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# **U.S. EPA Significant New Use Rule & ECC Canada / Health Canada Significant New Activity Provisions**

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## Acronym Listing

BLDA	Bilateral Limited Disclosure Agreement
CAS RN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CCPSA	Canada Consumer Product Safety Act
CDX	Central Data eXchange (U.S.)
CEPA	Canadian Environmental Protection Act
DSL	Domestic Substances List (Canada)
ECCC	Environment and Climate Change Canada
EPA	U.S. Environmental Protection Agency
HC	Health Canada
HCS	Hazard Communications Standards (U.S.)
MCAN	Microbial Commercial Activity Notice (U.S.)
NAN-C	North American Notification Consultation
NDSL	Non-Domestic Substances List (Canada)
NIOSH	National Institute for Occupational Safety and Health (U.S.)
NOI	Notice of Intent (NOI) (Canada)
NSN	New Substances Notification (Canada)
NSNR	New Substances Notification Regulations (Canada)
OSHA	Occupational Safety and Health Administration (U.S.)
PCB	Polychlorinated biphenyl(s)
PMN	Premanufacture Notice (U.S.)
PNC	Pre-Notice Consultation (Canada and U.S.)
PSI	Predetermined Set of Information
RCC	Regulatory Cooperation Council
SDS	Safety Data Sheet
SNAc	Significant New Activity (Canada)
SNAN	Significant New Activity Notification (Canada)
SNUN	Significant New Use Notice (U.S.)
SNUR	Significant New Use Rule (U.S.)
SRS	Substance Registry Services (U.S.)
TERA	TSCA Experimental Release Application (U.S.)
TSCA	Toxic Substances Control Act (U.S.)
U.S.	United States

## 1. Introduction

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### 1.1 Purpose

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The purpose of this primer is to compile easy-to-use information for stakeholders potentially regulated under similar United States (U.S.) and Canadian requirements—Significant New Use Rules (SNURs) in the U.S. and Significant New Activity (SNAc) provisions in Canada. Information in this document will assist the regulated community in determining their compliance obligations, in engaging their supply chains in communication activities to facilitate compliance, and in sharing best practices for meeting SNUR and SNAc requirements.

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### 1.2 Canada-United States Partnership and the Regulatory Cooperation Council (RCC) Process

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Environment and Climate Change Canada (ECCC), Health Canada (HC), and the U.S. Environmental Protection Agency (EPA) collaborated in the implementation of a Regulatory Cooperation Council (RCC) Work Plan on Chemicals Management that focused on SNURs and SNAcs.<sup>1</sup>

EPA and ECCC/HC held two roundtable meetings in September 2015, to convene stakeholders throughout the supply chain and facilitate discussions focused on the SNUR and SNAc programs. An overarching issue identified by the roundtable participants was the need for improved outreach and education, ranging from the basics of the

SNUR/SNAc programs to specific requirements for various stakeholders, especially for potentially less-informed stakeholder groups, such as foreign suppliers, and small, niche companies in the United States and in Canada. Educational materials are intended to ease compliance challenges of the various stakeholder groups. Key terms are defined in section 5.



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<sup>1</sup> <https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan/canada-united-states-regulatory-cooperation-council/workplan-stream-a-new-activity-provisions.html>, accessed April 5, 2017.

## 2. U.S. Significant New Use Rules (SNURs): Existing and New Chemicals, under the Toxic Substances Control Act (TSCA)

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### 2.1 Overview of SNURs

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Section 5(a)(2) of the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act, authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors. These factors include:

- The projected volume of manufacturing (including import) and processing of a chemical substance;<sup>2</sup>
- The extent to which a use changes the type or form of exposure of humans or the environment to a chemical substance;
- The extent to which a use increases the magnitude and duration of exposure of humans or the environment to a chemical substance; and
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.<sup>3</sup>

Under TSCA section 5(a)(1), a person desiring to manufacture or process for commercial purposes the chemical substance or mixtures containing it for a significant new use identified in the SNUR must notify EPA at least 90 days prior to initiating manufacture or processing for the significant new use [see [40 CFR §721.5\(a\)\(1\)](#)].

This notification initiates EPA’s evaluation of the conditions of use, which means the circumstances under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of, associated with the significant new use within the applicable review period. The person may not manufacture or process the chemical substance or mixture for the significant new use until EPA has conducted a review of the notice, made a determination on the notice under section 5(a)(3), and taken such actions as are required in association with that determination. SNURs can be promulgated for existing chemicals and new chemicals.

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<sup>2</sup> Under TSCA Section 3, the definition of the term “manufacture” includes import into the customs territory of the United States. “Import” is included whenever “manufacture” is used in the context of TSCA in this document.

<sup>3</sup> TSCA § 5(a)(2), 15 U.S.C. § 2604(a)(2).

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## **2.2 “Existing” versus “New”<sup>4,5</sup>**

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EPA classifies chemical substances as either “existing” or “new.” “Existing” chemical substances are chemicals that were already in commerce when TSCA was enacted in 1976, and those that have undergone EPA review since then and have been added to the TSCA Chemical Substance Inventory.<sup>6</sup> Any chemical substance that is not on the TSCA Inventory is classified as a new chemical. To determine if a substance is a new chemical, it is necessary to consult EPA’s TSCA Inventory, which lists “existing” substances. EPA’s Substance Registry Services can be used to determine if a chemical substance is listed on the public TSCA Inventory (see section 2.10.1). The public version of the Inventory does not contain chemical identities that are claimed confidential. Someone with a valid commercial need for EPA to verify if a substance is on the Inventory can submit a Bona Fide Intent to Manufacture or Import Notice (“bona fide notice”) to obtain a written determination from EPA. A chemical is considered new until it is reviewed under the TSCA New Chemicals Review program and is added to the Inventory.

The TSCA Inventory uses special flags to identify those substances on the Inventory that are the subject of an EPA rule or order promulgated under TSCA, as well as to indicate types of full or partial exemption from TSCA reporting requirements. The meanings of the flags are described on the EPA TSCA Inventory website.<sup>7</sup>

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## **2.3 Substances Excluded from TSCA**

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Certain substances are generally excluded from TSCA, including: pesticides (when manufactured, processed, or distributed in commerce for use as such); foods, food additives, drugs, and cosmetics (when manufactured, processed, or distributed in commerce for use as such); tobacco and tobacco products; nuclear material; and munitions, provided that they do not also have uses subject to TSCA. For the most part, these substances are covered under other federal laws.

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## **2.4 The Premanufacture Notice (PMN) Process**

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This discussion of the PMN process is relevant to SNURs, as prior to manufacture or processing of a new chemical, a notice must be filed with EPA under section 5 of TSCA. A PMN must be

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<sup>4</sup> <https://www.epa.gov/tsca-inventory>, accessed April 7, 2017.

<sup>5</sup> <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/basic-information-review-new>, accessed September 1, 2016.

<sup>6</sup> <https://www.epa.gov/tsca-inventory/how-access-tsca-inventory>, accessed September 1, 2016.

<sup>7</sup> *ibid.*



submitted at least 90 days prior to initiating the activity. Significant New Use Notices (SNUNs) submitted in response to a SNUR are handled the same way.

Further, there are similar TSCA section 5 notice requirements for the manufacture or processing of living microorganisms, which can also result in issuance of a SNUR. A Microbial Commercial Activity Notice (MCAN) is submitted for commercial “new” (intergeneric) microorganisms.<sup>8,9</sup> Further information on MCANs and regulation of biotechnology under TSCA can be found in the EPA Fact Sheet, “Microbial Products of Biotechnology Summary of Regulations under the Toxic Substances Control Act.”<sup>10</sup>

In general, TSCA section 5 notices require that all reasonably ascertainable information on chemical identity, production volume, byproducts, use, environmental release, disposal practices, and human exposure be included in the notice. In addition, EPA requires that the following information be submitted with the notice: any health and environmental information in the possession or control of the submitter, parent company or affiliates, and a description of any other applicable information known to or reasonably ascertainable by the submitter. See [40 CFR 720.45](#) and [40 CFR 720.50](#) for specific requirements. Electronic PMN software<sup>11</sup> allows manufacturers of TSCA chemical substances to use the Internet, through EPA’s Central Data eXchange (CDX), to submit TSCA section 5 notices to EPA.

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## **2.5 New Chemical Determinations<sup>12</sup>**

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Under TSCA,<sup>13</sup> once EPA receives a PMN, MCAN, or significant new use notice (SNUN), the agency must make one or more of the following determinations:

- “*Not likely to present an unreasonable risk*” Determinations (See TSCA section 5(a)(3)(C)) – In cases where EPA determines that a new chemical or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including unreasonable risk to a potentially exposed or susceptible subpopulation under the conditions of use, EPA will notify the submitter of its decision under TSCA section 5(a)(3)(C) and the submitter may commence manufacture of the chemical or manufacture or processing for the significant

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<sup>8</sup> Those who manufacture, process, and/or import microorganisms for research and development activities are required to submit a TSCA Experimental Release Application (TERA) in lieu of an MCAN.

<sup>9</sup> Please see EPA’s webpage for Filing a Biotechnology Submission under TSCA for further guidance:

<https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca>

<sup>10</sup> <https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/tsca-biotechnology-regulatory-and-policy-related>, accessed November 4, 2016.

<sup>11</sup> <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/how-submit-e-pmn>, accessed September 1, 2016.

<sup>12</sup> [https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/regulatory-actions-under-tsca#5\(f\)](https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/regulatory-actions-under-tsca#5(f)), accessed November 4, 2016.

<sup>13</sup> <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>, accessed September 1, 2016.

new use notwithstanding any remaining portion of the 90-day review period. EPA will publish its findings in a statement in the *Federal Register* pursuant to TSCA section 5(g). This includes cases for which EPA had concerns regarding the conditions of use of a PMN chemical substance, but such concerns were adequately addressed through amendment of the PMN made during the review period in conjunction with the issuance of a SNUR, or issuance of a SNUR without amendment of the PMN.

- “*Insufficient Information*” Determinations (See TSCA section 5(a)(3)(B)(i)) – In cases where EPA determines that the available information is insufficient to allow EPA to make a reasoned evaluation of the health and environmental effects of the new chemical substance or the significant new use, EPA must issue an order under section 5(e) of TSCA. A section 5(e) order must prohibit or limit the manufacture, processing, distribution in commerce, use or disposal to the extent necessary to protect against an unreasonable risk, and may include testing requirements.
- “*May present an unreasonable risk*” Determinations (See TSCA section 5(a)(3)(B)(ii)(I)) – In cases where EPA determines that in the absence of sufficient information, the manufacture, processing, distribution in commerce, use, or disposal of the chemical may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the EPA Administrator under the conditions of use, EPA must issue an order under section 5(e) of TSCA. A section 5(e) order must prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal to the extent necessary to protect against an unreasonable risk, and may include testing requirements. Most TSCA section 5(e) orders issued by EPA are consent orders that are negotiated with the submitter of the PMN, MCAN or SNUN.
- “*Exposure-based*” Determinations (See TSCA section 5(a)(3)(B)(ii)(II)) – In cases where EPA determines that the chemical substance is or will be produced in substantial quantities and either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance, EPA must issue an order under section 5(e) of TSCA. A section 5(e) order must prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal to the extent necessary to protect against an unreasonable risk, and may include testing requirements.
- “*Presents an unreasonable risk*” Determinations (See TSCA section 5(a)(3)(A)) – In cases where EPA determines that the chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the EPA Administrator under the conditions of use, EPA must take action under section 5(f) to protect against the unreasonable risk. Pursuant to section 5(f), EPA may propose a rule under section 6(a) or may issue an order

to prohibit or limit the manufacture, processing, or distribution in commerce of the substance.

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## **2.6 New Chemical SNURs and TSCA Section 5(e) and Section 5(f) Orders**

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***SNURs not associated with Consent Orders.*** Promulgation of a significant new use rule (SNUR) can be an effective and efficient way to address reasonably foreseen conditions of use about which EPA has concerns, as part of the basis for EPA to conclude that the chemical is not likely to present an unreasonable risk of injury to health and the environment under the conditions of use under section 5(a)(3)(C). A SNUR requires that any manufacturer or processor – including the PMN submitter – who intends to undertake the activities subject to the SNUR must submit to EPA a significant new use notice (SNUN). EPA must either conclude, following review of a SNUN, that the activities are not likely to present an unreasonable risk under the conditions of use, or take appropriate action under section 5(e) or 5(f) to protect against any unreasonable risk. The review would factor in the conditions of use of the chemical specifically associated with the significant new use and, as appropriate, any other conditions of use relevant to the evaluation of significant new use under section 5(a)(3). A SNUR enables EPA to focus its technical analysis on the intended conditions of use of a chemical and defer further analysis of reasonably foreseen conditions of use until such time as the submitter (or any other entity) actually intends to undertake them. This is consistent with EPA’s long-standing use of SNURs to defer detailed analysis of activities associated with chemicals until such time as someone indicates the intention to undertake the activities by submitting a SNUN. See, e.g., 80 Fed. Reg. 2071 (January 15, 2015).

It can be more efficient for EPA to address concerns associated with reasonably foreseen conditions of use by issuing a SNUR that applies to all parties, including the submitter, rather than by issuing an order to the submitter addressing activities the submitter does not intend to undertake, and then taking an additional regulatory action to issue a SNUR.

***SNURs following Consent Orders.*** TSCA section 5(e) and section 5(f) orders are typically consent orders negotiated with the submitter of the PMN and are only binding on the original PMN submitter for that substance. Consequently, after issuing a section 5 order, EPA generally promulgates a SNUR that requires notice to EPA by any manufacturer or processor who wishes to manufacture or process the chemical in a way other than described in the terms and conditions contained in the order. TSCA section 5(f)(4) requires EPA to either initiate a SNUR rulemaking or explain its reasons for not doing so following action under section 5(e) or 5(f). As described above, a SNUR requires that manufacturers (including importers) and processors notify EPA at least 90 days before beginning any activity that EPA has designated a “significant new use.” These new use designations are typically those activities prohibited by the section 5 order. The required notification initiates EPA’s evaluation of the conditions of use associated with the chemical substance within the applicable review period. Manufacturing (including import) or

processing for the significant new use cannot commence until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination.

In cases where EPA must issue an order under section 5, the consent order typically contains some or all of the following requirements as conditions:

- Testing for toxicity or environmental fate once a certain production volume or time period is reached
- Use of worker personal protective equipment
- New Chemical Exposure Limits (NCELs) for worker protection
- Hazard communication language
- Distribution and use restrictions
- Restrictions on releases to water, air and/or land
- Recordkeeping.

## 2.7 Existing Chemicals

In addition to new chemicals, SNURs can also be promulgated for new uses of existing chemicals. In these cases a SNUR would require notice to EPA, and that EPA conduct a review of the notice, make a determination on the notice, and take such action as required in association with that determination before new uses could begin or resume. SNURs for existing chemicals typically occur in three circumstances: (1) the chemical has been phased out or taken off the market for certain uses or has not been manufactured for a certain use before, (2) the chemical is no longer being manufactured or processed for any use, or 3) there is a potential or likely use of a chemical that has not commenced. This second

### Example existing chemical SNUR: trichloroethylene (81 FR 20535)

EPA's June 2014 Work Plan Chemical Risk Assessment for TCE identified health risks associated with several trichloroethylene uses, including the arts and craft spray fixative use, aerosol and vapor degreasing, and as a spotting agent in dry cleaning facilities. In 2015, EPA worked with the only U.S. manufacturer of the trichloroethylene spray fixative product resulting in an agreement to stop production of the trichloroethylene-containing product and to reformulate the product with an alternate chemical. The trichloroethylene spray fixative product was being used by artists, picture framers, graphic designers, and printers to provide a water repellent and protective finish.

After the product was taken off the market, EPA then took action by issuing a SNUR to ensure that no other manufacturers enter the marketplace for TCE spray fixatives and other consumer uses unless EPA is notified of the significant new use, makes a determination and takes such actions as are required in association with the determination. The significant new use was determined to be the manufacture or processing for use in a consumer product, with an exception for ongoing use of trichloroethylene in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray.

Source: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/trichloroethylene-tce>, accessed September 1, 2016.

situation is often referred to as a “dead chemical SNUR.” EPA can promulgate an existing chemical SNUR to ensure that no company will be able to manufacture or process the chemical for a specific use (circumstance 1) or for any use (circumstance 2) without prior notification to EPA, and EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination.<sup>14</sup>

## 2.8 Consumer Products and Articles addressed by SNURs

### 2.8.1 Consumer products

EPA defines consumer product at [40 CFR 721.3](#) as “a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation” and defines consumer as “a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.” The key issue in this definition is that the chemical

substance be sold or made available to the consumer for her or his own use; for example, the ink in a pen is made available for the consumer’s use but the refrigerant that comes within the cooling system of a newly purchased car is not made available for the consumer’s use.

### 2.8.2 Articles

Importers and processors of a chemical substance as part of an article are generally exempted from SNURs pursuant to [40 CFR 721.45\(f\)](#), but the exemption can be made inapplicable in a particular SNUR if EPA makes an affirmative finding that there is reasonable potential for exposure to a chemical substance through an article or category of articles [see TSCA section 5 (a)(5)].

Examples of SNURs for Consumer Products	
SNUR Citation	Regulatory Text
<a href="#">80 FR 37161</a> June 30, 2015; <a href="#">40 CFR 721.10182</a>	“. . .use in consumer products other than products used to recharge the motor vehicle air conditioning systems in passenger cars and vehicles in which the original charging of motor vehicle air conditioning systems with the PMN substance was done by the motor vehicle OEM [original equipment manufacturer].”
<a href="#">79 FR 74639</a> December 16, 2014; <a href="#">40 CFR 721.10229</a>	“Any use in a consumer product.”  “Any use in a consumer product, except as a solvent in consumer adhesives, in brake fluid, as a component of consumer paint/graffiti removers, and in consumer paints.”

<sup>14</sup> <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/actions-under-tsca-section-5%23SNUR#SNURs>, accessed September 1, 2016.

For SNURs, the Agency relies on the following definition of article in [40 CFR 720.3\(c\)](#): “a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end-use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.”

### 2.8.3 Distinction between articles and consumer products

Articles can contain chemical substances that are considered consumer products. If an article makes available a chemical substance for consumer use, then it would be considered an article that contains a consumer product. An example would be an ink pen. The pen would be considered an article that contains ink that is made available to the consumer for her or his use.

An example of a difference between an article and a consumer product is automotive brake fluid. Brake fluid would be considered part of an article when already included within an automobile’s brake lines, but the chemicals in the brake fluid would not be considered to be a consumer product because the automobile was not purchased for the brake fluid. When the brake fluid is purchased by a consumer at a car supply store to add to the automobile, that brake fluid would be considered a consumer product because it has been sold or made available to consumers for their use.

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## **2.9 SNUR Provisions**

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There are generally applicable SNUR provisions found in Subpart A of the Code of Federal Regulations (40 CFR part 721), which include requirements such as recordkeeping. In addition, the Subpart B provisions are cited for individual SNURs, some of which are described below. These include workplace protections, hazard communication programs, and restrictions on disposal and releases to water. As with all SNURs, they are applicable to manufacturers and processors. The corresponding Canadian topics and provisions are presented in Section 3.3 below.

### 2.9.1 Are there notification requirements for protection in the workplace and hazard communication?

New chemical SNURs often use standard language designating certain activities as significant new uses, set forth in Subpart B of part 721. The sections titled "Protection in the workplace" ([40 CFR 721.63](#)) and "Hazard communication program" ([40 CFR 721.72](#)) were modeled on Occupational Safety and Health Administration (OSHA) and National Institute for Occupational Safety and Health (NIOSH) regulations. When subject to these requirements, a SNUN would be required before manufacture or processing associated with any use of the SNUR substance



without establishing personal protective equipment or hazard communication programs described in those sections, including dermal protective equipment, respirators, a written hazard communication program, labeling, Safety Data Sheets (SDS), employee information and training, and certain precautionary statements. EPA has proposed in the *Federal Register* (see [81 FR 49598](#); July 28, 2016) changes to the TSCA SNUR regulations to align these regulations with revisions to the OSHA Hazard Communications Standard (HCS), which are proposed to be cross-referenced, and with changes to the OSHA Respiratory Protection Standard and the NIOSH respirator certification requirements pertaining to respiratory protection of workers from exposure to chemicals.

section 5(f)(5) of TSCA addresses workplace exposure, instructing the EPA Administrator to consult with OSHA prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which EPA has made a determination under 5(a)(3)(A) or (B) to address workplace exposures.

#### 2.9.2 Are there notification requirements for industrial, commercial, and consumer activities?

The section titled “Industrial, commercial, and consumer activities” can be found at [40 CFR 721.80](#). Using this provision, a SNUN would be required before manufacture or processing associated with a wide range of activities (25 are listed in the regulations), including use only in enclosed processes, a specific use, a specific production volume limit, a specific concentration limit, limits on the physical form in which a chemical may be used, use in a consumer product, and specific application method during use (e.g., aerosol). No further detail is provided in the regulations for the terms “industrial, commercial, and consumer activities,” beyond the definitions provided generally in [40 CFR 721.3](#). EPA decided that in many instances it was more practical to simply identify the category of use that is of concern. Evaluation of a specific new use occurs at the time of SNUN submission.

#### 2.9.3 Are there notification requirements for disposal?

The section titled “Disposal” can be found at [40 CFR 721.85](#). Using this provision, a SNUN would be required before manufacture or processing associated with certain methods of disposal, such as incineration, landfill, or deep well injection.

#### 2.9.4 Are there notification requirements for water releases?

The section titled “Release to water” can be found at [40 CFR 721.90](#). Using this provision, a SNUN would be required before manufacture or processing associated with any predictable or purposeful release of a manufacture, processing, or use stream to surface waters associated with any use of the SNUR substance. This can be a requirement to notify if the Significant New Use (SNU) is any release, release without certain treatment methods, or release beyond a specified surface water concentration identified by EPA. [40 CFR 721.91](#) (“Computation of estimated surface water concentrations; instructions”) provides guidance to the regulated community on how to compute estimated surface water concentrations from their facilities.

### 2.9.5 Are there recordkeeping requirements?<sup>15</sup>

The main purpose of the recordkeeping requirements is to know who is making the SNUR substance, how much are they making, and to whom they are distributing it. It is also important to have records that show compliance with any provisions that a SNUR may have. The actual recordkeeping requirements will be SNUR specific. For example, if the significant new use is solely related to a manufacturing process, regardless of downstream processing and use, then there would likely not be recordkeeping requirements for downstream processors.

Specific records may be required on the following: 1) documenting the manufacture and importation volume of the substance and the corresponding dates of manufacture and import; 2) documenting volumes of the substance purchased in the US by processors of the substance, names and addresses of suppliers, and corresponding dates of purchase; 3) documenting the names and addresses of all persons outside the site of manufacture, importation, or processing to whom the manufacturer, importer, or processor directly sells or transfers the substance, the date of each sale or transaction, and the quantity of the substance sold or transferred on such date.

Records could also be required to document the establishment and implementation of a program for the use of any applicable personal protective equipment required; and/or documenting the establishment and implementation of a hazard communication program; and/or that the chemical protective clothing, if required, is impervious to the substance.

The actual recordkeeping requirements will vary depending on the conditions of the SNUR. For example, if water discharge limitations are imposed, then records may be required to document compliance with those limits. In some cases, for example, if the SNUR only applies to manufacturers (e.g. manufacture only at a certain average molecular weight), recordkeeping by downstream processors may not even be needed. The figure on the following page describes the elements of a SNUR using siloxanes and silicones as an example.

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<sup>15</sup> [40 CFR 721.125](#), accessed September 1, 2016.



**Elements of a SNUR: Siloxanes and Silicones Example (§ 721.10888)**

<p>This SNUR is patterned after an accompanying TSCA section 5(e) consent order signed by EPA with the PMN submitter.</p>	<p><b>§ 721.10888 Siloxanes and Silicones, 3-[(2-aminoethyl)amino]propyl Me, di-Me, reaction products with cadmium zinc selenide sulfide, lauric acid and oleylamine.</b></p>
<p>Section (a)(1) lists the substance to which the SNUR provisions apply. Substance(s) will generally be listed by their PMN number and/or CAS number.</p>	<p>(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as siloxanes and silicones, 3-[(2-aminoethyl)amino]propyl Me, di-Me, reaction products with cadmium zinc selenide sulfide, lauric acid and oleylamine (PMN P-15-59; CAS No. 1623456-05-2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.</p>
<p>Section (a)(2) describes the significant new uses that apply to the listed substances. This means that any use other than those described in section (a)(2) requires notification and Agency review prior to being allowed to engage in that new use. In this particular example, that would include not using dermal protection in the workplace for persons reasonably likely to be exposed, use other than as a down converter for an optical filter, etc., or disposal other than by incineration in a permitted hazardous waste incinerator.</p>	<p>(2) The significant new uses are:</p>
<p>This SNUR is subject to the Protection in the workplace requirements with references to 40 CFR 721.63(a)(1),(a)(2)(i),(a)(3),(b), and (c). A general description of workplace and hazard communication requirements can be found in Section 2.9.1 of this primer.</p>	<p>(i) Protection in the workplace. Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for §721.63 (a)(1) engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.</p>
<p>This SNUR is subject to requirements for industrial, commercial, and consumer activities. The specific uses and processes are described here. More general information on requirements for industrial, commercial, and consumer activities can be found in Section 2.9.2 of this primer.</p>	<p>(ii) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(p)(three months and eighteen months). A significant new use of the substance is manufacture, process, or use the chemical substance other than as a down converter for an optical filter for light emitting diodes used in displays, or other than in a liquid formulation.</p>
<p>This SNUR is subject to disposal requirements. More general information on disposal requirements can be found in Section 2.9.3 of this primer.</p>	<p>(iii) Disposal. Requirements as specified in § 721.85. It is a significant new use to dispose of the chemical substance other than by incineration in a permitted hazardous waste incinerator.</p>
<p>Required recordkeeping requirements for all new chemical SNURs can be found in: 40 CFR 721.125(a), (b), and (c). Additional requirements in 721.125 correspond to the significant new use restrictions described above. Each manufacturer (including importer) and processor of the substance shall maintain the records for 5 years from the date of their creation. More general information on recordkeeping requirements can be found in Section 2.9.5 of this primer.</p>	<p>(b) Specific requirements. The provisions of subpart A of this part apply to this section except as modified by this paragraph.</p>
	<p>(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a), (b), (c), (d), (e), (i), and (j) are applicable to manufacturers and processors of this substance.</p>
	<p>(2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.</p>

Source: 40 CFR 721.10888

### 2.9.6 How are imports and exports affected?

As noted above, under TSCA section 3, the definition of the term “manufacture” includes import into the customs territory of the United States. Imported chemicals may be in bulk or a part of a mixture or article, as TSCA section 13 makes clear.<sup>16</sup> Since imported chemicals are included in the definition of “manufacture,” imported chemicals are generally subject to SNURs and other TSCA section 5 reporting requirements, though there may be applicable regulatory exceptions.<sup>17</sup> For example, someone is not subject to the notification requirements if the person imports or processes the substance as part of an article (unless otherwise specified in a specific SNUR) or manufactures or processes the chemical substance solely for export (see [40 CFR 721.45\(f and 40 CFR 721.45\(g\)\)](#)).

In order for a substance to enter the United States, importers must certify that their imported chemical substance either is subject to and complies with TSCA (“positive certification”) or is not subject to TSCA (“negative certification”).<sup>18</sup> If a TSCA chemical substance is subject to a SNUR, the positive certification would include the fact that the imported substance is in compliance with the SNUR. Certain chemicals or chemicals that are a part of articles, are exempt from import certification (unless they are required by a specific rule under TSCA).

Under TSCA section 12(b), any person who exports or intends to export from the United States a chemical substance or mixture subject to a SNUR must notify EPA of their intent to export, and EPA will share the information about the substance with the country of import.<sup>19</sup> Certain chemicals, such as mercury, asbestos, hexavalent chromium, and polychlorinated biphenyls (PCBs), have specific export requirements or limitations.<sup>20</sup> Also see [40 CFR 761.97](#).

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### **2.10 Resources to determine if a chemical substance is subject to a SNUR**

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EPA has multiple resources to determine whether or not a chemical substance is subject to a SNUR. These include Substance Registry Services (SRS) and ChemView.

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<sup>16</sup> 15 U.S.C. §2612 (2016), [http://uscode.house.gov/view.xhtml?req=\(title:15%20section:2612%20edition:prelim\)](http://uscode.house.gov/view.xhtml?req=(title:15%20section:2612%20edition:prelim)), accessed September 1, 2016.

<sup>17</sup> EPA. (2016). “TSCA Requirements for Importing Chemicals.” Retrieved from <https://www.epa.gov/tsca-import-export-requirements>, accessed July 27, 2016

<sup>18</sup> Customs and Border Protection’s Import Regulations at [19 CFR 12.118 to 12.127, and 127.28](#).

<sup>19</sup> EPA. (2016). “TSCA Section 6 Import/Export Requirements for Specific Chemicals.” Retrieved from <https://www.epa.gov/tsca-import-export-requirements/tsca-section-6-importexport-requirements-specific-chemicals>, accessed July 27, 2016. See [40 CFR 707 subpart D](#) for details.

<sup>20</sup> 15 U.S.C. §2611 (2016), <http://uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title15-section2611&num=0&saved=%7CKHRpdGxIOjE1IHNIY3Rpb246MjYwMSBIZGI0aW9uOnByZWxpbSk%3D%7C%7C0%7Cfalse%7Cprelim>, accessed September 1, 2016.

### 2.10.1 EPA's Substance Registry Services (SRS)<sup>21</sup>

Substance Registry Services ([SRS](#)) is EPA's central system for information about substances that are tracked or regulated by EPA or other sources. It is a resource for basic information about chemicals, biological organisms, and other substances of interest to EPA and its state and tribal partners.

SRS makes it possible to identify which EPA data systems, environmental statutes, or other sources have information about a substance and which synonym is used by that system or statute. It becomes possible, therefore, to map substance data across EPA programs, regardless of a given naming convention.

**SRS can be accessed at the following link:**

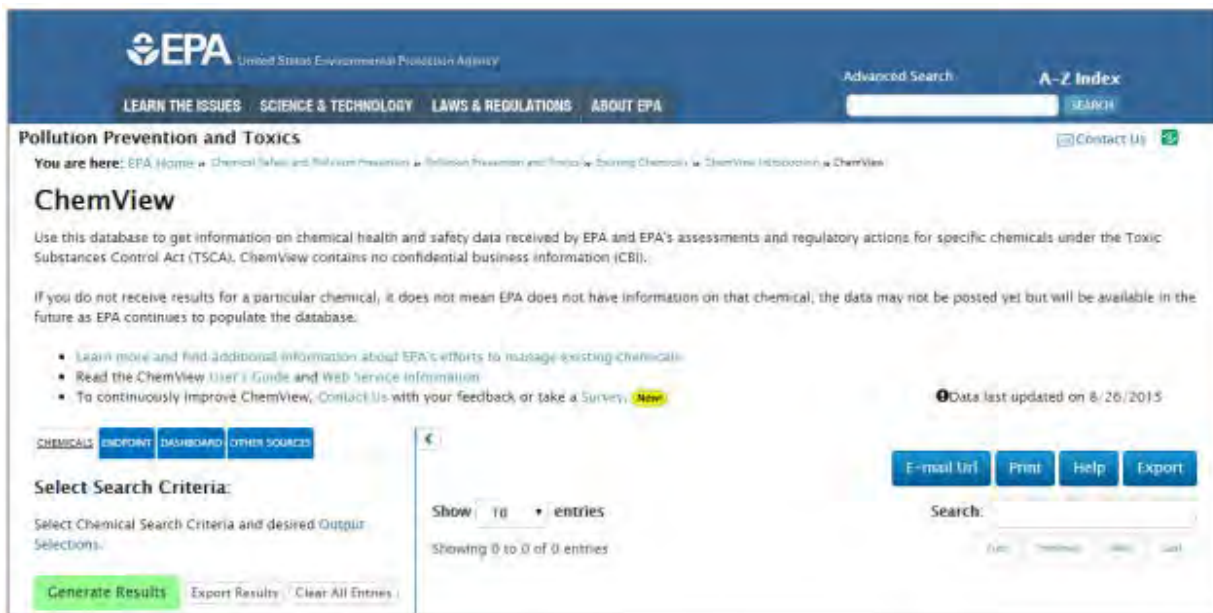
[https://iaspub.epa.gov/sor\\_internet/registry/substreg/searchandretrieve/substancesearch/search.do](https://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/substancesearch/search.do)

SRS can be searched for a specific chemical, with the results providing the type of regulation or other characteristic that affects the status of a chemical. If a chemical is associated with a SNUR, then the results will be presented as either “TSCA 5(a) Final SNUR” or “TSCA 5(a) Proposed SNUR.” SRS users can also search for complete lists of the “TSCA 5(a) Final SNUR” chemicals and the “TSCA 5(a) Proposed SNUR” chemicals.

<sup>21</sup> [https://iaspub.epa.gov/sor\\_internet/registry/substreg/searchandretrieve/substancesearch/search.do](https://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/substancesearch/search.do), accessed September 1, 2016.

## 2.10.2 ChemView<sup>22</sup>

EPA created [ChemView](https://chemview.epa.gov/chemview) to improve chemical safety and provide more streamlined access to information on chemicals. This database greatly improves access to health and safety data on chemicals regulated under TSCA. The database currently contains summary and in-depth information on more than 15,000 chemicals as well as proposed and final SNURs for over 2,800 chemicals. ChemView offers access to thousands of documents including data submitted to EPA, EPA assessments, and EPA actions such as test data, hazard characterizations, alternatives assessments, and TSCA regulatory actions. Users can search on a number of parameters, such as chemical identifier, endpoint, functional use, chemical category, and chemical group. For links to step-by-step instructions on how to use ChemView to determine if a chemical has a SNUR, please see Section 5.2.

The screenshot shows the EPA ChemView website. At the top, there is the EPA logo and navigation links for 'LEARN THE ISSUES', 'SCIENCE & TECHNOLOGY', 'LAWS & REGULATIONS', and 'ABOUT EPA'. A search bar is located on the right side. The main heading is 'Pollution Prevention and Toxics' with a sub-heading 'ChemView'. Below this, there is a brief description of the database and a list of links for more information, including 'Learn more and find additional information about EPA's efforts to manage existing chemicals', 'Read the ChemView User's Guide and Web Service Information', and 'To continuously improve ChemView, Contact Us with your feedback or take a Survey'. There are also buttons for 'E-mail Us!', 'Print', 'Help', and 'Export'. A search bar is visible at the bottom right of the interface.

**ChemView can be accessed at the following link:**

<https://chemview.epa.gov/chemview>

<sup>22</sup> <https://chemview.epa.gov/chemview>, accessed September 1, 2016.

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## **2.11 Significant New Use Notice (SNUN)<sup>23</sup>**

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If EPA determines by rule that a use of a chemical substance is a significant new use, TSCA requires submission of a SNUN to EPA at least 90 days before a person manufactures or processes the chemical substance for that use.

If the manufacturer or processor intends to distribute the chemical in commerce for a significant new use, he or she must submit a SNUN, unless he or she notifies the recipient, in writing, that the substance has a SNUR, or the manufacturer knows that the recipient already knows this, or knows that it would be impossible for the recipient to undertake the new use.

While the manufacturer or processor is not legally obligated to enforce the recipient's actions, if at any time the manufacturer becomes aware of the fact that the recipient is engaging in the new use without submitting a SNUN, then the manufacturer needs to stop supplying the SNUR substance to that recipient and the manufacturer may also need to submit a SNUN (exact requirements are detailed at [40 CFR 721.5](#)). An example of this would be a SNUR that does not allow for the spray application of the chemical and the recipient of the chemical undertakes spray application without submitting a SNUN.

The SNUN uses the same form and electronic submission method as the PMN, and initiates EPA's evaluation of the intended use within the applicable review period. Manufacture and processing for the significant new use is unable to commence until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination. EPA recommends that SNUN submitters include information that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture, processing, use, distribution in commerce, or disposal, as required by the PMN process (see section 2.4). EPA encourages persons to consult with EPA before submitting a SNUN. As part of this optional Pre-Notice Consultation (PNC), EPA would discuss specific data that it believes may be useful in evaluating a significant new use.

### **2.11.1 When does a person distributing a chemical substance in commerce NOT need to submit a SNUN?**

A person who intends to manufacture or process for commercial purposes a chemical substance identified within [40 CFR part 721](#), subpart E, and intends to distribute the substance in commerce is nonetheless **not required** to submit a SNUN if that person can document one or more of the following as to each recipient of the substance from that person:

1. The person has notified the recipient, in writing, of the specific section in subpart E of Part 721 that identifies the substance and its designated significant new uses.

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<sup>23</sup> <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-significant-new-use-notice>, accessed September 1, 2016.



2. The recipient has knowledge of the specific section in subpart E of Part 721 that identifies the substance and its designated significant new uses.
3. The recipient cannot undertake any significant new use described in the specific section in subpart E of Part 721.<sup>24</sup>

Even if a person is not required to submit a SNUN under the circumstances above, that person would have to submit a SNUN if that person:

1. Knows at the time of commercial distribution that a recipient intends to engage in a significant new use without submitting a SNUN ([40 CFR 721.5\(b\)](#)); or
2. At any time thereafter, has knowledge that a recipient is engaging in a significant new use without submitting a SNUN, subject to limited exception ([40 CFR 721.5\(d\)\(1\)](#)).

Additionally, a person who processes a chemical substance identified within [40 CFR Part 721](#), Subpart E for a significant new use of that substance is **not required** to submit a SNUN if that person can document each of the following:

1. The person does not know the specific chemical identity of the chemical substance being processed, and
2. The person is processing the chemical substance without knowledge that the substance is identified in [40 CFR Part 721](#), Subpart E.

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<sup>24</sup> [40 CFR 721.5](#), accessed September 1, 2016.

### 3. Canada's Significant New Activity (SNAc) Provisions<sup>25</sup>

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#### 3.1 Canadian Authority for SNAcs

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The Significant New Activity (SNAc) provisions of the [Canadian Environmental Protection Act, 1999](#) (CEPA) trigger an obligation for a person (individual or corporation) to provide the Government of Canada with information about a substance when proposing to use, import, or manufacture the substance for a significant new activity.<sup>26</sup> The government then assesses the substance for potential risks to human health and/or the environment. The decision to apply the SNAc provisions for a specific activity in relation to a substance is based on risk. Where potential changes in exposure to a substance could occur due to the “significant new activity,” SNAc provisions allow for an assessment to take place prior to the commencement of these activities. If risks are identified during the assessment, the government could impose management measures. For further details, [sections 80-89](#) in Part 5 of CEPA<sup>27</sup> set out requirements related to Substances and Activities New to Canada and [sections 104 to 115](#) in Part 6 of CEPA<sup>28</sup> set out requirements related to Animate Products of Biotechnology.

Current information on SNAc provisions can be accessed on the ECCC webpage on “[The Significant New Activity Provisions under CEPA.](#)”<sup>29</sup>

#### 3.1.1 What are “significant new activities”?

A “significant new activity” is any activity that results or may result in a higher quantity or concentration of a substance into the environment or in exposing the environment in a different manner or circumstance, which could affect environmental or human exposure to the substance. What constitutes a significant new activity is specific to each substance and is described in the relevant SNAc publication in the *Canada Gazette*. It is important to note that the definition of a “significant new activity” in a SNAc publication for a given substance could include more than one activity.

#### 3.1.2 What substances are subject to SNAcs?

SNAc provisions can be applied to the full suite of substances regulated under CEPA, and defined in section 3 of the Act. This includes: chemicals, polymers, biopolymers, biochemicals,

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<sup>25</sup> <https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/significant-new-activity-provisions.html>, accessed November 1, 2017.

<sup>26</sup> <http://laws-lois.justice.gc.ca/eng/acts/c-15.31/>, accessed April 7, 2017.

<sup>27</sup> <https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/publications/canadian-environmental-protection-act-1999/part-5.html>, accessed November 1, 2017.

<sup>28</sup> <https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/publications/canadian-environmental-protection-act-1999/part-6.html>, accessed November 1, 2017.

<sup>29</sup> <https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/significant-new-activity-provisions.html>, accessed November 1, 2017.

nanotechnology and animate objects of biotechnology (living organisms). This includes use of these substances in industrial and commercial activities and in consumer products.

Section 3 of CEPA also indicates that mixtures, manufactured items, animate matter, and mixtures that are contained in effluents, emissions or wastes are not considered “substances” for the purpose of notification requirements under SNAC provisions. However, it should be noted that individual components of a mixture could be notifiable under the SNAC provisions. Please refer to the box below for additional information about SNAC provisions and how they apply to manufactured items and consumer products.

[Subsections 81\(6\)](#) and [106\(6\)](#) of CEPA<sup>30,31</sup> exempt certain uses of substances from notification under the SNAC provisions such as: using a substance to manufacture or importing a substance for use in pesticides, fertilizers, and feeds since notification of these uses is required under other Acts of Parliament, which are listed in Schedules 2 and 4 of CEPA. Additional exclusions are listed in these subsections and include: transient reaction intermediates that are not isolated; impurities, contaminants and partially unreacted materials; and incidental reaction products.

For notification and assessment purposes, CEPA distinguishes between “new” substances and “existing” substances. The Domestic Substances List (DSL) is a compilation of all known substances that were in Canadian commerce between 1984 and 1986 or that have been added to the DSL in accordance with CEPA. The DSL is the sole basis for determining whether a substance is new for the purposes of the Act and the Regulations and is amended regularly. A substance not listed on the DSL is considered to be a new substance in Canada. Any person who intends to import or manufacture a new substance in Canada is required to notify under the *New Substances Notification Regulations (Chemicals and Polymers)* [NSNR (Chemicals and Polymers)] or the *New Substances Notification Regulations (Organisms)* [NSNR (Organisms)]. Following the assessment under these regulations of a new substance, the SNAC provisions can be applied. For information on the notification of new substances, refer to ECCC’s *Evaluating New Substances* webpage.<sup>32</sup>

Substances listed on the DSL are considered to be existing substances in Canada. Under the Chemicals Management Plan,<sup>33</sup> prioritized existing substances have been subject to risk assessment and, where warranted following a risk assessment conclusion, subject to SNAC provisions.

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<sup>30</sup> <https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/related-documents.html>, accessed November 1, 2017.

<sup>31</sup> <https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/related-documents.html>, accessed November 1, 2017.

<sup>32</sup> <https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances.html>, accessed November 1, 2017

<sup>33</sup> <https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan.html>, accessed November 1, 2017.



The Non-Domestic Substances List (NDSL) is an inventory of substances that are not on the DSL, but are accepted as being in use internationally. The NDSL is based on the US EPA's TSCA Chemical Substance Inventory. Substances that are not on the DSL, but are listed on the NDSL, are subject to the NSNR (Chemicals and Polymers) and NSNR (Organisms). However, they are subject to fewer information requirements.

### 3.1.3 When are SNAc provisions put in place?

The decision to use the SNAc provisions is risk-based. The SNAc provisions are considered for use once a new or an existing substance has been reviewed in accordance with CEPA, and based on that review, ECCC and HC suspect that new activities with a substance may result in new or increased risks to the environment and/or human health. That conclusion could be based on a number of factors including: the specific properties of the substance, the function of the substance, or the presence of the substance in markets in other jurisdictions. In addition, SNAc provisions could be applied to an existing substance if it is no longer in Canadian commerce, or it is in Canadian commerce with limited use(s).

## SNACs and Consumer Products/Manufactured Items

Consumer products and manufactured items are treated differently by SNAcs. The following explains how they are different.

In Canada, where the term "consumer product" is used in a SNAc notice or order, the term normally references the *Canada Consumer Product Safety Act (CCPSA)*. Section 2 of the Act defines a consumer product as "a product, including its components, parts or accessories that may reasonably be expected to be obtained by an individual to be used for non-commercial purposes, including for domestic, recreational and sports purposes, and includes its packaging." This definition includes products used/provided in commercial settings (e.g., daycare facilities, hotels, etc.) as well as products that may be purchased by a consumer. The term "consumer product" normally includes only those products to which the CCPSA applies (Section 4 and Schedule 1 of the CCPSA list products which are excluded from the definition). If products to which the CCPSA does not apply are of potential concern, they will be specifically described in the SNAc definition.

A manufactured item is defined under section 3 of CEPA as "...formed into a specific physical shape or design during manufacture and has, for its final use, a function or functions dependent in whole or in part on its shape or design." Where the substance is in a manufactured item, it is generally excluded from notification under SNAc provisions. However, substances in fluids and particles contained within a manufactured item may be notifiable if they are released during normal use in an uncontrolled or dispersive manner.

*Source: Canadian Environmental Protection Act (1999); Guidelines for the Notification and Testing of New Substances, Chemicals and Polymers (2005) and; Canada Consumer Product Safety Act*

For further details about when SNAC provisions are applied, refer to the *Policy on the Use of Significant New Activity Provisions of the Canadian Environmental Protection Act, 1999*.<sup>34</sup>

#### 3.1.4 How are SNACs published?

All SNAC notices and orders are published in the *Canada Gazette*, the official newspaper of the Canadian Government. There are different procedures and policies in place for publishing SNAC requirements related to new and existing substances.

The following graphic provides an example of a SNAC publication and identifies the information contained in each section.

SNAC notices for new substances are published in the *Canada Gazette*, Part 1 (Notices and Proposed Regulations) within 90 days after the expiry of the assessment period of the related new substance notification. Once published, the SNAC notice normally comes into force immediately. There is no formal comment period prior to or after the publication of the SNAC notice. A notifier can submit, at any time, information that could have a bearing on the notice. ECCC and HC will review this information and take appropriate action, if required.

SNAC orders for existing substances are published in the *Canada Gazette*, in two parts. First in Part I, a Notice of Intent (NOI), which is considered a draft SNAC order, is published for a 60-day comment period. This is an opportunity for stakeholders to provide comments to inform the Canadian Government of any information relating to the existing substance and its current use. Following the consultation period, a final order applying the SNAC provisions to the substance is published in *Canada Gazette*, Part II (Official Regulations). Generally the SNAC order is in force on the day it is adopted, but occasionally entry into force can occur on a later date.

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<sup>34</sup> <https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=5CA18D66-1>

**Elements of a SNAc Publication: Quinoline Example (SOR/2015-73)**

2015-04-22 Canada Gazette Part II, Vol. 149, No. 8 *Gaz*

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

Column 1	Column 2
<b>Substance</b>	<b>Significant new activity for which substance is subject to subsection 81(3) of the Act</b>
91-22-5 S'	<p>1. Any activity involving, in any one calendar year, more than 100 kg of the substance quinoline in its isolated form, namely, quinoline that is extracted from naturally occurring sources or that is manufactured.</p> <p>2. For each proposed significant new activity, the following information must be provided to the Minister at least 180 days before the day on which the quantity of the substance exceeds 100 kg in any one calendar year:</p> <p>(a) a description of the proposed significant new activity in relation to the substance;</p> <p>(b) the anticipated annual quantity of the substance to be used;</p> <p>(c) if known, the three sites in Canada where the greatest quantity of the substance is anticipated to be used or processed and the estimated quantity by site;</p> <p>(d) the information specified in items 3 to 7 of Schedule 4 to the <i>New Substances Notification Regulations (Chemicals and Polymers)</i>;</p> <p>(e) the information specified in paragraphs 2(d) to (f) and 8(a) to (g) of Schedule 5 to those Regulations;</p> <p>(f) the information specified in paragraph 11(b) of Schedule 6 to those Regulations;</p> <p>(g) the products and, if known, end-use products that are anticipated to contain the substance, the intended use of those products and the function of the substance in those products;</p> <p>(h) a summary of all other information or test data in respect of the substance that are in the possession of the person proposing the significant new activity, or to which they have access, and that are relevant to identifying hazards of the substance to the environment and human health and the degree of environmental and public exposure to the substance;</p> <p>(i) the identification of every government department or agency, either outside or within Canada, to which the person proposing the significant new activity has provided information regarding the substance and, if known, the department or agency's file number and, if any, the outcome of the assessment by the department or agency and the risk management actions in relation to the substance imposed by the department or agency;</p> <p>(j) the name, civic and postal addresses, telephone number and, if any, the fax number and email address of the person proposing the significant new activity and, if any, the person authorized to act on their behalf; and</p> <p>(k) a certification stating 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 authorized to act on their behalf.</p> <p>3. The above information will be assessed within 180 days after the day on which it is received by the Minister.</p>

SNACs may be published in either the *Canada Gazette* Part I (Notices - for SNACs on substances not on the DSL; Notices of Intent - for SNACs on substances on the DSL) or *Canada Gazette*, Part II (Orders - for SNACs on DSL substances). In all cases, information related to the substance identity, definition of significant new activities, and data requirements for SNACs is in the same format.

**Column 1** is where the substances are listed to which the SNAC provisions apply. Substances will be listed by their CAS RN and are followed by a flag: the "S" flag indicates a new substance newly added to the DSL for which there are existing SNAC provisions in force; or the "S prime" (S') flag indicates that the substance was already listed on the DSL and SNAC provisions have been applied to that existing substance.

In the example here, the (S') flag is indicated, specifying that this is an existing substance for which SNAC provisions are in force.

**Item 1** under **Column 2** is where the definition of what constitutes a "new activity" is described in the SNAC Notice or Order. It is important to review this section to see if a person's intended use of the substance is included in this definition.

In this example, the significant new activity is defined as "any activity involving more than 100 kg of the substance in its isolated form...extracted from naturally occurring sources or that is manufactured."

**Item 2** under **Column 2** is where the submission requirements are listed for each new use under the SNAC provisions. This initial section indicates when the information must be submitted to the Minister (government). In this particular case the requirement is "...180 days before the day on which quantity exceeds 100 kg in any one calendar year."

**Sub-items** under **Item 2**, here listed as (a) through (k), indicate the information that must be provided to the Minister within the timeframes specified in Item 2. Information requirements listed are often made with reference to Schedules under the *New Substances Notification Regulations (NSNR)*, which have a similar process and information submission requirements. The regulations and associated schedules can be found by searching the consolidated regulations found on the Government of Canada website: <http://laws-lois.justice.gc.ca/eng/regulations/>.

**Item 3** under **Column 2** identifies the length of time granted by the Government to review and assess the information provided. The assessment period can range from 90 to 180 days. In this particular case, the assessment period is 180 days after the day on which the information is received for that particular submission.

Source: [Canada Gazette \(2015\) Part II: Vol.149, No.8, Page 2, SOR/2015-73](#)

### 3.1.5 Available resources to determine if SNAc provisions have been applied to a substance

The [Substances search](#) tool (see example graphic below) can be used to identify substances on the DSL, substances on the NDSL, as well as substances subject to the SNAc provisions.<sup>35</sup> Substances listed on the DSL that are subject to SNAc provisions will be identified using either “S” or “S’” (S prime) flags. The image below is a screen shot from the Substances search tool on the Government of Canada website. Users can search for substances using a specific list or group (DSL, NSNR, SNAc), a substance identifier (Chemical Abstracts Service Registry Number, CAS RN), or a substance name.

The [list of Significant New Activity Publications](#) is a dataset that includes information on all SNAc orders and notices published under the authority of CEPA and is available on the Government of Canada’s [Open Government Portal](#). Information in the dataset is organized by substance and includes web addresses to relevant Canada Gazette publications.<sup>36</sup> See section 5 *Resources and Other Supporting Materials* for a list of web-based resources.


Substances listed on the confidential portion of the DSL are published with confidential accession numbers. SNAc notices published for such substances, as well as those published for substances not on the DSL where the substance identity is confidential, are referenced by their confidential accession numbers. Anyone who intends to engage in a significant new activity for a substance that has been published with a confidential accession number may seek confirmation from the Substances Management Information Line (see section 5, *Resources and Other Supporting Materials*, for contact information).

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<sup>35</sup> <http://pollution-waste.canada.ca/substances-search>, accessed June 14, 2017.

<sup>36</sup> <http://open.canada.ca/data/en/dataset/bfab5876-77e5-4dbf-8693-3b0bc69428b8?wbdisable=false>, accessed November 1, 2017.

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## Substances search

**Find legislative status and program priorities for substances (e.g. chemicals, polymers, and biotechnology organisms).**

To see what is currently available, expand the "List or group" pick-list below. Updates are made regularly and new lists and groups will be added ongoing.

**Search by list or group** to view all substances for the selected list or group.

**Search by substance identifier** (using one of the following formats) to view all associated lists and groups applicable for the searched substance:

- Chemical Abstract Service Registry Number (CASRN) (e.g.: 50-00-0)
- Environment and Climate Change Canada Confidential Accession Number (e.g.: 10000-1)
- National Pollutant Release Inventory substance identifier (e.g.: NA - 12)
- Enzyme Commission Number (e.g.: 1.1.23.21)
- American Type Culture Collection (ATCC) Number. (e.g.: ATCC11866)

**Search by substance name:** enter any part of a substance name to view a list of substance names containing that part. Select one to view all associated lists and groups applicable. Substance names can vary widely for a substance, so it is recommended to search by identifier where possible.

List or group :

### ***3.2 Obligations for substances subject to SNAc provisions***

#### ***3.2.1 Are there SNAc obligations to notify recipients?***

Sections 86 and 111 of CEPA outline the requirement for mandatory recipient notification for certain substances subject to SNAc provisions. Under these sections, when transferring possession or control of a substance that is not listed on the DSL and that is subject to SNAc provisions (including if the substance is in a mixture), all recipients must be notified of the obligation to comply with SNAc provisions. This notification enables recipients to determine their own compliance obligations with respect to the SNAc.

For substances on the DSL subject to a SNAc, it is recommended that this notification also be carried out to allow recipients to be in a position to determine their own SNAc compliance obligations. Additionally, notifying recipients ensures open communication within the supply chain, allowing recipients to inform suppliers/distributors about the SNAc and their use of the substance.

#### ***3.2.2 What are Significant New Activity Notifications (SNANs)?***

A Significant New Activity Notification (SNAN) is the information submitted to the government in compliance with a SNAc notice or order. The SNAN must contain all of the information

prescribed in the published notice or order. SNANs must be submitted to the Minister of the Environment, through [Program Development and Engagement Division](#) at ECCC.<sup>37</sup>

#### Who needs to submit a SNAN?

If a person's proposed activities with a substance are captured by the significant new activity definition of a notice or order, and are not subject to any exemptions (see section 3.1.2), that person is required to submit a SNAN to the government for assessment prior to the commencement of these activities. The foremost source of information to determine if a SNAC applies is the SNAC notice or order. Specific timeframes for submission of a SNAN are mentioned in the specific SNAC publication.

For substances not on the DSL and subject to SNAC provisions, those persons who intend to use the substance should review the description of the significant new activity in the SNAC notice to determine whether their proposed activities meet the definition of a significant new activity. Substances not listed on the DSL also have separate notification requirements under the NSNR (Chemicals and Polymers) or the NSNR (Organisms) before they are imported or manufactured.

For substances on the DSL and subject to SNAC provisions, manufacturers, importers, and users of substances who are planning an activity in relation to the substance must determine whether a SNAN notification is required for their planned activity. Anyone with any questions regarding whether or not a SNAC order applies to their activities are encouraged to contact the Substances Management Information Line (see section 5, *Resources and Other Supporting Materials*).

A company can submit a SNAN on behalf of its customers (known as an "umbrella SNAN"). For example, in cases where a person receives possession and control of a substance from another person, the recipient may not be required to submit a SNAN under certain conditions if the activities were covered by the original SNAN submitted by the supplier. The Substances Management Advisory Note, [Clarification in relation to the submission of Significant New Activity Notifications in application of the Canadian Environmental Protection Act, 1999](#), provides more detail on this subject.<sup>38</sup>

#### What is required in a SNAN?

The information required to complete a SNAN is unique to each substance and is described within the *Canada Gazette* publication that applies the SNAC provisions to the substance. Many of the information requirements of SNACs reference the schedules of the [NSNR \(Chemicals and Polymers\)](#) and the [NSNR \(Organisms\)](#).<sup>39,40</sup>

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<sup>37</sup> <https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/significant-new-activity-provisions.html>, accessed November 1, 2017.

<sup>38</sup> <http://ec.gc.ca/subsnouvelles-newsups/default.asp?lang=En&n=CC526AE6-1>, accessed April 7, 2017.

<sup>39</sup> <https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances.html>, accessed November 1, 2017.

<sup>40</sup> <https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances.html>, accessed November 1, 2017.



Additional guidance on preparing a SNAN can be found in the [Guidelines for the Notification and Testing of New Substances \(Chemicals and Polymers\)](#) and the [Guidelines for the Notification and Testing of New Substances \(Organisms\)](#).<sup>41,42</sup>

Although a specific reporting form is not available for submitting a SNAN, nor is it required, sections of the [New Substances Notification \(NSN\) Reporting Form](#) may be used as appropriate.<sup>43</sup>

A Pre-Notice Consultation (PNC) is available for notifiers who wish to consult with the program during the planning or preparation of their SNAN to discuss any questions or concerns about the prescribed information and test plans. To request a PNC or receive more information, contact the [Substances Management Information Line](#).<sup>44</sup>

### What is a SNAN Assessment?

Once a SNAN is submitted to the government, the Minister of Environment and the Minister of Health assess the information provided, as well as other available information, to determine whether the substance could pose a risk to the environment and/or human health, and whether further risk management measures are required.

Prescribed periods for SNAN assessments are indicated in a SNAN publication. The assessment period for SNANs can vary, but typically for a new substance SNAN it is 90 days,<sup>45</sup> while the assessment period for organism SNANs is 120 days.<sup>46</sup> The time required to complete an assessment could vary depending on a number of factors, including the information provided in the SNAN and the complexity of the substance and/or activities being assessed. The Ministers do have the power to extend the assessment period for a SNAN under [subsections 83\(4\)](#) and [Section 108\(4\)](#) of CEPA,<sup>47</sup> to a maximum of double the number of days identified in the SNAN notice or order. The new activity cannot be undertaken until the assessment period of the SNAN has expired.

### What is the outcome of a SNAN?

The outcome of the SNAN assessment determines if the substance is considered toxic or not under [Section 64](#) of CEPA,<sup>48</sup> and also informs decisions concerning risk management measures

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<sup>41</sup> <https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/chemicals-polymers/guidance-documents.html>, accessed November 1, 2017.

<sup>42</sup> <https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/biotechnology-living-organisms/guidelines.html>, accessed November 1, 2017.

<sup>43</sup> <https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/chemicals-polymers/notification-forms/reporting.html>, accessed November 1, 2017.

<sup>44</sup> <https://www.canada.ca/en/health-canada/services/chemical-substances/contact-us.html>, accessed November 1, 2017.

<sup>45</sup> <http://laws-lois.justice.gc.ca/eng/acts/C-15.31/index.html>, accessed November 1, 2017.

<sup>46</sup> <http://laws-lois.justice.gc.ca/eng/acts/C-15.31/index.html>, accessed November 1, 2017.

<sup>47</sup> <http://laws-lois.justice.gc.ca/eng/acts/C-15.31/index.html>, accessed November 1, 2017.

<sup>48</sup> <https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/publications/canadian-environmental-protection-act-1999/part-5.html>, accessed November 1, 2017.

for the substance if required. There are generally two potential outcomes for a SNAN: toxic or not toxic.

If the assessment concludes a substance is toxic, risk management measures may be imposed on the substance to address the new or increased risk to the environment and/or human health. For new substances this could include conditions or prohibitions under section 84 of CEPA. For existing and new substances, a range of tools could be implemented, including: voluntary agreements, addition to the list of toxic substances of CEPA (Schedule 1), regulations, guidelines, codes of practice, and pollution prevention plans. The SNACs may also be amended to exclude those specific activities because they are being risk managed by alternate means, and to avoid duplicative notification.

When the assessment concludes a substance is not toxic following the assessment, the SNAC may be amended to exclude those activities that are not of concern and for which notification is no longer required, or the SNAC could possibly be rescinded, to allow companies to undertake those activities.

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### ***3.3 Additional SNAC Information***

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This section describes comparable requirements and other information for SNACs, similar to those described for US SNURs in section 2.9.

#### ***3.3.1 Are there requirements for protection in the workplace and hazard communication?***

Health Canada contributes to occupational health and safety (OHS) issues by administering the Workplace Hazardous Materials Information System in partnership with the federal, provincial and territorial (FPT) OHS regulatory agencies. Labor legislation falls under the jurisdiction of Canada's FPT OHS agencies. Consequently, SNACs do not have requirements for protection in the workplace and hazard communication.

#### ***3.3.2 Are there requirements for industrial, commercial, and consumer activities?***

While CEPA and the CCPSA do permit industrial and commercial significant new activities to be included in SNAC provisions, they are not set out in the same way as is done under TSCA for significant new uses. These types of activities can be described in a SNAC in three basic ways: (1) broadly applicable, (2) broadly applicable with exclusions, and (3) targeted. The table below presents an example of each type. A SNAC definition could be broad and define a significant new activity as any activity with the substance above a specific threshold. Similarly, a specific activity regarding the use of a substance in a consumer product could be targeted. It depends on the substance and for which activities the Canadian government is trying to obtain information for evaluation. It is incumbent on companies who may be impacted to review the SNAC publication carefully to determine if their activity could be included in the definition of significant new activities.



### Examples of Different Types of Significant New Activity Definitions Published in SNAcs

<p><b>Broadly Applicable</b> (any use, manufacture or import above a threshold)</p>	<ul style="list-style-type: none"> <li>Order 2013-87-03-01 (CAS RN 116-66-5): “<b>Any activity</b> involving, in any one calendar year, more than 100 kg of the substance 1<i>H</i>-indene, 2,3-dihydro-1, 1,3,3,5-pentamethyl-4,6-dinitro-.”</li> </ul> <p><a href="#">Canada Gazette, Part II: Vol.147, No.14, Page 1904</a></p>
<p><b>Broadly Applicable, with exclusions</b> (any use, manufacture or import activity above a threshold other than x, y, z)</p>	<ul style="list-style-type: none"> <li>Order 2013-87-11-01 (CAS RN 88-72-2): “<b>Any activity</b> involving, in any one calendar year, a total of more than 100 kg of the substance Benzene, 1-methyl-2-nitro-, <b>other than</b> an activity involving its use in the manufacture of explosives.”</li> </ul> <p><a href="#">Canada Gazette, Part II: Vol.148, No.2, Page 183</a></p>
<p><b>Targeted</b> (specific activity with threshold)</p>	<ul style="list-style-type: none"> <li>SNAc Notice No. 18020: ...a significant new activity is the <b>use of the substance in a quantity greater than 100 kg per calendar year in any cosmetic or drug</b> as defined in section 2 of the <i>Food and Drugs Act</i>, <b>or in any natural health product</b> as defined in subsection 1(1) of the <i>Natural Health Products Regulations</i>.</li> </ul> <p><a href="#">Canada Gazette, Part I: Vol.149, No.23, Page 1096</a></p>

#### 3.3.3 Are there disposal requirements?

There are no requirements for disposal in SNAc publications. Also, as outlined in section 3.1.2, section 3 of CEPA lists mixtures as part of effluents, emissions or wastes as not considered substances for the purposes of notification requirements under SNAc provisions. However, individual components of mixtures could be notifiable in a SNAc under the definition of the significant new activity.

#### 3.3.4 Are there release-to-water requirements?

Release-to-water requirements are not managed by SNAc provisions as they are with SNURs. There are other regulatory risk management tools that the Canadian government uses that have similar release-to-water requirements (e.g., Ministerial Conditions). Moreover, there are other federal and provincial laws, such as the federal Fisheries Act, which could apply to these releases. Persons engaged in activities which include releases to water should follow the requirements that apply in the jurisdiction where their activities take place.

#### 3.3.5 Are there recordkeeping requirements?

Typically, there are no record-keeping requirements for SNAcs.

## 4. Comparison of the Two Programs

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### 4.1 Differences in Regulatory Frameworks for US SNURs and Canada SNACs

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As outlined above, both Canada and the United States have the authority to require notification and evaluate risks associated with substances that are new to each country and with substances that could be used in new ways. In Canada, the Canadian Environmental Protection Act, 1999 (CEPA) is the key authority for the government to require that new activities associated with chemicals manufactured or imported to Canada to be assessed for their potential risks to the environment and human health. From time to time, the Domestic Substances List (DSL) is amended to indicate the requirement to submit specific information to the government prior to undertaking a “Significant New Activity” (SNAC) in relation to that substance. Under the Toxic Substances Control Act (TSCA), the United States issues “Significant New Use Rules” (SNURs) to require notification of significant new uses of a substance and evaluates those notifications for potential unreasonable risk to human health or the environment. The table below describes the key differences between the two regulatory authorities.

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### 4.2 Enabling Bilateral Communication

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In Canada and the U.S., pre-notice consultations are primarily used by notifiers to consult government officials during the planning or preparation of NSNs and PMNs to discuss any questions or concerns they may have regarding notification procedures or regulatory requirements. The North American Notification Consultation (NAN-C) process allows companies wishing to notify simultaneously in both Canada and the U.S. the option of consulting with both jurisdictions via a joint PNC.

Challenges to information-sharing during bilateral communication between jurisdictions involve enabling discussions on EPA-defined Confidential Business Information (CBI) (e.g., masked substance names, CAS RNs) and NSN/PMN assessment timelines. As part of the NAN-C process, a bilateral limited disclosure agreement would be provided by the notifier to enable sharing of CBI information. Use of the NAN-C process by notifiers interested in initiation of NSNs or PMNs will enable timely communication on SNACs and SNURs where these are an outcome of the new substance review.

For more information about the NAN-C process in **Canada** please contact the Substances Management Information Line: Toll-free in Canada, 1-800-567-1999; Outside Canada, 1-819-938-3232; Fax, 1-819-938-5212; Email, [ECCC.substances.ECCC@canada.ca](mailto:ECCC.substances.ECCC@canada.ca).

In the **U.S.** please contact the Toxic Substances Control Act Hotline at 202-554-1404.

## Differences in US and Canadian Authorities for SNURs and SNACs under TSCA and CEPA

<b>Occupational safety and health</b>	
<b>US:</b> Assessments under TSCA can include consideration of occupational exposures, and TSCA provides authority for US EPA to establish new chemical exposure limits (NCEs) among other worker protection requirements.	<b>Canada:</b> Assessments under CEPA don't include consideration of occupational exposures. However, SNACs may require information to assess a substance and the risks it may pose in a work environment.
<b>Food and Drug Act uses</b>	
<b>US:</b> Uses of chemicals regulated under the US Food, Drug and Cosmetic Act are exempt from TSCA requirements, <sup>49</sup> and SNURs cannot be applied to these uses.	<b>Canada:</b> Substances used in products regulated under Canada's <i>Food &amp; Drugs Act</i> are not exempt from CEPA, and SNACs can be applied to these substances in Canada.
<b>New organisms</b>	
<b>US:</b> TSCA's authority in this area is limited, as only certain genetically modified microorganisms can be captured under the TSCA definition of "chemical substance" and therefore subject to TSCA authority (e.g., bacteria, fungi, algae, viruses, protozoa).	<b>Canada:</b> SNACs can be issued for new organisms under CEPA including more complex genetically modified organisms.
<b>Downstream notification requirements for new and existing substances</b>	
<b>US:</b> SNURs require information-sharing down the supply chain regardless of whether they are new or existing substances. Specifically, a person that intends to manufacture, import, or process for commercial purposes a chemical substance subject to a SNUR, and intends to distribute that substance in commerce, must either document that the person has notified the recipient in writing of the SNUR and the significant new use, document that the recipient already has knowledge of the SNUR and the significant new use, or document that the recipient cannot undertake the significant new use.	<b>Canada:</b> Sections 86 and 111 of CEPA outline requirements for substances not listed on the DSL (new substances) and subject to SNAC provisions; all recipients must be notified of the obligation to comply with SNAC provisions. For substances on the DSL (existing substances) subject to a SNAC order, it is recommended that this notification also be carried out to allow recipients to be in a position to determine their own SNAC compliance obligations.
<b>"Manufactured items" and "Articles"</b>	
<b>US:</b> Under TSCA, standard regulatory exemptions in SNURs can be made inapplicable, e.g., the "article" exemption can be made inapplicable to allow articles containing substances of concern, including those that are unintentionally released, to be captured by SNUR requirements.	<b>Canada:</b> Currently, SNAC provisions in CEPA do not apply to most substances contained in manufactured items. Substances in fluids and particles contained within a manufactured item may be notifiable if they are released during normal use in an uncontrolled or dispersive manner.
<b>Export notification</b>	
<b>US:</b> There are export notification requirements for substances subject to SNURs.	<b>Canada:</b> There are no export notification requirements for substances subject to SNACs.

<sup>49</sup> TSCA SNURs do not apply to pesticides; tobacco (or tobacco products); firearms and ammunition; source material by-products or special nuclear material defined by the Atomic Energy Act; and food, food additives, drugs, or cosmetics covered under the Federal Food, Drug and Cosmetic Act.

## 5. Resources and Other Supporting Materials

EPA Resources	
EPA website	<a href="https://www.epa.gov/">https://www.epa.gov/</a>
EPA's ChemView	<a href="https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/introduction-chemview">https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/introduction-chemview</a>
EPA's Substance Registry Services (SRS)	<a href="https://ofmpub.epa.gov/sor_internet/registry/subst_reg/searchandretrieve/substancesearch/search.do">https://ofmpub.epa.gov/sor_internet/registry/subst_reg/searchandretrieve/substancesearch/search.do</a>
SNUNs are reported using the standard e-PMN form and are subject to a 90-day review process similar to that for a PMN. Access to the e-PMN form	<a href="https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/how-submit-e-pmn">https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/how-submit-e-pmn</a>

ECCC/HC Resources	
SNAC Webpage	<a href="https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/significant-new-activity-provisions.html">https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/significant-new-activity-provisions.html</a>
Significant New Activity Publications under the Canadian Environmental Protection Act, 1999 dataset	<a href="http://open.canada.ca/data/en/dataset/bfab5876-77e5-4dbf-8693-3b0bc69428b8?wbdisable=false">http://open.canada.ca/data/en/dataset/bfab5876-77e5-4dbf-8693-3b0bc69428b8?wbdisable=false</a>
Substances Search Tool (chemicals, polymers and organisms)*	<a href="http://pollution-waste.canada.ca/substances-search/Substance?Error=1&amp;Id=1257085-86-1&amp;ExactMatch=False">http://pollution-waste.canada.ca/substances-search/Substance?Error=1&amp;Id=1257085-86-1&amp;ExactMatch=False</a>
Canada Gazette general website – where SNAC orders and notices are published	<a href="http://www.gazette.gc.ca">http://www.gazette.gc.ca</a>
Government of Canada RCC webpage	<a href="https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/canada-united-states-regulatory-cooperation-council.html">https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/canada-united-states-regulatory-cooperation-council.html</a>
HC general website	<a href="https://www.canada.ca/en/health-canada.html">https://www.canada.ca/en/health-canada.html</a>
ECCC general website	<a href="https://www.canada.ca/en/environment-climate-change.html">https://www.canada.ca/en/environment-climate-change.html</a>
Substances Management Information Line	Toll-free in Canada: 1-800-567-1999 Outside Canada: 1-819-938-3232 Fax: 1-819-938-5212 Email: <a href="mailto:ECCC.substances.ECCC@canada.ca">ECCC.substances.ECCC@canada.ca</a>

\* The Substances search tool is a searchable database of substances previously published in the *Canada Gazette* (e.g., substances on the DSL, NDSL, and new and existing substances subject to the SNAC provisions). *Canada Gazette* publications are the official source for SNAC publications.

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## 5.1 Explanation of Key Terms

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**Canada Notice of Intent (NOI)** – An NOI to amend the DSL is published in the *Canada Gazette*, Part I (CG I), followed by a public comment period, and publication of an order amending the DSL in the *Canada Gazette*, Part II (CG II). The SNAC provisions apply as soon as the order is registered (i.e., in force) unless the order indicates otherwise.

**Canada Significant New Activity (SNAC)** – An activity conducted with a substance in a different quantity, concentration, or in different circumstances that could affect the environment or human exposure. What constitutes a significant new activity (or activities) is specific to each substance and is found in the relevant SNAC publication in the *Canada Gazette*.

**Canada Significant New Activity Notification (SNAN)** – If a person's proposed activities with a substance are captured by the definition of a significant new activity, that person is required to submit a SNAN to the government for assessment within the specified regulatory time period prior to the new activity being undertaken.

**Canadian Environmental Protection Act, 1999 (CEPA)** – An Act respecting pollution prevention and the protection of the environment and human health in order to contribute to sustainable development.

**U.S. Premanufacture Notice (PMN)** – Anyone who plans to manufacture (including import) a new chemical substance for a non-exempt commercial purpose is required by TSCA to provide EPA with notice before initiating the activity. A PMN must be submitted at least 90 days prior to the manufacture of the new chemical or significant new use. An online version of the PMN form is available on EPA's website in an electronic (e-PMN) format.

**U.S. Significant New Use Notice (SNUN)** – A manufacturer (including importer) or processor intending to engage in a designated significant new use must submit a SNUN to EPA at least 90 days before manufacturing or processing the chemical for the significant new use. This notification initiates EPA's evaluation of the chemical within the applicable review period. Manufacture and processing for the significant new use is unable to commence until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination.

**U.S. Significant New Use Rule (SNUR)** – EPA issues regulations designating significant new uses of a chemical so that Agency review occurs before chemical substances are used in new ways that might create environmental and human health concerns. Once EPA designates a significant new use for a chemical, manufacturers and processors of that chemical who wish to initiate that use must submit a SNUN before manufacturing or processing the chemical for the significant new use.

**U.S. Toxic Substances Control Act (TSCA)** – Provides EPA with authority to establish reporting, recordkeeping, testing requirements, and restrictions relating to chemical substances or mixtures. TSCA addresses the production, importation, use, and disposal of specific chemicals.

**Importer (TSCA)** – Any person who imports a chemical substance, including a chemical substance as part of a mixture or article, into the customs territory of the U.S. Importer includes the person primarily liable for the payment of any duties on the merchandise, or an authorized agent acting on his/her behalf.

**Manufacturer (TSCA)** – A person who imports, produces, or manufactures a chemical substance.

**Processor (TSCA)** – Any person who processes a chemical substance or mixture. To process means to prepare a chemical substance or mixture, after its manufacture, for distribution in commerce in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or as part of a mixture or article containing the chemical substance or mixture.

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## 5.2 ChemView Instructions

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The EPA ChemView website <https://chemview.epa.gov/chemview> has links to a ChemView User's Guide<sup>50</sup> and Web Service Information. The User's Guide includes

- Selecting chemical search criteria
- Selecting outputs
- Generating results
- Viewing results
- Appendix of specific sources.

The Web Services URLs (uniform resource locators) site describes dropdowns for the user to select the chemicals, SNUR uses, uses, groups, categories, and endpoints. The site also enables the user to select different sources to get the chemical results. The default output format is JavaScript Object Notation (JSON). ChemView also provides the ability to download to Excel, XML, and PDF.<sup>51</sup>

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<sup>50</sup> ChemView Public UI [User Interface] Guide Release 1.3, U.S. Environmental Protection Agency, October 2015, 42 pages. Available at: <https://chemview.epa.gov/chemview/resources/ChemView%20Public%20UI%20Guide.pdf>.

<sup>51</sup> ChemView Web Services URLs. Release 1.1, U.S. Environmental Protection Agency, February 19, 2014. Available at [https://chemview.epa.gov/chemview/resources/ChemView\\_WebServices.pdf](https://chemview.epa.gov/chemview/resources/ChemView_WebServices.pdf).