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U.S. Environmental Protection Agency  
Document Control Office (7407-M)  
Office of Pollution Prevention and Toxics  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460-0001

Re: Proposed Rule; Chemical Substances When Manufactured or Processed as Nanoscale Materials:  
TSCA Reporting and Recordkeeping Requirements

To Whom It May Concern:

The Nanotechnology Coalition (Coalition), an independent trade association affiliated with The Society of Chemical Manufacturers and Affiliates (SOCMA), is pleased to submit these comments on the April 6, 2015 *Federal Register* Notice seeking comments on Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements. The Coalition is composed of nanomaterial producers, users and other stakeholders that focus on environmental, health, and safety issues to promote the safe development of nanomaterials, communicate industry positions to regulatory agencies, address standards and definitions in nanotechnology, and promote development of nanotechnology stewardship programs.

The Coalition appreciates the opportunity to provide these comments. However, the proposed rule does not appear to be sufficiently focused to provide relevant useful information to evaluate the safety of nanoscale materials. The Coalition offers the following specific comments and recommendations concerning the proposed rule:

**1. Identifying the chemical substances that would be subject to reporting.**

**Discrete Forms**

While the generally accepted definition of nanoscale materials includes an approximate size range of 1-100 nm, the proposed rule should clearly specify that the size of the nanoscale material subject to reporting falls within this range *for its intended use* (not an intermediate).

Several terms used in the proposed rule make it exceedingly difficult for any producer or user of nanoscale materials to determine if they are required to meet any reporting and recordkeeping

regulatory obligations. The term 'discrete form' relies on changes to physical characteristic rather than molecular identity. Minor changes in the physical characteristics of a single substance such as size can mean a large difference in surface area, thus triggering a reporting requirement despite the statement indicating that size changes alone would not trigger a reporting requirement.

While the Agency indicates that the reporting of 'discrete forms' would be based on a combination of factors, the Agency does not indicate how each of the factors would be used to make such a determination. The current language in the proposed rule would allow the Agency to require reporting for any single individual factor as easily as for meeting the requirements of all three factors. It should be noted that nanoscale materials are developed and marketed to meet specific performance characteristics. To accomplish this, manufacturers routinely change their process "to affect a change in size and/or a change in properties of the chemical substances." This fact alone would mean that a large number of manufacturers would automatically meet the first factor. A 10% particle size change at the nanoscale is a relatively narrow window. For example, a process change that increases the size of a nanoscale material from 80 nm to 90 nm would meet the first two determining factors. For all practical purposes, a 10 nm change in size will meet the second factor for all nanoscale materials using the generally accepted definition. Also, it should not be assumed that producers of nanoscale materials routinely measure any of the cited properties (i.e., zeta potential, surface area, etc.).

**Recommendation:** The use of any combination of physical factors (discrete forms) to determine reporting and recordkeeping requirements for nanoscale materials will result in an undue burden to manufacturers and processors and it should be eliminated from this proposed rule. Any reporting or recordkeeping requirement should be more specific and related to any potential risk associated with the substance. Factors cited in the proposed rule to identify 'discrete forms' have not yet been proven to provide a direct link to environmental health and safety. Use of this term should be eliminated from the proposed rule.

### **Trace Amounts**

The use of the term "trace amounts" in determining the regulatory status of a nanoscale material is inherently unclear, imprecise, vague, arbitrary, and thus inappropriate. Use of this term will inevitably lead to arbitrary and thus unlawful regulatory determinations lacking a basis in sound science. It also diminishes regulatory certainty making it impossible for producers and users to understand their obligations with regard to compliance and thus exposes them to substantial enforcement jeopardy. In determining if an existing bulk material now capable of being produced at the nanoscale is a reportable substance, the proposal uses vague and imprecise terminology to allow producers to determine if a substance is reportable.

**Recommendation:** In previous comments provide to EPA, the Nanotechnology Coalition has offered a mass-based threshold in place of using the term "trace" when described small quantities of nanoscale materials. An important addition to the proposed regulations would be a threshold for the mass quantity of nanoscale materials within any bulk solid material. Given the fact that bulk powders are often milled or ground down to a specific particle size, there is always the possibility of a size distribution that includes materials at the nanoscale. It is further recommended that EPA provide

guidance on what it considers to be a trace as opposed to impurities or by-products (including the same material unintentionally manufactured at the nanoscale).

### **Nanoscale Materials Stewardship Program**

Several producers made a good faith effort to provide data to EPA as part of the Nanoscale Materials Stewardship Program. The Agency indicates this data does not need to be submitted again unless the information has changed or new information is available. Given the length of time since completion of the NMSP it is reasonable to assume that additional information may now be available for many, if not all, of the previously-submitted nanoscale substances.

**Recommendation:** All submitters of data and other information under the NMSP should be exempt from any reporting until this proposed rule. If they are not exempt, the submissions will essentially now become mandatory if there are any deviations from the information provided in the earlier voluntary data collection program. Failing to acknowledge the voluntary actions of nanoscale producers will have a negative effect on any future voluntary data collection activities. Producers will be hesitant to participate in any voluntary data collection program know the Agency will require the data collection at some point in the future.

In order to protect the confidentiality of business information under this proposed rule it is recommended that the Agency allow study data on nanoscale material safety be submitted in robust summary format.

### **2. Distinguishing between nanoscale forms of a reportable chemical substance.**

Several nanoscale substances would be exempt from the requirements of the proposed rule (nanoclays, zinc oxide, and nanoscale substances as part of a film on a surface) due to sufficient characterization or low exposure potential. EPA provided no information on how it evaluated the data set for those substances that are exempt yet given the number of nanoscale metals and metal oxides in commerce with bulk counterparts, it is reasonable to assume that there is a rich set of data which will allow additional exemptions not identified in the proposed rule.

**Recommendations:** EPA should continue to work with industry to identify nanoscale materials in commerce which may provide the greatest potential for exposure. EPA should also provide additional information on the data needed for exemption from this and future reporting and recordkeeping rules. The Nanotechnology Coalition participated in the Canada-United States Regulatory Cooperation Council (RCC) effort to identify nanomaterials in commerce and the resultant data provided a roadmap for EPA to identify substances which would be candidates for risk assessment and management. The effort by Canadian regulators to identify and assess those nanoscale materials in commerce with the greatest potential for exposure is an approach the EPA should consider rather than trying to collect information on all nanomaterials, many of which have a very low exposure potential.

### **3. Reporting discrete forms at least 135 days before commencement of manufacture and processing.**

Within this proposed information collection rule the EPA seeks information on revising the current statutory 90-day requirement Premanufacture Notice review period to 135 days. This proposed review period is not consistent with the proposed rule being a Section 8(a) reporting rule, but is instead a Section 5 PMN.

**Recommendation:** The proposed rule should be withdrawn and re-proposed properly identifying it as a Section 5 with appropriate justifications for this action and supporting explanations. The current statutory requirement of a 90-day Premanufacture Notice review period should be retained. The EPA has provided no scientific rationale or legal basis for an increase in the review time period to 135 days. The proposed rule asks commenters to “explain why the time period they suggest is appropriate.” EPA should explain why the existing chemical substances subject to this rule require a longer review period than new chemical substances.

It is recommended that EPA provide a rationale for amending this statutory requirement through a separate rulemaking process rather than asking stakeholders to justify a change to the existing law in this proposed rule. While the Agency may seek guidance on the appropriateness of such a change, comments submitted in response to this rule should not be construed to reflect agreement in any way that such a change should be made for nanoscale materials.

### **4. Considerations for the Agency’s economic analysis.**

Many of the sources used for establishing the size of the industry are severely outdated. In an industry of leading edge high-tech manufacturing, the business model differs significantly from traditional chemical manufacturing sectors. Understanding the basics of this type of startup industry is critical to understating financial impact of this proposed rule.

Companies in a startup mode often begin with little more than an idea and minimal cash forcing infusions of operating capital through venture funding, joint ventures, and spinoffs. These companies rarely see profits during the early years of market capitalization. Establishing a reporting and recordkeeping requirement on companies with \$4M in revenue would place an administrative burden on businesses focused on innovation.

While the EPA may not require Small Business Administration (SBA) approval for a new definition of small business, if the agency has not established any justification for the proposed change. As performance materials, nanoscale substances are often high value products resulting in elevated revenues for limited production levels.

**Recommendation:** The Agency has not provided any rationale for revising the small business definition by reducing sales levels or by eliminating production levels entirely. The proposed change to the definition of a small business would ultimately become an impediment to small business innovation. The current \$40M sales standard should remain unchanged.

The retention of a production standard is important for the innovation of nanoscale substances. Startups cannot afford to meet reporting and recordkeeping requirements simultaneously with

production of the first gram of material. EPA should continue to work with stakeholders and SBA to establish a reasonable production level. The work should include an updated economic analysis of that segment of industry involved in the production and sale of nanoscale substances.

## **5. Electronic reporting.**

Electronic reporting under the Toxic Substances Control Act has been fraught with difficulty, confusion, and has been an administrative burden on those entities attempting to fulfill reporting requirements. The current system has proven difficult to navigate with little assistance to regulated stakeholders who have often relied on contractors and the CDX Help Desk to assist with the submissions resulting increased costs to stakeholders. Also, EPA's difficulty in keeping current with Java updates, combined with frequent user updates remains an impediment to efficient electronic reporting.

**Recommendation:** The Nanotechnology Coalition has no objection to the use of the electronic reporting but significant improvements to the system must be made to make it fully functional.

## **6. Consideration of potential future rulemaking regarding periodic reporting.**

If future periodic reporting was required, what would be reported and how will the information be used? Until this initial information collection activity is completed and evaluated, there should not be any consideration for future reporting or recordkeeping. The open-ended nature of many of the questions raised in this proposed rule reflects a continued search for a greater understanding of the nanotechnology industry and the information it uses in manufacturing. If the information provided in the proposed rule is to be used for regulatory purposes or the creation of any type of nanoscale material inventory, the data requested here must be much more specific to the assessment of potential hazards and the reporting and recordkeeping requirements must be clearly understood by the regulated stakeholders.

**Recommendation:** The intent of information collection under TSCA 8(a) is not to put in place a permanent reporting and recordkeeping requirement. The need for information on a one-time basis to provide EPA with additional data to assist in regulatory enforcement or rule-making activities may be reasonable. However, this proposed information collection is premature in light of the need for additional guidance on substance characterization, clarification of definitions and terms used in the rule, additional guidance on what constitutes modified nanoscale substances triggering reporting, and development of a small business definition that accurately reflects the universe of nanoscale producers (or retains the existing statutory definition).

## **7. Establishment of an inventory**

The agency states the "EPA is not proposing to publish an inventory of chemical substances manufactured at the nanoscale based on the information that would be collected pursuant to these proposed TSCA section 8(a) reporting requirements." In stating this, the agency has not explained how it intends to differentiate between those chemical substances that are subject to the reporting requirements, the various discrete forms that require reporting under the proposed rule and those

identified by the same CAS number that would be excluded from the reporting requirement. Further, the agency states “EPA will make non-confidential information reported under the proposed rule available in ChemView (see <http://www.epa.gov/chemview/>.” This will be a *de facto* list which will be used by downstream customers as a negative list, effectively blacklisting chemical substances that are identified by a reported CAS number.

**Recommendation:** This proposed listing using ChemView be deleted from consideration. The Agency should as well identify how it intends to differentiate the various identified chemical substances bearing the same CAS Number. Until these issues are clarified, the proposed rule should be withdrawn and repropose and made available for further comments.

### Summary

The Coalition agrees that there is value in EPA seeking information on nanoscale materials with new and existing applications to establish product safety for relevant use patterns. EPA must, however, more specifically correlate the information EPA seeks with the way it intends to use that information to address potential risks that have yet to be identified with any category of nanoscale material. This is exactly what EPA has not done and the random information EPA seeks in the notice provides no rational basis to obtain this information.

**Recommendation:** The proposed rule should be withdrawn with any information collection activity deferred until EPA provides additional clarity on data needed for assessment of safety for nanoscale materials.

The SOCMA Nanotechnology Coalition is prepared to assist EPA in developing a science-based approach to the application of nanotechnology to the pesticides community. The Coalition appreciates this opportunity to provide these comments.

Sincerely,



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