Canadian Environmental Law Association
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CSM
Chemical Sensitivities Manitoba

July 16, 2013

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Re: Response to Consultation on RCC Nanotechnology Policy Principles for Decision-Making Concerning Regulation and Oversight of Nanotechnology and Nanomaterials

Background:

The Canada-US Regulatory Cooperation Council (RCC) was formed in February 2011 to increase regulatory transparency and coordination between the two countries. The RCC Joint Action Plan is an integral component in the ongoing process of regulatory cooperation between Canada and the United States. It addresses four key sectors which include 29 initiatives in total, including nanotechnology.

Chemical Sensitivities Manitoba and the Canadian Environmental Law Association are providing the following comments in response to the Canadian approach to nanomaterials. Over the years, there has been an exponential growth of the nanomaterial industry. The global market for products containing nanotechnology is expected to reach $2.6 trillion by 2015.[1] This trend is not expected to decline in the near future. However, our regulatory response to effectively address and manage emerging concerns regarding nanomaterials has lagged behind considerably. Based on our past experience with the introduction and use of existing and new chemicals, it is difficult and burdensome for society to continue to support a reactive approach regarding the assessment and management of new materials such as a nanomaterial. Our organizations urge the government to pursue an approach that supports and utilizes the precautionary principle, pollution prevention and furthers the requirements for transparency with regards to nanomaterial use in Canada.

At present, the Government of Canada relies on existing policies and regulatory frameworks for new substances to evaluate the potential risks to human health and the environment from

[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.

nanomaterials. We have expressed our on-going concerns regarding this approach in recent meetings with government officials. Hence, we are taking this opportunity to reiterate comments previously made as we respond to the Government of Canada's *Policy Principles for Decision-Making Concerning Regulation and Oversight of Nanotechnology and Nanomaterials.*[2] We also urge you to refer to a submission by CELA dated August 27, 2010 in response to Health Canada's consultation document, *Interim Policy Statement on Health Canada's Working Definition for Nanomaterials.*[3]

Specific Comments & Recommendations

Definition for nanomaterial

Nanomaterials are used in many sectors of the marketplace, for both commercial and consumer products. At present, the Government of Canada has no definition for nanomaterials and nanotechnology but Health Canada has developed a working definition for nanomaterials which indicates that a manufactured substance or product and any component material, ingredient, device, or structure is considered to be a nanomaterial if *"(a) it is at or within the nanoscale (1-100nm) in at least one external dimension or has internal or surface structure at the nanoscale; or (b)it is smaller or larger than the nanoscale in all dimensions and exhibits one or more nanoscale/properties/phenomena".* Nanotechnology is described as the control of matter at the nanoscale or utilizing nanoscale phenomena to enable novel applications.

Comments:

- The above definition and description of nanotechnology are consistent with information from the U.S. Nanotechnology Initiative Website. However, other agencies in different jurisdictions (for example, the UK House of Lords Science and Technology Committee and the State of California) have considered more stringent ranges for defining a nanomaterial.

- We have on-going concerns that the provisional scale of a nanomaterial (1 – 100 nm) is very restrictive. There is also heightened international concern that this range may not be the most appropriate range to distinguish nanomaterials from their bulk counterparts with respect to health and safety concerns. Particles can be larger than 100 nm and exhibit similar anatomical and physiological behaviour to nanomaterials.[4] With such a restrictive

[2] RCC Nanotechnology Policy Principles for Decision-Making Concerning Regulation and Oversight of Nanotechnology and Nanomaterials. Accessed at http://nanoportal.gc.ca/6AEDAEBA-759A-4C21-A3C0-52CAA61783AE/RCCenglish2.pdf

[3] Canadian Environmental Law Association. 2010. Response to Interim Policy Statement on Health Canada's Working Definition for Nanomaterials. Access http://www.cela.ca/sites/cela.ca/files/738-submission%20to%20HC%20on%20nanotechnology%20%28Aug%202010%29.pdf

[4] 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

scale, some nanomaterials could be missed even though one pre-requisite from Health Canada's Working Definition on Nanomaterials [5] covers dimensions greater than the upper limit of 100nm for materials exhibiting nano-behaviour. Identification of substances that are greater than 100nm in dimension and exhibit nano-properties could require significant effort. While dimension is important for identification, the other properties that work in concert with size (e.g. surface charge, shape) are also important factors in the determination of the toxicity of the substance.

Recommendation: Canada should formalize a definition for a nanomaterial that is less restrictive than Health Canada's current working definition for nanomaterials as it applies to dimensions in the ~~f~~range: 1 – 100nm. **The definition for nanomaterial should be revised to include sizes in the range up to 1000 nm.**

Limited data on nanomaterials and products containing nanomaterials

Comments:

- While it is important to ensure that the approach to assess and manage nanomaterial is science based, the current regulatory framework lacks adequate data requirements, particularly at the lower trigger volumes, to conduct its assessment and evaluation. Also, the framework does not require the establishment of a monitoring regime to track the presence and effects of nanomaterials in the environment.
- There is limited available data on the effects of nanomaterials on human health and the environment. But there is a growing body of evidence that demonstrates the effects of specific nanomaterials to workers. Currently, the approach does not explicitly outline under what conditions the precautionary principle will be applied in making decisions on the toxicity of nanomaterials. Without ensuring if and how the precautionary priniciple can be applied in the assessment of nanomaterials, it is unclear how limited data could be used to make sound scientific and policy decisions and ensure scientific integrity. The challenge posed by the on-going existence of limited data or data gaps should not be further entrenched by government. The significant data gaps for human health effects and environmental impacts from nanomaterials should be addressed using the government's full authority under its laws to collect or

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http://nano.foe.org.au/sites/default/files/Nanotechnology%20in%20food%20and%20agriculture%20-%20web%20resolution.pdf

[5] Health Canada. Policy Statement describing Health Canada's Working Definition of Nanomaterials. Effective date: October 6, 2011. Accessed at http://www.hc-sc.gc.ca/sr-sr/pubs/nano/pol-eng.php

generate data essential to an assessment. For example, the use of mandatory surveys would require proponents to produce specific data on nanomaterials before their products would be permitted into the market. Under CEPA 1999, Health Canada and Environment Canada have the authority to require such data be submitted to complete their assessment of a nanomaterial. The reliance of the New Substances Program and the New Substances Notification Regulations (NSNR) to effectively assess the toxicity of nanomaterials would require some amendments for the adequate protection of human health and environment. Amendments to the NSNR may include but are not limited to the collection of data on nanomaterials at lower trigger volumes than those required for new substances or polymers. A more robust NSNR would give consideration to the health effects of vulnerable populations such as the fetus, children and workers exposed to nanomaterials.

- There is limited evidence to support a conclusion of 'no harm' or 'substantial equivalence' of nanomaterials as compared to their non-nanoscale analogs. In some cases, there is probably no bulk form available for comparison of properties. There are many existing chemicals in commerce with limited toxicity data so attempts to use the current database to help guide or fill in any data gaps that may exist for a new nanomaterial or even an existing nanomaterial, could be problematic.
- There are a growing number of studies outlining health concerns related to nanomaterial. For example, there are concerns that some nanomaterials may have the potential to cross the blood brain barrier.[6] Another study involving fibrous nanomaterials made of carbon has shown evidence that they can induce inflammation in the lungs in ways that are similar to asbestos.[7] Within an occupational setting, carbon nanotubes require consideration, no different to that of persistent fibres and possibly, this is where one may expect to see potential health effects for some of these materials. These issues require discussion, not only between government departments but also with interested stakeholders thereby allowing transparency to the system.
- To better inform exposure data, it would be valuable for Canada to consider undertaking large population studies and increase environmental monitoring so that exposure and risks to certain nanomaterials could be better identified and defined.

Recommendation: Health Canada and Environment Canada should use its full authority under CEPA 1999 to issue mandatory surveys to collect or generate information on the

[6] Gilmore, JL. et al. 2008. Novel nanomaterials for clinical neuroscience. J Neuroimmune Pharmacol. June: 3(2): 83-94.

[7] National Institute of Health Sciences, U.S. Department of Health and Human Services, U.S. Federal Government. Accessed at http://www.niehs.nih.gov/health/topics/agents/sya-nano/

toxicity of nanomaterials to improve industry accountability as well as reduce current data gaps in their decision making process.

Recommendation: The government should amend the New Substances Notification Regulations so that it can more appropriately deal with nanomaterials and acquire increased toxicity data at lower trigger volumes.

Recommendation: The regulatory regime for nanomaterials should ensure implementation of section 70 of CEPA to ensure that any new data for a substance pertaining to health and the environment, should be forwarded to the government in writing without delay. Once reviewed, any appropriate changes or requirements for additional information in the assessment should be undertaken and reflected in risk management measures.

Recommendation: The lack of data and in particular, historical data on nanomaterials, should dictate that a more precautionary approach be adopted in their evaluation and management. The government should apply the precautionary principle in the absence of data showing the impacts to the environment or human health.

Recommendation; The government should ensure that monitoring programs are established for nanomaterials and consider large population studies for nanomaterials exposure.

Recommendation: The government should review the approaches for evaluating and managing nanomaterials applied by other jurisdictions so that Canada's approach to nanomaterial is harmonized to reflect the most protective approach taken by other jurisdictions.

Vulnerable populations and vulnerable ecosystems

Comment:

- The current regime to evaluate and manage nanomaterials in Canada does not provide any consideration into how it will address unique vulnerabilities by subpopulations such as workers, children, or developing fetuses. In addition, special consideration should be given to the effects and detection of nanomaterials in vulnerable ecosystems in Canada, such as the Great Lakes-St. Lawrence River Basin or the arctic regions. For these regions, adequate monitoring programs are necessary to track the presence and fate of nanomaterials.

Recommendation: The government's assessment process should require special consideration for the potential effects of nanomaterials on vulnerable populations such as workers, developing fetuses and children as well as impacts to vulnerable ecosystems such as the Great Lakes-St. Lawrence River Basin or the arctic regions.

Canada does not have a database for nanomaterials and products

Comments:

- Nanomaterials are likely being imported in finished consumer and industrial products and at present, there is very little data to indicate which nanomaterials are likely to present a harmful scenario to human health and the environment. A database, available to the public that lists nanomaterials in consumer and industrial products would facilitate tracking nanomaterials in commerce, addressing their life-cycle and acquiring comprehensive information on nanomaterials that are in commerce.

- There is a likelihood that some manufactured nanomaterials may currently be in commerce without having gone through proper notification with the government. Our organizations are expressing our concerns that the government does not have a clear plan forward to rectify this situation.

Recommendation: CSM and CELA urge the Canadian government to establish a publicly available database for manufactured nanomaterials and their products.

Public engagement

Comment:

- Throughout the process in establishing a regime to track and evaluate nanomaterials, there has been very limited and vague public engagement. At best, this engagement has been sporadic and inconsistent. This level of engagement does not provide an opportunity for valued input on important matters such as the quality of data required for evaluation, definition of a nanomaterial, or the importance of accountability and transparency. The lack of public engagement to discuss the applicability of the New Substances Program to assess nanomaterials will continue to be very problematic unless the government increases its efforts in public engagement and transparency.

Recommendation: Government should consider various methods of public engagement that would include webinars, face-to-face meetings, and bilateral meetings with stakeholders, so as to encourage participation beyond academia and industry.

Recommendation: Canada should fully engage and support the participation of Canadian public interest organizations in developing policies for nanomaterials at the national and international processes, with special focus to engage environmental, health, labour and First Nations organizations in these matters. This involvement should include

the participation of Canadian non-governmental organizations in the OECD Working Group discussions on nanotechnology and nanomaterials.

Addressing confidential business information

Comments:

- As an emerging science, nanotechnology is expected to generate a considerable number of requests for confidential business information (CBI). Based on our experience with the approach used to assess existing substances, the request for CBIs may not be sufficiently justified and validated by the government. The public cannot challenge CBIs. This would be expected to continue with nanomaterials. With an expected excessive and non-justified use of CBI, relevant information on nanomaterials cannot be divulged nor can the evaluation and decision making process be transparent. It is likely the final decisions on evaluation of nanomaterials will continue to be questioned or scrutinized where CBIs have been increasingly requested.

- Furthermore, the use of CBI also limits right to know. For example, the public may be unaware that consumer products may include nanomaterial or workers may not be provided adequate information on nanomaterials with the potential exposure hazards to these substances in the workplace.

Recommendation: Careful consideration should be given when granting CBI claims for nanomaterials as some of them may not be valid.

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