American Chemistry Council | Nanotechnology Panel

MCTA
Massachusetts Chemistry & Technology Alliance

October 5, 2017

The Honorable Matthew A. Beaton
Secretary, Executive Office of Energy and Environmental Affairs
Commonwealth of Massachusetts
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Beaton:

The Nanotechnology Panel of the American Chemistry Council[1] and the Massachusetts Chemistry and Technology Alliance are writing to provide essential background on the November 18, 2016, petition requesting the Massachusetts Toxic Use Reduction Act (TURA) Program take steps to address petitioners' concerns about the production and use (both commercially and in research) of nanomaterials in Massachusetts.[2] We believe the petitioners' request is based on several statements that are factually inaccurate and appreciate this opportunity to provide information for your consideration.

Perhaps most importantly, petitioners state that that there is a "near-complete lack of policy and regulatory attention to nanomaterials." The basis for this claim is unclear given the amount of publicly available information on nanomaterial regulation. Nanotechnology has been subject to significant regulatory programs and assessment activities of our own federal agencies and their international partners for well over a decade.

The U.S. EPA has a comprehensive regulatory program for nanomaterials under the Toxic Substances Control Act (TSCA). That program consists of two parts, one for new chemicals (*i.e.*, those not already on the TSCA Inventory) and one for existing chemicals (*i.e.*, those already on the TSCA Inventory). Regarding new chemicals, EPA reviews and regulates new chemicals through its pre-manufacture notice (PMN) program. Anyone wishing to domestically produce or import a "new" nanomaterial under TSCA must submit a PMN to EPA. Since 2005, EPA has received and reviewed over 160 PMNs for "new" nanomaterials, including several types of carbon nanotubes.[3] It is our understanding from communication with EPA that approximately 50% of the PMNs received for nanomaterials are either withdrawn by the submitter or for other reasons never actually reach commercialization. This number is similar for all PMNs, not just nanomaterial PMNs, reviewed by the agency's new chemicals program.

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[1] Members of the ACC Nanotechnology Panel are 3M, BASF Corporation, Cabot Corporation, Chemours, DuPont, Evonik Corporation, and Procter & Gamble.

[2] Untitled petition dated November 18, 2016, addressed to Matthew Beaton, Secretary of Energy and Environmental Affairs, Commonwealth of Massachusetts. Stamped "received" by the Office of Energy and Environmental Affairs November 22, 2016.

[3] U.S. EPA. *TSCA Inventory Status of Nanoscale Substances – General Approach January 23, 2008.* Available at https://www.epa.gov/sites/production/files/2015-10/documents/nmsp-inventorypaper2008.pdf.

As part of its evaluation, EPA considers health and safety studies in the literature or unpublished studies provided with the PMN. If EPA's evaluation of the PMN indicates that the commercialization of the nanomaterial may present an unreasonable risk to humans or the environment, EPA may regulate the nanomaterial. The Agency has taken a number of actions to control and limit exposures, when warranted, including:

- Requiring the generation of additional hazard or exposure information;
- Limiting the uses of the nanomaterials;
- Requiring the use of personal protective equipment and engineering controls;
- Limiting environmental releases; and
- Requiring testing to generate health and environmental effects data.

Under TSCA, EPA has allowed limited manufacture of nanomaterials that would be considered "new chemicals" through the use of consent orders or Significant New Use Rules (SNURs), which require manufacturers and importers to notify EPA if they plan to use nanomaterials for a use other than those notified to the agency or allowed in the SNUR. In some cases EPA has allowed for the manufacture of new chemical materials under the terms of certain regulatory exemptions, but only in circumstances where exposures were tightly controlled to protect against unreasonable risks to human health or the environment.

The recently enacted Lautenberg Chemical Safety Act enhances EPA's new chemicals review program by requiring the agency to make a positive safety determination for the substance's intended use. If the agency is unable to make a safe use determination on initial consideration, the LCSA preserves EPA's ability to require additional information, impose controls, or take other actions as described above.

Regarding EPA's regulation of nanomaterials made from existing chemicals (*i.e,* those already on the TSCA Inventory), EPA recently issued a final regulation requiring one-time reporting and recordkeeping of existing exposure and health and safety information on certain nanomaterials in commerce, as defined in the rule, pursuant to its authority under TSCA section 8(a).[4] The rule requires companies that manufacture, import, or process certain chemical substances already in commerce as nanomaterials to notify EPA of certain information, including:

- chemical identity;
- production volume;
- methods of manufacture;
- processing, use, exposure, and release information; and
- available health and safety data.

EPA has been very clear to state that the regulation was not developed under the assumption that nanomaterials will cause harm to human health or the environment. Rather, EPA has stated clearly that it will use information gathered through the rule to determine whether any further action is needed. The rule requires manufactures, importers, and processors to report on their activities with nano-scale materials prior to the effective date of the regulation (August 14, 2017).[5]

EPA has and continues to work closely with countries around the world to share information and best practices around nanomaterial assessment. For example, on February 4, 2011, Prime Minister Stephen Harper and U.S. President Barack Obama announced the creation of the Canada-U.S. Regulatory

[4] 82 Fed. Reg. 3641 (final rule)
[5] 82 Fed. Reg. 22088 (effective date)

Cooperation Council to better align the two countries' regulatory approaches in various areas, including nanotechnology. As part of this initiative, a Nanotechnology Work Plan was developed to increase regulatory transparency and coordination between both countries with respect to nanomaterials. An important outcome of the initiative was the development of consistent policy principles on the regulatory oversight of nanomaterials.[6] The initiative recommended ways Canada and the United States can align their work on nanomaterials that are classified as new substances.

At the global level, the U.S. EPA actively participates in the Working Party on Manufactured Nanomaterials (WPMN) of the Organization for Economic Cooperation and Development (OECD), a 35-country organization dedicated to enhancing the economic well-being of people around the world. OECD established the WPMN over 10 years ago, since which it has engaged in a variety of projects to discuss issues around the assessment and regulation of nano-scale materials, as well as refining existing toxicological and exposure assessment methods.[7] Importantly, the OECD has determined that its members' existing chemical regulatory frameworks are sufficient for assessing and regulating potential human or environmental risks from nanomaterials.[8]

Besides the EPA, several other federal agencies have and continue to make significant investments in nanotechnology. The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control (CDC) has had a robust site outreach and evaluation program, as well as a strong research program to evaluate specific nanomaterials used in commerce and make recommendations for proper controls to protect workers, to the extent additional controls are appropriate. NIOSH has also created a field studies team to assess workplace processes, materials, and control technologies associated with nanotechnology. Research laboratories[9], producers and manufacturers working with engineered nanomaterials have the opportunity to participate in a cost-free, on-site assessment. NIOSH has produced several guidance documents, including recommended occupational exposure limit for specific nanomaterials such as titanium dioxide and carbon nanotubes. Additionally, NIOSH has developed guidance for small businesses, on medical surveillance of nanotechnology workers and engineering controls.

The Consumer Product Safety Commission (CPSC) and the Food and Drug Administration (FDA) both have active programs involving the assessment or regulation of nanomaterials and are actively engaged in national and international regulatory conversations. CPSC has programs evaluating the release and risks associated with the use of nanomaterials in manufactured products. An example of this activity is the report, "*Quantifying Exposure to Engineered Nanomaterials (QEEN) from Manufactured Products – Addressing Environmental, Health and Safety Implications.*" FDA has widespread activities involving nanotechnologies and, like EPA, regulates nanomaterials under its existing statutory and regulatory authorities, in accordance with the specific legal standards applicable to each type of product under its

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[6] *RCC Nanotechnology Policy Principles for Decision-Making Concerning Regulation and Oversight of Nanotechnology and Nanomaterials*. 2013. Available at http://nanoportal.gc.ca/default.asp?lang=En&n=6AEDAEBA-1.

[7] *See* http://www.oecd.org/science/nanosafety/ to learn about the comprehensive work of the OECD's WPMN.

[8] *OECD. Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials.* September 19, 2013. Document C(2013)107 as amended May 30, 2017. Available at http://acts.oecd.org/Instruments/ShowInstrumentView.aspx?InstrumentID=298&InstrumentPID=314&Lang=en&Book=False.

[9] Available at https://www.cpsc.gov/s3fs-public/qeenworkshopreport2016.pdf.

jurisdiction. FDA has also developed guidance documents for manufacturers of nanomaterial-enable products regulated by FDA.[10]

Finally, we note that the petition makes several unsupported over-arching statements about the "inherent toxicity" of nanomaterials. The idea that there is a unique toxicity associated with nano-scale materials was debunked several years ago, and scientists understand that the same types of toxicological considerations apply.[11] For many types of nanomaterials, their properties are predictable based on what we know about larger forms. In other words, the properties scale with size. Substances with properties that do emerge when the substance is at the nano-scale are generally well known, and the vast majority of the ones found in commerce have been the subject of significant research to understand their properties and any potential risks to humans or the environment. In fact, many of them were known to regulatory agencies around the world decades before we had the technology and scientific understanding to consider substances at the nano-scale.

Petitioners also make an unsupported claim about the "tens of thousands of types of materials that could be manufactured at the nano-scale." Based on our experience, the "tens of thousands" comment is unfounded. While one could conceive that a laboratory supply company could grind many substances to the nano-scale at a customer's request, it is a significant jump between that scenario and considering nanomaterials that are widespread in commerce, and petitioners do not in any way substantiate such a significant, alarmist claim.

In conclusion, we believe the petition should be denied on the grounds that petitioners have clearly failed to account for the significant federal and international work underway for decades on nanomaterials regulation and assessment. Furthermore, petitioners make broad, sweeping statements about nanomaterial toxicity and the numbers of nanomaterials in commerce without any substantiation.

Thank you for the opportunity to provide these comments, and please do not hesitate to contact us if you have additional questions.

Sincerely,

Jay West
Senior Director
Chemical Products & Technology
American Chemistry Council

Katherine Robertson
Executive Director
Massachusetts Chemistry &
Technology Alliance

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[10] *Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology: Guidance for Industry*. June 2014. Available at https://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm; *Guidance for Industry: Safety of Nanomaterials in Cosmetic Products*. June 2014. Available at https://www.fda.gov/Cosmetics/GuidanceRegulation/GuidanceDocuments/ucm300886.htm; and *Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives*. June 2014. Available at https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm300661.htm.

[11] Donaldson, K., and Polond, C. 2013. Nanotoxicity: challenging the myth of nano-specific toxicity. Current Opinion in Biotechnology 24(4): 724-734; Nel, A.; Xia, T.; Meng, H. *et al.* Nanomaterial toxicity testing in the 21st century: Use of a predictive toxicological approach and high-throughput screening. 2013. Accounts of Chemical Research 46: 607–621; Gebel, T.; Foth, H.; Damm, G. *et al.* 2014. Manufactured nanomaterials: categorization and approaches to hazard assessment. Archives of Toxicology 88: 2191–2211.