May 29, 2015

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VIA E-MAIL (Brad.Fisher@ec.gc.ca and Lorraine.Tetreault@hc-sc.gc.ca)

**Re: Public Consultation on *"Proposed Approach to Address Nanoscale Forms of Substances on the Domestic Substances List"***

Dear. Mr. Fischer and Ms. Tetreault:

The Nanotechnology Panel of the American Chemistry Council[1] (the Panel) appreciates the opportunity to submit comments on the public consultation document "*Proposed Approach to Address Nanoscale Forms of Substances on the Domestic Substances List (DSL) – Consultation Document"* (March 3, 2015) (consultation document).[2] We strongly urge Environment and Health Canada (the agencies) to consider the comments submitted by the Canadian Environmental Protection Act Industry Coordinating Group's Nanomaterials Sub-Committee (CEPA ICG Nano SC), which the Panel supports in its entirety. We provide the following additional comments in supplement of the CEPA ICG Nano SC comments.

**The Panel supports the stepwise approach described in the consultation document.[3]** Determining what nanoscale forms of existing substances are in commerce in Canada is a logical first step for addressing nanoscale forms of substances on the DSL. Doing so will create a basis for more targeted, prioritized information gathering and decision-making activities for both the agencies and industry, as "there is no consistent causal link between nano size alone and

[1] Members of the ACC Nanotechnology Panel are 3M, BASF Corporation, Cabot Corporation, DuPont, Evonik Corporation, Lockheed Martin Corporation, and Procter & Gamble.
[2] Available at http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=1D804F45-1&offset=&toc=hide (last accessed May 21, 2015).
[3] *See* Section 3 of the consultation document.

*The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is an $812 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for twelve percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.*

hazards."[4] The Panel also appreciates that the consultation document clearly outlines potential future next steps and the potential outcomes of prioritization.

**The Panel strongly urges Canadian and U.S. authorities to collaborate to the greatest extent possible in their parallel information gathering activities.** The Canadian consultation document was released just prior to publication of the U.S. Environmental Protection Agency's (EPA) proposed rule for reporting requirements under Section 8(a) of the Toxic Substances Control Act.[5] The Panel recommends that Canada and the U.S. continue to work as closely as possible in the spirit of the Nanotechnology Work Plan of the Canada-U.S. Regulatory Cooperation Council *"to increase alignment in regulatory approaches for nanomaterials . . . in order to reduce risk to human health and the environment, promote the sharing of scientific and regulatory expertise, and foster innovation."*[6]

The Panel believes there are significant opportunities for the two countries to align their approaches with regard to the goals and objectives of their respective exercises, the scope of materials covered, information needs and subsequent reporting requirements, and the criteria used to prioritize materials for possible future action. Alignment has tremendous potential in terms of efficiency and cooperative learning between the countries and with affected industry. The Panel is extremely concerned that if the Canadian and U.S. approaches are not more closely aligned, the comparability of information and ability to move forward in a coordinated manner would be at risk and that the reporting burden on industry could be extremely high.

**In this spirit, the Panel recommends that Canada delay plans for a mandatory Section 71 survey until stakeholder feedback on both this consultation and the EPA's proposed rule are available and can be considered.** The Panel asks the agencies to consider whether a delay of a few weeks to a month would pose a considerable burden. The Panel believes public comments submitted in response to the U.S.'s regulatory proposal by the July 6 deadline could be extremely informative for the Canadian exercise.[7]

**The Panel respectfully requests that existing information be utilized to determine if further data are needed.** As noted by the CEPA ICG Nano SC, a number of the substances included in Appendix A are part of other regulatory evaluation programs, specifically the US High Production Volume (US HPV) Program (e.g., silane, dichlorodimethyl-, reaction products with silica), the US EPA Nanomaterials Stewardship Program (e.g. silica., titanium dioxide, carbon black), and/or EU REACH. The Nanomaterials Sponsorship Program of the Organisation for Economic Co-operation and Development (OECD) has generated substantial information on several manufactured nanomaterials as well. Data (particularly toxicological/safety information)

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[4] European Commission. 2011. Questions and answers on the Commission Recommendation on the definition of nanomaterial. MEMO/11/704. Available at http://europa.eu/rapid/press-release_MEMO-11-704_en.htm (last accessed May 24, 2015).
[5] 80 Fed. Reg. 65,18330 (April 6, 2015).
[6] *See* http://nanoportal.gc.ca/default.asp?lang=En&n=5a56cb00-1 (last accessed May 21, 2015).
[7] *See* EPA Docket EPA-HQ-OPPT-2010-0572-0001. Available at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2010-0572-0001 (last accessed May 26, 2015).

are available through these programs. In the spirit of streamlining and reducing duplication in efforts, the Panel respectfully requests this information be evaluated first to determine whether additional substance-specific data are needed.

**The Panel requests clarification of the proposed criteria for defining existing nanomaterials.** Section 4.3 of the consultation document outlines criteria for defining existing nanomaterials, one of which is that the substance is at the nanoscale in at least one dimension or has internal or surface structure at the nanoscale. This criterion would capture substances whose properties are easily predictable based on size scaling, as well of those that may exhibit novel size-related properties. The Panel recommends that the agencies focus their attention on the latter, which appear to be the concern driving this exercise.[8] Doing so could significantly streamline the process for both the agencies and industry and would more closely align the Canadian and U.S. approaches.

**The Panel requests clarification of the criteria used for excluding certain nanomaterials.** As noted above, some nanomaterials are not intrinsically hazardous. Thus, the Panel supports the exclusion of some materials and encourages the agencies to articulate the criteria utilized to develop the exclusion list provided under section 4.3. So as to focus resources appropriately, we encourage the agencies to determine if other substances meet the criteria, specifically inorganic pigments and dyes.

**The Panel requests clarification of the description of Appendix A.** The Panel appreciates that the list of existing substances in Appendix A is a starting point for the agencies' review. Specifically, section 4.3 states that validating the list in Appendix A is one objective of the review exercise. The opening paragraph of Appendix A, however, suggests otherwise and makes the list seem conclusive. The Panel requests that the agencies make it clear in future documents that the Appendix A list is a list of substances *potentially* in commerce in Canada at the nanoscale so that the meaning and validity of the list is not misinterpreted.

**The Panel appreciates Canada's implementation of the OECD Council Recommendation that calls on member governments to apply their existing legal and regulatory frameworks to address nanomaterials.**[9] The Panel views the Council Recommendation as an important policy touchstone for the management of manufactured nanomaterials in OECD countries. Furthermore, the Panel believes that our recommendations for Canada and the U.S. to align their parallel approaches are consistent with the concepts of alignment and harmonization in the Council Recommendation.

[8] As stated in section 2.3 (Domestic) of the consultation document: "The potential novel properties of existing nanomaterials generally have not been considered as part of the risk assessments conducted under the Act, and as a result, the potential risks to the environment and to Canadians have not been examined."
[9] Organisation for Economic Co-operation and Development. *Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials.* 19 September 2013. C(2013)107.

In summary, the Panel:

- supports the stepwise approach described in the consultation document;
- strongly urges Canadian and U.S. authorities to collaborate to the greatest extent possible in their parallel information gathering activities;
- recommends that Canada delay future action on a mandatory Section 71 survey until stakeholder feedback on both this consultation and the EPA's proposed rule are available and can be considered;
- requests that existing information be utilized to determine if further data are needed;
- requests clarification of the proposed criteria for defining existing nanomaterials;
- requests clarification of the criteria used for excluding certain nanomaterials;
- requests clarification of the description of Appendix A; and
- appreciates Canada's implementation of the OECD Council Recommendation that calls on member governments to apply their existing legal and regulatory frameworks to address nanomaterials.

The Panel appreciates the opportunity to comment and would welcome further dialogue with the agencies on this topic. Please do not hesitate to contact me if you have any questions (Jay_West@americanchemistry.com; 202-249-6407).

Sincerely,

Jay West
Senior Director, Chemical Products and Technology Division
ACC Nanotechnology Panel