American Chemistry Council | Nanotechnology Panel

September 23, 2016

Via Email: eccc.substances.eccc@canada.ca

Environment and Climate Change Canada
Substances Management Information Line
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Gatineau, Québec K1A 0H3

To Whom It May Concern:

The Nanotechnology Panel (Panel) of the American Chemistry Council[1] appreciates the opportunity to comment on Environment and Climate Change Canada's and Health Canada's (ECCC and HC) consultation document *Proposed Prioritization Approach for Nanoscale forms of Substances on the Domestic Substances List.*[2] The Panel generally agrees with the proposed approach and appreciates the statement that the prioritization process *"is not meant to be a surrogate for a risk assessment, and the overall priority ranking of the nanomaterials may not necessarily reflect potential human health or environmental health risks"* (Section 3.2). The Panel supports the risk-based approach described in the consultation document and the parent material approach for grouping (List 1). The comments below are offered in the spirit of refining the prioritization process and identifying key points that, in the Panel's opinion, require additional explanation.

Data rich substances should be handled separately. The Panel strongly recommends that data-rich substances for which there are no critical hazard concerns should be set aside so that they do not "dilute" their parent substance group (List 1) and potentially obscure materials for which less information is available and, therefore, may be of higher interest for future information-gathering regulatory activity. Many nanoscale substances have been in commerce for decades and have robust health, safety, and environmental databases from which to draw information (e.g., many metal oxides). Removing data-rich, historical substances from their parent material group will allow more meaningful prioritization of more novel substances through the proposed parent material group approach.

Experience with substances that have been in commerce for long periods should not be set aside in the prioritization exercise. The Panel is concerned that the proposed approach treats nanoscale substance as if they are all new and novel, which is clearly not the case. The many decades of experience with some nanoscale materials should be incorporated into the process in order to make meaningful prioritization conclusions that direct agency resources appropriately. For example, if it is well documented that sensitive populations, including children, have been exposed to products containing a certain

[1] Members of the ACC Nanotechnology Panel are 3M, BASF Corporation, Cabot Corporation, Chemours, DuPont, Evonik Corporation, Lockheed Martin Corporation, and Procter & Gamble.
[2] July 2016. Available at http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=FA3C8DBF-1 (accessed September 21, 2016).

nanomaterial on a regular basis due to direct use in consumer products and no indication of adverse reactions have been identified, then the priority level should be consciously reduced. Integrating experience may produce more meaningful results than simply following the lines of a flow chart.

More explanation is needed regarding application of North American Industry Classification System (NAICS) codes. The consultation document says *"human and ecological exposure will be determined separately using information obtained from the s.71 survey such as information on volume, sector (based on reported . . . NAICS codes) and use (based on reported substance function code)"* (Section 3.2.1). However, we were unable to find in Figure 2 or the accompanying text a clear explanation or example of how the NAICS codes would be applied to differentiate human and ecological exposure potential. The Panel strongly recommends that this aspect of the prioritization process requires further elucidation and clarification.

More explanation is needed regarding how prioritization conclusions will be made. The consultation document states prioritization will result in material groups being places in one of three bins: "*no further action at this time, nanomaterials prioritized for risk assessment, and nanomaterials that will be set aside for future consideration due to insufficient information"* (Section 3.3). The document says that the binning results will determine the next steps for potential additional actions. However, the Panel finds the consultation document unclear with regard to how three human exposure considerations (Section 3.2.1), three ecological exposure considerations (Section 3.2.1), three human exposure prioritization flags (Table 1), and three ecological hazard flags (Table 2) will be combined to determine which of the final bins is appropriate. For example, if the substance is reported to be used in a children's product, will it automatically be prioritized for risk assessment? More explanation is needed to understand how ECCC and HC will make final prioritization decisions.

The consultation document does not explain how indirect exposure will be considered. Figure 2 contains an arrow indicating indirect exposure in the event of environmental release from an industrial facility. The description of Figure 2 and the remainder of the document provide little information on how ECCC and HC will consider indirect exposure potential in addition to direct exposure potential in prioritization. The statement that indirect exposure *"will be considered if the import/manufacture volumes are considered high and the information is available"* (Section 3.2.1) is vague and does not explain how indirect exposure will be incorporated into the prioritization decision-making process with other factors described in the consultation document. The Panel would appreciate additional clarity on this matter.

Ecological exposure potential should not be tied to the potential for release alone. The potential for release (yes/no) is relatively uninformative unless the volume of material, the mode of release, and the environmental compartment(s) to which the material settles and/or accumulates are also considered (e.g., into the air, into waterways, into sediments). The Panel urges ECCC and HC to consider that the mode of release for a nanoscale form of an existing material may not be appreciably different than for the non-nanoscale form of the substance, and knowledge about the environmental behavior of non-nanoscale forms should be used to inform prioritization.

ECCC and HC should consult information on non-nanoscale forms to contextualize environmental exposure potential. Additional considerations for informing the ecological exposure potential include the likelihood the nanoscale form evades natural surface passivation processes, the amount of the substance occurring naturally, and the amount of time it takes for a released engineered nanoscale material to become indistinguishable from naturally occurring materials. Such dimensions add complexity, but the

Panel believes that for many substances, the existing literature on environmental fate and behavior can be leveraged to inform predictions of nanoscale materials in the environment.
The Nanotechnology Panel appreciates the opportunity to provide these comments to ECCC and HC. Please do not hesitate to contact me (Jay_West@americanchemistry.com) if you have any questions.

Sincerely,

Jay West
Senior Director, Chemical Products and Technology