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CSM
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PREVENT CANCER NOW

May 25, 2015

David Morin
Director General
Science and Risk Assessment Directorate
Environment Canada
c/o Substances Management Information Line
Chemicals Management Plan
Gatineau, QC K1A 0H3

Transmission by e-mail: substances@ec.gc.ca

Dear Mr. Morin:

Re: NGOs Response to consultation document – Proposed Approach to Address Nanoscale Forms of Substances on the Domestic Substances List

The Canadian Environmental Law Association (CELA), Chemical Sensitivities Manitoba (CSM) and Prevent Cancer Now (PCN) are submitting the following comments in response to the consultation document titled, *"Proposed Approach to Address Nanoscale Forms of Substances on the Domestic Substances List,"* released in March 2015.[1]

Present overview

Over the years, CELA and CSM submitted substantial comments related to the adequacy of the assessment framework addressing nanomaterials in Canada. The present consultation document represents a partial approach for the adequate identification, assessment and management of nanomaterials in commerce in Canada. The consultation document focuses on the listing of existing nanomaterials with consideration given to setting priorities. A clear commitment defining the timelines for completion of the work should be made available to the public.

[1] Environment Canada. March 2015. Consultation Document: Proposed Approach to Address Nanoscale Forms of Substances on the Domestic Substances List. http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=1D804F45-1

Nanomaterials have been used for many years in diverse Canadian products and applications. Exploitation of the diverse properties of nanomaterials in consumer products has led to rapid increases of types and quantities of these materials to which Canadians are being exposed. Health concerns have been identified principally on the basis of the very small size of nanomaterials that may permit them to pass through cellular membranes, as well as material-specific effects. Much of the evidence showing impacts of nanomaterials have focused on the occupational setting, but there are many data gaps regarding public health effects and environmental impacts. For example, one area of burgeoning business is nano-food packaging utilizing nanomaterials such as nanosilver and nanoclay, but yet the degree of migration of these materials to the packaged food product and possible subsequent human health effects from the migrated nanomaterial, are still not defined.[2]

We acknowledge the progress made in assessing new nanomaterials under the New Substances Program and Health Canada's development of a working definition for nanomaterials; however, the New Substances Program is generally inaccessible to the general public. Within the legal framework as outlined in the *Canadian Environmental Protection Act*, 1999 (CEPA), the public does not have opportunities to comment on the assessment and risk management of any new nanomaterial.

Future context

The research and economic incentives associated with nanomaterials are expected to continue to grow substantially, so although the present consultation is in the context of existing nanomaterials, the framework and criteria introduced in the current proposal will be relevant to upcoming substances. It is our opinion that the present methodology will not be adequate to keep pace with the nanomaterials and nano-containing products in coming years. We see the proposed work as an important component of the work that is needed on nanomaterials; however, a comprehensive policy and regulatory framework is required for Canada.

[2] Nattinee Bumbudsanpharoke, Seonghyuk Ko. May 2015. Nano-food Packaging: An Overview of Market, Migration Research, and Safety Regulations. Journal of Food Science. 80(5): R910-R923.

Comprehensive, Precautionary Approach to Nanomaterials Needed

In addition to the present consultation, the current efforts on nanomaterials under the Regulatory Cooperation Council (RCC) framework undertaken by Canada and the United States will result in new information being collected and reviewed. While these efforts provide an advantage for both jurisdictions, no improvements over the current system are evident to provide more transparency with respect to public access to risk assessment and risk management documents and opportunities to provide comments. As a result, public stakeholders are unable to decipher how the government makes its final decisions on these substances. It is particularly problematic that there is a lack of knowledge of the government's ongoing efforts in assessing the persistence, bioaccumulative or inherently toxic properties of new nanomaterials that could have the potential to embed themselves in mitochondria and nuclei of living cells. This issue becomes even more critical when there could be significant data gaps for these new substances.

We echo our on-going concerns regarding the lack of transparency in the current New Substances Regulation framework, that parallel our concerns regarding the government's proposed approach to the factors required to prioritize and assess existing nanomaterials on Canada's Domestic Substances List (DSL). The proposed approach to identify, prioritize, and subsequently assess existing nanomaterials is grounded in a risk-based approach, and is therefore reactive – waiting until harm ensues and has eventually been proven. The government should establish a framework that focuses on a preventative approach that places greater emphasis on avoiding inherently hazardous properties that could be associated with nanomaterials, rather than an approach that relies heavily on estimating exposure risks.

By way of explanation, given the inherently hazardous properties of nanomaterials, establishing a preventative approach that adequately analyzes imported nanomaterials and manufactured products containing nanomaterials before they are allowed to enter the marketplace, will represent substantial strides towards the protection of the environment and human health. A risk based approach would permit the introduction of nanomaterials (with their inherent hazards), to the point where excessive human exposure and/or environmental release have been demonstrated. This will be evident only after considerable harm has ensued. We continue to urge

the government to establish an approach for nanomaterials through a regulatory framework that is rigorous and precautionary, and one that promotes prevention at the onset.

The following are our responses to the questions in the consultation document:

A. LIST OF EXISTING NANOMATERIALS:[3]

1) Is the list of nanomaterials in Appendix A of this document a good preliminary reference list?

The list of nanomaterials on the DSL represented in Appendix A is a starting point towards the development of a nanomaterials inventory but it may not have captured all the nanomaterials currently on the DSL. The updated list of nanomaterials on the DSL would require validation. This process should be supported through a data call in or inventory update issued by the Government through a CEPA section 71 survey for nanomaterials in the Canadian market. Any nanomaterial not captured through the survey will be automatically subject to the New Substances Notification Regulations (NSNR). (See response to Question 3 below).

The use of identical Chemical Abstract Services Registration Numbers (CAS RNs) for both the nanoscale and the macroscale of chemicals with the same chemical composition and the lack of accurate nomenclature for nanomaterials have significantly hindered the formation of an accurate list of nanomaterials currently on the DSL. For example, the same CAS RN is used for the nanoform and the macroscale for each of these substances - titanium dioxide (TiO_2), zinc oxide (ZnO) and silver (Ag), while a variety of CAS RNs are used for the pure carbon materials: carbon black (1333-86-4), fullerene C60 (99685-96-8), and elemental carbon (7440-44-0). Nanomaterials require distinct CAS numbers, or perhaps a CAS number suffix to indicate nanomaterial properties (the latter would retain unique identification of chemical composition).

Some substances listed in Annex A require additional descriptions for clarification. For example: Clays with CAS RN: 1302-87-0, should include additional information to outline whether these bentonite clays have surface treatments. This information would more accurately describe the clay.

[3] Ibid. Appendix A

Appendix A suggests that fullerenes and other carbon based nanomaterials including carbon fibers are not on the DSL. We would include these substances to be on the DSL. Additional information to clarify this observation is necessary.

For consideration is a list of nanomaterials that could possibly be on the DSL but are not included in Appendix A:

- Lead molybdate - silica modified
- Carbon black and carbon-based nanosubstances (e.g. C60 fullerenes, carbon nanotubes)
- Calcium carbonate
- Talc
- Alumina trihydrate
- Fillers e.g. calcium carbonate, talc and alumina trihydrate, treated with silanes, titanates, zirconates
- Titanium dioxide (anatase and rutile grades) with silane pretreatment
- Platinum compounds
- Barium sulphate
- Indium tin oxide
- Catalysts

It is essential that any exclusions of specific nanomaterials in Appendix A (e.g. more extensive list of pigments), must be accompanied by specific references and rationale that demonstrate the absence of these substances in the Canadian market. For the purposes of the proposed approach, Appendix A should include the list of substances above.

NOTE: In Appendix A, CAS RN 69012-64-2 Fumes, silica – should be Fumed.

2) What additional criteria could be considered to identify existing nanomaterials?

Additional criteria to further identify existing nanomaterials could include claims of unique physicochemical properties and uses that are not consistent with the macroscale counterpart of the nanoscale substance. Such criteria could include the following:

- improved strength, flexibility, lightness particularly for sporting goods;
- electrical, magnetic and optical properties;
- anti-bacterial/antimicrobial/preservative properties;

- air and water purification;
- usage in textiles to significantly improve water and stain resistance but not impact breathability;
- use as a potent sun protector in cosmetics;
- pesticide use;
- suggestions that a substance could be used an indicator for food spoilage or as a temperature indicator in food packaging;
- catalysis, to speed reactions in chemical synthesis, manufacturing or as a surface treatment; or
- occupational health claims and toxicity data with respect to the environment that are not consistent with the macroform of a substance, may also provide important evidence implying the use of a nanomaterial.

This type of information may not be readily available for nanomaterials related to the DSL list.

While determining the properties of nanomaterials, it is important to consider the end of life breakdown products of these substances, particularly if they penetrate biological structures (e.g. cells and organelles), or tend to remain in different environmental zones as compared to their macroscale counterparts (e.g. remaining airborne, thereby offering greater exposure potential, and migrating greater distances).

3) What methods can be used to collect information to develop a more comprehensive list or verify information on existing nanomaterials in commerce in Canada?

With nanomaterials being used in so many sectors and the lack of any legal requirement for labeling to indicate their presence in industrial and consumer products, both Canadian and non-Canadian data sources should be utilized to develop a more comprehensive list or/and verify information on existing nanomaterials in commerce in Canada.

Similar to the approach taken to establish the Domestic Substances List in 1988 through the *Canadian Environmental Act* and subsequent inventory updates, it may be more appropriate to consider a parallel system specifically for nanomaterials. This approach would place greater

responsibility for accountability on manufacturers and importers of nanomaterials because if these substances are not identified or submitted through this inventory update, they would automatically be subjected to the NSNR.

The government's proposed approach may not result in defining a complete list of nanomaterials in commerce in Canada.

Below, is a starting list of databases or contacts that could provide useful information, although verification would be required of the Canadian use of any nanomaterial:

a) Woodrow Wilson Database

An inventory of nanotechnology-based consumer products on the US market. (See: http://www.nanotechproject.org/cpi/)

b) The Household Products Database of the National Library of Medicine (US)

(See: http://hpd.nlm.nih.gov/about.htm)

c) Consumer Product Information Database

This database has a listing of nano-products and an ingredients list with a CAS RN for each product; however, it does not specify which ingredient is in the nanoscale. (See: http://whatsinproducts.com/index.php)

d) Inventory Update

As mentioned in the Consultation Document, a mandatory data call-in for nanomaterials through the use of a Section 71 survey would help to determine the accuracy of Appendix A, and detect the presence of other nanomaterials that are present on the DSL. This approach would provide some basic information for prioritization. The level of information required through the Section 71 survey should not be restricted by a volume threshold since there is significant value to understand initially the range of nanomaterials and products that are in the Canadian market.

Nanomaterial applications are developing rapidly, so it is possible that a material that would not meet a volume threshold today might soon surpass the threshold.

The survey should be completed by recipients, including importers and manufacturers (throughout the supply chain). Industry associations may be helpful in facilitating the completion of such surveys with their members, as nanomaterials are used in a wide variety of sectors. The survey should request information such as:

- The respondent's definition of a nanomaterial;
- Whether the substance is intended to be used as a nanomaterial;
- Chemical name, CAS RN, chemical formula (when applicable) of the nanomaterial;
- All synonyms for this nanomaterial;
- Any claims for a difference in properties of the nanoform and the macroform of the substance;
- Particle size (smallest and other dimensions) and particle size distribution;
- Particle size description (encapsulated, spherical, cylindrical, etc.);
- Use patterns;
- Whether the substance is intended for use in children's products, with details of use and the types of expected exposures;
- A list of known breakdown products (including nanoscale forms);
- Availability of toxicological data (persistence, physiological distribution and bioaccumulation, endocrine disruption, neurodevelopmental toxicity, carcinogenicity, mutagenicity, aquatic and terrestrial distribution and toxicity, etc.) relevant to human health and the environment;
- Indication of whether monitoring and surveillance programs are in place for the nanomaterial;
- Present quantities used, manufactured, imported, recaptured/recycled and released per annum, and recent historical trends, relevant to Canada;
- Reporting of releases to air, soil and water to Canada's National Pollutant Release Inventory (NPRI).

The above approach should emphasize the need to collaborate with key government departments within Health Canada including the Pest Management Regulatory Agency, Consumer Product Safety, the Food Directorate, and Industry Canada, as nanomaterials on the DSL could be used in more than one sector.

4) What other sources of information are available to determine the commercial status of existing nanomaterials in Canada?

A formal multi-stakeholder technical work group to address evaluation and management of nanomaterials in Canada should be formed by government to establish transparent and accountable dialogue between government, industry, academia, and non-governmental organizations. Apart from being beneficial to the process, this working group would also be better positioned to promote alignment with the regulatory framework. The absence of such a work group adds to the complexity of accurately detecting and verifying the presence of nanomaterials on the DSL, reducing transparency and accountability in the system. (This recommended group would be separate from the Technical Expert Group for nanomaterials established within the Regulatory Cooperation Council and the Nanotechnology Sub-committee of the Industry Coordinating Group for the *Canadian Environmental Protection Act).*

Other sources of information to determine the commercial status of existing nanomaterials in Canada include:

- Green Chemistry organizations or similar organizations in Canada and the U.S. may help to identify nanomaterials that are probably in commerce in Canada, from which the government could subsequently determine the commercial status.
- Continued contact with academia in the field of nanotechnology and nanotechnology organizations in Canada, the U.S., European Union and Asia.

5) What barriers exist to obtaining/providing information on existing nanomaterials in Canada?

- The absence of a clear legislative framework in Canada that would more clearly address nanomaterials has engendered a reactive approach. The lack of a comprehensive Canadian

inventory list of imported or manufactured products (consumer and commercial) containing nanomaterials, adds to the complexity of compiling information on these substances on the DSL. At present, this is not feasible until the existing nanomaterials have been verified and more information about their uses are identified.

- It is unclear if the nanomaterials listed in Appendix A, and intended to be listed, include nanomaterials that are in imported manufactured (consumer and industrial) goods. If not, the government approach should require inclusion of nanomaterials in imported products. While this may create significant challenges and it is a labour intensive effort, it is essential that responsibility lies with the importer. The government should communicate to its industry stakeholders the importance of this type of information. The government has been effective in information gathering through the use of other surveys to reach out to manufacturers and suppliers. Eventually, this type of information would better inform the government as to the ingredients of imported manufactured goods entering the country and the end of life management options.
- The premature exclusion of known nanomaterials in the monitoring and surveillance program contributes to the difficulty in identifying these substances in the marketplace. (Nanomaterials that have been known to be in the marketplace for several years are known to have the potential to negatively impact human health or the environment).
- Lack of consensus for the nomenclature of nanomaterials adds to the complexity of identifying and obtaining comprehensive, unambiguous information on nanomaterials.
- Canada's main environmental legislation, CEPA, does not currently recognize nanomaterials in its legislation. The absence of the specific recognition of nanomaterials creates substantial challenges in establishing appropriate criteria to identify nanomaterials as well as outlining the requirements for conducting assessment and, where warranted, managing nanomaterials.

B) PRIORITIZATION OF EXISTING NANOMATERIALS

The exercise of the prioritization of existing nanomaterials should be a baseline for the work that will ultimately be done to assess the potential risks related to the exposure to nanomaterials. As a result, it is assumed that prioritization will ultimately include the identification of nanomaterials of lower concern, as well as those that require further consideration.

Please note that the questions in this section lack clarity and should have provided definitions for key terms such as ‘factors’ and ‘outcomes’. As a result, responses to the following questions may not have been provided in a comprehensive and complete manner.

Additional public consultation is required on the prioritization process.

1) ***What factors should Environment Canada and Health Canada consider when prioritizing nanomaterials?***

- Nanomaterials may exert toxic effects as a result of particle characteristics (e.g. similar to asbestos) as particles may access subcellular spaces. There are also toxicities inherent to the substance itself (e.g. toxic metals), that may escape/dissolve from particles, once the particle has gained access to the cellular space. Attempting to group similar substances for prioritization and subsequent assessment can have significant limitations at this stage since health and environmental data on nanomaterials do not appear to be readily available. The possible use of read-across and analogs to address data gaps for these substances raises concerns with regards to the acceptance of any uncertainty associated with the data.
- There should be communication with other jurisdictions, industry and stakeholders (e.g. academics, etc.) in an attempt to fill data gaps in the prioritization process.
- Attention should be given to nanomaterials that in their macroform are known carcinogens, endocrine disruptors or sensitizers. Also, any data indicating persistence, bioaccumulation and biodistribution, or inherent toxicity, are also considerations that require top priority when prioritizing nanomaterials.
- Nanomaterials that are fibers or in tubular form may have the potential to have properties similar to asbestos with regards to carcinogenicity. Priority should be given to these substances in terms of occupational exposures, and their incorporation into consumer and industrial products.
- The recommended uses for a nanomaterial, particularly if it is intended for products that target children or pregnant women, should be clearly defined in any nanomaterial survey.

2) ***What outcomes should Environment Canada and Health Canada consider when prioritizing nanomaterials?***

The factors listed above for consideration for the prioritization of nanomaterials by Environment Canada and Health Canada are all essential pieces of data when attempting to prioritize these substances. The need for prioritization should focus on promoting preventative approaches in the use of nanomaterials. Such an approach will rely on a framework that places emphasis on avoiding specific inherent hazardous properties in nanomaterials. For example, persistence and bioaccumulation should be key elements for prioritization. Similarly, nanomaterials that demonstrate specific toxicity impacts such as carcinogencity, neurodevelopmental toxicity or endocrine disruption, should also be factors for prioritization in prevention. In this approach, consideration for risk of exposure should not be the primary focus.

- It should be noted that there could be 'nanoscale behaviour' for some chemicals with particle dimensions greater than 100nm and chemical structures that would not normally be cause for concern. How these would be detected is not well established. There would have to be some reliance on data from other jurisdictions in order to make comparisons to the present list of nanomaterials that are on the DSL as well other non-nanomaterials substances that are currently on the DSL.
- Lifecycle considerations are also important with respect to how a nanomaterial will be used. Furthermore, identification and evaluation of all breakdown products or metabolites and their impacts to the environment or human health are necessary.
- A piecemeal approach will not provide a comprehensive strategy for nanomaterials in Canada. The government should consider a categorization exercise similar to that applied to the DSL in 2000. An initial inventory update will be required before a categorization approach could be applied. A categorization approach for nanomaterials will provide substantial advancement in understanding the toxicity and environmental fate of these materials. The government's proposed approach for nanomaterials on the DSL could not be effectively achieved without establishing a legal obligation that outlines more nano-specific criteria for categorization beyond persistence, bioaccumulation and inherent toxicity. Specific timeframes in which to undertake this work would also have to be defined.

Resources:

Development of an inventory for consumer products containing nanomaterials - Final Report. 2010 http://ec.europa.eu/environment/chemicals/nanotech/pdf/study_inventory.pdf

Jeffrey Wong. November 2013. Department of Toxic Substances Control, California Environmental Protection Agency. Presentation for the Sustainable Nanotechnology Organization, Santa Barbara, CA
http://www.susnano.org/images/sessions2013/P6Wong%202013SCPRNanoTalkv11.pdf

Molly M. Jacobs, et al. March 2014. Precarious Promise: A Case Study of Engineered Carbon Nanotubes. University of Massachusetts Lowell.
http://www.sustainableproduction.org/downloads/ECN_casestudy_0325.pdf

Contacts:

Fe de Leon
Researcher
Canadian Environmental Law Association
Tel: 416 960 2284
Email: deleonf@cela.ca

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Sandra Madray
Chemicals Sensitivities Manitoba
Tel.: 204 256 9390
Email: madray@mts.net

Meg Sears PhD
Co-chair
Prevent Cancer Now
Tel: 613 832 2806
Email: meg@preventcancernow.ca