

Canadian Environmental Network

CONSULTATION REPORT FORM

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Title of Consultation:

Workshop on a Proposed Regulatory Framework for Nanomaterials under *CEPA*

Date(s) held:

Thursday, September 27, 2007

Location:

Holiday Inn Hotel on King (370 King St. West) in Toronto

Delegate Name and Affiliation: Maria Castro, Beyond Factory Farming Coalition

Maureen Carter-Whitney, CIELAP

Number of ENGO Delegates at Consultation: 2 RCEN delegates, 5 NGOs represented

What was the purpose of the consultation?

Environment Canada and Health Canada are seeking comments on their suggested approach to developing a regulatory framework to assess and manage the risks that nanomaterials may present to human health and the environment. The workshop was held to solicit input from stakeholders involved in the manufacture, use or sale of nanomaterials, undertaking nanomaterials research, or concerned with the potential health or environmental impacts of nanomaterials.

The federal government is considering the development of a regulatory framework for nanomaterials under the *Canadian Environmental Protection Act, 1999*ⁱ (*CEPA*) because current data requirements for more 'traditional' chemicals and polymers may not be appropriate to permit adequate risk assessments for nanomaterials. In June 2007, the government issued a New Substances Program Advisory Note stating that substances on the Domestic Substances List whose nanoscale forms do not have unique structures or molecular arrangements are to be considered “existing,” while those that do will be considered “new.”

Health Canada and Environment Canada are proposing 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 nanomaterials.
- Consider whether legislative amendments to *CEPA* or amendments to the New Substances Notification Regulation (NSNR) 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 NSNR 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 Domestic Substances List where it is suspected that a significant new activity in relation to a substance already in commerce might result in the substance becoming “toxic” as defined by *CEPA*.

What were the outcomes of the consultation?

A great deal of information was presented on current activities related to nanomaterial regulation in Canada, the US and internationally. Industry was represented by a very broad range of companies ranging in size from GE and BASF to the very smallest R&D companies, from Canada, the US and Europe, as well as some associations and consulting groups. There clearly was a great deal of interest in how Canada is planning to move forward. There was also representation from USEPA, and from a number of other Canadian ministries. The stakeholders present were divided into break-out groups in the afternoon to discuss specific elements of the proposed regulatory framework, such as whether or not information should be gathered on a voluntary or mandatory basis. There was also discussion on how best to engage stakeholders and the public with respect to nanotechnology and how to capture research activity in the regulatory framework. Participants generated a broad range of ideas and opinions that were noted by Environment Canada and Health Canada.

The government departments accepted further comments on the consultation document until October 31, 2007. CIELAP and CELA are preparing additional, more detailed and more expansive comments in response to the paper and consultation. The government

plans to make available minutes of the workshop by the end of November and to respond to stakeholders' comments by the end of January 2008. Environment Canada and Health Canada hope to develop an information-gathering survey for early 2008. The timing of the next consultation on a regulatory framework for nanomaterials will be determined and information to stakeholders will be ongoing.

What are the implications of the outcomes of the consultation?

Nanotechnology involves the manipulation and manufacture of materials and devices on the scale of minuscule materials (i.e., atoms or small groups of atoms). Nanotechnology development is becoming increasingly lucrative and the Canadian government is investing heavily in research, development and commercialization. There are currently more than 580 manufacturer-identified consumer products on the world market that use nanotechnology, and many more are poised for development in fields such as medical applications, cosmetics, industrial coatings, environmental sensors and remediation.

Nanomaterials have value because materials at this scale can exhibit novel properties that are different from the same substance's properties at the macro or even micro scales. However, the environmental and health effects of nanomaterials are largely unknown. Early studies have found nanoscale particles to be substantially more toxic and biologically reactive than larger particles of the same material – possibly because of their greater surface area.

Given the potential for toxicity in nanomaterials and the lack of knowledge about those toxic properties at present, it is vital that a regulatory framework be developed carefully with strong input from all stakeholders and members of the public, and that the precautionary principle be respected.

It is clear that the regulatory environment, as well as the science surrounding risk assessment and classification of nanomaterials is globally lagging significantly behind technological development. It will be difficult to develop regulatory frameworks until some of the data gaps have been plugged. It was pointed out that in the interim EC has the power under the NSNR to request additional data on any new substance that is notified and may pose a risk. As these data may currently simply not be available, this may mean in some cases that substances would be prevented from going into use in Canada. It is unclear how current NSNR trigger volumes and the lack of differentiation of bulk substances already on the DSL from their nano forms may allow things to “slip through the net.”

Industry is, unsurprisingly, concerned about regulatory burden, particularly for the many very small development companies who may not have adequate resources to deal with it, and about intellectual property protection. While some industry representatives attempted to downplay the potential risks of nanomaterials, others frankly admitted the potential for harm. The levels of confidentiality surrounding development of new substances is such that it appears that in some cases the company employees are unaware of what they are

actually working on. This raises issues around workplace health and safety. (Note: I did not notice any labour representation at the workshop.)

It was also apparent that industry has been “stung” by the negative associations that now surround the label “biotech”, mostly as a result of the various debacles associated with the inadequate regulatory environment for GMOs. It can only be hoped that the lesson has been learned and that industry will seek to avoid another negative image problem by accepting responsibility for the potential harm their activities might cause and co-operating fully and in good faith with regulators and civil society in developing risk mitigation strategies.

Another point of note is that EC under CEPA is “spearheading” the Canadian development of a regulatory framework for nanomaterials, but that similar regulations will have to be developed for all the acts that are scheduled and have equivalency under CEPA, i.e. Pesticides Management Act, Seeds Act, Feeds Act etc. It appears that the other departments are currently standing by to see what EC will do, and talking internally.

What action, in your opinion, should be taken by the ENGO community in the aftermath of this consultation?

It is important to educate the wider ENGO community and the general public about the swift development and commercialization of nanomaterials. It is also vital that ENGOs continue to participate actively in the process of developing a regulatory framework.

This will be a lengthy and often very technical process, and the ENGO community should start thinking quickly about developing appropriate capacity and resources. Also, while the New Substances Division in EC has a track record and willingness to involve the environmental community, other departments that administer the scheduled acts, e.g. CFIA, PMRA, have not. We will likely have to be pro-active about initiating dialogue with those departments.

ⁱ S.C. 1999, c. 33.