



## Nanotechnology Coalition

July 18, 2016

Mr. Kevin McLean  
Associate General Counsel  
Pesticides and Toxic Substances Law Office  
Office of General Counsel  
U.S. Environmental Protection Agency  
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1200 Pennsylvania Avenue, N.W.  
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Washington, DC 20460

Re: Proposed Rule: Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements; **EPA-HQ-OPPT-2010-0572**

Dear Mr. McLean:

On behalf of the Nanotechnology Coalition, I thank you for the opportunity to highlight for your office particular legal concerns raised by the Coalition's and others' public comments on the pending proposed rule, *Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements*, 80 Fed. Reg. 18330 (Apr. 6, 2015). In advance of our meeting, we wanted to provide the following brief summary of the points we intend to highlight:

- A. Unlawful Moratorium on Manufacturing / Processing of Existing Chemicals. The proposed 135-day pre-manufacturing and pre-processing notice requirement (proposed §704.20(f)(2)) is contrary to the law for several reasons:
1. No Authority Under TSCA §8 to Prohibit Manufacturing or Processing. TSCA §8(a)(1) authorizes the Agency to require companies to keep records and submit reports, but it does not contemplate, or authorize EPA to impose, even a temporary moratorium on the manufacture or processing of existing chemicals.
  2. Duplicative Reporting. Contrary to TSCA §8(a)(2), the proposed rule makes no provision to avoid duplicative and unnecessary reporting that will arise from the proposed 135-day notice requirement – (e.g., from every new processor customer of a single manufacturer of a reportable substance).
  3. Reporting Period Contrary to TSCA §5(a)(1), (2). The TSCA §5 significant new use rule (SNUR) provisions specify the only circumstances (and procedures) for imposing temporary moratoria on the manufacture or processing of existing

chemicals to allow for EPA risk review. EPA has no authority under TSCA § 8 either (i) to ignore the TSCA §5 significant new use notice selection criteria and procedures (§5(a)(2)) in choosing reportable substances subject to the moratorium, or (ii) to extend the statutory review period for existing chemicals from 90 to 135 days. To the extent the proposed rule is intended also to apply to *new* chemicals (not clearly excluded from the proposal), EPA also has no § 8 authority to extend the TSCA §5(a)(1) pre-manufacture review period for new chemicals from 90 to 135 days.

4. Arbitrary Class Selection. The proposed rule lacks factual predicate or a rational basis to justify singling out and imposing the perpetual 135-day manufacturing/processing moratoria on the class of materials selected by the Agency. The proposed rule states that EPA has made no risk or exposure based finding with respect to nanomaterials as a class. The definition of a chemical substance reportable under §8 is grounded in the concept of particular molecular identity not distinguished physical form. There is no legal basis upon which to regulate either the particular class of materials chosen for regulation, or for the particular regulation imposed (moratorium on manufacturing/processing).
- B. Arbitrary Applicability Determination Criteria. The proposed rule provides no factual predicate or other rational basis to explain how and why EPA selected the particular applicability criteria it chose to propose to define a reportable chemical substance or distinguish among “discrete” physical forms. EPA does not explain how these criteria effectuate the agency’s objectives for the data collection or why they are needed to understand the nature of the reportable substances. The proposed technical criteria are also arbitrary because some of them do not even apply for characterizing certain reportable substances, a fact that is not acknowledged by the proposal. The absence of designated test methods for particular technical applicability criteria will lead to inconsistent and arbitrary results.
- C. §8(a) Does Not Authorize Compelled Product Testing. Many companies would need to do new product testing to determine whether their respective materials triggered the proposed, highly technical reporting applicability criteria (particularly for “discrete substances”); however, TSCA §8 does not authorize EPA to compel such product testing. Applicability determinations for the same material by different persons made with and without the indicated test data will be inconsistent with each other and lead to arbitrary reporting results (as will determinations for the same materials based on data from different test methods for the same endpoint).
- D. §8(a) Does Not Authorize Compelled Reporting of Certain Data Elements. The data elements required to be reported under the proposed rule are contrary TSCA §8(a)(2) because they include a number of categories not authorized for collection under that section. These categories include physical and chemical property information (proposed § 704.20(d)(2)-(3)), weight percentage of impurities ((d)(4)), detailed methods of manufacturing and processing ((d)(7)), estimates of general population exposure and

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consumer exposure ((d)(8)), environmental release information ((d)(9)), and risk management practices ((d)(10)).

- E. EPA Must Re-Propose Large Parts of the Rule. As noted here, many public comments were focused on the absence of critical decision information from the proposal and why it was important, e.g., failing to specify a measure and test method for size and other applicability criteria leading to arbitrary results, and failing to demonstrate the rational basis for selecting the particular applicability criteria or imposing moratoria. It is not sufficient for EPA to now simply fill these and other voids with new substantive positions and rationales and issue a final rule because the public has not yet had the opportunity to review and comment on the substance of these new aspects of EPA's proposal.

Rather than issuing a final reporting and moratorium rule at this time, the Nanotechnology Coalition has urged EPA to reopen the dialog with the public to discuss these issues raised by the proposal, with the aim of proposing in the future a practicable reporting rule tailored to meet reasonable information and oversight needs.

We look forward to our meeting with you July 21<sup>st</sup>.

Sincerely,



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