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# **New Substances Program Advisory Note 2014-02**

**Assessment of nanomaterials under the *New Substances  
Notification Regulations (Chemicals and Polymers)***

The purpose of this advisory note is to inform Canadian manufacturers and importers that **new substances** that fall within the nano-scale size range (1 -100 nanometres) must be notified under the *New Substances Notification Regulations (Chemicals and Polymers)*.

It is also meant to inform notifiers that information on particle size and particle size distribution will likely be requested for substances that fall in certain chemical classes.

## Background

The New Substances (NS) program must ensure that new substances, including substances that are at the nano-scale (i.e. nanomaterials), are assessed to determine if they are toxic or capable of becoming toxic, as required by the *Canadian Environmental Protection Act, 1999* (the Act). The approach to the control of new substances is both proactive and preventative, employing a pre-manufacture and pre-import notification and assessment process.

The Domestic Substances List (DSL) is the sole basis for determining whether a substance is new for the purposes of the Act. Substances listed on the DSL do not require notification unless they are subject to the Significant New Activity (SNAc) provisions of the Act as indicated with an 'S flag' on the DSL. For extra clarity, nano-scale forms of substances listed on the DSL are not subject to notification. Substances, including nanomaterials, not appearing on the DSL are considered to be new to Canada and are subject to notification under *the New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations).

## Assessment of Nanomaterials under the New Substances program

Nanomaterials typically have larger surface-to-volume ratios relative to their non-nanoscale forms, which can lead to greater reactivity. They may also exhibit changes in other chemical and physical (e.g. optical, magnetic, electric) properties that cannot be predictably extrapolated from their non-nanoscale forms. These differences may increase or decrease nanomaterials' potential to cause harm to humans and the environment and additional information may be needed to further evaluate these potential concerns.

In line with the 2013 OECD Council Recommendation<sup>1</sup>, Canada is using its existing chemical regulatory framework to manage nanomaterials, making adaptations where necessary to take into account the specific properties of nanomaterials.

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<sup>1</sup> Organisation for Economic Cooperation and Development (OECD). 2013. *Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials*. Available online at: <http://acts.oecd.org/Instruments/ShowInstrumentView.aspx?InstrumentID=298&InstrumentPID=314&Lang=en&Book=False>

Although there is no internationally recognized regulatory definition for this type of substance, the New Substances (NS) program is using the *Health Canada Working Definition for Nanomaterial* as the basis for identifying these types of substances: “(1) having one or more dimensions (or internal or surface structure) at the nanoscale (1-100 nanometers inclusive); or (2) exhibiting nanoscale-related phenomena above or below the nanoscale.”

Within this definition, the NS program may request information on particle size and particle size distribution in order to determine if a notified substance is on the nanoscale. The NS program would request this information by contacting the notifying company directly as early as possible in the evaluation period. Providing this information will allow for better identification of new chemicals as nanomaterials, leading to more informed risk assessment and if necessary, more appropriate control measures. While the Regulations prescribe the information that must be submitted to the NS program, they also generally require the submission of all other information and test data in the manufacturer or importer’s possession or to which they ought to have access.

Information on particle size and particle size distribution will generally be requested for substances that fall into certain chemical composition-based “classes”, which were developed as part of the Canada-United States Regulatory Cooperation Council Nanotechnology Initiative<sup>2</sup>. Scientific literature and NS program experience indicates that nanomaterials within these classes are likely to behave differently than their non-nanoscale forms. The classes are:

1. Carbon nanotubes
2. Inorganic carbon (e.g. fullerenes, graphene, graphitic sheets)
3. Metal oxides and metalloid oxides
4. Metals, metal salts and metalloids
5. Semi-conductor quantum dots

The NS program may also request information on particle size and particle size distribution for substances that fall outside these classes if there is sufficient evidence that they behave differently than their non-nanoscale form. These categories will be revisited from time to time as new information becomes available and science evolves to determine if changes to these categories may be required.

In accordance with the Regulations, risk assessments of nanomaterials will be conducted on a substance-specific basis. The outcomes of each individual risk assessment will determine whether any control measures, such as Significant New Activity (SNAc) Notices, are required.

As is currently done, the NS program may request certain nano-specific information in control measures (e.g. SNAc Notices). This information would be used to improve the accuracy in nanomaterial risk assessments. The information could include, but is not limited to:

- physicochemical properties specific to each class of nanomaterial<sup>3</sup>;
- agglomeration (aggregation) state, shape, surface area and surface charge of the substance;
- leachability potential of the substance and its precursors from a final product;

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<sup>2</sup> For more information about the classes, including the nano-specific physicochemical information of interest for each class, a Regulatory Cooperation Council Nanotechnology Initiative document is available upon request.

<sup>3</sup> Ibid

- ecotoxicity data and tests; and
- human health toxicity data and tests.

### **Pre-Notification Consultation**

Although not required, the NS Program recommends notifiers of nanomaterials request a Pre-notification Consultation (PNC). A PNC is an option for any person who wishes to consult with the NS Program during the planning or preparation of their New Substances Notification (NSN) package to discuss any questions or concerns they have about the required prescribed information, and to determine the acceptability of waiver requests and/or test protocols. PNCs for nanomaterials could also be used to discuss specific nano considerations, such as additional data that could support the risk assessment, and guidance on test methods.

### **Contact Information:**

If you have any questions, please contact the Substances Management Information Line:

Telephone: 1-800-567-1999 (toll-free in Canada)  
1-819-938-3232 (outside Canada)

Facsimile: 1-819-938-3231

E-mail: [substances@ec.gc.ca](mailto:substances@ec.gc.ca)

You may also visit the New Substances Web site at <http://www.ec.gc.ca/subsnouvelles-newsubs/>

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Signed on July 28, 2014