Canadian Environmental Law Association
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CSM
Chemical Sensitivities Manitoba

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Transmission by email

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Dear Brad Fisher and Doug Green:

Subject: NGO response to Work Element 2 from the Regulatory Cooperation Council's (RCC's) Nanotechnology Results Workshop/Webinar – January 14, 2014.

The Canadian Environmental Law Association (CELA) and Chemical Sensitivities Manitoba (CSM) are providing the following comments and recommendations for your consideration to Work Element 2 from the Regulatory Cooperation Council's (RCC's) Nanotechnology Results Workshop/Webinar that was held on January 14, 2014.

Regulatory Cooperation Council (RCC) Nanotechnology Initiative, Work Element 2

The intent of the Regulatory Cooperation Council (RCC) Nanotechnology Initiative (Initiative) is to increase the alignment in the regulatory approaches for nanomaterials between Canada and the United States (US)[1]. The Initiative focuses on new nanomaterials in Canada and the US under the *Canadian Environmental Protection Act*, 1999 (CEPA 1999) and *Toxic Substances Control Act* (TSCA), respectively.

Work Element 2 of the Nanotechnology Initiative deals with the development of a classification scheme for nanomaterials regulated under the New Substances Programs of Canada and the United States (the Programs).

The proposed classification scheme for industrial nanomaterials is based on similarities for chemical composition. It includes six categories with the organic category being a new addition.

[1] Regulatory Cooperation Council (RCC) Work Element 2 (Draft Document) – page 2

Each category has a proposed listing of physicochemical parameters relevant to the category. Additionally, there is a category titled 'other'.

The following are comments and recommendations related to the draft Work Element 2 document.

Comments & recommendations for Work Element 2

1) **Identification of a nanomaterial**

Comments:
At present, neither Canada nor the US has a regulatory definition for a nanomaterial. Currently, both countries use a range of 1-100nm to describe a nanomaterial, but the US uses additional parameters such as a minimum of 10% of the particles need to be between 1-100nm and/or particles which exhibit properties unique to their nano size, to describe a nanomaterial. Health Canada completed a working definition of nanomaterial in 2011, it is as follows:

Health Canada considers any manufactured substance or product and any component material, ingredient, device, or structure to be nanomaterial if:

- *It is at or within the nanoscale in at least one external dimension, or has internal or surface structure at the nanoscale, or;*
- *It is smaller or larger than the nanoscale in all dimensions and exhibits one or more nanoscale properties/phenomena.*

For the purposes of this definition:

- *The term "nanoscale" means 1 to 100 nanometres, inclusive;*
- *The term "nanoscale properties/phenomena" means properties which are attributable to size and their effects; these properties are distinguishable from the chemical or physical properties of individual atoms, individual molecules and bulk material; and,*
- *The term "manufactured" includes engineering processes and the control of matter.* [2]

CELA has provided substantial comments regarding the limitations related to the HC working definition for nanomaterials which have been attached to this submission.

[2] Health Canada. 2011. 2011. Policy Statement on Health Canada's Working Definition for Nanomaterial

(Appendix A) Despite on-going efforts to assess nanomaterials under Canada's New Substances Program, the comments made by CELA related to the definition for nanomaterials have not been fully addressed. The current proposed framework under the Initiative will further compound the issues identified in CELA's preliminary work on the HC working definition.

- With the RCC Nanotechnology Initiative aiming at increasing alignment in the regulatory approaches for industrial nanomaterials between Canada and the US, it is essential to review and revise the descriptions for a manufactured nanomaterial and attempt to better harmonize the descriptions.
- The document does not provide a scientific rationale for setting the 100nm upper threshold for the description of a nanomaterial although several jurisdictions use 100nm as the upper threshold. Reconsideration is being sought concerning this upper bound threshold as it is too restrictive in light of scientific evidence to indicate that particles up to and greater ~~larger~~ than 100 nm in size can exhibit similar anatomical and physicological behaviour to that of a nanomaterial.[3] Non-governmental organizations in Europe have made recommendations to consider reviewing the European definition of nanomaterials which included a range of 1 – 300nm instead of 1 – 100nm.[4] Considering the current myriad number of applications of nanomaterials that are expected to enter the market, a larger size range would capture a wider range of nanomaterials that would not be otherwise addressed. This proposed approach should theoretically broaden the scientific data on nanomaterials and eventually give a better understanding of the behaviour and fate of these substances with regards to human health and the environment, for regulatory purposes.
- Revised descriptions of manufactured nanomaterials should include aggregates and agglomerates and particle size distribution instead of a mass concentration threshold. By providing consideration to a particle size distribution, it will give a better picture of potential chemical reactivity of the substance.
- For some commonly used nanomaterials, there should be targeted research to investigate the relationship between increasing particle size and nano-scale effects but with the recognition that a combination of physicochemical factors and dosage are likely to influence the outcomes. However, a generalization across all categories of nanomaterials cannot be made.

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[3] Friends of the Earth (FOE). Out of the Laboratory and on to our Plates: Nanotechnology in Food & Agriculture. 2nd edition 2008. Page 6. Accessed at http://nano.foe.org.au/sites/default/files/Nanotechnology%20in%20food%20and%20agriculture%20-%20web%20resolution.pdf

[4] NGO recommendations for the European definition of nanomaterials. Accessed March 2014. http://www.pan-germany.org/download/NGO_position_nanomaterials.pdf

- There is also concern about the safety of nanomaterials that are less than 1 nm in diameter. The draft document fails to mention how concerns related to nanomaterial measuring < 1 nm would be addressed assuming that any particles under this size are not single or groups of atoms.

Recommendations:

- The draft document and respective legislation in US and Canada should review and revise the definition/description of a manufactured nanomaterial and give consideration increase the particle size range from 1 – 300 nm, at a minimum.
- The draft document should provide scientific justification for the setting of 100 nm as the upper threshold for a manufactured nanomaterial.
- The proposed framework should include regularly scheduled reviews and updating of the descriptions of nanomaterials to ensure that new scientific data are considered as they become available.
- The definition/description for nanomaterial should also include the consideration of:
  - aggregates and agglomerates; and
  - particle size distribution.

2) Classification framework for nanomaterials

Comments:

- The proposed classification scheme for industrial nanomaterials is based on similarities in chemical composition. It is appropriate to modify the scheme for the inclusion of the 'other' category to capture future new nanomaterials, as the technology advances. However, with time, it would also be necessary to review the categories in the classification. For example, there may be the need to validate any uncertainties in the classification categories.
- In the classification framework, each chemical category has a listing of physicochemical properties that are relevant to the category and would allow the use of read-across/analogues to fill in data gaps, once there is sufficient data. We question if these chosen physicochemical properties for any one chemical category are adequate to sufficiently characterize the chemical category since this base data is pivotal in determining if a material is of concern or no-concern. Other important physicochemical considerations for manufactured nanomaterials should be added such as particle size distribution, particle surface area, aggregation/agglomeration potential, flexibility, conductivity, solubility in different environments, the presence and concentration level of contaminants and surface treatments. The availability of detailed physicochemical information reduces the data gaps and characterizes a chemical with more certainty, if read-across/analogues determinations have to be made.

- In the proposed framework, it is critical that the federal government 's uses their full authority to fill in data gaps rather than rely on analogues and a read-across approach so as to reduce any uncertainties associated with a nanomaterial.
- For the metal oxides and metalloid oxides category as well as the category for metals, metal salts and metalloids, it is unclear if the surface modification of these materials would result in the placement of the resulting materials into the 'other' category and if this would require assessment on a case-by-case basis.
- It is unclear if a wider variety of stakeholders, including non-governmental organizations, would be engaged in the process of further modifications to final classification scheme since their participation to date in the RCC Nanotechnology Initiative, have been limited. Engagement by public stakeholder is essential to uphold transparency and accountability regarding decisions on nanomaterials.

Recommendations:

- Consideration should be given to expand the physicochemical parameters, if appropriate, for most of the categories in the classification scheme for manufactured nanomaterials.
- The classification scheme should be reviewed when new scientific evidence is known and the current scheme is outdated.
- Classification clarifications are required for metal oxides, metalloid oxides, metals, metal salts and metalloids, if there is surface modification of these materials.
- The review and update of the classification scheme should be scheduled on a regular basis and include participation from wider variety of stakeholders, including public interest organizations.

3) Use of analogues and read-across information –limitations with application

The classification scheme proposed in draft Workplan 2 will be used to select appropriate analogues/read-across information within a class, and as science develops, approaches for selecting analogues/read-across information for different classes will be considered.

Comments:

- The use of a classification scheme is appropriate for manufactured nanomaterials but at present, the working description/definition of a manufactured nanomaterial lacking of a particle size distribution and the narrow particle size range are viewed as weak points related to the classification scheme. The categories in the scheme could be under-populated and without an expansion of the number of physiochemical parameters in the classification scheme, more uncertainty will be introduced thereby further limiting the use of read-across/analogues.

- In Work Element 2, there was no direct reference to the possible impact of confidential business information (CBI) claims and the intentions/plans for obtaining information for the parameters listed in the classification scheme. It is questionable if all CBI claims are indeed valid. It is critical that there is public discussion on this issue as there are concerns that CBI claims could result in less pertinent information being submitted and the possibility that human and occupational health effects are fully considered.
- Both countries require industry to notify their new substances prior to import or manufacture within their jurisdictions but there is significant difference in the approach taken by both countries regarding the required information packages for new substances. For example, in Canada, volume triggers range from ≥100kg/calendar year to ≥50,000kg/calendar year but in the US, there are no triggers but a pre-market notification requests all available information to be submitted to the US government. Only after this initial screening, the US government could require more information if there are concerns regarding human safety and/or the environment.

  In Canada, the information required at the notification stage for the lowest volume trigger of a new substance are not sufficiently robust to accurately identify the properties of a new nanomaterial in terms of concern and no-concern, and to subsequently use the data for selecting read-across/analogues purposes or even a robust risk assessment. Requesting that industry supplies as much scientific data at the point of notification is not a solution as this is viewed as more of a voluntary measure. A mandatory expanded dataset for manufactured nanomaterials at the notification stage for the NSNR, including parameters from the categories in the classification scheme are more likely to result in a database with less data gaps and one that would be more useful in determining substances of concern /no-concern and the accurate use of read-across/analogue information. This would require the present Canadian New Substances Regulations to be amended with a significantly lower notification trigger and an expended schedule requiring substantial safety data to reflect the unique features of nanomaterials. There was no mention of the development of a systematic framework that would help characterize uncertainty when read-across or analogue data are used to fill in data gaps. Furthermore, the proposed framework does not require the rationale to be provided in situations where there is the possibility of the subsequent use of analogues or read-across data to conduct assessments of other nanomaterials where validation would be required. The development of any such framework should be transparent and include public input.

Recommendations:

- The proposed classification scheme should be expanded for data parameters in each category. Similarly, using accurate scientific data to indicate or validate which parameters are the most appropriate for selection when considering the use of read-across/analogues is needed.
- Canada's *New Substances Notification Regulations* under *CEPA 1999* should be amended to address ongoing concerns associated with the risk assessment framework for nanomaterials. The risk assessment approach for nanomaterials should include parameters that are nano-specific at the point of notification (e.g. agglomeration/aggregation, particle size distribution, conductivity, flexibility)starting at the lowest level of notification.
- Further consideration and rationale should be given to review the validity of CBI claims in the proposed framework. In particular, claims of CBI related to human and occupational health should not be protected through CBI.
- Each government should fill in data gaps using its full authority under their respective legislation. Lack of data should trigger measures to prevent or severely restrict the use of the nanomaterial.

Conclusion

Consideration should be given to a revised working definition for a manufactured nanomaterial; one that is more inclusive of a wider particle size range of nanomaterials, among other parameters.

The draft classification scheme with categories for industrial nanomaterials is seen as being essential but would eventually require validation.
The proposed use of the classification scheme to aid in the selection of appropriate analogues/read-across information within a class would only be appropriate once there is a significant increase in scientific data about nanomaterials. The proposed parameters for the categories are viewed as being too limiting and an expansion is suggested.

For Canada, the *New Substances Notification Regulations* would require an amendment requesting more substantive data requirements at the time of notification of a new nanomaterial and particularly, at low levels of usage. This would require a significant reduction in the lowest trigger volume. The validity of CBI would also require some discussion as it could impact on data collection for nanomaterials.

If there are any points that require clarification, please do not hesitate to contact us.

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Appendix A

Response to Interim Policy Statement on Health Canada's Working Definition for Nanomaterials

(2010)

Response to Interim Policy Statement on Health Canada's Working Definition for Nanomaterials

Submitted to:
Health Canada
Policy, Planning and Coordination Division
Science Policy Directorate
Strategic Policy Branch

Prepared by:
Canadian Environmental Law Association

August 27, 2010

Introduction

The Canadian Environmental Law Association (CELA) (www.cela.ca) is a non-profit, public interest organization established in 1970 to use existing laws to protect the environment and to advocate for environmental law reform. It is also a legal aid clinic that provides legal services to citizens or citizens' groups who are otherwise unable to afford legal assistance. In addition, CELA also undertakes substantive environmental policy and legislation reform activities in the areas of access to justice, pollution and health, water sustainability and land use issues. Under its pollution and health program, CELA has been actively involved in matters that promote the prevention and elimination of toxic chemicals addressed in the *Canadian Environmental Protection Act, 1999* (CEPA 1999) including the categorization process and implementation of the Chemicals Management Plan (CMP), improving the New Substances Program, protection of vulnerable populations such as children from exposure to toxic chemicals and promoting the development of an effective regulatory framework to address nanomaterials and nanoproducts in Canada.

Background

The use of nanomaterial and nanotechnology in Canada is expected to increase significantly in the coming years. Currently, it is estimated that there are over 1000 products containing nanomaterials in the commercial market. This number will grow as nanotechnology continues to develop and gain popularity. Many of these products are being used extensively in consumer products, particularly in sporting equipment and clothing/apparel, cosmetic products, energy production and medical devices to name a few. The global market for products containing nanotechnology is growing and expected to reach $2.6 trillion by 2015.[1]

At the same time, very limited information is available on the toxicity of nanomaterials or the impacts of these materials on the environment and human health. This significant gap in knowledge coupled with the absence of a regulatory framework in Canada to assess and manage nanomaterials raise concerns for the safety of the environment and human health. Nanotechnology, like any other emerging and growing industry, such as biotechnology, needs an established regulatory and policy framework that ensures accountability and transparency. Based on the Canadian experience to manage the use, sale, manufacture and import of chemicals that have been in the Canadian market for many decades but have not been fully evaluated for their impact to the environment and human health, we hope that the government seeks to establish a regulatory framework for nanomaterials and nanotechnology that is established on precaution and prevention rather than a reactive framework. Such a framework is needed now given the amount of growth and money expected to be invested on nanomaterials and nanotechnology. Significant delays or slow progress in this area makes Canadians more vulnerable to the potential or unknown negative impacts of nanomaterials.

The comments below urge the Government of Canada to proceed expeditiously to develop further the national policy and regulatory framework on nanomaterials and, at the same time, provide comments to the initial efforts put forth by Health Canada to determine a working definition of nanomaterials as outlined in its consultation document, *Interim Policy Statement on Health Canada's Working Definition*

[1] United States, Government of Accountability Office, Nanomaterials Are Widely Used in Commerce, but EPA Faces Challenges in Regulation Risk. Report to the Chairman, Committee on Environment and Public Works, U.S. Senate. May 2010, GAO-10-549.

for Nanomaterials. Health Canada's initial efforts are appreciated. There has been no substantial public debate on this matter for several years in Canada despite several initial workshops and the release of a proposed policy framework by Environment Canada and Health Canada in 2007.[2] Much of the debate on nanomaterial and its management in Canada has focused on Canada's engagement at the OECD or in a bilateral format with industry, scientists and other government departments. By in large, the public has not been part of these policy dialogues.

National Approach on Nanotechnology Requires Improved Public Engagement and Effective Provisions for Accountability

The release of Health Canada's *Interim Policy Statement on Health Canada's Working Definition for Nanomaterials* highlights the lack of a coordinated national approach on nanomaterials and nanotechnology. While it is appreciated that Health Canada has taken the lead to seek input on the working definition of nanomaterials, it only focuses on one federal department's perspectives on nanotechnology and fails to provide the perspective of other federal government departments on nanotechnology. Since the policy discussions on the management of nanomaterials by the federal government have been very limited to date, it is critical to use this public comment opportunity to ensure that a comprehensive and substantial policy dialogue is promoted on the issue of nanomaterials not just with a focus on Health Canada but across the federal departments. The proposals by Health Canada to focus on a working definition of nanomaterial are working in isolation of other departments. Given the absence of proposals by other departments to develop a definition of nanomaterial, we expected the work of Health Canada may pre-empt a more comprehensive public policy dialogue on this matter. Hence, it is important that the definition for nanomaterials and nano phenomena be comprehensive in its scope to ensure that all products of nanotechnology and nanomaterials will be covered under the Canadian regulatory and policy regime. ***Health Canada should expand the scope of its consultation document to provide additional information on how its effort fits into the overall Canadian approach on nanomaterial and nanotechnology and how potential discrepancies in approach and interpretation of terms may be resolved.***

In addition, the proposals by Health Canada do not sufficiently acknowledge how its consultation document fits in with the joint efforts that Environment Canada and Health Canada initiated in 2007 on nanomaterial. To date, the federal government is relying on the New Substances regime established under the *Canadian Environmental Protection Act, 1999* (*CEPA 1999*) to conduct assessments for nanomaterials in Canada. This approach requires a joint role for Health Canada and Environment Canada, particularly in the assessment process. A notice of this approach was released for public comment in September 2007 and titled, *Proposed Regulatory Framework For Nanomaterials Under The Canadian Environmental Protection Act, 1999.*[3] Under this framework, the Departments of Health and Environment had proposed to conduct activities at the international and domestic levels in two phases starting in 2006. The proposed framework included commitments to:

- Consider whether amendments to *CEPA 1999* or the NSNR would be needed to facilitate the risk assessment and management of nanomaterials.

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[2] Environment Canada and Health Canada. Proposed Regulatory Framework For Nanomaterials Under The Canadian Environmental Protection Act, 1999. September 10, 2007. Accessed at http://www.ec.gc.ca/subsnouvelles-newsubs/default.asp?lang=En&n=FD117B60-1

[3] Ibid.

- *Consider establishing data requirements under the NSNR specific to nanomaterials.*
- *Consider the use of the Significant New Activity (SNAc) provision of CEPA 1999 to require notification of nanoscale forms of substances already on the DSL.*[4]

No new proposals to further these efforts have been released for public discussions. It is our perspective that this current approach remains inadequate and leaves significant gaps in the government's approach on nanomaterials. CELA and the Canadian Institute for Environmental Law and Policy submitted substantial comments on this consultation document and participated in a workshop to discuss the policy framework. Many of these comments and recommendations still remain relevant for Health Canada's policy work on nanomaterials. Our comments to this consultation document are attached as an appendix to this submission.

We are again outlining three outstanding issues related to the use and development of nanomaterials and nanotechnology in Canada that were identified and discussed in the 2007 document. First, *CEPA 1999* doesn't explicitly mention nanomaterials or nanotechnology. Second, the scope of assessments required under *CEPA* address existing and new substances as well biotechnology products in Canada but the scientific datasets required for nanomaterials to be effectively assessed will have to be expanded to effectively evaluate nanomaterials and nanotechnology. Third, these matters require substantial public discussion before adequate policy and regulatory framework for nanomaterials can be finalized in Canada. The Health Canada initiative offers opportunities to make progress on these issues.

Furthermore, there are additional efforts that have occurred in the recent months that should also influence the progress made on the management of nanomaterials and nanotechnology in Canada. For example, Bill C-494 introduced into the House of Commons by Member of Parliament, Peter Julian, in March 2010 demonstrates progress towards addressing nanomaterials in *CEPA 1999*. The aim of Bill C-494 is to integrate the nanomaterial provisions into *CEPA 1999* by seeking to apply similar provisions required for biotechnology products. Bill C-494 establishes provisions in *CEPA* for assessing and managing nanotechnology in Canada. While more detailed public discussion will be required on the effective implementation of this provision, the effort to legalize the terms of nanotechnology and nanomaterials in Canadian legislation is essential for transparency and accountability. ***We urge Parliamentarians to ensure the passing of Bill C-494 in an expeditious manner in the coming Parliamentary session.***

Also, in June 2010, the House of Commons' Standing Committee on Health, held hearings on nanomaterials and nanotechnology. The testimonies provided by a number of witnesses at the hearings have provided valuable insights into this growing field. There have also been substantial comments that would support an increased focus by our regulators to finalize a Canadian policy and regulatory framework on nanomaterials and nanotechnology. (see below for more details on hearings of the Standing Committee on Health)

Any definition designed to address nanomateials should eventually be adopted under *CEPA* as well as other statutes that will be required to address management matters on nanomaterials. As noted

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[3] Ibid.

previously, the government should present a statement reflective of the Federal government position and process related to nanomaterials rather than an individual policy statement by Health Canada. Therefore, we recognize that these efforts are intended to be an interim policy statement and we hope it creates the impetus for all federal departments to coordinate on this file. Since the consultation document does not provide an explanation on how the proposals compare to the positions of other government departments, it leaves potential for significant range in approach and interpretation by Canada on nanomaterials. Given the initial efforts in 2007, the approach should, at a minimum, represent the perspective of Health Canada and Environment Canada, as the two departments have joint responsibility for administrating and implementing the scope of obligations under the *Canadian Environmental Protection Act, 1999,* which provides the basic mechanism for assessing and managing chemicals in Canada and establishes a level of accountability to the public.

Specific Comments to Sections in the Interim Statement

The consultation document does not only focus on a discussion of definition but presents Health Canada's approach on nanotechnology generally. We offer the following comments on scope of the consultation document.

Objectives

The set of objectives established for the Interim Policy Statement outlines essential elements for managing nanomaterials in Canada. However, there are several critical elements in the listing of objectives that should be considered but that are currently absent. These include:

1. Reference to the joint responsibility of Health Canada and Environment Canada in activities that support the identification, assessment and management of nanomaterials and nanotechnology. While the consultation explicitly is a Health Canada initiative, the document does not provide any reference to the joint work required between other federal departments including Environment Canada, particularly in its role as co-administrator of *CEPA*, the key legislative statute for assessing and managing nanomaterials and nanotechnology.
2. Explicit reference to the commitment required by Health Canada and Environment Canada to identify and address gaps in the existing legislations such as *CEPA*, etc. as it relates to nanomaterials and nanotechnology;
3. Explicit focus for communication activities as well as implementation activities that aim to engage the public, with particular focus on vulnerable populations such as children, advocates, workers, indigenous groups and people of low income. Based on our extensive experience working on other chemicals management policy matters, the views and insight of vulnerable populations are unique and should be sought at every phase of these policy dialogues.

Additional comments to specific objectives.

Objective #2 as proposed is scoped too narrowly. This objective focuses on maintaining information for only government use when it is necessary to promote public accountability and transparency. Access to information on nanomaterials and nanotechnology for the public is long overdue. The scope of this objective should be revised to include public inventories rather than restrict the focus of the objective to the development of internal inventories only. This objective would be essential in promoting public accountability by providing the public with up to date knowledge by industry and government with

respect to products, materials, substances, ingredients devised, systems or structures that contain or make use of nanomaterials. For example, an inventory database that can be accessed by the public is needed urgently to identify cosmetic and personal care products in Canada that contain nanomaterials. These products are intended for direct use and application on the body. In the absence of a regulatory framework and the limited information available currently on the toxicity of the nanomaterials, the Canadian public should be given the necessary information to make personal choices on the products that may contain nanomaterials through a public database and comprehensive labelling provisions. The European Union, under the Cosmetic Products Regulations, requires the establishment of a catalogue to list all cosmetic products containing nanomaterials.[5] Under Article 16, Section 10(a), the regulations states:

> *By 11 January 2014, the Commission shall make available a catalogue of all nanomaterials used in cosmetic products placed on the market, including those used as colorants, UV-filters and preservatives in a separate section, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions. This catalogue shall be regularly updated thereafter and be made publicly available.*[6]

The EU Regulations also has provisions to require labelling of ingredients in cosmetic products that contain nanomaterials.[7]

Objective #3 focuses on communication with stakeholders. In principle, this is an essential objective. However, the objective should be expanded to ensure two way communications are established between government and stakeholders, with particular focus on the public. This objective should include reference to support on-going communications on policy development that provide an opportunity for stakeholders, including public interest organizations, to discuss policy gaps and benefits to government departments. We have noted in our comments the need to focus communication as well as implementation activities to include vulnerable populations.

Objectives #4 is essential to promote effective implementation activities under Health Canada. However, as noted in the first comments on objectives, the joint efforts between Health Canada and Environment should be explicitly referenced to demonstrate the joint requirements under *CEPA* as well as the collaboration that currently exists on these matters. Finally, this objective should also include the reference to development of monitoring programs and a reporting mechanism aimed to support effective communication to all stakeholders such as the public on the management of nanomaterials in Canada as should be required by Health Canada and other government departments.

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[5] European Union, Official Journal of the European Union, 342/59. REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009, Access http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF (August 27, 2010)

[6] Ibid.

[7] REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009. Access http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF (August 27, 2010) Also see European Commission Cosmetic Cosing Database, Access at http://ec.europa.eu/consumers/cosmetics/cosing/ (August 27, 2010)

Policy Statement

As noted, it is expected that Health Canada's effort to define nanomaterials and nanotechnology will establish the foundation necessary to effectively conduct the assessment and management of nanomaterials in Canada. Hence, this interim policy should be presented as a Government of Canada effort rather than the efforts of one department.

To ensure that the definition considered by Health Canada will effectively identify and take necessary action to assess and manage nanomaterials in Canada, it should carefully consider some of the comments received by the House of Commons Standing Committee on Health, which held hearings in June 2010 to "understand nanotechnology."[8] Witnesses appearing before the Standing Committee on Health were primarily from academic, research and industry organizations, providing their views on nanomaterials and nanotechnology, including some of the relevant policy and scientific issues that require attention by regulators. While there were no witnesses representing the views and concerns of the public at these hearings, some of the comments received from key witnesses offered some very important views on complexities of identifying nanomaterials, the toxicities of nanomaterials and potential impacts of nanomaterial/particles to public health. Furthermore, comments focused on the evolution of nanomaterials, the significant investments made in research on nanomaterials but the lack of investment in assessing health impacts, particularly on vulnerable populations such as workers, and the current state of the knowledge gap to address the various uncertainties that include characterization of nanomaterials, determination of bioaccumulation and persistence factors or other impacts to the environment of nanomaterial and nanotechnology. These comments are important in influencing how Health Canada proceeds to define nanomaterials. For example, the current knowledge gap on toxicity of nanomaterials suggest that the definition of nanomaterials should be flexible and will be influenced, in large part, by the effective application of the precautionary principle as nanomaterials are assessed. The first step in the assessment process would be effective identification.

The comments of several key witnesses appearing before the committee are noted below, including comments by M. Claude Ostiguy, Director, Research and Expertise Support Department; Dr. Nils Petersen, Director General, National Research Council Canada, National Institute for Nanotechnology; and Dr. Claude Emond, Toxicologist, Department of Environmental and Occupational Health, University of Montreal. The testimonies of these witnesses, whether directly discussing what is considered nanomaterial or the approach needed to address nanomaterials and nanotechnology in Canada deserve some attention. These comments should be given careful consideration in the further consideration of defining nanomaterial or nanotechnology.

For example, Mr. Ostiguy noted in his testimony that:

- "It is important to mention first that toxicological studies aiming to establish whether nanoparticles demonstrate some toxicity cover only a small proportion of existing nanoparticles. Second, for those that are documented, knowledge is generally insufficient to be able to

[8] House of Commons' Standing Committee on Health. Evidence. June 10, 2010. HESA, Number 23, 3rd Session, 40th Parliament. Chair: Mrs. Joy Smith. Access http://www2.parl.gc.ca/content/hoc/Committee/403/HESA/Evidence/EV4611275/HESAEV23-E.PDF.

accurately quantify the hazard. NPs that are insoluble or not very soluble in the biological fluids are of the most concern…."[9]

- "...several nanoparticles demonstrate a higher toxicity than the same chemical products of larger size. The measured toxic effects are poorly correlated with the mass..They are better correlated with different parameters, namely the number of particles, size, surface area and some surface properties."[10]
- "The behaviour of nanoparticles in the body can be different from that of larger-size particles.;"[11]
- "What we find in the literature is that almost all of the particles that are in the nanometric size will be more toxic than will be the same mass of particles in the micro size."[12] and
- "Very little is known about the long-term effects of nanoparticles. …, it will be difficult to quantify the specific toxicity of the nanoparticle to which workers are exposed."[13]

In Mr. Ostiguy's testimony, he appropriately highlighted the limited toxicity information available on nanomaterials and their long term impacts, particularly to workers, discussed how nanoparticles may have higher toxicity than the same chemical with a particle size, and discussed how nanoparticles behave differently in the body compared to the larger sized particle.

Dr. Nils Petersen stated:

- "It is not just because of the size….It is basically a scale at which we can think about materials having different kinds of properties."[14]
- "…when we think about risk management, we do not think it is something we manage by saying 'anything less than 100 nanometers we need to worry about.' We need to worry about each of the different applications and each of the different products in a different way."[15]
- "…there have been jurisdictions around the work where people have been thinking about trying to do regulations or whatever based simply on scale. I think that's the wrong path."[16]

Dr. Petersen's testimonies indicate that scale is not the only parameter that needs consideration when it comes to nanoparticles. Consideration of nanomaterals is beyond scale.

Dr. Emond's testimony included comments such as:

- "So the money also exclusively supports the development of nanotechnology in commercialization, but there is not enough on the health effects of the presence of nano-particles."[17]
- "We don't know what is the best metric to characterize the toxicity. Should we use weight? Should we use the surface? There is some deficiency in the metrology, characterization, and toxicology…"[18]

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[9] Ibid, pg. 2.
[10] Ibid, pg. 2.
[11] Ibid, pg. 2.
[12] Ibid. pg. 7.
[13] Ibid, pg. 2.
[14] Ibid, pg. 3.
[15] Ibid, pg. 3.
[16] Ibid, pg. 3.
[17] Ibid, pg. 3.
[18] Ibid, pg. 4.

- "The nanoparticles are distributed on the entire organism…They decrease the cell viability: DNA damage, oxidative stress, blood thrombosis, inflammation, and all these effects."
- "We need a national strategy in regard to nanotechnology development…"[19]
- "…yes to the precautionary principle, but improving the knowledge and doing real assessment of the risk is better in the long run."[20]

Dr. Emond's testimony highlighted several important aspects related to nanoparticles in Canada. He highlights the lack of funds directed to assess impacts to health effects. He discussed the complexity of nanoparticles, in general, and outlined the extensive and potential impacts associated with nanoparticles. One of his recommendations focused on the need to establish a Canadian Strategy Initiative, similar to the US National Nanotechnology Initiatives, which would be relevant and important for Canada.

Definition

In providing input to Health Canada's working definition on nanomaterials, the issues and comments raised by the various witnesses appearing before the House of Commons Standing Committee should influence the development of the definition. The testimonies of the witnesses clearly noted that scale is not the only parameter that should be considered for nanomaterials. There has to be flexibility in the approach to ensure that all products containing nanomaterials or result from nanotechnology are identified and assessed. As such, the definition should be broad and not limiting. The Health Canada approach and the proposed definition for nanomaterials currently does not adequately consider the complexities associated with nanomaterials, which were appropriately noted by the witnesses appearing before the Standing Committee on Health. As such, the proposed definition is narrow in its scope and requires further refinement.

We would also propose that the work of other jurisdictions and agencies around the world working on nanomaterials should be considered since they consider applying definitions for nanomaterials or nanoparticles that are more inclusive than that proposed by Health Canada.

For example, the UK House of Lords Science and Technology Committee report in 2010, offered the following comments on the nanoscale regulatory limits:

> *We recommend that the Government should work towards ensuring that any regulatory definition of nanomaterials proposed at the European level, in particular in the Novel Foods Regulation, should not include a size limit of 100 nm but instead refer to the "nanoscale" to ensure that all materials with a dimension under 1000 nm are considered. A change in functionality, meaning how a substance interacts with the body, should be the factor that distinguishes a nanomaterial from its larger form with the nanoscale.*[21]

Similarly, the State of California through its *California Safer Consumer Product Alternatives Act* proposes to consider nanoscale between 1-1000 nanometers. The definition proposed by the State of

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[19] Ibid, pg. 4.
[20] Ibid, pg. 4.
[21] UK House of Lords Science and Technology Committee, Nanotechnologies and Food . January 8, 2010. Volume 1, paragraph 5. 24, p. 76. Access http://www.publications.parliament.uk/pa/ld200910/ldselect/ldsctech/22/22i.pdf (August 27, 2010).

California would promote greater flexibility to the approach in identifying products containing nanoparticles in Canada.

Adoption of the scale between 1-1000 nm rather than the 1-100 nm is more inclusive and would identify more nanomaterials that may not be considered otherwise for further assessment and management. It would substantially expand the approach used under the New Substances Notification Regulations considered which focuses on the 1-100 nm scale.

To build on and support the definition on nanomaterials as recommended by the UK House of Lords Science and Technology Committee and the recent proposal by the State of California, we recommend the following amendments to Health Canada's proposed definition, see bold and italics:

Recommendation: The definition for nanoscale should be revised. The term "nanoscale" means 1 to 1000 nanometer, inclusive;

Recommendation: The definition for the term "nanoscale phenomena" should be expanded. The term "nanoscale phenomena" means properties of the product, material, substance, ingredient, device, system or structure which are attributable to its size, shape, surface area, dimensions, or reactivity as distinguished from the chemical or physical properties of individual atoms, individual molecules and bulk materials; and

The expansion of the term "nanoscale phenomena" is necessary to provide more specific criteria of elements that trigger the identification of nanomaterials rather than leaving it vague by proposing the term "distinguishable from…"

Require immediate government action in absence of regulatory and policy regime

The section on application of the interim policy should be more explicit with its scope and timeframe. While the efforts by Health Canada to develop a working definition for nanomaterial and nanotechnology are in progress and the regulatory framework on nanomaterials as initiated in 2007 have not been finalized, the Canadian population and the environment continue to be exposed to nanomaterials and nanotechnology products. The Government of Canada should take precautionary steps immediately to reduce and prevent exposure and unknown risks to nanomaterials in the absence of a comprehensive regulatory framework and the availability of safety data to protect the public and the environment. **The initial steps for the Government of Canada to consider include:**

1) **Support the passing of Bill C-494 on nanomaterials in the 2010 Fall session of Parliament to explicitly address nanomaterial and nanotechnology products in the *Canadian Environmental Protection Act 1999*, with amendments to the Bill to strengthen the provisions for assessment, seek safety data information from affected industry, and require public engagement and public reporting.**
2) **Place an immediate interim ban on use of nanomaterials and technology in cosmetic products, personal care products and other consumer products such as clothing due to the direct exposure of nanomaterials to human health, particularly to vulnerable populations.**
3) **Following the European Union's recent revisions to its Cosmetic Products Regulation, promote public access to information through the development of a public inventory for**

Canada of nanomaterial and nanotechnology products, with specific emphasis on cosmetic, personal care products and other consumer products such as clothing.

4) **Apply a precautionary and preventive approach on nanomaterials including:**
    a. **supporting amendments to the New Substances Regime to require the expansion and requirement for new toxicity data for assessments and include public engagement and reporting in the assessment process, to name a few. The Government should establish a stakeholder consultation process to further these efforts immediately.**
    b. **Protection of vulnerable populations, particularly workers and children, from exposure to nanomaterials in the absence of adequate toxicity information.**

There are opportunities to expand this work in the coming months, therefore it is of some importance that Health Canada expands on their intentions and the scope of work on nanomaterials and nanotechnology it plans to undertake in the four major federal legislations listed in page 4 of the Interim Policy document. For example, the *Food and Drug Act*, and in particular, the Cosmetic Regulations, and the *Hazardous Products Act*, are in different phases of review or revisions and should be flagged for further discussion on nanomaterials. Currently, there has been very limited dialogue on these matters in these processes on nanomaterials. CELA, jointly with the Canadian Institute for Environmental Law and Policy, indicated in 2007 the inadequacy of the *New Substances Notification Regulations* to address nanomaterials but no response to the recommendations by our respective organizations have been received to date.

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APPENDIX

Submission by:
Canadian Environmental Law Association and Canadian Institute for Environmental Law and Policy
November 15, 2007
Response to Proposed Regulatory Framework for Nanomaterials under the Canadian Environmental Protection Act, 1999.

November 15, 2007

Bernard Madé
Director
New Substances Division
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

CELA Publication #537

March 16, 2006

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Dear David and Mary Ellen:

On behalf of the Canadian Environmental Law Association (CELA), we are writing to you regarding your email dated March 6th, 2006 announcing the publication of a Canada Gazette Notice for March 4th, 2006 entitled *Notice with respect to Selected Substances identified as Priority for Action* in *Part I* of *Canada Gazette*. CELA is expressing its concern and surprise over the timing of the release of this notice. As you know from previous multi-stakeholder meetings on matters regarding the Domestic Substances List (DSL) categorization process, CELA has been keenly interested in the development of this and subsequent surveys in relation to the DSL categorization work. We expressed our eagerness to participate in meetings and teleconferences on this topic because the government viewed surveys as a means of gathering industry information for the purposes of prioritizing substances for assessments. The efforts initiated by your department to facilitate discussions with CELA and others on the development of surveys were welcomed.

At the last such teleconference on January 27, 2006, CELA and industry representatives were provided with a draft copy of the survey and asked to provide comments. We welcomed the invitation to participate in this important discussion, and we did so with the understanding that there would be additional opportunity to review (and comment on) the next draft of the survey before its final publication. Indeed, this understanding was confirmed by government representatives at the end of the call.

CELA recognizes that government is under a significant time pressure to publish and incorporate the results from the surveys. However, CELA is concerned that the publication of this survey in the absence of further discussion with stakeholders participating on the January 27th call demonstrates a departure from the consultation process which had been outlined. Such a development weakens the transparency of government's actions. Upon further reflection, it appears that the process to develop surveys, which already included ongoing dialogue with industry representatives, was in its late phases. Hence, CELA's participation in the later stages of this process did not provide the opportunity for real engagement and input into these matters.

Given these developments, CELA identifies below some examples of issues and concerns which have yet to be addressed by government in the course of survey development. At least one of these issues, the application of confidentiality requirements, has been raised repeatedly by us in previous DSL

categorization discussions. Not only does the current notice in the Canada Gazette fail to reflect consideration of our recommendations on confidentiality requirements, CELA also has yet to receive any government response to, or acknowledgement of, the concerns we expressed during the meetings. It is noted that nearly all of the final changes made to the draft survey reflected industry concerns, and such changes were made without the opportunity for CELA and other public interest organizations to respond to these amendments.

Confidentiality

The text on confidentiality found in both the Gazette notice and the accompanying Guidance document is wholly inadequate. In the Gazette notice, notifiers are simply asked to indicate for which items they are claiming confidentiality, and to provide an open-ended written justification. The Guidance document provides a list of considerations which may provide the basis for their justification. The list includes such considerations as "the information is not available to the public." In the public interest, CELA would argue that such a circular justification (i.e., the public should not be allowed access to this information because the public does not have access to this information) is overly permissive. While recognizing that the text of the Gazette notice and Guidance document is a legal interpretation of section 313 of *the Canadian Environmental Protection Act* (CEPA), we contend that government's interpretation of this section has become increasingly vague and open-ended over time. Evidence of this is found in the Guidelines for the Notification and Testing of New Substances, in which the New Substances Program construes the same section in a more restrictive manner. Namely, in section 9.2.1 of that document the list of confidentiality "considerations" is portrayed as a list of criteria, each of which must be met in order to successfully claim confidentiality. Furthermore, the New Substances Notification Guidelines require notifiers to sign a specific Certification Statement pertaining to their confidentiality claim, in addition to signing-off on their notification package as a whole. While we would still argue that the criteria used are overly broad, the New Substances Program's approach at least attempts to provide concrete guidance and oversight for notifiers claiming confidentiality.

CELA is concerned that this recent development for claiming confidentiality by industry or other affected facilities may lead to further weakening provisions for public access to information and limiting transparency in process.

Date and Volume Restriction

The Gazette notice is restricted to persons manufacturing or importing more than 100 kilograms of a substance during the 2005 calendar year. Additionally, there is a Stakeholder Identification section in the Declaration of Non-Engagement which allows companies to indicate their interest in a substance even if they do not meet with notice requirements. Presumably, government has structured the survey in this manner so as to minimize the number of mandatory responses while still allowing others to participate on a voluntary basis. However, this approach introduces several legal complications which remain unresolved. It is our understanding that government may apply restrictive Significant New Activity (SNAc) notices to those substances which were not in use in 2005 in amounts over 100 kg. As a result, companies which used the substances in 2004 or previously, or plan to use the substances in 2006 or subsequently, or currently use the substances in amounts under 100 kg, will have to proceed through the New Substances Notification Regulations.

While this approach would seem justified for those substances which truly are not present in Canadian commerce, this survey does not appear to provide such information. CELA views the lack of additional

and relevant information outlining conditions required to notify a SNAc as a significant gap in conducting these surveys. For example, industries may use different batches of substances over time as their product lines change and evolve, and companies which used high volumes of the substances in 2004 may not meet the survey requirements for 2005. Nonetheless, government is still obliged to assess the impacts of these substances on the environment and human health through screening assessments.

Similarly, unlike the *New Substances Notification Regulations* (NSNR), there are no volume triggers for the assessment of existing substances sections 73 and 74 of CEPA. If substances meeting the categorization criteria are currently used in amounts under 100 kg, they should still receive screening assessments (even if they are not assigned a high priority for this next step).

It is entirely possible that substances manufactured or imported in some year other than 2005, or in amounts smaller than 100 kilograms, nonetheless pose a hazard. The reasons for this could include their persistence in the environment, synergistic effects with other DSL substances, or potential for long range transport, to name a few. There is therefore a need and a legal obligation to assess their toxicity and determine appropriate risk management strategies. However, under the terms of this survey it will be impossible for government to identify which substances truly are not in Canadian commerce, and which simply were not in heavy use in 2005. The problem is exacerbated by the Guidance document, which fails to identify the anticipated next steps for these substances (i.e., possible SNAc notices). The document merely states that "confirmation of substances not currently in commerce in Canada will allow government to ensure that post-categorization efforts are focused on substances with potential for release into the Canadian environment." Since the serious implications of "non-responses" have not been communicated, companies may not be motivated to complete the voluntary Stakeholder Identification section of the notice.

Additional Issues

It is noted that the Gazette notice and Guidance document have been additionally weakened to reflect industry concerns. We highlight two such instances:

- the removal of volume information for substances hazardous to human health (see section 3 of schedule 1), and,
- the use of the phrase "may meet the categorization criteria" under the description of which substances have been included in survey.

Based on level of uncertainty implicit in Health Canada's estimations on exposure, we are disappointed that government has foregone this opportunity to gather information on the quantity range for manufacture or import in 2005. This information had been previously included in the draft survey, and was challenged by industry at the January 27 conference call.

With respect to the phrase "may meet categorization criteria", we note that this is very misleading given the high level of concern associated with the categorization packages decisions for these substances. Based on available data and application of government approached for categorization process, the substances targeted under the notice do meet the criteria under Section 73 as of March 4th. Furthermore, as of September 14, 2006, it will become technically inaccurate to use the word "may"; once the categorization process is complete, these substances will have met the criteria, though they may or may not be declared as toxic in the final analysis. Thus, government should be cautious in using qualified language in an effort to lessen the stigma associated with these substances.

In conclusion, CELA would like to articulate that the application of surveys (section 71) is necessary and critical in the categorization process. It is expected that the information gathered through surveys provide extremely valuable information for setting priorities for the departments among other things. However, the surveys announced in the Canada Gazette notice of March 4th may prove to be nothing more than an exercise to further reduce the number of substances which meet the criteria outlined in section 73 of CEPA that should be identified for further screening level risk assessments by government. From this perspective, CELA is very concerned that the surveys are being applied in a very limited manner and scope which may result in underestimating the number of DSL substances that truly require further attention by Environment Canada and Health Canada to protect the Canadian environment and human health.

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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