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April 6, 2017

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Tayyaba Waqar
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Small Business Administration
409 3rd St, SW
Washington, D.C. 20416

Re: Request to Recommend Reducing Regulatory Burdens on Nanomaterials by Rescinding *Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements*, 82 Fed. Reg. 3641 (Jan. 12, 2017).

Dear Ms. Waqar:

The Nanomanufacturing Association (“NMA”) understands that pursuant to President Trump’s January 30, 2017 *Executive Order on Reducing Regulation and Controlling Regulatory Costs*¹ (“Executive Order”), the Small Business Administration (“SBA”) is soliciting suggestions on ways to reduce regulatory burdens on domestic industry. NMA submits these comments to provide the SBA with information about the regulatory burdens imposed by the Environmental Protection Agency’s (“EPA”) Final Rule entitled *Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements*, 82 Fed. Reg. 3641 (Jan. 12, 2017) (hereinafter the “Reporting Rule”). NMA recommends that SBA identify the Reporting Rule for either elimination or significant revision under the Executive Order’s requirement that two regulations be repealed for every one new regulation.

NMA is an alliance of private companies and trade associations established to advocate for a responsible business and regulatory climate for products in which nanomaterials are used or are essential.² Since 2001, Federal agencies and Cabinet-level departments have invested more than \$23 billion in nanotechnology research, development and commercialization.³ Nanotechnology-enabled products are responsible for a growing percentage of the U.S. economy.

¹ Exec. Order No. 13771, 82 Fed. Reg. 9339.

² For more information: <http://www.nanomanufacturingassociation.com/about-1.html>.

³ NNI 2016 Strategic Plan, http://www.nano.gov/sites/default/files/pub_resource/2016-nni-strategic-plan.pdf, p. 1.

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The Reporting Rule is the primary regulation of concern for NMA. The rule goes well beyond the information collection authorized in section 8(a) of the statute to create a de facto permitting program. Starting May 12, before a nanomaterial that is widely commercially available is manufactured or processed by a company for the first time, the business must file a burdensome report 30 to 135 days ahead of the planned commercial activity. During this time, EPA may decide to require testing or restrict the commercial activity. The Data Submission Form and information requirements closely track the form required to notify new chemicals to EPA; however, these are existing substances in commerce and not new chemicals (See Enclosure 1 for a copy of the Data Submission Form).

The EPA has failed to provide industry with a clear understanding of the substances that are subject to reporting. For example, in response to industry requests to provide exemptions for low risk products such as polymers and pigments, EPA simply withdrew the exemptions it had proposed so that reporting is exclusively based on subjective concepts that are open to challenge by EPA and that will result in uneven reporting, such as company intent and whether the reportable substance contributes one or more “unique and novel” properties. Industry members risk wasting resources on reporting when not required because the agency has not sufficiently clarified the rule.

The annualized cost of the rule for industry is \$2.71 million with a 3 percent discount rate and \$2.97 million with a seven percent discount rate (See Enclosure 2 for the EPA’s economic analysis). By EPA’s own estimate, many of the companies faced with the reporting burden are small businesses who have never had to submit reports under TSCA. The rule creates a unique regulatory regime for nanotechnology-enabled products against the express direction provided in the *Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials* issued by the Office of Science and Technology Policy on June 9, 2011. (See Enclosure 3).

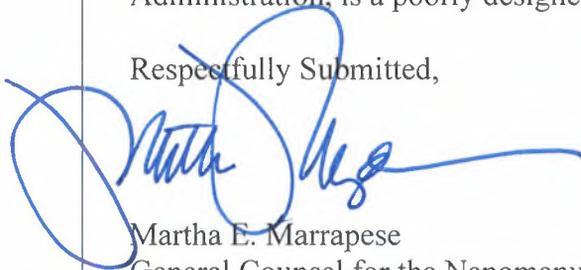
NMA filed public comments that described in detail the problems with the Reporting Rule. (See Enclosure 4 for NMA’s comments). This rule –

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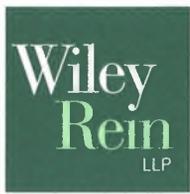
- Ignores the statutory directive to “not require reporting which is unnecessary or duplicative” [TSCA 8(a)(5)(A)] by requiring processors to report on the same chemicals as manufacturers, potentially generating hundreds of duplicative reports on the same chemicals.
- Fails to carry out EPA’s stated intent that companies should not have to wait for 30 - 135 days before manufacturing or processing a nanomaterial on the TSCA Inventory for the first time.
- Compels companies to perform testing as a practical matter since it will not be possible otherwise to determine whether each grade of product meets EPA’s criteria for reporting, even though TSCA Section 8(a) rules are limited to collecting existing information.
- Leaves unanswered concerns about a definition fundamental to the implementation of this rule, “unique and novel properties,” because the definition first appeared in the final rule.
- Relies on a “small business” definition EPA has acknowledged should no longer be used under the new Toxic Substances Control Act statute, leaving many small businesses subject to reporting that would otherwise be exempt from the rule.

NMA asks that the SBA recommend the TSCA Section 8(a) Reporting Rule for Nanomaterials for repeal under the Executive Order’s directive. NMA made repeated requests to EPA to revise and re-propose this rule given the significant concerns and uncertainties with the proposed rule. These requests went unheeded and we believe the final rule, which was rushed out in the final days of the previous Administration, is a poorly designed and written regulation.

Respectfully Submitted,



Martha E. Marrapese
General Counsel for the Nanomanufacturing Association



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Enclosures (4)