



NanoManufacturing Association

March 16, 2016

Via Electronic Mail and Mail

Maria Doa, Ph.D.
Director, Chemical Control Division
Office of Pollution Prevention and Toxics
Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Mail Code: 7405M
Washington, D.C. 20460

Re: Proposed EPA Reporting Rule on Chemical Substances Manufactured or Processed as Nanoscale Materials

Dear Dr. Doa:

Thank you for meeting with the Nanomanufacturing Association (NMA) on February 24, 2016, to discuss the U.S. Environmental Protection Agency's proposed rule, *Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements*, 80 Fed. Reg. 18330 (April 6, 2015). Our members sincerely appreciated the opportunity to share their concerns and to discuss solutions for creating a more manageable rule that provides EPA with relevant, high-value information on nanomaterials.

As NMA's comments on the proposed rule described in detail,¹ NMA believes that significant clarifications and a reduction in scope are necessary for a workable program. To lessen the likelihood of duplicative reporting, we ask EPA to consider limiting the requirement to report information on nanomaterials to a one-time event for manufacturers only, and not include processors. Specifically, processors do not have the same level of access to the information EPA is proposing to require. If required to report, processors will simply request from manufacturers the information that manufacturers themselves will submit under the rule, resulting in duplicate reporting. For this reason, we think the level of duplicative reporting would be extensive.

NMA is gravely concerned about the anticompetitive effect of having to submit new reports on an on-going basis, and having to wait for close to half a year afterward before a product could be lawfully commercialized. We think this waiting period is a barrier to commerce that exceeds EPA's

¹ EPA Docket Document No. EPA-HQ-OPPT-2010-0572-0121.

Maria Doa, Ph.D.
March 16, 2016
Page 2

authority under section 8(a). If EPA desires to create an evergreen information collection system for nanomaterials, a more sound approach would build experience through reviewing responses from the one-time notification requirement to improve and streamline future information collections to limit the negative impact on U.S. innovation.

Because EPA does not intend the exemption provided in the proposed rule for “chemical substances manufactured at the nanoscale as part of a film on a surface” to apply to polymers, polymer dispersions (emulsion polymers), or pigment dispersions containing nanomaterials, we urge that these materials be exempt from both the one-time and any on-going reporting obligation in the final rule issued by EPA. These are well-established products which have proven to be safe for decades. Finally, we also think that manufacturers will need to generate new data to have the physical-chemical information that EPA is proposing to require for distinguishing discrete physical forms of the same chemical substance. We ask EPA to refrain from requiring information that is not routinely generated in finalizing this rule. Validated and standardized protocols are essential because EPA is proposing to require regulatory reporting based on a relative change in these specifications. Whether or not relative changes between specifications could be determined with the existing state of analytical methods, we question the value that flawed and inconsistent data on physical-chemical properties could provide to EPA in assessing risk across nanomaterials. The rule must be designed to provide EPA with meaningful information to justify the reporting burden placed on companies.

Thank you again for consideration of NMA’s comments. Should EPA have any questions or require further information, please do not hesitate to contact us.

Cordially yours,



Martha E. Marrapese
General Counsel
National Manufacturing Association

cc: Jeff Morris, Deputy Director for Programs, OPPT
Greg Schweer, Chief, New Chemicals Management Branch, CCD/OPPT
Jim Alwood, Program Manager, Chemical Control Division, OPPT