



# Nanomaterials

Nanotechnology is a rapidly emerging field with the potential for use in a wide variety of applications across a broad range of sectors. Nanomaterials are substances that are manufactured at or within the nanoscale (1 to 100 nanometres inclusive), or have internal or surface structures in the nanoscale. As international consensus on a definition for the products of nanotechnology has not yet been reached, a working definition described in the [Policy Statement on Health Canada's Working Definition for Nanomaterial, is used when addressing manufactured nanomaterials](#) under the *Canadian Environmental Protection Act, 1999* (CEPA 1999).

Nanomaterials may behave differently from conventional chemical substances with regard to their potential risk to human health and the environment. As such, there is a need to assess nanomaterials differently from conventional chemicals.

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# Regulation of nanomaterials in Canada

Chemical substances, including nanomaterials, in Canada are regulated under CEPA 1999, which provides the authority to collect information, to assess and to manage risks to the environment and human health. Under CEPA, the Domestic Substances List (DSL) determines if a substance is considered in commerce (existing) or is new to the Canadian market. Chemical substances, including nanomaterials, that are not listed on the DSL are subject to the New Substances Notification Regulations (Chemicals and Polymers) under CEPA 1999.

The DSL lists substances by their Chemical Abstracts Service Registry Number (CAS RN). The assignment of CAS RNs is generally based on the chemical composition of a substance. CAS RNs do not distinguish between:

- substances with the same chemical composition at the nanoscale versus the non-nanoscale (bulk) form
- the various nanoscale forms of a substance, including shape and size variations

Nanoscale forms of substances listed on the DSL are considered to be existing nanomaterials. Nanoscale forms have not been explicitly considered in the risk assessments of existing substances (CAS RNs) conducted under Canada's Chemicals Management Plan (CMP). The Government of Canada is taking initiatives so that nanomaterials currently in commerce in Canada undergo ecological and human health risk assessments and takes appropriate control measures when required.

## Framework for the risk assessment of manufactured nanomaterials in Canada

On June 17, 2022, the draft Framework for the Risk Assessment of Manufactured Nanomaterials under the Canadian Environmental Protection Act, 1999 was published for a 60-day public comment period.

The purpose of the document is to establish a framework for the risk assessment of nanomaterials under CEPA 1999, including both existing nanomaterials on the DSL, and new nanomaterials notified under the *New Substances Notification Regulations (Chemicals & Polymers)*.

A plain language summary of the draft framework is also available.

Any person may, within 60 days of publication of this framework, file with the Department of the Environment, written comments on this proposed framework. All comments must cite the framework title and be sent to the Executive Director, Program Development and

Engagement Division, Department of the Environment, Gatineau, Quebec K1A 0H3, or by email to [substances@ec.gc.ca](mailto:substances@ec.gc.ca).

Comments and information received will be considered in the development of the final framework.

In accordance with section 313 of CEPA 1999, any person who provides information in response to this publication may submit, with the information a request, that it be treated as confidential.

## Health Canada data gap analysis

In October 2021, a [Data gap analysis of nanoscale forms of substances on the Domestic Substances List: a human health perspective](#) was published. This document describes the approach used by Health Canada to analyze available data and information on certain nanomaterials under CEPA 1999. It also presents the results of this analysis and identifies data needs for each of 53 nanomaterials reported as being in-commerce in Canada through a mandatory survey under section 71 of CEPA 1999.

## Risk assessment summaries of new nanomaterials

Health Canada and Environment and Climate Change Canada are increasing the transparency of the [New Substances Program](#) by publishing summaries of environmental and human health risk assessments for new substances.

The nanomaterial risk assessment summaries for notifications received as of January 1, 2013 are posted on a regular basis.

For more information and to see the full list of risk assessment summaries for chemicals and polymers, visit: [new substances risk assessment summaries: chemicals and polymers](#).

## Existing nanomaterials screening assessments

In 2021, the Government of Canada initiated screening assessments of the nanoscale forms of nano zinc oxide and nano titanium dioxide. These substances were identified as a priority based on use, quantities in commerce and potential exposure of humans and the environment.

The Government of Canada is welcoming any additional information on these two substances. To provide information, or to fill a declaration of stakeholder interest and to be informed of developments in these assessments, please contact [substances@ec.gc.ca](mailto:substances@ec.gc.ca).

# Information gathering

## Mandatory survey - section 71 notice

On July 25, 2015, a notice was issued in the [Canada Gazette, Part I: Vol. 149, No. 30 – July 25, 2015](#) under section 71 of CEPA 1999. The notice applied to the nanoscale forms of [206 substances](#) listed in the notice. The purpose of the notice was to determine the commercial status of these nanomaterials in Canada to help inform prioritization activities and decision-making for the assessment of existing nanomaterials. Table 1 lists substances surveyed that were reported to be in commerce.

**Table 1. Nanoscale substances reported to be in commerce out of the 206 substances surveyed**

CAS RN	Substance name
471-34-1	Carbonic acid calcium salt (1:1)
1302-87-0	Clays
1305-62-0	Calcium hydroxide (Ca(OH) <sub>2</sub> )
1305-78-8	Calcium oxide (CaO)
1305-79-9	Calcium peroxide (Ca(O <sub>2</sub> ))
1306-38-3	Cerium oxide (CeO <sub>2</sub> )
1309-37-1	Iron oxide (Fe <sub>2</sub> O <sub>3</sub> )
1309-42-8	Magnesium Hydroxide (Mg(OH) <sub>2</sub> )
1309-48-4	Magnesium oxide (MgO)
1313-13-9	Manganese oxide (MnO <sub>2</sub> )
1313-99-1	Nickel oxide (NiO)
1314-13-2	Zinc oxide (ZnO)
1314-23-4	Zirconium oxide (ZrO <sub>2</sub> )
1317-34-6	Manganese oxide (Mn <sub>2</sub> O <sub>3</sub> )
1317-38-0	Copper oxide (CuO)
1317-61-9	Iron oxide (Fe <sub>3</sub> O <sub>4</sub> )

CAS RN	Substance name
1327-36-2	Aluminatesilicate
1332-37-2	Iron oxide
1333-84-2	Aluminum oxide, hydrate
1344-28-1	Aluminum oxide (Al <sub>2</sub> O <sub>3</sub> )
1344-43-0	Manganese oxide (MnO)
1345-25-1	Iron oxide (FeO)
7439-89-6	Iron
7440-22-4	Silver
7631-86-9	Silica
7758-87-4	Phosphoric acid, calcium salt (2:3)
7778-18-9	Sulfuric acid, calcium salt (1:1)
9004-32-4	Cellulose, carboxymethyl ether, sodium salt
9004-34-6	Cellulose
9004-36-8	Cellulose, acetate butanoate
9004-39-1	Cellulose, acetate propanoate
9004-57-3	Cellulose, ethyl ether
9004-58-4	Cellulose, ethyl 2-hydroxyethyl ether
9004-62-0	Cellulose, 2-hydroxyethyl ether
9004-65-3	Cellulose, 2-hydroxypropyl methyl ether
9004-70-0	Cellulose, nitrate
9032-42-2	Cellulose, 2-hydroxyethyl methyl ether
12004-35-2	Aluminum nickel oxide (Al <sub>2</sub> NiO <sub>4</sub> )
13463-67-7	Titanium oxide (TiO <sub>2</sub> )

CAS RN	Substance name
14059-33-7	Bismuth vanadium oxide ( $\text{BiVO}_4$ )
20344-49-4	Iron hydroxide oxide ( $\text{Fe}(\text{OH})\text{O}$ )
24623-77-6	Aluminum hydroxide oxide ( $\text{Al}(\text{OH})\text{O}$ )
63231-67-4	Silica gel
67762-90-7	Siloxanes and Silicones, di-Me, reaction products with silica
68187-51-9	Unspecified (predominantly iron zinc oxide ( $\text{Fe}_2\text{ZnO}_4$ ))
68610-92-4	cellulose, ether with $\alpha$ -[2-hydroxy-3-(trimethylammonio)propyl]- $\omega$ -hydroxypoly(oxy-1,2-ethanediyl), chloride
68611-44-9	Silane, dichlorodimethyl-, reaction products with silica
68909-20-6	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica
68937-51-9	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, reaction products with ammonia, octamethylcyclotetrasiloxane and silica
68988-89-6	Silica, [(ethenyldimethylsilyl)oxy]- and [(trimethylsilyl)oxy]-modified
69012-64-2	Fumes, silica
112926-00-8	Silica gel, pptd., cryst.-free
112945-52-5	Silica, amorphous, fumed, cryst.-free

Another section 71 survey may be issued on the substances that were previously identified as being in-commerce at the nano-scale in Canada (Table 1), and subsequently prioritized for assessment. If necessary, this second survey would enable the program to collect

information that will be used in the risk assessments.

## Approach to address nanomaterials on the Domestic Substances List

The Government of Canada has undertaken a stepwise approach to address nanoscale forms of substances on the DSL. The proposed approach consists of 3 phases:

- establishment of a list of existing nanomaterials in Canada
- prioritization of existing nanomaterials for risk assessment
- action on substances identified for further work

The approach was first described in a consultation document entitled Approach to nanoscale forms of substances on the Domestic Substances List, published on March 18, 2015. This consultation document was open for a 60-day public comment period to solicit feedback from stakeholders.

A second consultation document entitled Prioritization approach for nanoscale forms of substances on the Domestic Substances List was published on July 27, 2016. In this document, the approach proposed for prioritization of existing nanomaterials on the DSL is described, taking into consideration the results of the section 71 notice.

## International and domestic activities and cooperation

### Organisation for Economic Co-operation and Development Working Party on Manufactured Nanomaterials

Canada is an active member of the Organisation for Economic Co-operation and Development (OECD) Working Party on Manufactured Nanomaterials (WPMN). The WPMN addresses human health and environmental safety of manufactured nanomaterials and examines approaches for their safety testing and risk assessment. The OECD has also published guidance documents and test guidelines related to nanomaterials.

Companies should consider Publications in the Series on the Safety of Manufactured Nanomaterials when generating data for the notification of a new nanomaterial under the *New Substances Notification Regulations (Chemicals and Polymers)*.

# International Organization for Standardization Technical Committee 229 – Nanotechnologies

Government of Canada actively participates in different working groups under the International Organization for Standardization Technical Committee 229 ([ISO TC 229](#)), working on a number of projects related to the development of terminology and nomenclature, measurement and characterization, health, safety, and environment aspects, as well as products and applications.

## Regulatory Cooperation Council Nanotechnology Initiative

The purpose of the [Canada-United States Regulatory Cooperation Council \(RCC\)](#) Nanotechnology Initiative is to better align the two countries' regulatory approaches. As part of the [Assessment Collaboration Framework](#), there have been successive efforts to consult on ongoing initiatives, such as developing the Framework for the Risk Assessment of Manufactured Nanomaterials under the *Canadian Environmental Protection Act, 1999*, and Data gap analysis of nanoscale forms of substances on the Domestic Substances List: a human health perspective. Future collaborations on near- or long-term initiatives are being explored.

## Related publications

### Guidance documents

For general guidance related to the administration of the *New Substances Notification Regulations (Chemicals and Polymers)*, including guidance on nanomaterials, visit:

- [Guidance document for the New Substances Notification Regulations \(Chemicals and Polymers\)](#)

### Orders

Published orders can include ministerial conditions, ministerial requests for additional information, ministerial prohibitions, significant new activity notices, and waivers. For information on these orders, visit:

- [Canadian Environmental Protection Act Registry: Notices, orders and permits](#)

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