

National Industrial Chemicals Notification and Assessment Scheme  
Proposal for Regulatory Reform of Industrial Nanomaterials

RESPONSE FROM CANADA  
Prepared by Environment Canada and Health Canada  
New Substances Program

General comments

Canada is supportive of the NICNAS proposal for regulatory reform and how the proposal begins to address some of the major issues regarding regulation and assessment of nanomaterials.

Canada is considering a similar approach to regulatory reform under the *New Substances Notification Regulations (Chemicals and Polymers)* (NSNR) and the *Canadian Environmental Protection Act, 1999* (CEPA 1999). The New Substances Programs of Environment Canada and Health Canada are drafting a preliminary proposal and are in the early stages of planning multi-stakeholder consultations as a follow up to the first consultations held in September 2007. The proposal will take into consideration the findings of a report by the Council of Canadian Academies published in July 2008 which identified many of the same major issues as noted in the NICNAS proposal for regulatory reform, including the classification of nanomaterials and regulatory triggers (Council of Canadian Academies, 2008).

Canada is very interested in the outcomes and responses to this first round of consultations undertaken by NICNAS. Continued cooperation will benefit both programs and may give rise to other opportunities.

In addition, to the general comments above, we offer more detailed comments in the following two areas.

Working Definition

Health Canada released an interim policy statement on a working definition for nanomaterials on March 2, 2010 (Health Canada, 2010). The primary objective of the statement is to establish a means of identifying nanomaterials to assist Health Canada in gathering safety information about products containing nanomaterials.

Health Canada identified the need to start with a broad, overarching definition for nanomaterials to ensure that all nanomaterials were captured in the wide range of products categories and applications under the authority of Health Canada. It is recognized, however, that a significant challenge with a broad working definition is that it may capture substances which fall outside the scope of a specific regulatory program and conversely may exclude substances which do

fall within the scope. As such, Canada's intent is to refine the broad working definition as required for specific regulatory and legislative contexts within Canada.

Furthermore, in examining possible approaches to defining nanomaterials for a specific regulatory program, Canada has considered the use of inclusion and exclusion criteria. It was felt that this would allow some flexibility to refine the definition as more information becomes available and it would also reduce some uncertainty in identifying what nanomaterials are and are not within the scope of the specific regulatory program.

In moving forward with developing a regulatory definition for nanomaterials, Canada believes it is important to monitor the work of ISO TC229 and the outcomes from the nomenclature project group (PG11) led by Canada. The objective of the ISO work is to establish a framework for the development of nomenclature models for nano-objects and the work is expected to be completed by fall 2011. It is recognized that an internationally accepted nomenclature system for nanomaterials is a key element in developing robust regulatory frameworks.

#### Research & Development

The proposed trigger of 100 g seems low and it would be helpful to us to know the basis for this proposed trigger. Based on our limited knowledge of R&D in Canada, it was determined that such a low trigger volume would include government departments and academic institutions which may be outside the intended scope of the Canadian regulatory program under CEPA. It is recognized that it is difficult to determine an appropriate trigger for R&D when there is lack of clarity of what volumes of a particular nanomaterial are representative of potential commercialization.

## References

- Council of Canadian Academies. (2008). *Small is different: A Science perspective on the regulatory challenges of the nanoscale*. Ottawa, Canada: Author. <http://www.scienceadvice.ca/nanotechnology.html>
- Environment Canada and Health Canada. (2007). *Proposed regulatory framework for nanomaterials under the Canadian Environmental Protection Act, 1999*. Ottawa, Canada: Authro. [http://ec.gc.ca/substances/nsb/eng/nanoproposition\\_e.shtml](http://ec.gc.ca/substances/nsb/eng/nanoproposition_e.shtml)
- Health Canada. (2010). *Interim Policy Statement on Health Canada's Working Definition for Nanomaterials*. Ottawa, Canada: Author. <http://www.hc-sc.gc.ca/sr-sr/consult/2010/nanomater/index-eng.php>