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April 25, 2017

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U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

Re: Information for EPA's April 25, 2017 Meeting in Support of EO 13777
Enforcing the Regulatory Reform Agenda; EPA-HQ-OA-2017-0190

Dear Sir or Madam:

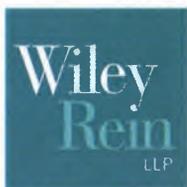
On behalf of our client, the Nanomanufacturing Association (“NMA”) understands that the U.S. Environmental Protection Agency (EPA) is soliciting comments regarding the impact of Federal regulations on domestic industry and ways to reduce those regulatory burdens.

NMA submits these comments to provide information about the unprecedented regulatory burden on emerging technology in the United States as a result of the 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 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. Since 2001, Federal agencies and Cabinet-level departments have invested more than \$23 billion in nanotechnology research, development and commercialization. Nanotechnology-enabled products are responsible for a growing percentage of the U.S. economy.

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.

The EPA has not provided industry with a clear understanding of the substances that are subject to reporting. For example, in response to industry



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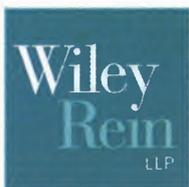
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requests to provide exemptions for low risk products such as polymers and pigments, EPA simply withdrew the exemptions it had proposed so that reporting is exclusively based on subjective concepts that are open to challenge by EPA and that will result 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. However, by EPA’s own estimate, the majority of companies faced with the reporting burden are disproportionately small businesses who have never had to submit reports under TSCA.

The rule creates a unique regulatory regime for nanotechnology-enabled products in contravention of 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. NMA filed public comments that described in detail the problems with the Reporting Rule. This rule –

- 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



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definition first appeared in the final rule which left no opportunity to provide public comments.

- Relies on a “small business” definition EPA has acknowledged should no longer be used under the new Toxic Substances Control Act statute.

The TSCA Section 8(a) Reporting Rule for Nanomaterials was issued as a discretionary action that EPA was not required to take under TSCA and it will not adversely impact environmental protection to eliminate this paperwork reporting rule. Thank you in advance for your consideration.

Respectfully Submitted,

A handwritten signature in blue ink, appearing to read "Martha Marrapese", with a long horizontal flourish extending to the right.

Martha Marrapese, Esq.