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CANADIAN ENVIRONMENTAL LAW ASSOCIATION
*L'Association canadienne du droit de l'environnement*

November 15, 2007

Bernard Madé
Director
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Environment Canada
351 St. Joseph Blvd, 14th floor
Gatineau, QC K1A 0H3

**Re: Proposed Regulatory Framework for Nanomaterials under the *Canadian Environmental Protection Act, 1999***

Dear Mr. Madé,

Thank you for the opportunity to provide comments on the discussion paper on a Proposed Regulatory Framework for Nanomaterials under the *Canadian Environmental Protection Act, 1999*.

The Canadian Environmental Law Association (CELA)(www.cela.ca) is a public interest group founded in 1970 for the purpose of using and improving laws to protect the environment and conserve natural resources. Funded as a community legal clinic specializing in environmental litigation, CELA also undertakes public education, community organization, and law reform activities. The Canadian Institute for Environmental Law and Policy (CIELAP) (www.cielap.org) was also founded in 1970, with the mission of providing leadership in the research and development of environmental law and policy that promotes the public interest and sustainability. In March 2007, CIELAP published a *Discussion Paper on a Policy Framework for Nanotechnology*. CIELAP was a delegate of the Canadian Environmental Network at the September 2007 consultations on Environment Canada's and Health Canada's Proposed Regulatory Framework for Nanomaterials under the *Canadian Environmental Protection Act, 1999*.

As set out in the discussion paper on a Proposed Regulatory Framework for Nanomaterials under the *Canadian Environmental Protection Act, 1999* (*CEPA*), Environment Canada and Health Canada have acknowledged that nanomaterials may not fit easily into the current New Substances Program. In particular, the current data requirements for more 'traditional' chemicals and polymers may not be appropriate to permit adequate risk assessments for nanomaterials. As a result these government departments are proposing the following approach for the development of a regulatory framework for nanomaterials under *CEPA*.

Health Canada and Environment Canada have proposed the following process for developing a regulatory framework addressing nanomaterials:

Phase I (began in Fall 2006):

- Continue to work with international partners to develop scientific and research capacities.
- Inform industry and the general public about the issues related to nanotechnology and nanomaterials, including information gathering initiatives and regulatory responsibilities under *CEPA*.
- Gather information from industry on uses, properties and effects of nanotechnology and nanomaterials.
- Consider whether legislative amendments to *CEPA* or amendments to the NSN Regulations are needed to facilitate risk assessment and the management of nanomaterials. For example, *CEPA* may be amended to provide the authority to require notification and assessment of "substances," or the definition of "substance" under s. 3 of *CEPA* could be amended to clearly include nanomaterials.

Phase II (to begin in 2008):

- Resolve terminology and nomenclature through the International Standards Organization.
- Consider establishing data requirements under the NSN Regulations specific to nanomaterials. Also consider modifying or developing test methods for nanomaterials.
- Consider using *CEPA*'s Significant New Activity provision to require the notification of nanoscale forms of substances that are already on the DSL where it is suspected that a significant new activity in relation to a substance already on the market might result in the substance becoming "toxic" as defined by *CEPA*.

At the present time, the environmental and health effects of nanotechnology and nanomaterials are largely unknown, although in a number of studies nanoscale particles have been found to be substantially more toxic and reactive biologically than larger particles of the same material. It is generally believed that nanotechnology is a "platform" technology that will profoundly affect virtually every sector of society, and that its development will be very important to the economic success of Canada in the future. However, despite nanotechnology's immense potential and significance, in Canada at present there is no formal regulatory or explicit public policy framework for managing the risks and benefits of this technology, nor for informing and consulting the public about the issues related to it.

It is clear that the regulatory environment, as well as the science surrounding risk assessment, classification of and management of nanotechnology and nanomaterials is globally lagging significantly behind technological development. Given the potential for toxicity in nanomaterials and the lack of knowledge about those toxic properties at present, CELA and CIELAP recommend that the proposed regulatory framework be developed carefully with strong input from all stakeholders and members of the public, and that the precautionary principle and pollution prevention strategies be applied throughout the work. It is equally imperative to emphasize that time is critical in furthering this work. Our experience with assessment and management of toxic substances over several decades demonstrates that a timely and effective regulatory response is necessary to fully protect against negative impacts on human health and the environment.

*Working with International Partners*

The federal government is working with the Organization for Economic Co-operation and Development (OECD) and the International Organization for Standardization (ISO) in international efforts to understand the properties, effects, and behaviours of nanomaterials.

Although the OECD Working Party on Manufactured Nanomaterials includes representatives from governments, industry, and non-governmental organizations (NGOs), the only NGO representation is currently arranged through Friends of the Earth Europe. By excluding public interest participation in these discussions, the government contravenes its own policy on public consultation. Instead, Canada should emphasize the need to expand engagement from the public interest community at the domestic level as well as the international level on these matters. Given that the international discussion has had significant influence on the discussions on nanotechnology in Canada to date, public engagement at the international level is essential in promoting transparency on decisions made and access to the information on the basis of which such decisions are made.

A model that should be followed for public engagement by Canadian NGOs at the international level is the intergovernmental negotiation sessions on persistent organic pollutants (POPs) resulting in the Stockholm Convention on Persistent Organic Pollutants. In these negotiations, the government provided space to representatives of three sectors -- environmental groups, aboriginal organizations and industry -- on the Canadian delegation. Not only did the stakeholders feel engaged and receive information in a timely manner, the stakeholders established a working relationship with government officials addressing the issues of POPs. This framework for public engagement included consultations conducted in a broad manner in preparation and response to government positions on the issue. While the OECD discussions will not result in an international agreement on nanotechnology, applying a similar model for public engagement in these discussions is critical and essential. Public interest organization, and environmental organizations in particular, have extensive networks globally to address issues related to nanotechnology.

**Recommendation: Based on the model of the intergovernmental negotiation sessions on POPs that resulted in the Stockholm Convention, Canada should fully engage and support the participation of Canadian public interest organizations; in particular, environmental, health, labour and first nations organizations should be engaged domestically in and for the OECD Working Group discussions on nanotechnology and nanomaterials.**

*Informing the Public*

Bringing civil society stakeholders into policy discussions very early in the process is both the right thing and the prudent thing to do for the development of robust, publicly acceptable policy on nanotechnology. It should be noted that some organizations including the ETC Group and the National Farmers Union, alarmed by the lack of government oversight and the speed of commercialization, have already called for a moratorium on the technology. Others will probably follow if tangible progress on policy and regulatory action is patently unable to keep up with commercial activity.

There are many models for consultative involvement in Canada, and it should be noted that citizen groups require resources to participate effectively. Government-run fora in which information flows mainly from government experts to the public are an outmoded and ineffective approach. The Internet has made an enormous difference in the ability of a motivated public to become informed about a topic, and the best motivator is a real opportunity to be effectively involved in shaping aspects of policy decisions. A one-stop, comprehensive, well-designed, and easy-to-use website, although not so easy to achieve, can be a useful component of providing information. Consideration should be given to building on the single information window used for biotechnology, especially since future nanotechnology applications are likely to include components that are bioengineered. However, it is essential that the website contain credible information from a variety of perspectives.

To bring the Canadian public interest community up to date on discussions that have taken place at the international and national level, it would be useful for Environment Canada and Health Canada to hold a workshop focused on the process of, and opportunities for engagement in, the development of a regulatory framework on nanotechnology and nanomaterials. It is our understanding that the information session held on September 27th 2007 was the first meeting to which members of the Canadian Environmental Network were extended an invitation. In contrast, many industry participants at the meeting have had a number of opportunities to participate in fora or consultations to discuss issues related to nanotechnology through the US Environmental Protection Agency process as well as the OECD discussions on nanotechnology. CELA and CIELAP, as member organizations of the Canadian Environmental Network, would be available and interested in collaborating with the departments in the development of such a workshop to enhance NGO engagement in the development the framework. We request a meeting with the New Substances Division to discuss the scope of the proposed workshop for education and communication to NGOs.

**Recommendation: Environment Canada and Health Canada should consider holding a workshop focused on the process of, and opportunities for engagement in, the development of a regulatory framework on nanotechnology and nanomaterials to enhance NGO engagement in the development the framework.**

**Recommendation: CIELAP and CELA request a meeting with the New Substances Division to discuss the scope of the proposed workshop for education and communication to NGOs.**

*Gathering Information – Voluntary or Mandatory?*

As the federal government prepares to outline the elements of Canada's regulatory framework on nanotechnology, it is useful to highlight concerns about a voluntary approach in relation to collecting information or other aspects of the framework, including: uncertainty about what percentage of industry will respond to a voluntary survey; the lack of a systematic way of collecting information in a voluntary survey; and questions about accountability and reporting to the public because public involvement has been inconsistent and limited at best. There are examples of other efforts related to the assessment and management of toxic substances and nanotechnology that illustrate these concerns.

In June 2005, the U.S. Environmental Protection Agency Office of Pollution Prevention and Toxics introduced a potential voluntary pilot program for nanoscale materials in which volunteers would submit requested data, and apply risk management practices. The EPA's efforts to outline a stewardship program under its federal legislation, the *Toxic Substances Control Act*, have been criticized by such groups as Environmental Defense (a Washington D.C.-based environmental organization that has participated in the federal advisory committee work on nanotechnology) for a number of reasons, including: the absence of deadlines by which volunteers are to participate and/or apply risk management practices; the absence of a start date to the program; and the lack of a regulatory backstop to the program.

In Canada, voluntary initiatives for collecting data or promoting reduction of toxic substances through control measures have not proven as effective as the application of a regulatory requirement. Furthermore, the government's efforts in reporting to the public on the results of voluntary initiatives have been inconsistent in both frequency and quality of reporting over the years. This makes it difficult to ensure that measures outlined in voluntary programs results in effective protection of the environment or human health.

In our experience with *CEPA* implementation processes such as the categorization process, voluntary initiatives conducted through challenges for data collection from industry were not satisfactory for a number of reasons: they were time consuming; they resulted in less than full participation; and they did not result in substantial increases in knowledge regarding the toxicity of substances beyond that which could already be located through various scientific databases. In contrast, when mandatory reporting was required through surveys, clear timelines were established for data submission and a set of regulatory measures was applied to those facilities that did not respond to the survey.

Given the expectation that nanotechnology application and development will increase exponentially in the future, there is very little time to rely on a voluntary approach. As with other jurisdictions, Canada does not have a comprehensive database of facilities producing, manufacturing, exporting, importing, using, selling or disposing of nanotechnology products and particles. If Canada is to develop an effective regulatory framework in a timely manner and in accordance with the Government of Canada's legislative duties in *CEPA* regarding precaution and prevention, Canada should make use of its available *CEPA* data collection powers.

*CEPA 1999* has several key provisions to support Canada's efforts to require mandatory participation of industry facilities in data collection. The application of sections 46 or 71 of *CEPA* would provide the government with a level of certainty in the process and trigger non-compliance for those facilities that do not submit data. Therefore, CIELAP and CELA support an information-gathering mechanism that is mandatory and adheres to a strict timeframe.

The use of surveys under section 46 and 71 of *CEPA* could be useful tools in regulating nanotechnology products, particles and materials. Both provisions would enhance information gathered in Canada at different stages of developing and implementing a regulatory framework for nanoscale materials. Through surveys, government could achieve several purposes, including:

- Establishing a Canadian database on nanotechnology, nanomaterials, and nanoparticles (similar to the Domestic Substances List)
- Highlighting nanoscale materials that should be considered the government's priorities for further assessment and management practices (including the development of interim measures to manage or prohibit the use of nanomaterials and nanotechnology); and
- Informing Canada's participation in the international discussions on assessment and management of nanotechnology.

The government's efforts to categorize 23,000 substances on the Domestic Substances List under *CEPA* relied on section 71 to gather basic information from industry in various stages of the decision-making process. It is our view that the application of section 71 to nanotechnology is also necessary and should be seen as an essential element of the regulatory framework on nanotechnology. It should be noted, however, that non-government organizations expressed significant concerns about the type of information requested through the section 71 surveys for the categorization process, as well as the timing of the survey, input of other stakeholders in the development of the surveys and reporting out to the public on the results of the survey. Please see *Appendix A* for a copy of CELA's comments on surveys conducted during categorization.

It is imperative that the development of a survey to gather information either under section 46 or 71 include an effective and transparent process with public participation as an integral component at all stages of the development of the surveys and the review of results.

Data collection under sections 46 or 71 of *CEPA* should include the following essential elements:

1) There should be clear timelines for data submission of no longer than four months by industry.
2) The type of data requested should be clearly listed and include:
    a. volume without any thresholds established
    b. list of nanoparticle, nanoproduct or nanomaterial for the inventory (i.e., trade name, common name, chemical identity, molecular structure)
    c. range of application
    d. description of byproducts from manufacture, use, process, and disposal of each nanomaterial, nanoproduct or nanoparticle
    e. specific data to demonstrate safety
    f. any hazard data demonstrating persistence, bioaccumulation, potential for long range transport, chronic toxicity, carcinogenicity, endocrine disruptors, developmental and reproductive toxicity, neurodevelopmental toxicity and genotoxicity, etc.
    g. method of disposal for each nanoscale material.
3) There should be a clear list of information and conditions under which the government will consider information to be confidential business information (CBI). A claim of CBI should not be applied in a general manner to allow facilities to claim confidentiality without full justification.
4) Data collection should be aimed at producers, suppliers, manufacturers, importers, exporters, retailers and end users.
5) Data should be provided on all routes to human populations, in particular vulnerable subpopulations such as children and developing fetuses, and workers.

6) Any testing regimes already in place for nanoscale materials should be identified.

One purpose of applying the survey is to inform government priorities. Therefore, should information gathered in the preliminary phases demonstrate harm to the environment or human health, there would be an expectation that government should take immediate action on those nanoscale materials or technologies, including a moratorium or moratoria. Action should not be delayed on the basis that a regulatory framework on nanotechnology is under development.

The general rule for applying a section 71 survey is a suspicion of a substance's being or capable of becoming toxic. In the case of nanoscale materials, this requirement could be difficult to determine, given the limitations of our current knowledge base. Section 46 may offer greater flexibility in collecting critical data from industry. A mandatory survey should be applied and is preferred over the use of a voluntary program. Data collection under sections 46 and 71 may be used in a multi-phase process to promote efficiency in collecting, reviewing and managing data. Such an approach would reflect a shift in responsibility from the public or government to proponents.

**Recommendation: The federal government should apply a mandatory mechanism to collect information on nanotechnology that adheres to a strict timeframe of no more than four months, keeping in mind the essential elements for date collection listed above.**

**Recommendation: The inventory of nanotechnology products, particles and nanomaterials in use in Canada should be made public.**

*Potential for Amending CEPA/NSNR*

The June 2007 Program Advisory Note from the New Substances Division stated as follows:

> 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….
>
> 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.

This Advisory Note suggests that Environment Canada and Health Canada are not considering changing the identification requirements in Schedule 5(2) of the NSNR to include aspects such as particle size or surface area that might allow for specific identification of nanomaterials.

However, a literal reading of s. 3(1) of *CEPA* does not preclude the addition of particle size, surface area or other physical and chemical characteristics to the Schedule 5 identification requirements. In fact, s. 3(1) is phrased in very inclusive terms: it states that any "distinguishable" matter can be a substance. The Advisory Note's narrow view of nanomaterials indicates that the New Substances Program perceives "distinguishable" to mean of a different molecular structure. However, since the proper statutory interpretation of s. 3(1) "substance" has yet to be determined through the courts, the decision to ignore physical properties such as particle size and surface area seems open to legal questioning.

In December 2006, CIELAP called for amendments to *CEPA* to regulate the development and use of nanotechnology before the Standing Committee on Environment and Sustainable Development.

CELA and CIELAP urge the government to define and establish thresholds where necessary for "nanotechnology", "nanomaterials" and "nanoparticles" in *CEPA*. These include but are not limited to Section 3 (Definitions), Part 4 (Pollution Prevention), Part 5 (Toxic Substances) and Part 6 (Biotechnology). Appropriate definitions for nanotechnology, nanomaterials and nanoparticles will be essential to *CEPA* and will require further public consultation. However, the integration of nanotechnology into *CEPA* will ensure that commitment by the government on this matter is explicit and urgent.

The NSNR in its current form is inadequate for application to nanoscale materials. The NSNR as it applies to substances considered new in Canada has several limitations and gaps, including but not limited to:

- The absence of public transparency in the assessment and notification process, which does not include a public comment period on government decisions.
- The threshold for reporting under the NSNR continues to be problematic because very low volume substances may be used without notification, and it is unclear in how many substances this situation currently applies.
- Toxicity data to be submitted is prescribed according to volume and type of substance under notification.
- There is no requirement to seek additional test data demonstrating the level of exposure and route of exposure to vulnerable subpopulations, in particular children, developing fetuses, workers, pregnant women, etc.
- Industry is not required to provide toxicity data for endocrine disruptors, neurodevelopmental toxicity and chronic toxicity, to name a few.

Needless to say, the limitations noted above would also apply to nanoscale materials.

**Recommendation: The federal government should change the identification requirements in Schedule 5(2) of the NSNR to include aspects such as particle size or surface area that would allow for specific identification of nanomaterials, given that s. 3(1) of *CEPA* does not preclude the addition of particle size, surface area or other physical and chemical characteristics to the Schedule 5 identification requirements.**

**Recommendation: Appropriate definitions for nanotechnology, nanomaterials and nanoparticles should be developed for *CEPA*.**

**Recommendation: The federal government should address existing limitations and gaps in the NSNR, before considering applying it to nanoscale materials.**

*Resolving Terminology*

Terminology, metrology and related technical issues need to be resolved as soon as possible, preferably in collaboration with others internationally. Much that is essential for comprehensive legal and regulatory action depends on such activities.

**Recommendation: Terminology, metrology and related technical issues should be resolved, in collaboration with others internationally, as soon as possible.**

*Establishing Data Requirements*

More science in support of regulatory action is obviously needed. Granting councils should encourage safety and the environment as a design requirement of every project from its inception, along with supporting work on so-called NE3LS, nanotechnology and ethical, environmental, economic, legal and social concerns. Significant research funds should be allocated to proactive research on the potential environmental and health risks of nanotechnology.

**Recommendation: The federal government should ensure that safety and the environment is a design requirement of every project from its inception, and should fund supporting work on nanotechnology and ethical, environmental, economic, legal and social concerns.**

*Using CEPA's Significant New Activity Provision*

The government has suggested that the Significant New Activity (SNAc) provision could be used to compel notification of a nanomaterial where there is a suspicion that the nanoscale form of a substance already in commerce may pose a risk. It is our view that the use of the SNAc provision is wholly inadequate to fully protect human health and environment from the potential impacts of nanotechnology, even as an interim measure.

There are a number of limitations to the application of SNAc provisions, including the following:

1. There must be a suspicion that a significant new activity in relation to the substance may result in the substance becoming "toxic" under *CEPA 1999*. It is not clear how a SNAc notice can be applied to nanotechnology currently since Canada does not have a database to establish a benchmark of information for nanotechnology or nanomaterial. The government would be required to provide explicit criteria of the evidence that would signal suspicion of "toxicity" under *CEPA* as it applies to nanotechnology and nanomaterial. This proposal is far too ambiguous to ensure that all those affected will indeed notify under this provision.

2. There is an absence of public engagement in the process to assess substances being notified under the SNAc notice. Assessments and decisions on information received by the government departments are not released for public comment. Furthermore, it is unclear to the public at this time how many substances have been required to notify under the SNAc since *CEPA 1999* was passed. There is also a lack of public reporting on the level of effectiveness of the SNAc as a *CEPA* tool in assessing and managing substances. This lack of public review of the information submitted under the SNAc notice is unacceptable.

3. The information requested under the SNAc provisions is very limited. Currently, the SNAc notices focus on the quantity, concentration or range of application of the substance under notification. The SNAc notice does not require other essential data (including specific safety data and toxicity data) for assessing impacts on the environment and human health.

The application of the SNAc provisions to nanomaterials and nanoproducts cannot be supported until an inventory of nanotechnology and nanomaterials in use in Canada is established, as recommended above. To ensure that the federal government understands the range of nanotechnology and nanomaterials currently in use in Canada, a mandatory requirement to establish an inventory similar to the Domestic Substances List should be established.

**Recommendation: Due to the above-noted limitations of the SNAc provisions, the federal government should not consider applying SNAc notices to nanomaterials, but should put in place a mandatory requirement to establish an inventory of nanotechnology and nanomaterials similar to the Domestic Substances List.**

Thank you for your consideration of these matters. If you have any questions, feel free to contact us. We look forward to your response.

Yours truly,

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## APPENDIX A
## CELA_Letter to Environment Canada on CEPA Section 71 Surveys