August 10, 2017

Via E-Mail

Jeffery Morris, Ph.D.
Director
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Re: Request for Continued Stay of Nanoscale Materials Reporting Rule

Dear Dr. Morris:

We write to renew our collective request that the U.S. Environmental Protection Agency (EPA) continue to stay the effective date of the January 12, 2017, final rule, "*Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements*,"[1] which is now scheduled to expire on August 14, 2017,[2] until six months from issuance of the promised guidance. The reasons for our request are set forth below.

The purpose of the May 12, 2017, *Federal Register* notice was to stay the rule pending the issuance of guidance. Unfortunately, the promised guidance has not yet been issued in final form. A substantial number of thoughtful comments and detailed questions were submitted on the draft guidance. Our collective hope was that EPA's consideration of these comments and questions would result in a more user-friendly document that provided more meaningful guidance than merely repeating the instructions in the rule and addressed specific gaps that the rule did not acknowledge. The draft guidance did not, for example, address such fundamental matters as how to characterize changes to surface area and whether the one percent reporting threshold applies both to intentionally and unintentionally produced nanoscale particles.

In its May 12, 2017, notice, EPA noted the "complex issues regarding [the] reporting requirements of the rule."[3] We agree with this statement. The lack of EPA guidance on how to

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1 82 Fed. Reg. 3641 (Jan. 12, 2017).

2 82 Fed. Reg. 22088 (May 12, 2017).

3 *Id.*

address these complex issues is of significant concern, given our deep and abiding interest in ensuring that EPA's rule elicits the quality information it needs to fulfill its mission. Several industry sectors are specifically looking to the guidance for instructions on threshold issues such as how to determine the reporting status of their materials. For example, guidance on intentionality, surface area, surface treatment, the definition of a solid, physical-chemical property test protocols, and the appropriate starting material for making the seven standard deviation determinations is sought to make these reports. These and other examples can be found in the docket that contains the comments submitted by our respective associations, copies of which are appended here for your convenience.

Because the nanoscale materials reporting rule becomes immediately effective for new commercial introductions of nanomaterials, including by processors unfamiliar with this extensive level of reporting, we ask that EPA issue the final guidance and extend the effective date of the rule. Additional time is much needed to allow companies an opportunity to study the guidance and to assess their compliance obligations.

Given the potential for compliance issues to arise if the final rule and EPA's interpretative guidance of it are not well understood, EPA must ensure that the final interpretative guidance is released well in advance of the commencement of the reporting period. We note also, as many commenters on this rule predicted, the timing of this reporting over the next year will significantly overlap with the new industry reporting requirements under the final Toxic Substances Control Act (TSCA) Inventory notification (active-inactive) rule.[4] Manufacturers and importers must report to EPA, within 180 days of the rule's publication in the *Federal Register,* existing chemicals listed on the Inventory that are not already deemed active. The nanoscale materials reporting rule and the TSCA Inventory notification rule are important rulemakings. We are certain EPA shares our interest in ensuring that regulated entities are able to provide the most meaningful information possible in response to each, and this is best accomplished by delaying the effective date of the nanoscale materials reporting rule as outlined above.

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[4] EPA published a pre-publication version of the final rule on June 22, 2017. EPA, *Federal Register Notice: TSCA Inventory Notification (Active-Inactive) Requirements*, available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/federal-register-notice-tsca-inventory-notification.

Accordingly, for all the reasons noted above, the organizations listed below respectfully request that EPA consider the significant resources it is asking industry to commit in responding to the nanoscale materials reporting rule, acknowledge that the guidance is urgently needed, and extend the stay of the effective date of the rule until six months from the issuance of the final guidance. Thank you for your consideration of our request.

Sincerely,

John DiLoreto
Executive Director
Nanotechnology Coalition

John W. Hilbert III
Nanomanufacturing Association

Jay West
Senior Director, Chemical Products and Technology Division
Nanotechnology Panel of the American Chemistry Council

Vincent Caprio
Executive Director
NanoBusiness Commercialization Association

Lawrence E. Culleen
Counsel to the Chemical Users Coalition

Timothy A. Brown, Esq.
Vice President, Regulatory Counsel & International Affairs
Consumer Specialty Products Association

Attachments
cc: The Honorable E. Scott Pruitt (w/attachments) (via e-mail)
Ms. Wendy Cleland-Hamnett (w/attachments) (via e-mail)
Nancy B. Beck, Ph.D. (w/attachments) (via e-mail)

Nanotechnology Coalition

Submitted electronically via regulations.gov

June 15, 2017

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Re: Draft Guidance for Reporting of Chemical Substances When Manufactured or Processed as Nanoscale Materials; Notice of Availability and Request for Comment; EPA-HQ-OPPT-2010-0572

Dear Sir or Madam:

On behalf of the Nanotechnology Coalition, I thank you for the opportunity to submit comments to the U.S. Environmental Protection Agency (EPA) *Draft Guidance for Reporting of Chemical Substances When Manufactured or Processed as Nanoscale Materials; Notice of Availability and Request for Comment,* published in the Federal Register on May 16, 2017 (Docket EPA-HQ-OPPT-2010-0572).

We thank EPA for acknowledging the concerns of the companies that are most significantly impacted by the rule and for delaying its implementation until August while the Agency prepares to issue final reporting Guidance. While we appreciate the Guidance, as currently written it does little to clarify many of the definitions used by EPA that remain unclear, it provides confusing responses to questions submitted by stakeholders, and in some respects the Guidance raises additional areas of uncertainty regarding reporting requirements delineated in the rule. Our specific concerns with the final rule are noted in our comments submitted on May 15, 2017, appended and incorporated by reference here. For example, in the final rule EPA states "...**Because not all enhanced properties are unique or novel properties, EPA replaced the word enhanced with novel in section C.5. of the reporting form.**...", yet in the Guidance document the Agency has resurrected this term in response to Q&A 3 in a way that causes confusion and is contrary to the principles of physics.

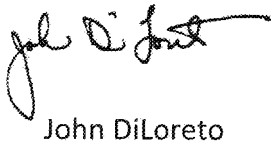
Recommendation

Although EPA has extended the implementation date from May 12, 2017 to August 14, 2017, the effective date of the rule should be extended further to address the many unresolved questions regarding the reporting requirement. EPA has delayed the effective date and/or compliance date of several significant rules in the recent past precisely to ensure the regulated community is equipped with the appropriate guidance to implement new regulatory requirements and/or to reduce

"compliance burdens" and to "help prevent disruptions to supply chains." *See* EPA Extends Compliance Date for Formaldehyde Emissions Standards, 82 Federal Register 23735 (May 24, 2017); EPA Delays Implementation of Agricultural Worker Protection Standard, May 11, 2017, letter from Acting Assistant Administrator Wendy Cleland-Hamnett to National Association of State Departments of Agriculture; and EPA delays Effective Date of Risk Management Program, 82 Federal Register 27133 (June 14, 2017).

We share EPA's desire for accurate information to inform EPA's judgment regarding the manufacture and process of nanoscale materials, but believe the final rule and draft reporting Guidance lack sufficient clarity to elicit accurate, quality information necessary to achieve this goal. We urge EPA to delay the effective date of the final reporting rule until EPA revises, re-proposes, and re-issues the final rule along the lines of many comments EPA received on May 15, 2017, and re-issues the reporting Guidance. Only these actions will enable EPA to obtain the information it needs to effectuate Congress' statutory goals underlying TSCA Section 8 in a way that does not impose unnecessary reporting burdens on regulated entities or disrupt supply chains.

Sincerely,



John DiLoreto
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Nanotechnology Coalition

Submitted electronically via regulations.gov

May 15, 2017

Sarah Rees, Ph.D.
Director, Office of Regulatory Policy and Management
Office of Policy
1200 Pennsylvania Avenue NW
Mail Code 1803A
Washington, DC 20460

Re: Evaluation of Existing Regulations; EPA-HQ-OA-2017-0190

Dear Dr. Rees:

On behalf of the Nanotechnology Coalition, I thank you for the opportunity to submit comments to the Environmental Protection Agency (EPA) in response to Executive Order 13777, *Enforcing the Regulatory Reform Agenda*. These comments focus on EPA's final rule, *Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements,* published in the Federal Register on January 12, 2017 (Docket EPA-HQ-OPPT-2010-0572).

We thank EPA for hearing the concerns of the companies who need to comply with the rule and delaying its implementation until August while the Agency develops it guidance for reporting. The Nanotechnology 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.

Nanotechnology, the science of understanding and harnessing the properties of materials that occurs at the nanoscale — about 100,000 times smaller than the width of a human hair — is leading to revolutionary new materials, devices, and structures that are improving human health, creating jobs, and strengthening our national defense. Companies of all sizes, including start-ups and small and mid-sized entrepreneurial companies, engaged in the manufacture, use, or sale of products enhanced by nanotechnology innovations have steadily moved nanoscale materials from the laboratory to the marketplace. Nanotechnology is now enabling

or enhancing products in a variety of sectors, including clothing, electronics, clean energy technologies, and automobiles.

With the continuation of scientific innovation through significant corporate and academic R&D investment, nanotechnology is poised to greatly improve how we diagnose and treat disease, enable comfortable garments that protect our troops from biological and chemical threats, improve existing consumer products in virtually every industrial sector, and provide innovative medicines and medical devices. Despite no evidence of specific hazards related to nanomaterials, the new regulation will necessitate unnecessary and costly reporting and recordkeeping requirements which will have the effect of discouraging new market entrants, and correspondingly reduce job creation and stifle technological innovation.

The referenced reporting tool is not required by the statute and the decision to develop the rule was wholly within EPA's discretion under TSCA §8. Below are several specific examples of regulatory overreach in the rule which will have a negative effect on the continued growth of the nanotechnology industry and particularly small businesses.

Unnecessary and Unlawful Moratorium on Manufacturing/Processing of Existing Chemicals

The final rule is unclear with regard to when manufacturing may commence for new nanoscale materials, due to the new requirement to submit reports at least 135 days prior to commencing manufacturing or processing an existing chemical. While the final rule helps clarify that TSCA requirements for a Premanufacture Notice at least 90 days prior to manufacturing will apply to new chemicals instead, this is only works to exempt the PMN submitter from this rule. All of the submitter's processor customers also will need to file duplicative reports under this rule. Many companies are confused as to when manufacturing may commence. Many manufacturers continue to believe that reporting on nanoscale materials must occur 135 days before initiation of manufacturing operations. The 135-day pre-manufacturing and pre-processing reporting requirement (§704.20(f)(2)) is contrary to TSCA 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. Despite comments from the EPA regarding when manufacturing may be initiated, the 135-day advance notice requirement still functions as a practical manufacturing bar if a company will face one-time or daily "late" reporting penalties if it begins to manufacture or process before the expiration of the 135-day period. In addition, the explanation EPA provided for why additional time is needed to implement a 135-day requirement has created additional uncertainty. EPA states that it will evaluate whether the activity requires regulation. Most companies will not want to go into production without a full and clear understanding of their regulatory requirements up front. Indeed, the explanation only confirms that the pre-manufacture or processing rule is

effectively a SNUR for nanoscale chemicals promulgated without meeting the TSCA Section 5(a) criteria for proposing a SNUR.

2. ***Duplicative Reporting.*** *Contrary to TSCA §8(a)(2),* the rule makes no provision to avoid duplicative and unnecessary reporting that will arise from the 135-day notice requirement (e.g., from every new processor customer of a single manufacturer of a reportable substance and new manufacturers and processors of nanoscale materials that have been through the PMN risk review with a different submitter since 2005).

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 subject to a properly promulgated SNUR from 90 to 135 days.

4. ***Arbitrary Class Selection.*** The rule lacks factual predicate or a rational basis to justify singling out and imposing the perpetual 135-day manufacturing/processing moratoria on an entire class of materials (i.e., nanoscale materials). The rule states that EPA has made no risk or exposure based finding with respect to nanomaterials as a class. Instead, the intent is to obtain reporting now and for all future users, for any material that presents even an innocuous size-related property unrelated to risk (e.g., change in color) on the unsupported theory that innocuous size-related properties "likely" are accompanied by changes in other properties that are relevant to risk. 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) in this manner.

5. ***Arbitrary Applicability Determination Criteria.*** The 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 rule's technical criteria also are 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. Although some recommendations were made in the final rule, these are voluntary and will not measurably improve the arbitrary nature of the data the agency may receive as a result.

6. ***Unfair Status for New Substances versus Existing Substances.*** The rule as proposed does not explicitly require testing for existing materials, while new substances must have a

minimum physical and chemical testing requirement. This creates an unfair preference for existing substances and inherently a potential under reporting for existing chemical substances.

Costs that Exceed Benefits

1. ***§8(a) Does Not Authorize Compelled Product Testing.*** EPA expects manufacturers to obtain and report all available information from customers in order to determine compliance with the rule. The public record on this rulemaking documents several valid reasons why not all of the physical-chemical data specified in the rule is routinely collected by companies. If manufacturers are unable to obtain the needed information, many companies may feel compelled to do costly new product testing to determine whether their respective materials triggered the rule's 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).

2. **Cost Estimate of Reporting Grossly Understated.** EPA's assessment of the reporting burden estimates 140 hours for each nanoscale material to be reported, while providing no explanation for the cost estimate. However, the agency has provided no estimate of the cost of testing to determine if each nanoscale material meets the requirement for reporting. The testing costs alone can be in the tens of thousands of dollars for each material and given the confusing requirements for what constitutes a 'discrete form of a chemical substance' in the nanoscale, industry will spend far more than the EPA estimate. For example, nanoscale materials can easily be modified to meet a broad range of performance characteristics which will require testing on materials with each small variation in size. A company manufacturing a carbon nanotube 50 nanometers in length may make the same nanotube in lengths of 60, 70, 80, or 90 nanometers just to allow manufacturers to vary performance depending on the final product use. Under this rule the company will be required to determine if these changes resulted from a change in process and whether the change in the size of the particle is seven standard deviations in difference from the mean measured value or if any property has changed to a similar degree. The perceived need to make these determinations will cause companies to feel they must test or simply report on each and every size carbon nanotube it manufactures. The alternative is that EPA is placing these companies in the position of failing to provide requested information to a federal government agency -- a position no responsible company wants to be in. There is the further complication that all of these substances will be classified by CAS Number with nothing to allow the Agency to determine whether these present different hazards from each other or are they different from those reported by another manufacturer (importer). The consequence of this lack of

identifier is that users reviewing the reporting will not be able to verify that the substance they have used has been reported or not.

3. **Impact on U.S. Manufacturers.** If allowed to go into effect this regulation will have significant financial impacts on U.S. manufacturers and processors of nanoscale materials including:

   - The creation of unwarranted regulatory costs and commercial stigma;
   - Manufacturing of innovated materials and products will be hindered in terms of time and cost;
   - Unnecessary or duplicative reporting by a group of companies (processors) with little or no experience in filling out EPA's extensive premanufacture notification forms and who will not have all of the information EPA is seeking;
   - Creation of an unwarranted economic burden on impacted small businesses, the number of which is grossly underestimated in the rule; and
   - Provides significant economic burden on legacy industries such as inks, paints, coatings, pigments, plastics, and rubber.

Summary

Arbitrary Rule/Regulation -- The finalized rule lacks factual predicate or a rational basis to justify singling out and imposing on an entire class of materials, without regard to risk, the perpetual 135-day manufacturing/processing reporting requirement. There is a commercial moratoria element to this requirement, whether or not the agency intended this to be the case. The rule is holding nanoscale materials to a higher standard of reporting than any other existing materials.

135-day Reporting Requirement – Despite the current 90-day review requirement for Premanufacture Notice (PMN) new chemical submissions under the Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA has made a gross presumption that companies have the intent to manufacture or process at least 135 days before manufacturing or processing nanoscale materials and requires this intent to be reported. The reasoning behind this presumption is not factually supported. The agency acknowledged this when it added an abbreviated 30 day reporting period to the final rule. As a result, the rule establishes a "double standard" for reporting that penalizes more prepared companies who have to wait longer to commercialize a substance that is already in U.S. commerce and being sold by its competitors.

Reportable Nanoscale Forms of Chemical Substances – The rule is based upon ambiguous and/or subjective applicability criteria the regulation creates arbitrary results in who reports and what is reported.

Cost – Due to confusion about what reporting is required under the rule, manufacturers will be required to perform costly eligibility analyses that will likely involve testing nanoscale materials. Higher regulatory costs prior to initiating manufacturing operations contribute to higher product introduction costs which negatively impact the introduction of new products into the marketplace.

The Coalition agrees there is value in EPA seeking information on nanoscale materials. EPA must not stretch the boundaries of the statute and common sense in doing so. It would be useful for the Agency to more specifically explain how it would establish that the information it seeks can be correlated with the identification of a potential risk. Instead, EPA seeks information without regard to quality, value, or cost. The rule places an undue economic burden on U.S. companies at the forefront of innovation that already has broad-based consumer benefits across a wide range of industry sectors.

Recommendation

EPA has several options. Based on the foregoing, we are grateful that EPA has chosen to suspend the effective date of the rule, presumably until such time as the foregoing issues have been addressed and EPA issues suitable guidance and/or amendments or clarifications. Although the Agency has extended the implementation date from May 12, 2017 to August 14, 2017, the rule should be made effective no earlier than one year from the issuance of such final guidance and/or clarification. If EPA is unable or unwilling to pursue this option, EPA should withdraw the final rule. We appreciate EPA's need for information, but there is a better, more efficient way to obtain such information. Starting over is our preferred alternative if EPA is unwilling to address the issues described above.

Sincerely,

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Wiley Rein LLP

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June 15, 2017

Jeffrey Morris
Acting Director
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

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

Dear Mr. Morris:

On behalf of our client, the Nanomanufacturing Association (NMA), the enclosed questions are provided for consideration by the Environmental Protection Agency (EPA) concerning the implementation of the final rule entitled Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements.[1]

NMA appreciates the opportunity to provide EPA with questions regarding the final rule for which NMA hopes to gain additional clarity. NMA respectfully requests that EPA provide answers to these questions in a response to NMA, and consider the inclusion of these topics as part of the guidance document that is currently out for public comment.[2]

Respectfully Submitted,

Martha E. Marrapese

cc: Maria Doa, Ph.D., Director, Chemical Control Division (CCD), OPPT
Raymond J. Alwood, CCD, OPPT

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1 82 Fed. Reg. 3641 (January 12, 2017).
2 82 Fed. Reg. 22452 (May 16, 2017) (Docket No. EPA–HQ–OPPT–2010–0572).

14114695.1

Nanomanufacturing Association

Questions for EPA Concerning Implementation of the Final Rule "Chemical Substances When Manufactured or Processed as Nanoscale Materials: TSCA Reporting and Recordkeeping Requirements (40 C.F.R. § 704.20)

1. Definition of Solid

a. In a suspension of a liquid in a liquid, particles in the 1 – 100 nm range are not solids for purposes of this rule provided they are 1) formed in suspension, 2) not separated, and 3) are droplets which are not stable in shape when suspended in the liquid matrix at 25°C at atmospheric pressure. Does EPA agree with this assessment?

b. Is a pigment purchased in the form of a paste a solid if the aggregate or agglomerate particle size of the pigment in the paste is less than 100 nm?

c. If a liquid mixture contains pliable solid particles that are < 100 nm and composed of a natural, oily or greasy heat-sensitive substance (i.e., a wax), consisting of hydrocarbons or esters of fatty acids that are insoluble in water but soluble in nonpolar organic solvents; are these particles considered a solid for purposes of this rule?

d. What if particles < 100 nm in the liquid matrix are liquid forms of paraffin, originating from petroleum and used in paper coating, as insulation, in crayons, and in medicinal preparations?

e. In a case in which the starting ingredients are liquids, a reaction takes place and polymer molecules are formed. Please address whether the solid definition is or can be met in the following cases:

   i. The physical form of the polymers formed from these liquids is not clearly a solid.

   ii. The physical form of the polymers formed are polymeric chains with no specific structure that are bound in a droplet.

   iii. The polymers formed are heavier liquids in a suspension of a liquid.

f. Please address if the following examples meet the definition of a solid for this rule: a solid particle < 100 nm at 25 C with irregular shape such as carbon black or carbon nanotubes when added to a liquid mixture?

2. Unique and Novel Properties

a. How does one determine if the "nano" portion of the substance has unique properties compared to the "non-nano" portion, especially for products that have been made the same way for decades? What is the standard or baseline EPA recommends that companies use?

b. Can EPA confirm that if particles < 100 nm are present at < 1% by weight in a mixture the chemical substance is not reportable, even if it contributes a unique and novel property to the mixture?

c. Does the threshold (1%) apply to exempt incidentally produced particles that are < 100 nm in a pigment from having to report even if they provide an intentional and known unique and novel function?

d. Does the 1% threshold apply to both intentionally and unintentionally produced nanoscale particles?

e. If a polymeric coating contains particles of a chemical substance that are solid at 25° C and between 1 – 100 nm, and these particles only contribute to matrix compatibility and homogeneous distribution, which is the same function the chemical substance performs at larger particle sizes, is the coating reportable?

f. If a solid raw material has particles of the same substance which exist in a range of particle sizes, which may include some in the nanoscale, but which do not behave differently and cannot be separated from the other particles of larger size, is the material reportable?

g. If a solid raw material has a range of particle sizes (all the same substance) which includes > 1 % below 100 nm but which do not behave differently (do not exhibit a unique and novel property) is the material an RCS under this rule?

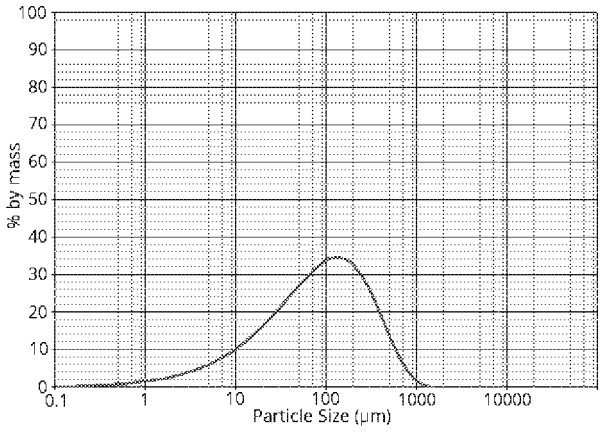
h. Carbon black may be produced at the nanoscale size, however the color is not unique or novel. If it can be purchased in different size ranges, should a downstream processor assume that there are different properties associated with each size which requires separate reports?

i. Does the fact that an RCS is encapsulated in a film during end use change the reporting obligation of processors and manufacturers upstream?

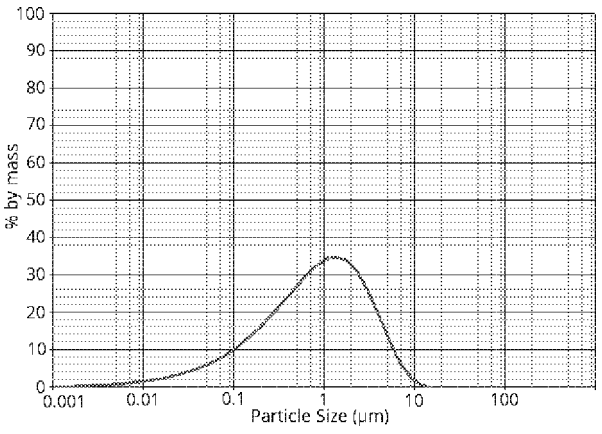
j. If a solid raw material has a range of particle sizes (all the same substance), which may include some in the nanoscale—but which do not behave differently (do not exhibit a unique and novel property) and cannot be separated from the other particles of non-nanoscale size—is the material a reportable chemical substance under this rule?

k. There are two particle size distributions, Distribution A and Distribution B, shown below. Distribution A has less than 1% by weight of solid particles < 100 nm (therefore not an RCS under the rule) and Distribution B has more than 1% by weight of solid particles < 100 nm. Both sets of particles are able to form a colloid (specifically a sol, which is solid particles in a liquid medium). Is a determination that both are able to form a colloid sufficient to conclude that Distribution B would not be a reportable chemical substance under the rule since its ability to form a colloid is not a unique and novel property?

Distribution A



Distribution B



l. If Distribution A was unable to form a colloid (sol) due to its larger particles and Distribution B could form a colloid (sol), then would Distribution B be an RCS?

m. If a pigment that is present as solid particles of < 100 nm in a paste causes the paste to blend more homogenously does it need to be reported? What if the pigment in this size range contributes to a more vibrant shade of the same color? What if the pigment in this size range causes the paste to become transparent? What performance properties are not unique and novel for a pigment in this size range to exhibit? Does the intensity of the color imparted by the pigment have to exactly match the shade imparted at larger particle sizes or is it sufficient to disqualify a pigment if they all impart red?

3. Discrete Forms

a. The rule says a discrete form is "A reportable chemical substance that is coated with another chemical substance or mixture at the end of manufacturing or processing has a coating that consists of a different chemical substance or mixture." If an additive is used in paint or coatings, is that a "different coating" and a discrete form? How does this language about coated particles apply to importers?

b. EPA's draft guidance includes references to surface treatments although the final rule only refers to coatings. Please address the following scenarios:

i. Silane is deposited on the surface of a silica particle that is < 100 nm. The silane is present as regions over a majority of the particle but it is not uniformly distributed over the entire surface of the particle. The silane chemistry is later modified but the manner in which it is deposited is the same.
ii. A covalently bound surface coating on a solid particle of < 100 nm is modified.
iii. EPA guidance indicates the adsorption to a particle is considered a mixture (not a reaction required to be notified as a new chemical under Section 5). A liquid mixture of nanoparticles contains a dispersing agent to prevent agglomeration. The dispersant is a polymer that is adsorbed onto the nanoparticle surface without forming covalent bonds. The polymer allows the nanoparticles to be compatible in the coating matrix and to ensure homogeneous distribution.

iv. If the coating on the surface is held by van de Wall forces, is this simply a mixture or does a change in the coating require a new report?

v. Does a change in a coating that forms a shell around a particle which is not covalently bound to the particle core require reporting?

c. If the rule does not require testing, and data are not available on the properties specified in the rule to distinguish discrete forms, should companies report all dispersions with coated nanoparticles?

d. Would EPA confirm that simply placing an RCS in a different suspension would not constitute a new "coating" for the nanomaterial if there were no strong bonds that made the (solid) coating a stable component of the nanomaterial?

e. Would EPA confirm that what is targeted by the shape criterion for reporting is whether or not changes in shape that are stable are altered? We understand the rule to mean that stable variations in shape may need to be separately reported as discrete forms of a RCS.

f. When determining whether the seven standard deviation degree of change is met, what is the standard material that companies should use as the starting point from which to gauge the degree of change? If a chemical substance identified by the same CASRN has at least 30 different ratios to vary performance, which one should be used to make this comparison?

4. Filing mechanics

a. Since both manufactures and processors are required to report under this rule, are manufacturers and importers allowed to support the processor notifications by their customers? Can a reference number be assigned to each report to allow the manufacture to submit information on behalf of their customers and for customers to reference in their submissions?

b. Company X is the manufacturer of Chemical Substance Y, a reportable chemical substance (RCS). Chemical Substance Y is not listed on the TSCA Inventory and no exemption from premanufacture notification (PMN) applies (i.e., it is a new chemical substance). Is Company X only required to file a PMN? Does Company X need to file a section 8(a) report? Assuming the PMN clears EPA review and a notice of commencement (NOC) is filed, what are the section 8(a) reporting obligations of the manufacturer's downstream customers who process the chemical? Does the answer change if they use the chemical for a use that is the same as the non-nanomaterial form of the chemical?

c. Company X forms the intent 6 months in advance to replace the resin in the coating. What does Company X have to report? What if Company X replaces the biocide or stabilizer in the coating less than 135 days before commercialization?

d. Due to continued confusion over the definition of "reasonably ascertainable," can EPA add the Chemical Data Reporting (CDR) guidance on "reasonably ascertainable" as an addendum to EPA's recently issued guidance on the nanomaterial reporting rule?

5. Testing Protocols

a. If analytical techniques are not being recommended by EPA, how will EPA be able to compare data derived from the use of different analytical methods for example with respect to particle size?

b. We are not required to measure substances in order to determine reportability. If analytical techniques for a particular chemical substance do not exist for the properties identified in the rule, can we conclude on this basis that a reportable substance determination cannot made and we do not need to report?

c. How can a person determine particle morphology for substances where the particles are not separated from a mixture such as when they are part of a liquid?

American Chemistry Council | Nanotechnology Panel

June 15, 2017

Submitted via regulations.gov and email (Alwood.Jim@epa.gov)

Mr. Jim Alwood
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC 20460

Re: Draft Guidance for Reporting of Chemical Substances When Manufactured or Processed as Nanoscale Materials; Notice of Availability and Request for Comment (Docket EPA-HQ-OOPT-2010-0572)

Dear Mr. Alwood:

The Nanotechnology Panel of the American Chemistry Council (the Panel)[1] is pleased to provide the attached comments on the U.S. Environmental Protection Agency's (EPA) "Draft Guidance on EPA's Section 8(a) Information Gathering Rule on Nanomaterials in Commerce" (Draft Guidance).[2] The Panel trusts that EPA will find our comments to be helpful in further developing the Draft Guidance to better clarify EPA's expectations for manufacturers and processors of nanoscale materials who may have reporting obligations under EPA's reporting and recordkeeping rule for nanoscale materials.[3]

The Panel's main objective is to promote the safe and responsible development of nanotechnology, and we recognize EPA's role in ensuring the appropriate oversight of nanomaterials. To clarify reporting requirements, the Panel submitted a set of questions to EPA that we hoped EPA would address when preparing the Draft Guidance. However, after reviewing the Draft Guidance, the Panel continues to seek further clarity on the original request in addition to new questions emerging from review of the Draft Guidance. Our comments are attached.

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[1] Members of the ACC Nanotechnology Panel are 3M, BASF Corporation, Cabot Corporation, Chemours, DuPont, Evonik Corporation, and Procter & Gamble.
[2] U.S. EPA. *Draft Guidance on EPA's Section 8(a) Information Gathering Rule on Nanomaterials in Commerce.* May 2017. Available at https://www.epa.gov/sites/production/files/2017-05/documents/draft_nano_section_8a_guidance_5_15_17_for_docket_clean_002.pdf.
[3] 40 C.F.R. § 704.20.

The Panel believes that EPA must further elaborate and clarify its expectations for reporting so the regulated community can understand its obligation clearly. Without significant additional clarifications and refinements of the scope and key concepts such as "unique and novel properties," "processing," "soluble substances," and "detailed information," the Panel is concerned that the reporting and recordkeeping rule will be perceived as confusing, subjective, and arbitrary.

The Panel recognizes the challenge that the EPA is facing and appreciates the opportunity to comment. We would welcome further dialogue with EPA on this matter. Please do not hesitate to contact me if you have any questions (Jay_West@americanchemistry.com; 202-249-6407).

Sincerely,

Jay West

Senior Director, Chemical Products and Technology Division
ACC Nanotechnology Panel

ATTACHMENT. Comments on the "Draft Guidance on EPA's Section 8(a) Information Gathering Rule on Nanomaterials in Commerce" (Draft Guidance).

Questions previously submitted by the Panel to EPA after the finalization of the rule are presented below in *italics*. The Panel's comments on the Draft Guidance are not italicized.

1. *EPA has not clearly addressed how surface-treated substances should be reported.*
   a. *There is disagreement within industry as to the meaning of "coatings". Please clarify: Some interpret "coatings" as full encapsulation of a particle (e.g., a core particle with a complete shell around it). Others interpret "coating" as a discontinuous/random surface treatment of a particle.*

      Panel Comment: EPA partially clarifies this question in the Draft Guidance when it says, "The term coating in the rule describes surface treating or coating of a reportable chemical substance with another chemical substance. The change in coating makes it a discrete form of a reportable chemical substance subject to reporting even if all the other intrinsic characteristics of the reportable chemical substance remain the same."[4] This answer implies that the term "coating" refers generally to manipulations via surface chemistry. This terminology needs to be clarified, as it is our understanding that the scientific community generally refers to coatings as continuous films on a surface (i.e., encapsulation), whereas surface treatments are more patchy.

      Due to the breadth of the inferred response, the Panel requests further clarity from EPA on whether the coating terminology refers to both chemically attached and physically attached coatings.

   b. *EPA has not clarified how surface-treated particles that are regarded as statutory mixtures under EPA's guidance should be reported. Based on EPA's response to comments, we understand that the "change in coating makes it a discrete form of a reportable chemical substance subject to reporting even if all of the other intrinsic characteristics of the reportable chemical substance remain the same."[5] The substrate particle is the reportable substance, correct? Where would information about the surface treatment be reported, if at all? If the substrate particle is the reportable substance, the final coated/ surface treated particle is not considered a reportable chemical, correct?*

      Panel Comment: The Panel does not feel that this question is addressed adequately in the Draft Guidance. At question 9 EPA says, "Mixtures are not reportable under this rule, however the components of any mixture that contains reportable chemical substances subject to the rule would be reported."[6] One possible interpretation of this statement is

[4] U.S. EPA, *supra* note 2, at 3.
[5] U.S. EPA. *Response to Comments to the Proposed Rule, Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements.* December 27, 2016. Docket # EPA-HQ-OPPT-2010-0572. Page 48.
[6] U.S. EPA, *supra* note 2, at 3.

that for a nanomaterial that is a statutory mixture, the substrate particle should be reported, and the surface treatment is not reportable unless it is independently reportable.

EPA should address this question directly. Surface-treated particles that are regarded as mixtures are not uncommon. The Panel suggests that a reasonable approach would be to report only the substrate particle for surface-treated nanomaterials considered to be statutory mixtures under TSCA. For surface-treated nanomaterials that are not considered to be statutory mixtures under TSCA, each surface-treated nanomaterial would be reported according to the clarifications EPA provides to the Panel's question 1 above.

c. *There are questions regarding whether surface-treated particles should be regarded as having "unique and novel" properties due to size. The behavior of the particle is determined by the chemistry of the surface treatment, which is predictable. Furthermore, the surface treatments would behave the same way regardless of the size of the substrate particle.*

Panel Comment: The Draft Guidance does not address this question directly. EPA states, "The rule does not require that every chemical substance coated or surface treated with another chemical substance be reported. However, any type of engineering including surface treatment of a chemical substance that results in a reportable chemical substance triggers a reporting requirement."[7] One could infer from those sentences that the reporting status of surface-treated particles depends on the fulfillment of the "unique and novel property" criterion and the chemically-bound criterion. However, the Panel remains concerned that what constitutes a "unique and novel property" is still vague and requires further clarification from EPA. Further concerns about the "unique and novel property" interpretation are articulated in many of our comments below.

d. *If a reportable substance is surface treated, is it automatically reportable as a new "discrete form"? How should the seven standards of deviation test apply?*

Panel Comment: EPA has not answered this question. Since mixtures are excluded, it is assumed that only chemically bound surface treatments would result in a reportable discrete form. However, how different do these surface treatments need to be? When is a surface treatment sufficiently similar to another that it does not require additional reporting? If the distribution of a surface treatment on a surface changes, but the percent composition remains constant, is that considered equivalent? Does the seven standards of deviation test apply? With respect to which measurand (e.g., mass, coverage, thickness, speciation) should the seven standards of deviation test apply, if any?

2. *EPA's definition of "unique and novel" does not resolve questions regarding properties, such as surface area or thermal conductivity, that vary predictably and continuously with size.*

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[7] *Id.*

a. *Does EPA consider these continuously scaling properties to be "unique and novel"? What about size itself?*

Panel Comment: EPA does not address this question directly. One possible interpretation from the Draft Guidance is that continuously scaling properties can be "unique and novel" simply because they are "different from properties at sizes greater than 100 nanometers and those properties are the reason why the chemical substance is manufactured in that form or size."[8] However, the Draft Guidance also says that "[n]ot all enhanced properties are unique or novel."[9] The Panel agrees that enhanced properties are not necessarily unique and novel, and EPA should make this distinction clearer.

The Panel recommends that the EPA apply terminology agreed upon in standards communities as much as possible to clarify their intentions. For example, the International Organization for Standardization (ISO) Technical Committee on Nanotechnologies (TC 229) uses two different terms to describe changes in properties facilitated by nanoscale size: "Nano-enhanced" (ISO/TS 8004-1:2015(en), 2.16) and "Nano-enabled" (ISO/TS 8004-1:2015(en), 2.15). Definitions of those terms are publicly available through ISO's online browsing platform (http://www.iso.org/obp) and are as follows:

> **2.15. nano-enabled:** exhibiting function or performance only possible with nanotechnology (2.3)
>
> **2.16. nano-enhanced:** exhibiting function or performance intensified or improved by nanotechnology (2.3)
>
> **2.3. Nanotechnology:** application of scientific knowledge to manipulate and control matter predominantly in the nanoscale (2.1) to make use of size- and structure-dependent properties and phenomena distinct from those associated with individual atoms or molecules, or extrapolation from larger sizes of the same material.
> Note 1 to entry: Manipulation and control includes material synthesis.

Do "unique and novel properties" pertain to "nano-enabled" properties? The Panel requests that EPA clarify the degree to which its thinking regarding the difference between "unique and novel properties" and "enhanced properties" aligns with existing definitions established by ISO.

The Panel notes that EPA has not answered definitively the question about whether size itself is a "unique and novel property." The Panel does not consider size itself a "unique and novel property." For example, if particle size is changed to the nanoscale to make dispensing easier or to facilitate the removal of larger contaminants, is that considered "unique and novel" for the purposes of establishing a reporting requirement? The Panel

[8] *Id.* at 1.
[9] *Id.* at 2.

does not believe these examples (and there could be more) illustrate "unique and novel properties."

b. *If the desirable property is particles that are small enough such that they do not interfere with visual clarity of materials, would this be considered "unique and novel" under the rule?*

Panel Comment: EPA has not addressed this question directly in the Draft Guidance. The Panel notes that EPA's definition of "unique and novel properties" indicates that the properties "vary from those associated with other forms or sizes of the same chemical substance," which the Panel interprets to mean that if the same chemical substance of a larger particle size distribution exhibits the same property, then the nanoscale material is not a reportable substance.

Following this logic, the Panel notes that many materials are transparent when formed into macroscopic bodies like glass panes or macroscopic films. Yet the common form of the material may have a particle size half the wavelength of light (i.e., >100 nm), such that it is no longer transparent due to light scattering from the particle surface. When the same material is taken to the nanoscale, it becomes transparent again. Thus, transparency should not be considered a "unique and novel property."

c. *What about color? Some substances like carbon black (and some pigments) are always produced at the nanoscale, yet do not have "unique and novel" properties due to size. Many processors use carbon black as a colorant, and the color of carbon black is not due to its size; it is an intrinsic property. Can it therefore be excluded from reporting?*

Panel Comment: EPA has not addressed this question clearly. At question 3, EPA says, "engineering pigments for better performance which results in almost all particles that are less than 100 nm would constitute a nanoscale material with unique or novel properties." However, at question 11, EPA says, "organic and inorganic pigments…are not reportable chemical substances unless they are manufactured at the nanoscale to exhibit unique and novel properties that are not exhibited by other forms or sizes of the same chemical substance." In our reading, these two statements concerning pigments do not align, and the Panel requests further clarity.

3. *Industry needs EPA to provide more clarity on the reporting expectation for "detailed information on methods of manufacturing or processing."*[10] *For discrete form(s), what "detailed information"? Does a standard/precedent exist under TSCA?*

Panel Comment: This question is not addressed in the Draft Guidance, and the Panel requests clarification.

[10] 40 CFR § 704.20(d)(7).

4. *EPA says that chemical substances that are manufactured or processed in a nanoscale form for the purposes of being sold to others for use as a component of a mixture, encapsulated material, or composite are subject to reporting. EPA further states that those substances do not require separate reporting for their incorporation.*
    a. *Doesn't the "unique and novel" properties criterion and the tests for determining a discrete form also apply in terms of determining whether either material is reportable? Shouldn't the sentence above say "discrete forms of a reportable substance"?*

       Panel Comment: The Draft Guidance sufficiently clarifies that the "unique and novel" property criterion always applies. However, the Draft Guidance does not address the second part of our question regarding the other tests for identifying a reportable discrete form.

    b. *Is the entity doing the incorporation required to report if that entity does not manufacture the substance and information is neither available nor reasonably ascertainable?*

       Panel Comment: EPA indicates in question 6 that each processor needs to report its activities under the rule.[11] In question 14, EPA also seems to indicate if the supplier does not have or supply information indicating the substance is reportable, then the processor is not required to report.[12] However, it remains unclear when the act of incorporation is considered "processing" under the rule. Some intended uses of nanomaterials are simply for incorporation into another mixture or chemical substance. In question 14 EPA states, "Companies that purchase formulations but do not change or modify those formulations and only use them are not considered processors and are not required to report under the rule."[13] What is considered a "formulation"?

5. *Some companies may manufacture/import substances with differing surface areas. The aggregate sizes of some grades may be larger than 100 nanometers, and others may have an aggregate size between 1-100 nm. Differing surface area is a reason that these grades are manufactured/imported. In this circumstance, does surface area meet the definition of a "unique and novel property" such that grades having aggregate sizes of 1-100 nm may be reportable under the final rule?*

   Panel Comment: EPA has not addressed this question directly. The Panel notes that materials with aggregate sizes above 100 nm may have identical surface areas to materials less than 100 nm. Does that indicate that surface area does not meet the definition of "unique and novel property"? The Panel requests further clarity.

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[11] U.S. EPA, *supra* note 2, at 3.
[12] *Id.* at 5.
[13] *Id.* at 6.

6. *EPA should clarify its definition of "processing" for the purpose of this rule. There is considerable confusion regarding which activities would require reporting under the rule, based on EPA's responses to comments. The ACC Nanotechnology Panel recommends that the scope of the term "processing" in this rule should be consistent with EPA's use of this term in other areas of TSCA, such as SNURs and CDR. For example, formulation, repackaging, and processing substances into articles would all be considered processing activities subject to reporting. However, some are reading the following EPA responses to comments as establishing a narrower definition that would exclude activities such as blending a raw material into a formulation without "changing" it.*
    a. *Comment 22: "Most of the activities described by commenters for exemption would only require reporting for a reportable chemical substance before it is incorporated into a formulated product or polymer matrix. Reporting would not be required by persons who use the formulated product or polymer matrix."*[14]
    b. *Comment 32: "Companies that purchase formulations but do not change or modify those formulations and only use them are not considered processors and are not required to report."*[15]

    Panel Comment: The Draft Guidance does not answer this question. The Panel requests further clarity on the definition of the terms "processing" and "formulation," including clarification of any changes to existing TSCA policy and TSCA guidance that EPA intends to apply to the nanoscale material reporting rule.

7. *Regarding the "reasonably ascertainable" standard, in the final CDR rule, EPA states clearly:*

    "[S]ubmitters are not required to conduct a new or additional customer survey (i.e., to pose a comprehensive set of identical questions to multiple customers) under this standard. If particular information cannot be derived or reasonably estimated from the information available to the company without conducting further customer surveys, it is not 'known to or reasonably ascertainable' to the submitter for purposes of the CDR."[16]

    However, in comment 3 of the nanomaterial rule Federal Register notice,[17] *EPA seems to expect processors to conduct supplier surveys as part of meeting the "reasonably ascertainable" standard. This expectation seems inconsistent with the standard established for the CDR. EPA should reconcile what appears to be a contradiction in forthcoming guidance.*

    Panel Comment: The Panel appreciates the clear reference to existing definitions of "known or reasonably ascertainable" in question 21 and the clear expectation in question 14 that processors should contact their suppliers to request information to understand and fulfill potential reporting obligations.

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[14] U.S. EPA, *supra* note 5, at 17.
[15] *Id.* at 25.
[16] 76 Fed. Reg. 50829 (August 16, 2011).
[17] 82 Fed. Reg. 3646 (January 12, 2017).

The Panel notes that question 21 repeats the CDR standard that "reasonably ascertainable" does not require customer surveys. The Panel's interpretation is that the same standard applies to processors with regard to supplier surveys. In that regard, if a supplier fails to provide a response, has the processor met its obligation? Does EPA also expect that processors conduct and document in-depth literature searches if the material supplier fails to provide information?

8. *Some companies may manufacture and sell products in aqueous dispersion. The particle size in solution would be within the range (including any agglomerates) specified in the rule, but the commercial product itself is never sold or used as a solid (i.e., evaporated or otherwise dried). In this circumstance, does the manufacturer have to report under the rule?*

   Panel Comment: This question is not addressed directly in the Draft Guidance. Are particles in suspension that are never handled in solid form reportable? The Panel would appreciate EPA's clarification.

9. *When is the electronic reporting tool going to be available? Will EPA develop user guidance for the new CDR reporting module?*

   Panel Comment: This question is not addressed in the Draft Guidance, and the Panel requests further information.

In addition, the Panel requests clarification on the following questions and issues that emerged during review the Draft Guidance.

1. Aggregates and Agglomerates. Although EPA indicates that aggregates and agglomerates larger than 100 nm are not reportable, further clarity on whether the terms "aggregates" "agglomerates" includes heterostructures (heteroagglomerates and heteroaggregates) would be useful. Are the terms "aggregates" and "agglomerates" specific to the chemical substance in question, or do the terms more broadly apply to mixtures of particles of different chemical substances that come together to form larger structures?

2. Data Utility and Transparency. EPA has been clear that the rules promulgated under TSCA Section 8(a) do not require the generation of new information (i.e., testing). EPA has also acknowledged that information received will not be standardized across reporting entities. It is assumed that this information will be applied, in part, for decision-making purposes. EPA also notes that non-confidential information under the rule will be made available in ChemView. Given that many of the parameters provided represent extrinsic properties (i.e. zeta potential), the Panel continues to have significant concerns about the utility of the data EPA will receive. Will EPA provide further guidance on how the data will be used and on its preferred fit-for-purpose methods? Will ChemView contain disclaimer language to note that the data were not necessarily produced in accordance with a globally recognized standard or test method? The Panel strongly recommends such disclaimer language to dissuade misrepresentation and, in the worst case, misuse of the data. Other federal agencies, states,

and foreign governments rely on information and data from EPA to inform their own chemical regulatory processes, and we therefore believe accuracy and context are essential.

3. Seven Standard Deviations. With regard to changes in particle size that may trigger a new reportable substance, one consideration (among others) is "a size variation in the man particle size that is greater than 7 times the standard deviation of the mean particle size."[18] For the properties to which changes are to be considered, the final language is not clear on the measure of central tendency.[19] The Panel assumes the measure of central tendency is also the man. However, the Panel does seek clarification on whether the standard deviations are around the sample mean or the population mean.

4. "And" or "Or." In the *Federal Register* notice for the final rule,[20] the accompanying question and answer document,[21] and the Draft Guidance, the phrases "unique **and** novel" and "unique **or** novel" (emphases added) are used to describe "properties." The Panel would like clarification as to which of the phrases is the correct, consistent, and intended language from EPA. The use of "and" versus "or" could potentially be a deciding factor in determining whether a nanoscale material is a reportable substance.

[18] 40 C.F.R. § 704.20(a), part (i)(B) of the definition of "Discrete form of a reportable chemical substance."
[19] *Id.*, part (i)(C).
[20] 82 Fed. Reg. 3641 (January 12, 2017).
[21] U.S. EPA, *supra* note 5.

May 12, 2017

Via Electronic Submission

Sarah Rees, Ph.D.
Director, Office of Regulatory Policy and Management
Office of Policy
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code 1803A
Washington, D.C. 20460

Re: Docket ID No. EPA-HQ-OA-2017-0190

Dear Dr. Rees:

We are writing on behalf of the NanoBusiness Commercialization Association (NanoBCA) in response to the U.S. Environmental Protection Agency's (EPA) request for input on regulations that may be appropriate for repeal, replacement, or modification. 82 Fed. Reg. 17793 (Apr. 13, 2017). EPA's request for comment is derivative of Executive Order 13777, *Enforcing the Regulatory Reform Agenda*, which seeks to establish a "federal policy to 'alleviate unnecessary regulatory burdens' on the American people." We are pleased to provide this information.

NanoBCA is the world's first nonprofit association focused on the commercialization of nanotechnologies. NanoBCA is dedicated to creating an informed and responsible commercial environment that nurtures research and innovation in nanotechnology, promotes the tech-transfer of nanotechnologies from academia to industry, encourages private capital investments in nanotechnology companies, and helps its member companies bring innovative nanotechnology products to the market.

We write to express our concerns with EPA's January 12, 2017, final rule, *Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements.* 82 Fed. Reg. 3641. As noted in our extensive comments on the proposed reporting rule, NanoBCA believes that the adoption of uniform recordkeeping and reporting requirements for nanoscale chemical substances could create a more level playing field, assuring that no individual company or group of companies is burdened with the responsibility to submit information on nanoscale chemical substances on behalf of an entire segment of the nanotechnology sector, and providing EPA with meaningful information to assist it in discharging its Toxic Substances Control Act (TSCA) responsibilities. In addition, if EPA had more useful, comprehensive, and accurate information concerning the nature and properties of nanoscale chemical substances, this could favorably and efficiently address unwarranted

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concerns that have been raised concerning the health and environmental effects of the products of nanotechnology, and promote more balanced and scientifically informed risk assessment and risk mitigation decisions.

Unfortunately, the final reporting rule includes many of the same legal deficiencies noted in our comments. This includes the inherent structural problem that EPA has no authority under TSCA Section 8(a) to require manufacturers or processors to make the measurements needed to implement any definition of a reportable chemical substance based on data on the size of particles, aggregates, or agglomerates. The definition of a chemical substance under TSCA is based on molecular identity, not size. The definition of a reportable chemical substance in the final rule is inherently subjective and, thus, confusing and unenforceable. Further, whether a chemical substance is deemed reportable under the final rule depends in large part on the technical method used to characterize particle size. This means that the measured results can be expected to vary widely depending upon the technical method used, calling into question the utility, reliability, and regulatory value of these results.

We also expressed concern with the requirement to report information on nanoscale chemical substances 135 days before commencing manufacture or processing, and note that this requirement has no legitimate legal basis. Notwithstanding our objection, and over the objections of many other commenters, this requirement has been retained, albeit modestly amended in the final rule.

Finally, NanoBCA remains concerned with the excessive reporting burden the rule imposes on regulated entities, particularly smaller businesses which reflect a substantial portion of NanoBCA's membership. Given the vagaries in the final rule, and the lack of clarity as to what must be reported and by when, the actual reporting burden on the regulated community will be significantly higher than EPA estimated.

For all the reasons noted above, in our comments, and consistent with the comments submitted by many others, NanoBCA urges EPA to suspend the effectiveness of the rule beyond the August 14, 2017, date, suspend the reporting deadline of May 12, 2018, address and resolve the many problems with the final rule as outlined briefly above, issue the guidance on the revised final rule that EPA committed to issue, and require reporting no earlier than one year from the date EPA actually issues guidance on the revised final rule. If EPA is unable or unwilling to agree to these measures, EPA should withdraw the final rule and essentially start over. We appreciate EPA's need for information, but there is a better, more efficient way to obtain such information, and starting over is the preferred alternative if EPA is unwilling to address the many issues industry has carefully identified with the final rule.

Thank you for providing an opportunity to bring this important matter to EPA's attention.

Sincerely,

Lynn L. Bergeson

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June 15, 2017

Mr. Jim Alwood
Chemical Control Division (7405M)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460–0001
Email: alwood.jim@epa.gov

Re: Comments of the Chemical Users' Coalition on the Draft Guidance on EPA's Section 8(a) Information Gathering Rule on Nanomaterials in Commerce; Notice of Availability and Request for Comment; EPA–HQ–OPPT–2010–0572; 82 Fed. Reg. 22452 (May 16, 2017)

Dear Jim ~~Mr. Alwood~~:

The Chemical Users Coalition ("CUC") appreciates the opportunity to provide the following comments on the Agency's draft guidance[1] on the final TSCA Section 8(a) rule establishing reporting and recordkeeping requirements for certain chemical substances manufactured or processed at the nanoscale.[2]

The CUC is an association of companies from diverse industries that are interested in chemical management policy from the perspective of those who use, rather than manufacture, chemical substances.[3] The CUC appreciates the need to protect human health and the environment while fostering the pursuit of technological innovation, two goals that can and must be made compatible if our society is to achieve sustainable economic development. Aligning these goals is particularly important in the area of chemical management policy, since chemistry underlies all aspects of manufacturing, and all products are made from chemicals. Our comments are offered with a view toward reducing the reporting burden on chemical manufacturers and processors without undercutting EPA's ability to collect the information it needs to identify nanomaterials in commerce and to gather existing information and data that might enhance the Agency's ability to characterize risks.

[1] *Draft Guidance for Reporting of Chemical Substances When Manufactured or Processed as Nanoscale Materials; Notice of Availability and Request for Comment*, EPA–HQ–OPPT–2010–0572; 82 Fed. Reg. 22452 (May 16, 2017).
[2] Final Rule: *Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements*, 82 Fed. Reg. 3641 (Jan. 12, 2017).
[3] The members of CUC are Intel Corporation, Procter & Gamble Company, American Honda Motor Corporation, Lockheed Martin Corporation, HP Incorporated, IBM Company, The Boeing Company, General Electric Company, and Airbus S.A.S.

Below, we offer comments concerning EPA's answers to specific questions in the draft guidance. We also are providing the attached redlined version of the draft guidance that reflects certain suggested changes that are self-explanatory.

Question 1

The answer to this question states that if, upon manufacture, a primary particle "almost immediately" forms aggregates and agglomerates that are larger than 100 nanometers (nm), that particle would not constitute a reportable chemical substance "unless the manufacturer was making a form of carbon black consisting solely of those primary particles that exhibit size-dependent properties." It is not clear why the Agency's draft answer addresses carbon black, since the question posed does not refer to carbon black. The reference to carbon black implies the substance is an example of a substance or a primary particle that does NOT aggregate or agglomerate "almost immediately" upon manufacture, and therefore would be a reportable chemical substance. We recommend EPA clarify the answer or delete the reference to carbon black entirely to avoid confusion, as indicated in the attached mark-up. Otherwise, then the Agency should explain why carbon black should be treated differently from other nanomaterials for purposes of this question and answer and the example provided.

Question 3

The first three sentences of the Agency's draft answer appear to indicate that an "enhanced property" is one which is only improved or strengthened when a substance is manufactured in a size range of 1-100 nm in at least one dimension, whereas a "unique and novel" property is a property that is exhibited only when a substance is manufactured in that size range. That makes sense. The last two sentences, however, create confusion as they imply that whether a property is "enhanced" or "unique and novel" depends upon the proportion of particles that are within the size range of 1-100 nm in at least one dimension. That does not make sense in light of the rest of EPA's draft reply. We recommend that EPA further edit the draft response and include an example along the following lines:

> If, for example, a pigment exhibits a specific property (e.g., adding blue tones to a resin) in all size ranges, but the blue tones are more apparent when the pigment particles are in the size range of 1-100 nm in at least one dimension, that would be an "enhanced" property. If the blue tones are apparent only when the pigment particles are in the size range of 1-100 nm in at least one dimension, that would be a "unique and novel" property.

Question 5

We agree with the Agency's reply that the final Section 8(a) rule does not require reporting on the basis of whether a use of a previously reported substance is new. Reporting for the 8(a) rule is determined by whether the substance in question represents a discrete form of a substance that also meets the criteria of being a reportable substance. The Agency's draft answer therefore is correct in saying that the Section 8 rule imposes no obligation to report a new use of a chemical substance that has been reported as a new chemical or reported previously under the Section 8(a) rule. On the attached mark-up, we are suggesting some changes to this answer to clarify that new uses of a chemical substance do not determine whether the chemical substance must be reported pursuant to this rule.

Question 6

The answer to this question states: "If a manufacturer sells a mixture containing a reportable chemical substance to multiple processors, then each processor also is required to report." As the CUC explained in CUC's August 5, 2015 comments on the proposed rule, requiring processors to report will result in duplicative reporting that is unlikely to provide significant new information to EPA. At minimum, processors should not be required to provide information that already has been provided by a manufacturer. Instead, processors should be expected to report only information that is unique to their operations and uses of the chemical substance (e.g., exposure and release information), and only to the extent the information is known or reasonably ascertainable by the processors. That would be consistent with Section 8(e) of TSCA, which does not require manufacturers/processors to report "substantial risk" information if the company has knowledge that the Agency already has been "adequately informed" of the information. CUC encourages EPA to consider amending the regulation to provide a mechanism whereby processors can confer with their suppliers and determine whether the supplier intends to submit information pursuant to the rule which would make a report from the processor duplicative.

Question 7

EPA should provide guidance on the method(s) and criteria that should be used to determine whether a chemical substance will disassociate completely in water to form ions smaller than 1 nm. That is necessary because dissolution is a dynamic process that is not only dependent upon a particle's chemical and surface properties, as well as size, but is also impacted by the surrounding media. Therefore, different approaches have the potential to produce very different results.

Question 8

The Agency's draft answer is not responsive to the question being asked. The question asks how a person is expected to determine whether a particle is, for example, a rod, wire, or needle. The answer provided in EPA's draft guidance addresses the question of when a change in shape results in a new reportable chemical substance. To answer the question asked, EPA should adopt and provide reference to the relevant definitions promulgated by the International Organization on Standardization, such as ISO/TS 80004-2:2015 (Nanotechnologies -- Vocabulary -- Part 2: Nano-objects), which defines terms such as nanofiber and nanorod.

Question 9

On the attached mark-up, we suggest changes to clarify that only those components of a mixture that meet the criteria for a "reportable chemical substance" need to be reported pursuant to the final Section 8(a) rule.

Question 10

Question 10 attempts to highlight the challenges in identifying forms of reportable chemical substance that might be "discrete" due to a coating. The answer is not responsive to the question, and is confusing in a number of respects.

First, the question asks why coated nanomaterials are treated differently than mixtures, but the answer does not say anything about mixtures.

Second, the preamble to the final rule describes three circumstances that can give rise to a "discrete form" of a reportable chemical substance. The third circumstance is expressed as: "forms of a reportable chemical substance that are coated with different chemical substances would be considered discrete forms for each chemical coating." 82 Fed. Reg. at 3644. That makes sense. The final rule, however, uses different language. The rule says that a "discrete" form occurs when "(iii) A reportable chemical substance that is coated with another chemical substance or mixture at the end of manufacturing or processing has a coating that consists of a different chemical substance or mixture." That description makes no sense, and could be read to mean that a reportable chemical substance must be coated with two different substances in order to be a "discrete" form. We do not believe that is what EPA intends.

Third, the answer says that a "change in coating makes . . . a discrete form . . . even if all of the other intrinsic characteristics of the reportable chemical substance remain the same." The next sentence then states that "[c]oating or surface treating a nanoscale material results in a

nanoscale material with different properties." That implies that coating or surface treating a nanoscale material always changes the intrinsic properties of the nanoscale material." Those two sentences are inconsistent.

Finally, the final rule and the answer fail to recognize that "coating" is not necessarily the same as "surface treating." EPA should re-examine this question and answer. and revise the answer to respond to the question.

Question 11

The answer states that "[i]n order to be a reportable chemical substance, the chemical must . . . be a *particle* in the size range of 1-100 nm." [Emphasis added.] The answer also implicitly acknowledges that monomers, polymers, colloids, pigments and dyes generally will not be reportable chemical substances. That is because polymers, pigments and dyes generally are not "particles" within the meaning of the rule, as they are not "minute piece[s] of matter with defined physical boundaries." EPA should clarify that monomers, polymers, colloids, pigments and dyes will be reportable chemical substances only if they are manufactured in a form with at least one dimension in the size range of 1-100 nm and exhibit a unique and novel property, and such property is a reason that the chemical substance is manufactured or processed in that form.

The last sentence of the Agency's draft answer is internally inconsistent and confusing. It says that "[l]arge molecules and ligands . . . that *do not meet* the definition do not need to be reported . . . unless they *meet* the definition." [Emphasis added.] EPA should either delete this sentence or revise it as we have recommended in the attached mark-up of the draft Guidance.

Question 13

EPA should reverse the order of the information provided in this draft answer. Because EPA states in the last paragraph that the Agency "considers most forms of carbon nanotubes [CNTs] as new chemical substances", CUC recommends making clear that the first question a CNT manufacturer or processor should ask is whether the CNT is a "new" chemical or the processing activity would be a "significant new use" that must be reported in the context of a PMN or SNUN. If the answer to that question is "yes", then the manufacturer "only needs to submit a new chemical [or new use] notification under TSCA." 82 Fed. Reg. at 3649.

If the CNT is not a "new" chemical, and a SNUN is not needed, then the next step is to determine whether the CNT is a reportable chemical substance. If the answer to that question is "yes", then and only then do the dates and deadlines discussed in the first paragraph of the answer come into play.

We note that EPA has not referenced in the draft guidance the 2008 memorandum, "TSCA Inventory Status of Nanoscale Substances – General Approach", https://www.epa.gov/sites/production/files/2015-10/documents/nmsp-inventorypaper2008.pdf (accessed on June 9, 2017). If that memorandum still is in effect, it should be referenced in the answer to Question 13.

Question 14

The guidance provided in the answer to Question 14 is similar, but not identical to, the guidance provided on the meaning of "reasonably ascertainable" in the context of the Chemical Data Reporting rule. To avoid confusion, instead of paraphrasing that guidance, EPA should simply refer the reader, and provide hyperlinks, to the definitions and guidance provided for the CDR.

As currently described, EPA's paraphrasing of the guidance provided for the CDR misstates the efforts processors must take to create or collect information from external sources, such as suppliers and customers. Specifically, the Agency's draft answer to Question 14 states:

> If processors do not know about specific physical properties of chemical substances, they must still take reasonable measures to ascertain the information that would determine whether they are subject to the rule. If processors do not know about specific properties such as particle size and other properties that would allow them to know if they are processing a chemical substance subject to the rule, **it would be within the reasonably ascertainable standard to ask their suppliers for information that would enable to processor to determine whether the supplier is selling them a nanoscale material subject to reporting and if so provide them with what reportable information they have.**

(emphasis added). This suggests an obligation to affirmatively ask suppliers for information that the processor does not otherwise have and to collect reportable information from suppliers (i.e., to create and collect information that is new to the processor).

Such an obligation is inconsistent with the definition of "known or reasonably ascertainable" in 40 CFR 704.3, which refers only to information in a company's possession and control ("all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know"). Processors do not possess or control information held by its supplier, and therefore requiring

processors to both create new information by surveying upstream suppliers and then to collect that information from upstream suppliers overstates a processor's obligations to fulfil its reporting obligations under Section 8(a).

This conclusion is supported by EPA's prior guidance for the CDR on these points where EPA stated explicitly that there is no such obligation:

> EPA would like furthermore to clarify that submitters are not required to conduct a new or additional customer survey (i.e., to pose a comprehensive set of identical questions to multiple customers) under this standard. **If particular information cannot be derived or reasonably estimated from the information available to the company without conducting further customer surveys, it is not "known to or reasonably ascertainable" to the submitter for purposes of the CDR.** However, to the extent that customer surveys are already in the submitter's possession or control, and to the extent that reasonable efforts to analyze or derive information from already-available customer surveys may inform processing and use information that is reported, the information is generally "known to or reasonably ascertainable."

76 Federal Register 50816, 50829-30 (August 16, 2011) (emphasis added). EPA should therefore revise Question 14 to either refer explicitly to the guidance for the CDR or to remove any suggestions that processors must create and collect from upstream suppliers information that the processor does not currently know nor possess and control.

Question 16

The answer states that "*Once a chemical substance has been incorporated into an article*, no further reporting is required as persons that manufacture or process chemical substances as part of articles are exempt from reporting." That could be read to mean that a person who purchases a reportable chemical substance solely for purposes of incorporating it into an article has a reporting obligation up until the time that the substance is incorporated into the article. EPA should provide further clarity and include in the final guidance specific examples of when a person who purchases a reportable chemical substance for purposes of incorporating it into an article is strictly a "user" of the substance who has no obligations under the Section 8(a) rule in contrast to a person who is a "processor" with reporting obligations under the final rule.

Question 17

The last sentence of the answer states: "EPA expects that in most cases such information will be in the company's possession or reasonably ascertainable." It is not clear what information EPA is referring to in that sentence. EPA should delete the sentence (as shown in the attached mark-up) or provide clarification and the basis for that expectation, especially since the question strongly implies that such information on critical physical-chemical properties might not be readily available. As the CUC explained in our August 5, 2015 comments on the proposed rule, methods for determining zeta potential, surface area, dispersion stability and surface reactivity of nanoscale materials have not been standardized, and no analytical methodologies have been approved by EPA. We recommend EPA simply delete the final sentence of the draft answer.

Questions 21 through 23

As with Question 14, we recommend that EPA simply refer the reader to the definitions and guidance provided for the CDR.

Question 24

A reportable chemical substance might be used to manufacture a consumer product, but not be present in the consumer product. EPA should confirm that a company need not provide information about a consumer product if it does not contain the reportable chemical substance.

To make it easier for companies to report use information, EPA should recommend that companies refer to the use tables and codes used for the CDR.[4]

Question 25

The answer to this question states: "[I]f a company desires to begin manufacture or processing less than 135 days after the submission for this rule is made, the company is free to do so. There is no obligation . . . to wait 135 days after reporting to manufacture or process." The final rule, however, clearly states that a report must be submitted:

[4] Codes appear in the Agency's 2016 Instructions for TSCA Chemical Data Reporting, U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, June 23, 2016. https://www.epa.gov/sites/production/files/2016-05/documents/instructions_for_reporting_2016_tsca_cdr_13may2016.pdf

> [A]t least 135 days *before* commencing manufacture or processing . . . except where the person has not formed an intent to manufacture or process that discrete form at least 135 days before commencing such manufacture or processing, in which case the information must be filed within 30 days of the formation of such an intent.

40 CFR 704.20(f)(2)(emphasis added).

CUC remains concerned that an EPA enforcement official might construe the rule to require that a person *must* wait either the full 135 days or at a minimum 30 days after reporting before commencing manufacture or processing. EPA should issue a technical amendment to the pertinent passage in the rule to conform the text of 704.20(f)(2) to the understanding expressed in the draft answer to this question.

To help companies determine whether they have a "discrete" form of a nanomaterial, EPA also should refer in the final version to this draft answer to the 2008 memorandum, "TSCA Inventory Status of Nanoscale Substances – General Approach", https://www.epa.gov/sites/production/files/2015-10/documents/nmsp-inventorypaper2008.pdf (accessed on June 9, 2017).

Question 26

This answer states that "updating with new information is not required unless [a] change in manufacture or processing creates a new discrete form of a reportable chemical substance." If a new discrete form is created, CUC interprets the final rule to require a separate report to be filed for each new discrete form of a reportable chemical substance, as opposed to filing an update to a previous submission under the rule. We recommend EPA clarify its response.

Question 32

The draft answer to this question is similar to the answer to Question16, in that this answer implies that a person who purchases a reportable chemical substance solely for purposes of incorporating it into an article has some type of reporting obligation covering activities that occur prior to the point at which the substance is incorporated into the article. CUC requests EPA provide greater clarity and provide examples of activities in the context of manufacturing an article that constitute solely on site "use" of a reportable chemical (for which reporting is not required) versus those activities that constitute "processing" of a substance prior to its incorporation into a finished article.

Question 35

This draft answer is incomplete. Before determining whether a substance is subject to the reporting rule, the manufacturer or processor should first determine whether the substance is a chemical substance within the meaning of TSCA; then determine whether the substance is subject to any reporting exemptions; and then determine whether the substance is on the Inventory or is a "new" chemical substance for which a PMN might be required. Depending upon the answers to those questions, the manufacturer/processor might or might not need to determine whether the chemical substance is a reportable chemical substance that is subject to the rule.

We also note that the answer refers to "the last principal reporting year." The term "Principal reporting year" is not used in the rule or elsewhere in the guidance. EPA should delete that term from the draft answer as recommend in the attached mark-up.

Question 37

This answer states: "In order to manufacture (including import) or process a chemical substance for a non-exempt commercial purpose, it must be: on the TSCA Inventory, a naturally occurring chemical substance, . . . or excluded by TSCA Section 3(2)(b). The draft answer requires clarification; the attached mark-up provides suggested edits to address the confusing portions of the draft sentence. EPA should add a reference to the need to submit a request to search the Confidential Inventory, and note there are exemptions from TSCA reporting requirements that could explain why a substance might not be listed on the Inventory (e.g., the polymer and LVE exemptions). EPA also should reiterate that if a PMN must be submitted for a new chemical substance, that substance need not be reported pursuant to the final Section 8(a) rule.

Question 38

EPA should reference its interpretation of the substantiation requirements that was published in January. *Statutory Requirements for Substantiation of Confidential Business Information (CBI) Claims Under the Toxic Substances Control Act (TSCA)*, 82 Fed. Reg. 6524 (Jan. 19, 2017).

Comments on Reporting Form

The version of the reporting Form appearing in the Agency's docket for the final rule is labeled "draft"; CUC request this be clarified. If the Form appearing in the docket is not yet "final", the CUC offers these additional comments on the draft Form:

- The draft Form in the docket fails to capture whether the submitter is reporting as a manufacturer/importer or a processor (or both) and should be amended to capture this information.
- The draft Form looks like the PMN Reporting Form, which was designed to serve a different purpose than Section 8(a) information gathering. The Form could be simplified considerably to focus more explicitly (and solely) on gathering the information items set forth in the final regulation at 40 CFR §724.20(d)(1) – (11).
- The final Form should provide a check box or other simple method for designating when an information item is not being supplied because it is "not known to or reasonably ascertainable" by the entity completing the Form. Such a check box could be positioned near the boxes provided throughout the draft Form for asserting CBI claims.

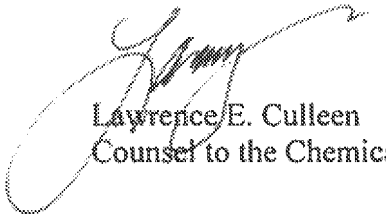
Conclusion

As our comments and those of other commenters indicate, the draft guidance will be unlikely to anticipate and provide answers to all of the potential questions that will arise as manufacturers and processors seek to comply with the rule and complete the reporting form when necessary. CUC recommends it is more appropriate for EPA to focus its limited resources on making entities who are unfamiliar with TSCA aware of the final regulation and providing assistance to manufacturers and processors seeking to comply, as opposed to emphasizing rigorous enforcement efforts -- especially where the requirements of the rule might be misunderstood or easily misinterpreted. Doing so will reduce disincentives to reporting and help to ensure EPA achieves its stated goals for the final rule: to "assist EPA in its continuing evaluation of chemical substances manufactured at the nanoscale, informed by available scientific, technical and economic evidence … on a case-by-case basis without a presumption of either harm or safety…".[5]

[5] *See* Final Rule at 3642.

The CUC appreciates your consideration of these comments. If you have any questions relating to these comments, please feel free to contact me.

Sincerely,



Lawrence E. Culleen
Counsel to the Chemical Users Coalition

Enclosure -- Mark-up EPA draft guidance document

Mark-up

EPA draft guidance document

Draft Guidance on EPA's Section 8(a) Information Gathering Rule on Nanomaterials in Commerce

What Chemicals are Reportable?

Question 1: My company manufactures a nanoscale material in the form of primary particles less than 100 nanometers in the reactor system but almost immediately due to ~~V~~an van der Waall forces forms aggregates and agglomerates with particle sizes far greater than 100 nanometers(nm). Are these types of nanostructured materials with particle sizes greater than 100 nm considered reportable chemical substances under this rule?

No. The definition of a reportable chemical substance under this rule is a combination of particle size and unique and novel properties. For the example given in the question, the form consisting of primary particles at "creation" would not meet the definition of a reportable chemical substance, unless the manufacturer was making a form ~~of carbon black~~ consisting solely of those primary particles that exhibit size dependent properties. Because in the example the particle size of the aggregates and agglomerates is greater than 100 nm, that form ~~of carbon black~~ as manufactured is not a reportable chemical substance.

Question 2: Can you describe what is considered a reportable chemical substance? Is there some way to differentiate between genuinely new nanoscale materials in commerce and traditional products?

Under this rule, a reportable chemical substance is a solid at 25 °C and standard atmospheric pressure, that is manufactured or processed in a form where any particles, including aggregates and agglomerates, are in the size range of 1–100 nm in at least one dimension, and that is manufactured or processed to exhibit unique and novel properties because of its size. A reportable chemical substance does not include a chemical substance that is manufactured or processed in a form where less than 1% of any particles, including aggregates, and agglomerates, measured by weight are in the size range of 1–100 nm in at least one dimension.

The rule also includes a definition of unique and novel properties. Unique and novel properties means any size-dependent properties that vary from those associated with other forms or sizes of the same chemical substance that are not in the size range of 1-100 nm in at least one dimension, and such properties are a reason that the chemical substance is manufactured or processed in that form or size. For purposes of this rule, EPA defined unique and novel properties to include an element of intent, meaning that those properties are the reason why the chemical substance is manufactured in that form or size. In order to be reportable it is not sufficient that a chemical substance contains particles in the size range of 1-100 nanometers in at least one dimension; it must also have a size-dependent property different from properties at sizes greater than 100 nanometers in all dimensions, and those properties are the reason that the chemical substance is manufactured or processed in that form or size.

Intentionally manufacturing or processing nanoscale gold so that it exhibits a red or purple color instead of a yellow color is an example of a unique or novel optical property seen at the nanoscale. Such a change would likely result in changes of other properties, such as specific

surface area, which can result in different health and safety impacts. Unique and novel properties which impact performance generally cannot be isolated from concurrent changes in properties that impact biological systems. Some nanostructured materials are stronger or have different magnetic properties compared to other forms or sizes of the same material. Others are better at conducting heat or electricity. They may become more chemically reactive or reflect light better or change color as their size or structure is altered. A property is novel when it is different from the properties associated with other forms or sizes of the same chemical substance. As noted on www.nano.gov, when particle sizes of solid matter in the visible scale are compared to what can be seen in a regular optical microscope, there is little difference in the properties of the particles. But when particles are created with dimensions of about 1–100 nanometers in at least one dimension, the materials' properties can change significantly from those at larger scales.

Question 3: What is the difference between enhanced properties and unique and novel properties?

Enhanced properties are generally described as increased reactivity or surface area when particle size decreases. While reactivity and surface area increase, there is often little difference in the intrinsic properties of the particles in ranges above 100 nanometers. When particles are created with dimensions in the 1–100 nanometer range, the materials' properties can change significantly from those at larger scales. Not all enhanced properties are unique or novel. For example, grinding or engineering pigments for better performance which results only in incidental amounts of particles between 1-100 nm would not constitute a nanoscale material with unique or novel properties. Grinding or engineering pigments for better performance which results in almost all particles that are less than 100 nm would constitute a nanoscale material with unique or novel properties.

Question 4: To what objects and collections of objects does the 1-100 nm measurement apply? In other words, does that mean any form with particles 1-100 nm or does that include aggregates and agglomerates greater than 100 nm but based on primary particles less than 100 nm?

Chemical substances required to be reported would include any form with more than 1% by weight of particles 1-100 nm in at least one dimension, but would not include aggregates or agglomerates greater than 100 nm in all dimensions even if they contain primary particles less than 100 nm in at least one dimension.

Question 5: If a reportable chemical substance is reported as a new chemical for one use but later has a different use from the one reported, would this require reporting under this rule?

Because this rule is one-time reporting of nanoscale forms of chemical substances in commerce, new uses of reportable chemical substances that have been reported previously pursuant to this rule or were previously reported on or after January 5, 2005 as a new chemical, do not ~~require additional reporting~~need to be reported under this Ssection 8(a) reporting requirement. However, if ~~under the new use the~~a person manufactures or processes a new discrete form of the reportable

chemical substance, then that person would be required to report under this rule. Note that there may be notification requirements unrelated to this Section 8(a) reporting rule if a company manufactures or processes the chemical substance for a use that is subject to a significant new use rule (SNUR) for the chemical substance.

Question 6: Is "reporting for mixtures" notifier-specific or substance-specific. For example, if a manufacturer reports and sells to 10 processors, does each processor report?

Reporting for mixtures is not required, but you must report each individual reportable chemical substance in a mixture. Any reportable chemical substance that is incorporated into a mixture or substrate would require reporting for manufacturing or processing of that chemical substance. If a manufacturer sells a mixture containing a reportable chemical substance to multiple processors, then each processor is also required to report based upon known or reasonable ascertainable data provided by the manufacturer.

Question 7: Please clarify the criterion to exclude chemical substances that dissociate completely in water to form ions that are smaller than 1 nm. How fast or what is the rate of dissociation?

The rate of dissociation or how fast that dissociation occurs in water does not affect which chemicals are excluded. If the chemical substance completely dissociates to form ions smaller than 1 nm it is not a reportable chemical substance.

Question 8: What are the criteria to discern one shape from another shape? How would manufacturers and processors distinguish between the different morphologies identified in the rule as for example a rod from an ellipsoid, needle, wire, and/or fiber as these shapes could be considered on a continuum?

A different morphology would be any change in the shape of particles. Different morphology does not include random shape changes or natural variation in shapes of particles that are not definitive and that occur in a continuum. Some nanoscale materials are engineered to give all the particles a certain morphology or shape. The change in shape needs to be a specifically engineered change in the shape of particles of a nanoscale material, to effect a change and form a unique or novel property for a chemical substance in the particle size range of 1-100 nm in at least one dimension.

Question 9: Are mixtures ever reportable under the rule?

Mixtures are not reportable under this rule, however the any components of any mixture that contains meet the definition of a "reportable chemical substances" subject to the rule would be reported. If you manufacture (including import) or process chemical substances as part of a mixture, you would evaluate each chemical substance in the mixture against the requirements of this rule. for each chemical substance in the mixture.

Question 10: Why are coated nanomaterials defined separately from chemical mixtures? What does the rule mean by coating? There are cases where discrete nanomaterials are

surface treated (commonly coated with polymeric substances) in a similar fashion as defined for chemical mixtures.

The term coating in the rule describes surface treating or coating of a reportable chemical substance with another chemical substance. The change in coating makes it a discrete form of a reportable chemical substance subject to reporting even if all of the other intrinsic characteristics of the reportable chemical substance remain the same. Coating or surface treating a nanoscale material results in a nanoscale material with different properties. The rule does not require that every chemical substance coated or surface treated with another chemical substance be reported. However, any type of engineering including surface treatment of a chemical substance that results in a reportable chemical substance triggers a reporting requirement.

~~Comment~~ Question 11: Is it EPA's intention to require reporting on large molecules within the size range of 1 – 100 nm, which are not normally considered to be nanoscale materials (for example, monomers, polymers, colloids, organic and inorganic pigments and dyes, polymer dispersions, etc.)? Are polymers or metals attached to ligands which are larger than 1 nm in size also considered a nanoscale material for reporting?

In order to be a reportable chemical substance, the chemical must not only be a particle in the size range of 1-100 nanometers in at least one dimension, it also, ~~It~~ must ~~also~~ have a unique or novel property (i.e., ~~which is~~ ~~any~~ size-dependent property that varies from those associated with other forms or sizes of the same chemical substance), and such property is a reason that the chemical substance is manufactured or processed in that form. While these categories of large molecules are not exempt per se, monomers, polymers, and colloids, organic and inorganic pigments and dyes, and polymer dispersions are not reportable chemical substances unless they are manufactured at the nanoscale to exhibit unique or novel properties that are not exhibited by other forms or sizes of the same chemical substance. Large molecules and chemicals attached to ligands greater than 1 nm that do not meet the definition do not need to be reported unless they meet the definition of a reportable chemical substance.

Who is Required to Report?

Question 12: My company manufactures ink/toner products and is planning to import ~~their~~ our products, which include a chemical substance with particle sizes of 1-100 nm in at least one dimension, used as a pigment and/or additive in toner and ink cartridges. Is my company required to report even though the chemical substance is incorporated into a formulation that is not manufactured or processed in the United States?

Under TSCA, the definition of manufacture is not limited to domestic manufacture; the definition of manufacture includes import. This includes importing a chemical substance as part of a formulation. The chemicals in the formulation are subject to any manufacturing reporting requirements under TSCA including the reporting and recordkeeping rule for chemical substances that are nanoscale materials. If the chemical substance is imported in a form that meets the definition of a reportable chemical substance, the importer of the toner must report under 40 CFR 704.20.

Question 13: My company is currently processing carbon nanotubes for research and development (R&D). Within the next few years there is a probability that we will be selling products containing the carbon nanotubes. At that point, we would not be exempt from this reporting requirement. Would it be proactive for us to report to the EPA now, even though we are still in the R&D phase, or should we wait until we are processing for production?

On May 12, 2017, EPA published a Federal Register notice extending the effective date of the rule. The rule will become effective on August 14, 2017. By August 14, 2018 you would need to report any non-exempt processing of a reportable chemical substance that occurred before August 14, 2017. If you begin non-exempt processing of a reportable chemical substance after August 14, 2017 you would need to report at least 135 days before commencing manufacture or processing of a discrete form of the reportable chemical substance, except if you have not formed an intent to manufacture or process at least 135 days before commencing such manufacture (including import) or processing, in which case the information must be filed within 30 days of the formation of such an intent. You are the best judge on when to report to meet the requirement of reporting 135 days before processing a reportable chemical substance or within 30 of forming an intent to manufacture or process.

You will also need to determine if the carbon nanotubes you are processing meet the definition of a reportable chemical substance. Not all carbon nanotubes contain particles less than 100 nm although most of them would be described as having unique and novel properties.

EPA considers most forms of carbon nanotubes as new chemical substances (See 73 FR 64946) Are you importing the carbon nanotubes or purchasing the carbon nanotubes from a domestic supplier? Can your supplier confirm they are on the TSCA Inventory? If you cannot confirm they are on the TSCA Inventory, then apart from this Ssection 8(a) reporting rule you may also need to submit a pre-manufacture notice (PMN) under TSCA Ssection 5 for the carbon nanotubes if you are the importer of record or your domestic supplier may need to submit a PMN. You can learn whether your nanotubes are on the TSCA Inventory by submitting a *bona fide* request to EPA pursuant to procedures in 40 CFR 720.25.

Question 14: What is required of processors that do not know about the particle size and other characteristics of formulations they process or use?

Reporting of information under the rule is required only to the extent that information is known or reasonably ascertainable. This standard applies both to the extent of an entity's obligation to determine whether it is required to report, and to the extent of information any entity is required to report. If processors do not know about specific physical properties of chemical substances, they must still take reasonable measures to ascertain the information that would determine whether they are subject to the rule. If processors do not know about specific properties such as particle size and other properties that would allow them to know if they are processing a chemical substance subject to the rule, it would be within the reasonably ascertainable standard to ask their suppliers for information that would enable to processor to determine whether the supplier is selling them a nanoscale material subject to reporting and if so provide them with what reportable information they have. Their supplier is not required to provide any additional

information to the processor but might provide other supporting information, for example, whether their supplier has reported or intends to report the chemical substance under this rule. If the supplier provides information indicating that the substance is not reportable or if the processor lacks any other means of reasonably ascertaining whether the substance is reportable, the processor does not need to perform tests to determine whether the substance is reportable. Information developed in the normal course of business or that the processor chooses to develop must also be used. The processor may want to document the steps they took to determine if reporting was required.

If the information provided by the supplier indicates that reporting is required, the processor is required to report information that is known or reasonably ascertainable, which may include information obtained from the supplier. This would include situations where the processor may not know the exact chemical identity or some of its physical properties. Companies that purchase formulations from a manufacturer/processor located in the US but do not change or modify those formulations and only use them are not considered processors and are not required to report under the rule. Importers that purchase formulations that contain reportable substances from a source outside of the US are considered to be the same as manufacturers and are required to report under the rule even if they do not change or modify those formulations and only use the formulation.

The obligations imposed by the reasonably ascertainable standard are discussed more fully in the Chemical Data Reporting final rule, 76 FR 50816, 50829 (August 16, 2011).

Question 15: Is a processor of a reportable chemical substance submitted as a PMN required to report?

Only persons who submitted the Ssection 5 submission after January 1, 2005 are exempt from reporting. Other manufacturers and processors would still be required to report.

Question 16: Where in the supply chain must a ~~nanoscale material~~ reportable chemical substance be reported: at every point in the supply chain, or only at the point of manufacture? Would this include incorporation into articles and substrates?

Each manufacturer and processor in the supply chain must report known or reasonably ascertainable information on the reportable chemical substance. Once a reportable chemical substance has been incorporated into an article, no further reporting is required as persons that manufacture or process chemical substances as part of articles are exempt from reporting.

Question 17: The physical properties that define discrete forms of a reportable chemical substance sometime cannot reliably be measured and the rule appears to require companies to conduct tests on these or other physical-chemical properties to determine whether they must report. Many of these tests are not commonly performed.

Testing is not required under a TSCA Ssection 8(a) rule. While manufacturers and processors are not required to test for the properties identified in the definition of discrete forms of a reportable chemical substance, they are still required to determine their compliance obligations

under the rule based upon information that is in their possession or which is reasonably ascertainable. If information within a company's possession or that is reasonably ascertainable does not demonstrate that the company is manufacturing or processing a discrete form of a reportable chemical substance, there is no obligation to report. ~~EPA expects that in most cases such information will be in the company's possession or reasonably ascertainable.~~

Question 18: If a company manufactures or processes a reportable chemical substance solely for export is the company subject to the reporting requirements?

Yes. Persons who manufacture or process reportable chemical substances solely for export are subject to the reporting requirements. TSCA Section 12(b) exemptions for export do not apply to Section 8(a) rules. Note, however, that the processing and use information is restricted to domestic activities, i.e., within the customs territory of the United States.

Question 19: Are importers of a reportable chemical substance required to report under the rule?

Yes. The definition of "manufacture" under Section 3(9) of TSCA includes import.

What Information is to be Reported?

Question 20: Can you clarify whether manufacturers and processors who are only required to report available or reasonably ascertainable information need to develop information to comply with the rule.

Manufacturers and processors are not required to conduct testing or develop information under this rule. However, they are required to report information that is known or reasonably ascertainable.

Question 21: Please provide further clarification on the scope of what would be required under the "known to or reasonably ascertainable by" reporting standard. How would this reporting standard apply to manufacturing, processing and use information?

The term "known to or reasonably ascertainable by" is defined at 40 CFR 704.3. It means "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." Under the "known to" portion of the standard, a submitter must therefore ascertain what they know about the manufacturing, processing and use of a chemical substance it manufactures (including imports) or processes, without confining its inquiry to what is known to managerial and supervisory employees. A submitter would also be expected to review other information which the manufacturer (including importer) or processor may have in its possession. This standard requires that submitters conduct a reasonable inquiry within the full scope of their organization (not just the information known to managerial or supervisory employees). The inquiry would be as extensive as a reasonable person, similarly situated, might be expected to perform within the organization. Information derived from customer surveys or other customer contacts, like any other information, would be "known to" the submitter if it is available after a reasonable inquiry within the organization. The

standard does not necessarily require that the manufacturer conduct an exhaustive survey of all employees.

Inquiry under the "reasonably ascertainable" portion of standard may also entail inquiries outside the organization to fill gaps in the submitter's knowledge. Note however, that if particular information cannot be derived or reasonably estimated without conducting further customer surveys (i.e., without sending a comprehensive set of identical questions to multiple customers), it would not be "reasonably ascertainable" to the submitter. Thus there is not a need to conduct new customer surveys for purposes of reporting under the rule. As described above, however, existing customer survey data may nevertheless be "known to" the organization.

Question 22: What are some examples of types of information that are considered to be in a person's possession or control or that a reasonable person similarly situated might be expected to possess, control, or know?

Information could be possessed by employees or other agents of the company reporting under the rule, including persons involved in the research, development, manufacturing, or marketing of a chemical substance. This information includes knowledge gained through discussions, symposia, and technical publications. Other examples include:
• Files maintained by the submitter or employees in the submitter's company, such as marketing studies, sales reports, or customer surveys;
• Information contained in standard references, such as MSDSs, that contain use information or concentrations of chemical substances in mixtures; and
• Identification numbers from the Chemical Abstracts Service (CAS) and from Dun & Bradstreet.

Question 23: A company manufactures or processes chemical substances but often does not know how these chemical substances are used by downstream customers. Does EPA intend for submitters to send questions to customers requesting information about downstream uses?

It depends on what is meant by sending "questions to customers." Submitters need not send out a comprehensive set of identical questions to multiple customers in order to fulfill the reporting standard. That is, they need not conduct a new survey of their customers. However, one way of fulfilling the reporting standard might involve limited" inquiries outside the organization (e.g., contacting a major customer or examining that customer's public website) to fill in gaps in the submitter's knowledge, where the submitter's current knowledge is less than what a "reasonable person similarly situated might be expected to possess, control, or know." See 40 CFR 704.3.

Question 24: All of a company's products are used to make commercial products through various process steps by different manufacturers. Should the company provide information about consumer uses even if its reportable chemical substance is not the end use product?

Yes, provided that the ~~. If~~ reportable ~~the~~ chemical substance is ~~used~~present in ~~a~~the consumer product~~,~~ and the ~~company would still report the~~ information ~~if it~~ is known to or reasonably

ascertainable by the company, even if the company does not manufacture the ~~end-use item~~consumer product. The information provided on the reporting form about downstream use is associated with the processing and use of reportable chemical substances and typically relates to processing or use that is outside of the manufacturing, importing, or processing site, unless, of course, the manufacturer, importer, or processor also processes or uses the reportable chemical substance.

Information on subsequent industrial users and processors and on commercial and consumer uses of the reportable chemical substance would be reported on the reporting form to the extent the information is known to or reasonably ascertainable by the manufacturer (includes import) or processor of the subject chemical substance. A company which is a manufacturer or processor must report information about the distribution and use of the chemical substance that is known to or reasonably ascertainable by the company. To the extent the information is not known or reasonably ascertainable, the company may report NKRA (i.e., "not known or reasonably ascertainable").

When is Reporting Required?

Question 25: Please clarify how the 135-day reporting requirement for new discrete forms would work. For example, can commercialization begin after notification to EPA or after 135 days after notification to EPA?

The 135-day period is not a formal review-period that prohibits manufacture before the end of the 135-day period. Rather, based on EPA's experience with the PMN reviews in the new chemicals program, EPA believes that in most cases companies have the requisite intent to manufacture or process a reportable chemical substance at least 135 days before manufacturing or processing will begin, and the rule requires reporting based upon this presumed intent. However, if a company does not form the requisite intent 135 days ahead of time, the company must report within 30 days of the formation of such an intent. Moreover, if a company desires to begin manufacture or processing less than 135 days after the submission for this rule is made, the company is free to do so. There is no obligation upon the company to wait 135 days after reporting to manufacture or process.

Question 26: Is there a mechanism or requirement to update any new information if there is a change in manufacture, processing or use after the initial reporting of a reportable chemical substance?

Because this rule only requires one-time reporting, updating with new information is not required unless the change in manufacture or processing creates a new discrete form of a reportable chemical substance.

Question 27: Can EPA clarify if the exemptions for new chemicals reported since January 1, 2005 and the Nanoscale Materials Stewardship Program (NMSP) would exempt information that has changed since the original reporting?

For a reportable chemical substance that was submitted as a new chemical substance under Ssection 5 of TSCA or as part of the NMSP, no updated information would need to be reported unless a manufacturing or processing change resulted in a new discrete form of the reportable chemical substance.

Question 28: What is the criterion for distinguishing new processing methods for a nanoscale material from existing methods? What would constitute a process change that would require filing a new report?

The type of process change is not the criterion; it is the intent of the process change. Any manufacturing or processing change that is intended to change particle size and properties would be a process change that could require new reporting.

General Questions

Question 29: The reporting rule was published in the Federal Register on January 12, 2017. When does this rule become law?

On May 12, 2017, EPA published a Federal Register notice extending the effective date of the rule 90 days; the rule will become effective on August 14, 2017.

Question 30: Is there a minimum production volume below which no reporting is required, such as 10 or 100 kg?

There is no exemption based on production volume or reporting threshold based on production volume.

Question 31: (a) Is research and development exempt from reporting under the rule? (b) Can you define small quantities? (c) Can companies sell research and development quantities for profit? (d) Is reporting required if the core commercial activity of a company is research and development?

(a) Yes. As described in 40 CFR part 704.5(e), a person who manufactures (including imports), processes, or proposes to manufacture or process a substance subject to reporting under this rule only in small quantities solely for research and development is exempt from the reporting requirements of the rule.

(b) Small quantities solely for research and development (or "small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product") is defined in 40 CFR part 704.3 to mean quantities of a chemical substance manufactured or processed or proposed to be manufactured or processed solely for research and development that are not greater than reasonably necessary for such purposes.

(c) Yes. The exemption may apply even if a company sells research and development quantities for a profit.

(d) The research and development exemption applies to use for which the specific chemical substance is manufactured. It is irrelevant whether the main commercial activity of the company is research and development or industrial sales or use.

Question 32: Are articles exempt from reporting under this rule?

As described in 40 CFR 704.5(a), a person who imports, processes, or proposes to import or process a reportable chemical substance subject to this rule solely as part of an article is exempt from the reporting requirements of this part with regard to that substance. Manufacturers (including importers) or processors of a reportable chemical substance that is incorporated into an article would be required to report any required information for activities before the chemical substance is incorporated into the article. An article is defined in 40 CFR 704.3 as manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.

Question 33: Can imported metal powders ever be considered "articles" regardless of their end use?

No. Powders cannot be considered articles. The definition of article includes the statement that "fluids and particles are not considered articles regardless of shape or design".

Question 34: Is the purpose of the rule to compile an inventory of nanoscale material chemical substances in commerce?

No. The purpose of the rule is to collect information on the manufacture (including importation); processing; and industrial, commercial, and consumer uses of certain chemical substances that are nanoscale materials. This rule will allow EPA to obtain basic data from those that manufacture or process existing nanomaterials made from substances that are on the TSCA Inventory. EPA will use information gathered through this rule to inform the Agency's understanding about the manufacture, processing and use of nanoscale substances and to determine if any further action under TSCA, including additional information collection, is needed in specific instances.

Question 35: How do I determine my reporting requirements?

Carefully review the regulations located at 40 CFR 704.20 to determine your reporting requirements. You should consider the following three steps to determine whether you are required to report for each chemical substance that you domestically manufactured (including imported) into the United States ~~since the last principal reporting year~~:

o Step I: Is your chemical substance subject to the reporting rule?
o Step II: Are you a manufacturer (including importer) or processor who is required to report?

o Step III: What information must you report?

Question 36: Must a submitter conduct new chemical analyses to report information?
No. The regulation does not require submitters to perform new chemical analyses. The information required by the rule is limited to information that is "known to or reasonably ascertainable." This standard is applicable to all information reported in accordance with 40 CFR 704.20.

Question 37: What should a company do if it determines that it manufactures or processes a chemical substance that is not included on the TSCA Inventory?

In order for a person to report a substance that it manufactures (including imports) or processes a ~~chemical substance~~ for a non-exempt commercial purpose, the substance~~it~~ must be~~:~~ on the TSCA Inventory~~, a naturally occurring chemical substance as defined by TSCA (see 40 CFR 710.4(b)), or excluded by TSCA Section 3(2)(B)*~~. You can visit Substance Registry Services to determine whether your chemical substance is on the TSCA Inventory. If your chemical substance is not on the TSCA Inventory, you may need to submit a PMN to the new chemicals program. Please see EPA's PMN Requirement flowchart to determine if a notice must be submitted to the Agency prior to manufacture (including import). You can also phone the TSCA Hotline at (202)-554-1404 for assistance.

For a chemical substance that is not on the TSCA Inventory, a naturally occurring chemical substance as defined by TSCA, or exempted in TSCA Section 3(2)(B)), a person must submit a notice as per 40 CFR 720.22(a)(1) prior to manufacture (including import).

If a person is manufacturing (including importing) a substance which is not on the TSCA Inventory and has not provided the required notice to EPA, each day of such manufacture or importation is a violation of Section 5 of TSCA and could subject the person to enforcement action. If a person finds that it has or may have manufactured or imported a chemical substance in violation of TSCA, contact the Agency at the following address: https://www.epa.gov/compliance/epas-edisclosure.

Significant reductions in penalties may be given to persons who voluntarily disclose such information. Note, however, that continued manufacture, (including importation) or use of such chemical substances remains in violation per Section 15 of TSCA, even after a person has contacted EPA, until the requirements of TSCA Section 5 have been met. These reporting requirements are distinct from the requirements at 40 CFR 704.20.

**Substances exempted in TSCA Section 3(2)(B) include: any pesticide as defined by the Federal Insecticide, Fungicide, and Rodenticide Act, when manufactured, processed, or distributed in commerce for use as a pesticide; any food, food additive, drug, cosmetic, or device, as defined by the Federal Food, Drug, and Cosmetic Act, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device; tobacco or any tobacco product; any source material, special nuclear material, or byproduct material as such terms are defined in the Atomic Energy Act of 1954; and, any article the sale of which is subject to the tax imposed by Section 4181 of the Internal Revenue Code.*

Question 38: If a company manufactures a reportable chemical substance for a non-TSCA use, is the company required to report under 40 CFR 704.20?

Substances exempted in TSCA Section 3(2)(B) need not be reported. Substances exempted in TSCA Section 3(2)(B) include: any pesticide as defined by the Federal Insecticide, Fungicide, and Rodenticide Act, when manufactured, processed, or distributed in commerce for use as a pesticide (but see Question 39 below regarding intermediates in the manufacture of an active ingredient in a pesticide); any food, food additive, drug, cosmetic, or device, as defined by the Federal Food, Drug, and Cosmetic Act, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device; tobacco or any tobacco product; any source material, special nuclear material, or byproduct material as such terms are defined in the Atomic Energy Act of 1954; and, any article the sale of which is subject to the tax imposed by Section 4181 of the Internal Revenue Code.

Question 39. A company manufactures Chemical C. Its customers use Chemical C for a variety of uses including as an intermediate in the manufacture of a chemical substance to be used as a pesticide active ingredient. Pesticides are exempt from regulation by TSCA. Does the company need to report industrial processing and use data for this chemical substance?

Yes. The manufacture of a chemical substance that is a pesticide intermediate is manufacture under TSCA.

Question 40: If a company manufactures or processes a reportable chemical substance which may be used for purposes regulated by TSCA and also for uses which are excluded from regulation under TSCA Section 3(2)(B), should the entire quantity that the company manufactures or processes be reported in the submission?

No. Report the manufactured or processed quantity intended for the TSCA use and do not report the quantity that is exempt from TSCA in Section 3(2)(B).

Question 41: Are small manufacturers and processors exempt from reporting requirements of the rule?

Yes. A small manufacturer or processor is defined in the rule as any manufacturer or processor whose total annual sales, when combined with those of its parent company (if any), are less than $11 million.

Question 42: What role does the technical contact play?

The technical contact is the person whom EPA may contact for clarification of the information in a submission. The technical contact should be a person who can answer questions about the reported chemical substance(s). Typically, a person located at the manufacturing or processing site is best able to answer such questions. However, companies may use their discretion in selecting a technical contact or multiple technical contacts. Submitters should consider, in

selecting the technical contact, that EPA may have follow-up questions about a submission one or more years after the submission date. The technical contact need not be the person who signs the certification statement.

Confidentiality

Question 43: What are the restrictions on submitting confidential information under the rule?

Information submitted under the rule may be claimed as confidential at the time it is submitted. Submitters must provide upfront substantiation of confidentiality claims for processing and use information as well as for confidentiality claims for site or chemical identity. See EPA guidance on asserting confidentiality claims at https://www.epa.gov/tsca-cbi.

Question 44: What must generally be considered in making a claim of confidentiality under TSCA?

EPA's procedures for processing and reviewing confidentiality claims are set forth at 40 CFR part 2, subpart B and 40 CFR 704.20(h). The Frank R. Lautenberg Chemical Safety for the 21st Century Act requires that for all claims for protection for any confidential information made with this submission the submitter certify they have:
(i) taken reasonable measures to protect the confidentiality of the information;
(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to my competitive position; and
(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering. 15 U.S.C. 2613(c).