

New Substances Program Advisory Note 2007-06

Requirements for nanomaterials under the *New Substances Notification Regulations (Chemicals and Polymers)*

This advisory note is to inform manufacturers and importers of nanomaterials and any other stakeholders of the requirements for the substances under the *New Substances Notification Regulations (Chemicals and Polymers)*.

Background

Under the provisions of the *Canadian Environmental Protection Act, 1999* (the Act), the *New Substances Notification Regulations (Chemicals and Polymers)* [the Regulations] ensures that any new substance (whether a chemical or polymer) undergoes a risk assessment of its potential effects on the environment and human health.

If you manufacture in or import into Canada a new substance, you may be required to notify information with respect to this substance pursuant to the Act and the Regulations. The Act requires that the prescribed information under the Regulations be submitted to the Minister of the Environment prior to exceeding specific regulatory triggers either through the manufacture or import of a new substance.

The Domestic Substances List (DSL) is the sole basis for determining whether a substance is new. Any chemical or polymer not listed on the DSL is considered to be new to Canada and is subject to the notification requirements under the Regulations. Substances listed on the DSL do not require notification¹ in advance of manufacture in or import into Canada.

The Act and the Regulations apply to new nanomaterials just as any other substance, whether a chemical or a polymer.

What is considered a nanomaterial?

Although there is no internationally recognized definition of this type of substance, nanomaterials can be described generally as substances having one or more dimensions in a nanoscale range, typically² between 1-100 nanometers.

¹ Exceptions include those substances listed on the DSL and identified with a) an "S" flag that are proposed for manufacture or import and used for a significant new activity as defined in the Significant New Activity Notice published for that substance, and b) a "P" flag and where the polymer substance proposed for manufacture or import is in a form that no longer meets the Reduced Regulatory Requirement polymer criteria.

² Note: certain nanomaterials fall outside the typical nanoscale range. For example, fullerenes (bucky balls) have all three dimensions smaller than 1 nanometer, while quantum dots may have all three dimensions greater than 100 nanometers.

Canada is collaborating with international partners through the International Organization for Standardization (ISO) to develop standard terminology and a formal nomenclature system for nanomaterials.

What are the requirements under the Regulations for nanomaterials which are manufactured or imported?

Nanomaterials which are manufactured³ in or imported into Canada are subject to the same regulatory requirements as chemicals and polymers, and notifiers must submit a New Substances Notification package prior to the manufacture in or import into Canada of the new substance (refer to *Guidelines for the Notification and testing of New Substances: Chemicals and Polymers*, Version 2005).

Although not required, Environment Canada and Health Canada recommend notifiers request a Pre-notification Consultation (PNC) during the planning or preparation of a notification. For example, a notifier can request a PNC to assist with determining whether the substance is notifiable, as well as to clarify notification procedures or information requirements, and to determine the acceptability of waiver requests and/or test protocols.

What nanomaterials are subject to the Regulations?

Nanomaterials which are manufactured in or imported into Canada that are not listed on the DSL are considered new. The nanoscale form of a substance on the DSL is considered a “new” substance if it has unique structures or molecular arrangements. New nanomaterials are subject to notification under the Regulations. For example, the nanomaterial fullerene (CAS No. 99685-96-8) is not listed on the DSL and is considered a “new” substance under the Regulations.

What nanomaterials are not subject to the Regulations?

Substances listed on the DSL whose nanoscale forms do not have unique structures or molecular arrangements are considered existing. Existing nanomaterials are not subject to the Regulations and do not require notification. For example, titanium dioxide (CAS No. 13463-67-7) is listed on the DSL and since its nanoscale form does not have unique structures or molecular arrangements, it is not subject to the Regulations.

In addition, incidentally produced or naturally occurring nanomaterials are not subject to notification.

³ Manufactured nanomaterials are purposefully made, in contrast to incidentally produced or naturally-occurring nanoscale materials. They may be manufactured through chemical and/or physical processes to create materials with different or enhanced properties and/or structures compared to the macroscale material.

Contact Information

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For additional information or documentation regarding the Regulations, please visit the New Substances Web site at http://www.ec.gc.ca/substances/nsb/eng/home_e.shtml.

Original signed by

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Signed on June, 2007
