



April 13, 2017

The Honorable Scott Pruitt
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

Re: Request for Agency Stay of Rule Pending Guidance; Chemical
Substances When Manufactured or Processed as Nanoscale Materials;
TSCA Reporting and Recordkeeping Requirements, 82 Fed. Reg. 3641
(January 12, 2017)

Dear Administrator Pruitt:

The Nanomanufacturing Association (NMA) is an alliance of private companies and trade associations established to advocate for a responsible and reasonable regulatory climate for U.S. products in which nanomaterials are used or are essential.¹ NMA respectfully requests that the U.S. Environmental Protection Agency (EPA) stay the effective date of the final rule entitled Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements (hereinafter the "Nanoscale Reporting Rule"), published in the Federal Register on January 12, 2017. NMA requests a meeting at your earliest convenience to discuss the need to stay this rule.

The final Nanoscale Reporting Rule indicated that EPA intends to issue guidance within six months of issuing the rule (by July 2017), which could be months after the May 12 effective date, and NMA requests that this rule be stayed at least until the guidance is issued. Issuing a stay of this rule is consistent with the Trump Administration's policy of reviewing previously issued regulations, as outlined in the January 20, 2017 Priebus Memorandum. That Memorandum instructed the heads of all executive agencies to extend the effective date for 60 days for rules that have been published in the Federal Register but not yet taken effect, which includes the Nanoscale Reporting Rule. Furthermore, a stay is necessary because NMA and its members are concerned that the Administration's April 5 guidance on implementing the January 30, 2017 Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs (Executive Order (E.O.) 13771), which clarifies that "substantial guidance" is within its scope, will cause further delays in EPA issuing

¹ For more information, visit our website at: <http://www.nanomanufacturingassociation.com/about-1.html>



guidance on the Nanoscale Reporting Rule, which would leave companies in the dark about compliance with the rule for even longer.

NMA continues to have serious reservations with this rule, which was issued in the final days of the Obama Administration over numerous objections to the rule's lack of clarity in many key aspects. Unless the effective date is extended, companies will be forced to comply with reporting requirements that – by EPA's own admission – are not clear and warrant the issuance of further guidance.

While companies who are already on the market do not have to report until 2018, starting on May 12, 2017, new market entrants must submit detailed reports before they can commercialize a nanomaterial. This rule is expected to impact business development and will require greater control over product distribution.

By EPA's own estimate, over half of the companies faced with this reporting burden are small businesses. Processors that have never had to submit these types of reports under TSCA comprise another significant segment of the companies affected by the rule. It is unreasonable to require these companies to report before the promised guidance is issued. As consistently reflected in the public comments on this rulemaking, the agency 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.

Delaying the effective date until July 2017 or later complies with the Administration's directive and provides the EPA with additional time to consider the substantial questions of law and policy this Rule raises, such as:

- May EPA ignore the statutory directive that warns against imposing duplicative reporting requirements on processors?
- Why does the wording of the final rule fail to carry out EPA's stated intent to let companies go to market as soon as these filings are made?
- Why did EPA create a permanent reporting regime unique for nanomaterials against the express directive 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?



- Why do companies believe they have to test before making these reports, even though EPA stated it did not intend to require any new testing in this rule and does not have this authority in section 8(a) of TSCA?
- Why didn't EPA provide the public with an opportunity to comment on the definition of "unique and novel properties" that fundamentally underpins the need to submit reports under the rule, or fix other areas of definition ambiguity (e.g., reportable substances) identified by the public.
- Why does the rule use the same "small business" definition that EPA previously acknowledged is out-of-date, subjecting many small businesses who should not have to report to the notification requirements of the rule?²

NMA thinks this rule should be reviewed for consistency with the Administration's regulatory reform goals. We also believe the rule is a poorly designed and written regulation that would be a good candidate for rescission under Executive Order 13371. NMA asks that this rule be stayed until July 2017 or longer to provide EPA with time to examine this rule and consider whether its burdens are warranted. Please contact me with any questions you may have.

Respectfully Submitted,

John W. Hilbert III
NanoManufacturing Association
1776 K Street NW
Washington, DC 20006
jhilbert@khaconsultants.com

cc: Martha Marrapese, Counsel to NMA with Wiley Rein LLP
Michael Flynn, Acting Deputy Administrator, EPA
John Reeder, Acting Chief of Staff, EPA
Wendy Cleland-Hamnett, Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention (OCSPP)
Jeffrey Morris, Acting Director, Office of Pollution Prevention and Toxics (OPPT)
Maria Doa, Ph.D., Director, Chemical Control Division (CCD), OPPT
Raymond J. Alwood, CCD, OPPT

² Notice; Environmental Protection Agency; TSCA Reporting and Recordkeeping Requirements; Standards for Small Manufacturers and Processors, 81 Fed. Reg. 90840, 90842 (Dec. 15, 2016).