPA, any person who transfers the physical possession or control of a substance subject to an order to another should 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.

In cases where a person receives physical possession or control of a substance subject to the SNAc provisions of CEPA from another person, they may not be required to submit a SNAN, under certain conditions, if their activities were covered by an original SNAN submitted by the supplier on behalf of its clients.

A <u>pre-notification consultation (PDF)</u> (PNC) is available 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 obligations to comply with an order, believes they may be out of compliance, or would like to request a PNC, they are encouraged to contact the Substances Management Information Line. ¹⁸

Enforcement

Orders amending the DSL to apply the SNAc provisions of CEPA to certain substances are enforced in accordance with the <u>Compliance and</u> <u>Enforcement Policy for the Canadian Environmental Protection Act</u>. In instances of non-compliance, deciding which enforcement measure to take will consider factors such as the nature of the alleged violation, effectiveness in achieving compliance with CEPA and its regulations, and consistency in the application of enforcement measures. Suspected violations under CEPA can be reported to the Enforcement Branch by email at <u>enviroinfo@ec.gc.ca</u>.

Service standards

In the event that a SNAN is submitted to the Minister in relation to AEEA, government officials will assess the information after the complete information is received, within the prescribed timelines set out in the

Order.

Contacts

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Footnotes

- <u>a</u> S.C. 2023, c. 12, s. 26
- <u>b</u> S.C. 1999, c. 33
- <u>1</u> SOR/94-311

- Substances managed under the Canadian Environmental Protection Act, 1999 (CEPA) include chemicals, polymers, biochemicals, biopolymers, nanomaterials, substances of unknown or variable composition, complex reaction products, or biological material (UVCBs) and animate products of biotechnology (living organisms). For more information on the definition of a substance, see <u>subsection 3(1)</u> of CEPA.
- The DSL is an inventory of substances manufactured in or imported into Canada on a commercial scale and can be accessed through <u>Substances Search</u>.
- The Chemical Abstracts Service Registry Number (CAS RN) 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.
- 5 Section 71 surveys are a tool under CEPA used to collect information from industry and individuals on surveyed substances, such as their uses, as well as manufacture and import quantities, which may inform assessment conclusions for those substances.
- <u>6</u> For more information, please refer to <u>section 64</u> of CEPA.
- ZFor more information, please refer to section 80 and
section 104 of CEPA.
- 8 For guidance on preparing a SNAN, please see section 1.3 and section 4 of the <u>Guidance document for the New Substances</u>
 <u>Notification Regulations (Chemicals and Polymers)</u>.

- 9 For more information on these terms, including their definitions, please see section 3.4 of the <u>Guidance document</u> for the <u>New Substances Notification Regulations (Chemicals and Polymers)</u>.
- For more information on these terms, including their definitions, please see section 3.2 of the <u>Guidance document</u> for the <u>New Substances Notification Regulations (Chemicals and</u> <u>Polymers)</u>. Please note that individual components of a mixture may be subject to notification requirements under certain circumstances.
- 11 The CEPA NAC, established under section 6 of CEPA, is the main intergovernmental forum for the purpose of enabling national action and avoiding duplication in regulatory activity among governments within Canada. This committee has a representative from the Department of the Environment and the Department of Health, a representative of each of the provinces and territories as well as up to six representatives of Indigenous governments.
- 12 For more information on SNAc instrument choice, please consult the <u>Policy on the Use of Significant New Activity</u> <u>Provisions of the Canadian Environmental Protection Act, 1999</u>.
- <u>13</u> 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 Canadians.
- <u>14</u> The one-for-one rule requires that, when a new or amended regulation increases the administrative burden cost on business, regulators are required to offset from their existing regulations an equal amount on business.

- 15 For more information on the agreements, please see the Compendium of Canada's engagement in international environmental agreements and instruments. Of particular interest are the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal; the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade; the Stockholm Convention on Persistent Organic Pollutants; and the Minamata Convention on Mercury.
- <u>16</u> 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.
- 17 Although a Safety Data Sheet (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 an order. Any person (individual or corporation) requiring additional information on product composition is encouraged to contact their supplier.
- <u>18</u> The <u>Substances Management Information Line</u> can be contacted at <u>substances@ec.gc.ca</u> (email), 1-800-567-1999 (toll-free in Canada), and 819-938-3232 (outside of Canada).