American Chemistry Council | Nanotechnology Panel

August 5, 2015

Submitted via regulations.gov

Mr. Jim Alwood
Document Control Office (7407M)
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 (EPA–HQ–OPPT–2010–0572)

Dear Mr. Alwood:

The Nanotechnology Panel of the American Chemistry Council[1] is pleased to provide the attached comments on the U.S. Environmental Protection Agency's (EPA) proposed reporting and recordkeeping rule for nanoscale materials (Proposed Rule).[2] The Nanotechnology Panel's (the Panel) 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. The Panel trusts that EPA will find our comments to be helpful in creating a workable, balanced, risk-based approach to collecting information on nanoscale materials in commerce. Our comments are organized according to questions EPA asked under the Proposed Rule (see Attachment), and we are providing general comments in this cover letter.

As an initial matter, the Panel feels that without significant additional clarity and refinement of scope and key concepts, the Proposed Rule will create a confusing, subjective, arbitrary, and uneven regulatory playing field for entities potentially subject to it. The Panel believes that EPA must elaborate and clarify its intentions for this information collection so the regulated community can understand its obligation clearly.[3]

The Panel strongly urges EPA to reconsider its proposal and instead propose a two-step information collection. The first step would have manufacturers of nanoscale forms of a prescribed set of chemical

[1] Members of the ACC Nanotechnology Panel are 3M, BASF Corporation, Cabot Corporation, Chemours, DuPont, Evonik Corporation, Lockheed Martin Corporation, and Procter & Gamble.
[2] Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements. 80 Fed. Reg. 18330 (April 6, 2014). Extension of Comment Period to August 5, 2015. 80 Fed. Reg. 38153 (July 2, 2015).
[3] "We insist that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly. Vague laws may trap the innocent by not providing fair warning." Grayned v. City of Rockford, 408 U.S. 104, 108 (1972) (internal citations omitted).

substances report the volumes and uses of the nanoscale forms in commerce. As a second step, EPA could then collect more detailed, targeted technical data on materials for which the agency identifies potential for concern. The current proposed approach of collecting so much information at once is confusing and, in many cases, can be characterized as duplicative, unnecessary reporting. **The Panel strongly urges EPA to re-propose the rule after due consideration of comments and clarification of key concepts and authorities.**

The Panel also notes that the Proposed Rule differs in many important ways from the approach being taken by Environment Canada and Health Canada[4] The Panel urges Canada and the U.S. to work as closely as possible in the spirit of the Nanotechnology Work Plan of the Canada-U.S. Regulatory Cooperation Council *"to increase alignment in regulatory approaches for nanomaterials . . . in order to reduce risk to human health and the environment, promote the sharing of scientific and regulatory expertise, and foster innovation."*[5]

The Panel believes there are significant opportunities for the two countries to align their approaches with regard to the goals and objectives of their respective exercises, the quantity and scope of materials covered, information needs and subsequent reporting requirements, and the criteria used to prioritize materials for possible future action. Alignment has tremendous potential in terms of efficiency and cooperative learning between the countries and with affected industry. The Panel is extremely concerned that if the U.S. and Canadian approaches are not more closely aligned, the comparability of information and ability to move forward in a coordinated manner would be at risk and that the reporting burden on industry could be extremely high.

The Panel recognizes that the ability to share information between the US and Canadian agencies would facilitate alignment. Therefore, the Panel requests that the agencies consider an option for submitters to authorize the sharing of confidential business information (CBI) provided under this rule and the corresponding Canadian data collection exercise. The sharing would be limited to EPA, Environment Canada, and Health Canada. Submitted CBI would otherwise be subject to the CBI protection policies of those agencies. Both programs' reporting forms could include a simple check box to authorize sharing of CBI. The Panel emphasizes that data and information requested by the U.S. and Canadian exercises should be aligned to the greatest degree possible to reduce the regulatory burden on both industry and government. Ideally, a data submission to one government should largely, if not completely, cover the data submission obligation to the other government.

The Panel also is concerned that reporting under this rule, if finalized, and the 2016 CDR reporting cycle could coincide. Reporting entities should not have to shoulder the burden of (a) complying with both rules at the same time, especially since one rule would be new and (b) having to go through the unnecessary and duplicative exercise of submitting information twice for some substances. The Panel suggests that any reporting obligations under this rule commence no earlier than September 30, 2017, one year after the 2016 CDR data reporting period closes.

Finally, the *Federal Register* notice references the voluntary Nanoscale Materials Stewardship Program (NMSP) conducted in 2008-2009. EPA claims that companies provided information on only about 10%

[4] Notice with respect to certain nanomaterials in Canadian commerce. Canada Gazette Part I July 25, 2015: 1942; *See also* Guidance for responding to the notice with respect to certain nanomaterials in Canadian commerce. The latter available at http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=AACFB2C0-1 (last accessed July 29, 2015).
[5] *See* http://nanoportal.gc.ca/default.asp?lang=En&n=5a56cb00-1 (last accessed May 21, 2015).

of the substances that were commercially available at the time.[6] The Panel feels that this is a mischaracterization and that given the state of the commercial marketplace at the time, the program was quite successful. EPA's estimate of the number of nanoscale materials in commerce was based in part on what material suppliers claimed was possible and did not actually reflect what was actually in the commercial marketplace. The Panel believes the NMSP generated useful data on high-volume nanoscale materials in commerce, and our attached comments make several suggestions for how that information can be used going forward.

The Panel appreciates the opportunity to comment and 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

[6] 80 Fed. Reg. at 18334.

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ATTACHMENT: ACC Nanotechnology Panel comments on "Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements" (EPA–HQ–OPPT–2010–0572)

CONTENTS

1. IDENTIFYING THE CHEMICAL SUBSTANCES SUBJECT TO REPORTING

1.1 EPA's approach to defining substances subject to the proposed rule raises many concerns. From our perspective, EPA would require manufacturers and processors to determine whether they are (or are not) subject to the Proposed Rule. This approach functionally gives manufacturers and processors broad discretion for interpreting their potential compliance obligations. The result could be an uneven regulatory playing field. This is especially true when the proposed approach is characterized by many vague terms and concepts that require more clarification and guidance regarding their application. Such terms are discussed below. The Panel notes that EPA's vague, self-determination approach differs markedly from the Canadian approach, which lists specific chemicals (and their CAS numbers) that would be subject to reporting (see also 2.3 below). The Canadian approach is more precise and lends itself to a rolling review process, which would facilitate compliance.

1.2 EPA cannot require information that violates the language under the Toxic Substances Control Act (TSCA) § 8(a)(2) prohibiting "any reporting which is unnecessary or duplicative."[7] The Panel is concerned that those entities who provided information to the EPA's Nanomaterial Stewardship Program (NMSP) will be required to submit unnecessary and duplicative information under the Proposed Rule. The NMSP resulted in rich databases of information that EPA could use to determine whether more specific, targeted data reporting might be required, but EPA did not provide such an analysis under the Proposed Rule. The Panel believes EPA has an obligation to review and report on the information gathered through the NMSP to ensure that new, additional reporting would not violate the "unnecessary or duplicative" requirement of Section 8(a).

Although the Proposed Rule contains an exemption for information on nanoscale materials submitted under the NMSP, the exemption only applies to cases where materials were described as "discrete forms" according to the Proposed Rule.[8] The EPA voluntary program did not specifically request submission of information for "each discrete form" of a substance, thus in many cases, substance data were provided as ranges. For submitters who voluntarily reported substance characteristics or properties using range(s), adherence to the proposed "discrete form" construct is not possible. Therefore, the exemption in the Proposed Rule likely has little value in practice for submitters to the voluntary program. EPA should revisit the data collected under the NMSP and ensure that manufacturers and processors who would be subject to a new § 8(a) reporting rule are not providing unnecessary and duplicative information.

1.3 EPA should exempt information submitted under the Chemical Data Reporting Rule (CDR) on the basis additional reporting would be unnecessary and duplicative. Some nanoscale substances are manufactured and/or imported in volumes that trigger reporting under the CDR.[9] Information made available to EPA for these substances should be exempt from the proposed reporting rule. EPA should provide an analysis and discussion of the CDR data and why additional reporting would not be unnecessary or duplicative.

1.4 EPA should sequence the information reporting requirements for manufacturers and processors. The Panel believes that in many cases, processors of a chemical may not routinely possess the same amount of information about the substance as the substance's manufacturer. In the context of the Proposed Rule, this places an entity who is solely a processor in the untenable position of not knowing whether it is in fact working with a nanoscale form of a substance that must be reported. When lack of compliance with a rule could trigger substantial penalties, such ambiguity is not acceptable.[10] The rule therefore should be modified so that processors are not obligated to report on discrete forms. That obligation should fall only with manufacturers and importers. In fact, the Panel recommends that EPA limit its initial information gathering effort to manufacturers and importers. Once that information is analyzed, EPA can make a determination of whether additional information is required of processors. Entities that manufacture and process their own nanoscale materials could provide information on both manufacturing and processing.

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[7] 15 U.S.C. § 2607(a).
[8] Proposed 40 C.F.R. § 704.20(c)(4).
[9] 40 C.F.R. Part 711; *see also* 76 Fed. Reg. 50816 (Aug. 16, 2011).
[10] 15 U.S.C. § 2615. *See also* The Enforcement Response Policy (ERP) for Reporting and Recordkeeping Rules and Requirements for TSCA Sections 8, 12, and 13. Available at http://www2.epa.gov/sites/production/files/documents/erp8_12r.pdf (last accessed July 30, 2015).

1.5 EPA should clarify the objects and collections of objects to which the 1-100 nm measurement applies. The proposed definition of "reportable chemical substance" includes the criterion "in a form where the primary particles, aggregates, or agglomerates are in the size range of 1-100 nm."[11] It is unclear whether EPA intends the inclusion of aggregates and agglomerates greater than 100 nm. The language could be interpreted two ways. It could be read to mean that 100 nm is the upper size boundary; any objects or collections of objects greater than 100 nm would fall outside of the proposed definition of "reportable chemical substance." Alternatively, the language could be interpreted to mean that all objects or collections of objects based on primary particles that are in the 1-100 nm range would be included. The Panel requests that EPA provide clarity on the application of the size criterion in the definition of "reportable chemical substance."

1.6 EPA should provide an explicit definition of the term "particle" as used in the definition of a "reportable chemical substance." The word "particle" is not a term with specific meaning. It is critical that EPA is clear about the definition of "particle" so that companies understand what materials require reporting. For example, does the term "particle" include solid objects that contain internal crystalline domains at the nanoscale? Does it include dispersions, suspensions, or aerosols? A definition of "particle" would provide an important starting point for determining whether a material is subject to reporting. It should take into account the ability of a "particle" to move freely in its environment. The Panel notes that the most recent report from the European Union examining the challenges associated with its recommended definition of "nanomaterial" discusses the importance of clearly defining "particle."[12] The International Organization for Standards (ISO) also recognizes the importance of defining the term "particle" in the context of nanoscale materials.[13] Both the EU and ISO documents discuss the issue of mobility with respect to defining the term "particle."

1.7 EPA should provide guidance on how the size of a particle should be determined. As size is a critical criterion for the determination of a reportable substance, further information is needed on the techniques and instrumentations that may be used in measuring particle size. As is well understood, size measurements are dependent on the method (e.g., optical diameter, stokes diameter, the d50 of transmission electron microscope image measurements, etc.).[14] EPA should provide guidance on particle size measurement, including the advantages and disadvantages of different methods for different types of nanoscale materials.

1.8 EPA should clarify the phrase "unique and novel characteristics or properties" as used in the definition of "reportable chemical substance." The Panel urges EPA to clearly define "unique

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[11] Proposed 40 C.F.R. § 704.20(a).

[12] Rauscher, H., et al. 2015. Towards a review of the EC Recommendation for a definition of the term "nanomaterial" Part 3: Scientific-technical evaluation of options to clarify the definition and to facilitate its implementation. European Commission Joint Research Centre, Institute for Health and Consumer Protection.

[13] ISO/TS 27687:2008—Nanotechnologies—Terminology and definitions for nano objects—Nanoparticle, nanofiber and nanoplate.

[14] *See* (1) Rauscher, H., et al. 2014. Towards a review of the EC Recommendation for a definition of the term "nanomaterial" Part 1: Compilation of information concerning the experience with the definition. European Commission Joint Research Centre, Institute for Health and Consumer Protection; and (2) Roebben et al. 2014. Towards a review of the EC Recommendation for a definition of the term "nanomaterial" Part 2: Assessment of collected information concerning the experience with the definition. European Commission Joint Research Centre, Institute for Health and Consumer Protection.

and novel characteristics or properties" under the Proposed Rule. The concept, though critical to understanding whether a compliance obligation exists, is vague and therefore prone to highly subjective interpretation. For example, some may interpret "unique and novel" to apply only to the characteristics and properties that delineate "discrete forms," while others may interpret it more broadly or more narrowly. The Panel believes that the critical issue is whether a nanoscale form of a chemical substance exhibits one or more biologically or environmentally relevant, size-dependent properties that differ from larger forms and therefore limit the use of hazard data from the larger forms to predict the properties of the nanoscale form and vice versa. Therefore, EPA should focus on properties that are emergent properties of the material only when it is at the nanoscale and are not predictable by scaling algorithms.

The Panel requests that EPA develop a short list of priority characteristics and a risk-based, scientific justification for each of them. Some size-dependent properties may have little or no relevance for hazard identification (e.g., melting point, color), which is an important factor in determining what "unique and novel characteristics or properties" matter to the agency for the purposes of reporting under this proposed rule. The Panel also believes detailed guidance should be provided on methods that can be used to make this "unique and novel" determination.

1.9 EPA should either clarify or eliminate the use of the adjective "enhanced" with regard to properties. The adjective "enhanced" is used in section II.B of the *Federal Register* notice and in Item 5 of the proposed data submission form. The use of yet another adjective further is confusing. In the Panel's interpretation, "enhanced" refers to properties that are observed at larger scales, but, due to size or surface area, are increased or decreased in magnitude at the nanoscale. When normalized by parameters like surface area, the distinction between nano and not nano would disappear. The Panel does not believe that focusing on predictable properties is the best use of EPA's or industry's resources. The Panel urges EPA to be consistent in the use of adjectives and to clearly state its intent with regard to what kinds of properties the agency is interested. For clarity, EPA might consider using one adjective consistently and clearly explain its meaning in the context of the Proposed Rule. The use of three adjectives—"unique", "novel", and "enhanced"—in a way that may or may not be interchangeable creates confusion. Furthermore, the Panel suggests that identifying properties of interest is a topic on which U.S. and Canadian authorities should attempt to harmonize in order to create consistency and reduce confusion.

1.10 The concept "trace amounts" as used in the definition of "reportable chemical substance" is arbitrary and should be clarified. The Proposed Rule states that "a reportable chemical substance does not include a chemical that only has trace amounts of primary particles . . . such that the chemical substance does not exhibit the unique and novel characteristics or properties because of particle size.[15] The Panel suggests that EPA develop a more risk-based approach to the concept or, at the very least, to clarify the phrase "unique and novel characteristics or properties," since the concept "trace amounts" is inextricably linked to it under the Proposed Rule. Because "trace amounts" is not defined, the application of this exception is arbitrary and will lead to inconsistent reporting and, in practice, an uneven playing field for entities potentially subject to reporting.

The Panel recommends three options for EPA to consider in order to better define "trace amounts". One would be to establish a weight-based quantitative *de minimis* value below which reporting would not be triggered. A second would be to borrow the concept of unintentional materials from

[15] Proposed 40 C.F.R. § 704.20(a).

TSCA's New Chemical Program and modify it to apply to mean particle diameter. The third would be to adopt the following definition of "trace amounts": *a concentration that does not influence the engineered material's properties.* The Panel believes EPA should discuss these options and those received from other commenters in a re-proposed rule.

1.11 EPA should clarify the treatment of "trace amounts" in mixtures. The proposed regulatory language and explanatory text of the Proposed Rule provide little guidance with regard to the application of the rule to mixtures. For example, does the "trace amounts" exception apply to each individual component of the mixture, or to the final mixture? The Proposed Rule is not clear, and EPA should make every effort to clarify.

1.12 EPA should provide a more detailed explanation of the exclusion of "chemical substances manufactured at the nanoscale as part of a film on a surface." The proposed exemption for "chemical substances manufactured at the nanoscale as part of a film on a surface" is unclear.[16] What is the definition of "film"? Are particles grown on a substrate a "film"? Is the exemption intended to exclude paints and coatings? The meaning and intent of this exemption need to be clarified in order to avoid inconsistent reporting. The Panel notes that a definition of "particle" that explicitly identifies the ability to move within its environment (see 1.6 above) could resolve this matter.

1.13 EPA should elaborate the criteria for excluding zinc oxide and nanoclays, as such criteria could potentially be applied to other materials. The Proposed Rule contains blanket exclusions for zinc oxide and nanoclays because "[t]he Agency believes that information collected on these materials would be of limited value because either they have been well characterized or they present little exposure potential."[17] The Panel believes that based on those criteria, many other substances, particularly those that have been in commerce for many decades (long before the discussion around nanomaterials began) and have rich databases, should be exempt. Examples include synthetic amorphous silica, carbon black, titanium dioxide, numerous polymers, and organic and inorganic pigments and dyes. The Panel requests that EPA make the analysis behind the proposed exemptions more transparent so that risk-based decisions could be made about other materials that are well characterized and/or present little exposure potential.

1.14 The Panel requests clarification on the criterion to exclude chemical substances that dissociate completely in water to form ions that are smaller than 1 nm.[18] Water solubility (or rather dissolution rate) is an important consideration in determining the timescale for which a nanoscale material may exhibit size-related properties. Size-related properties will be less important for rapidly soluble substances than for slowly soluble materials. Since there is a continuum of solubility rates for different materials, any selected cut-off will be somewhat arbitrary. However, a reasonable criterion for excluding substances might be their complete dissolution to ions less than 1 nm within a specified period of time under prescribed conditions. Any adverse effects caused by materials which meet this criterion would be expected to be due to properties of the released ions rather than size-related effects of the particles. The Panel recommends that EPA provide some guidance on biologically and environmentally relevant time

[16] Proposed 40 C.F.R. § 704.20(c)(1)(iii).
[17] Proposed 40 C.F.R. § 704.20(c)(1)(i-ii); Introduction Section III.A.2, 65 Fed. Reg. at 18335.
[18] *See* Proposed 40 C.F.R. § 704.20(c)(1)(vii).

frames, interpretations, and test conditions, since time, pH, temperature, and other factors can affect dissolution.[19]

1.15 EPA should add an explicit exemption for nanoscale substances that are unintentionally generated during manufacturing and processing. Manufacturers and processors who deal in solid particulate substances well above the nanoscale should not be compelled by this rule to analyze long-standing products and formulations out of concern over compliance. For example, one can reasonably predict that milling a solid substance will generate some fraction of particles at the nanoscale, but if the intent is to generate a product with an average particle size on the order of many microns, the generation of any nanoscale particles is clearly unintentional and inadvertent. There may also be unintentional and inadvertent production of nanoscale materials during the scale up of a new process. Such situations should not trigger a reporting requirement. A clear exclusion for unintentionally generated and inadvertently manufactured nanoscale materials will help to clarify the concept of "trace amounts" and provide much needed clarity to entities potentially subject to reporting. The Panel requests that EPA consider whether the concept of "unintentionally generated and inadvertently manufactured" may be a more easily measurable and documentable exclusion criterion than the "trace amounts" concept in the Proposed Rule.

1.16 EPA should add explicit exemptions for peptides, liposomes, antibodies, viruses, virus-like particles, organelles, and all microorganisms. The Panel does not believe it is EPA's intent to capture biological materials and entities under the rule (as evidenced by the proposed exemption for DNA, RNA, and proteins).[20] It is certainly not EPA's intent under the CDR, which explicitly excludes microorganisms,[21] defined by EPA as "organism classified, using the 5-kingdom classification system of Whittacker, in the kingdoms Monera (or Procaryotae), Protista, Fungi, and the Chlorophyta and the Rhodophyta of the Plantae, and a virus or virus-like particle."[22] Expanding the exemption as requested based on existing EPA reporting rules will provide enhanced clarity to the regulatory community.

1.17 EPA should add an explicit exclusion for naturally occurring nanomaterials. The TSCA Inventory Reporting Regulation defines "naturally occurring substance,"[23] and the CDR rule clearly exempts such substances from reporting.[24] The Panel believes the CDR rule sets a precedent and that EPA should also explicitly exempt substances that meet the definition of "naturally occurring substance" under this nanoscale material reporting proposal. The Panel understands that the CDR regulations require reporting if a substance that could be naturally occurring is produced by means other than those described in 40 CFR § 710.4(b). Similarly, a naturally occurring substance intentionally manufactured or processed at the nanoscale to exhibit one or more size-dependent "unique and novel characteristics or properties" should be reportable under this rule.

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[19] The Panel notes the importance of open system tests for environmental studies. Equilibrium conditions may be less likely in the environment, and closed system tests may not provide results that reflect real world potential for dissolution.
[20] Proposed 40 C.F.R. § 704.20(c)(1).
[21] 40 CFR § 711.6(a)(2).
[22] 40 CFR § 725.3.
[23] 40 C.F.R. § 710.4(b).
[24] 40 C.F.R. § 711.6(a)(3). *See also* guidance in U.S. Environmental Protection Agency Office of Pollution Prevention and Toxics. Instructions for the 2012 TSCA Chemical Data Reporting. January 2012. Available at http://www.epa.gov/cdr/tools/InstructionsManual.041712_revised-7_9_12.pdf (last accessed 29 May 2015).

Finally, the Panel notes that a naturally occurring exemption as described here would be another step toward harmonizing with the Canadian approach.

1.18 EPA should add an explicit exclusion for polymers to be consistent with other TSCA regulations. EPA excludes certain types of polymers from new chemical notifications under TSCA Section 5.[25] EPA clearly states, "It is the intention of the [polymer] exemption to encourage the manufacture of safer polymers by reducing industry's reporting burden for this category of chemical substances, and to concentrate the Agency's review resources on substances expected to pose higher risk."[26] Similarly, EPA excludes from CDR reporting polymers that are not also subject to certain TSCA actions.[27] CDR-exempt substances are assigned an "XU" flag on the TSCA Inventory for easy identification. The Panel believes that the experiences and findings that have led to the existing polymer exemptions under the New Chemicals Program and CDR should also be extended to the Proposed Rule. Doing so would be consistent with established TSCA policy and practice. EPA has not provided a clear, risk-based reason for not including a polymer exemption in this proposal and ought to do so.

1.19 EPA should add an explicit exclusion for the incorporation of nanoscale substances into a polymer matrix. EPA has stated in several final Significant New Use Rules (SNURs) for nanoscale materials that the SNUR conditions do not apply to the material when it is incorporated into a polymer. For example, the final SNUR for the compound rutile, tin zinc, calcium doped states, "The requirements of this rule do not apply to quantities of the PMN substance that have been incorporated into a polymer, glass, dispersion, cementitious matrix, or a similar incorporation."[28] The SNUR for the compound rutile, tin zinc, sodium doped contains similar language. [29] EPA has similarly exempted carbon-based nanoscale materials in polymers from SNUR requirements. For example, the SNUR for the compound "multi-walled carbon nanotubes (generic)" states, "The requirements of this rule do not apply to quantities of the chemical substance after it has been completely reacted (cured), incorporated or embedded into a polymer matrix that itself has been reacted (cured), or embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing."[30] EPA has used such language or very similar language in multiple SNURs for carbon-based nanomaterials.[31] The Panel urges EPA to apply the same analysis and logic for excluding the incorporation into polymer matrices to the proposed reporting requirements. The Panel notes that a definition of "particle" that explicitly identifies the ability to move within its environment (see 1.6 above) would address this matter.

1.20 EPA should add more clarity about the exemption from the rule for research materials. EPA has made clear that nanoscale materials used only in research and development (R&D) are exempt

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[25] Polymer Exlusion Guidance Manual. 1997. EPA 744-B-97-001. Available at http://www.epa.gov/oppt/newchems/pubs/polyguid.pdf (last accessed July 6, 2015).
[26] From the page Polymer Exclusion Overview: Available at http://www.epa.gov/oppt/newchems/pubs/polyexem.htm (last accessed July 14, 2015).
[27] 40 C.F.R. § 711.6(a)(1).
[28] 40 CFR § 721.10230 (a)(1).
[29] 40 CFR § 721.10231 (a)(1).
[30] 40 CFR § 721.10155 (a)(1).
[31] *See e.g.,* 40 CFR §§ 721.10183, 721.10156, 721.10266, 721.10267, 721.10268, 721.10269, 721.10270, 721.10274, 721.10275, 721.10267, 721.10277, and 721.10279.

from the Proposed Rule.[32] However, the Panel believes that additional clarity is needed. The preamble to the proposed rule states that the Section 8(a) R&D exemption "can apply" to the production of a substance for others to use in their R&D activities.[33] What is not clear from the language in the *Federal Register* notice is whether a company whose core commercial activity is manufacturing materials for their customers' R&D purposes is exempt. The Panel believes that several companies could benefit from clarity on this matter, especially since EPA is proposing to significantly alter the long-standing small business exemption. The Panel notes that reporting of materials manufactured in very small quantities and sold purely for R&D purposes would paint an inaccurate picture of nanoscale materials in commerce.

2. DISTINGUISHING BETWEEN NANOSCALE FORMS OF A REPORTABLE CHEMICAL SUBSTANCE

2.1. Separate reporting on each "discrete form" as currently described in the Proposed Rule is not adequately justified on the basis of health or environmental risk and would place a large burden on many nanomaterial producers and processors. Instead of separate reporting on each discrete form of a nanoscale material, the Panel suggests a substance approach similar to that used for the earlier voluntary program in which information on the substance as a whole is reported in a single report. The Panel strongly encourages EPA to allow industry to report nanoscale forms in a single submission with appropriate identification of ranges in material properties and coating compositions. We believe that this approach would still meet EPA's informational needs and would be much less time-consuming for affected companies and EPA. We provide additional comments below that demonstrate why the "discrete form" concept described in the proposed rule is unjustified and unworkable.

2.2. The discrete forms construct is a significant departure from the definition of "chemical substance" that has been the underpinning of TSCA since it was first enacted. The definition of "chemical substance" that serves as the foundation of TSCA relies on distinct molecular identity as the basis for regulation.[34] The discrete forms concept essentially moves from molecular identity to grades of a chemical substance, which is a significant departure from the existing statutory and regulatory framework. The Proposed Rule provides neither analysis nor justification for this significant change in EPA's approach to TSCA. EPA is obligated to provide more analysis of its authority under TSCA to significantly expand the statutory definition of "chemical substance" to require reporting on individual grades or classes of a substance that share the same molecular identity.

2.3. EPA should consider the Canadian approach for identifying substances that would be subject to a nanoscale substance reporting rule.[35] The Panel notes that the proposed "discrete form" approach in the Proposed Rule closely resembles the "product grades" approach being taken by the European authorities. Anecdotally, that approach has resulted in significant gridlock, challenge, and enormous use of resources by both government and industry. The Panel therefore recommends more alignment to the approach chosen by the Canadian authorities, which provides a more direct,

[32] 80 Fed. Reg. at 18335, III.A.3.
[33] *Id.*
[34] 40 C.F.R § 720.3(e).
[35] Proposed 40 C.F.R. § 704.20(a).

easily understandable way to (a) better estimate the number and volume of nanoscale chemical substances in commerce; (b) gather information on uses of nanoscale chemical substances; and (c) collect a sufficient degree of health and safety information to determining whether additional, targeted information collection activities may be required.

2.4. EPA must provide a more risk-based rationale for the criteria in the proposed definition of "discrete form of a reportable chemical substance." The proposed definition includes several criteria, including change in process to affect a change in size and/or a change in one for more of the properties of the reportable chemical substance. EPA then goes on to list the properties: zeta potential, specific surface area, dispersion stability, and shape. A change in one of those properties of the magnitude described in the proposal could, in combination with other factors, trigger a reporting requirement.

The Proposed Rule describes what each of these properties is from a materials science standpoint, but explains neither why this subset of properties are important to understand for the purposes of safety assessment nor how EPA will use this information for any purpose. While there may be specific examples of nanomaterials for which properties such as *zeta* potential and surface reactivity have been shown to be associated with increased *in vitro* toxicity, these associations have not been demonstrated *consistently* across large numbers of nanomaterials, nor has *in vitro* toxicity of nanomaterials been shown to be consistently associated with health or environmental risk. Moreover, the Panel notes that within the context of EPA's proposed "discrete forms" construct, the number of discrete forms an entity reports will depend on the property selected as the basis for comparison.

2.5. The shape criterion in the proposed criteria for identifying discrete forms is too vague and therefore unworkable. Under the Proposed Rule, reportable substances that differ only in morphology would be considered to be discrete forms with separate reporting obligations.[36] It is unclear how different the shapes of two forms would have to be in order to trigger the discrete forms requirement. The language in the Proposed Rule is unclear on several counts. For example, would a 4 micron nanofiber be discrete from a 2 micron nanofiber? Would a 20 nm by 40 nm rod-shaped particle be considered discrete from a 30 nm spherical particle? Does the 7 standard deviation rule apply to nanoparticle dimensions, or would all rod-shaped versions of a nanoscale substance be considered one discrete form for the consideration of morphology? In the absence of guidance, entities cannot understand whether they have a reporting obligation. The Panel believes EPA should provide guidance that provides a small number of descriptors to define physically and, where possible mathematically, each of the morphologies listed in the second criterion for discrete forms and to make that guidance available for public comment.

2.6. EPA should develop a list of conditions, methods, and/or approaches that would help the regulated community gauge the level and kind of information that would be informative to EPA at this stage of information gathering. Uncertainty around methodology has the potential to create tremendous inefficiencies. Several properties proposed to delimit discrete forms (i.e. zeta potential, surface reactivity, and dispersion stability) are media-dependent. Furthermore, it is widely recognized that standard protocols broadly applicable to all types of nanomaterials (i.e., carbon-based, metal oxide, etc.) may not exist for these properties. These uncertainties—test conditions and test methods—lead to an inefficient, undesirable, and largely avoidable outcome.

[36] Proposed 40 C.F.R. § 704.20(a)(2).

Regardless of the fact that EPA is not specifically requiring the generation of new data,[37] the Panel predicts that many potentially regulated entities will have to develop new information in order to determine whether they have a reporting obligation. EPA clearly anticipates the development of new data in the context of the Proposed Rule as well.[38] Given the uncertainty in test conditions and methods, it is unclear that EPA will receive data that are sufficiently robust to determine what nanoscale materials might warrant a more targeted review. Insufficiently robust data will, in turn, lead to future data requests for more robust, methodologically consistent data. EPA can and should avoid creating such an inefficient reporting treadmill. Such guidance should point out utility and limitations of various methods for different types of nanomaterials. There are many sources that have analyzed various methods and would be useful for EPA.[39]

2.7. The Proposed Rule's language about coatings is vague and unworkable. The Proposed Rule states that a reportable chemical substance coated with another chemical substance or mixture at the end of manufacturing or processing is a discrete form.[40] The Panel is not aware that the term "coating" is defined under TSCA. Coating has been used in the commercial market to describe films (another imprecise term as noted above), liquids that when applied to the surfaces of articles leave a contiguous layer (such as a paint), or a covering of an object. It is not clear that any of these definitions capture the information that EPA seeks. EPA should provide clarity on how it defines the term "coating" and provide illustrative examples. Any inconsistencies or departures from existing TSCA policy framework should be justified.

3. REPORTING DISCRETE FORMS AT LEAST 135 DAYS BEFORE COMMENCEMENT OF MANUFACTURE OR PROCESSING

3.1. The proposed 135-day pre-commencement period discriminates against nanomaterials.[41] The proposed 135-day pre-commencement requirement treats nanoscale materials differently than non-nanoscale forms and sends a signal to the marketplace that nanoscale forms of substances inherently pose more risk. Doing so unfairly and unjustifiably puts nanomaterials at a competitive disadvantage, and the Panel believes the 135-day pre-commencement proposal clearly contradicts the June 9, 2011, memorandum "Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials," which states:

> *"Federal agencies should avoid making scientifically unfounded generalizations that categorically judge all applications of nanotechnology as intrinsically benign or harmful. In this regard, identification of specific risks in the context in which they arise—based on scientific evidence to support the judgement—will help to ensure*

[37] 40 Fed. Reg. at 18337, IV.
[38] *Id.*
[39] *See e.g.,* (1) Arts, J.H.E. et al. 2015. A decision-making framework for the grouping and testing of nanomaterials (DF4nanoGrouping). Regulatory Toxicology and Pharmacology 71:S1-S27, supplementary tables; (2) Gaillard, C. et al. 2015. The NanoDefine Methods Manual. NanoDefine Consortium; (3) ISO/TR 13014:2012—Nanotechnologies—Guidance on physicochemical characterization of engineered nanoscale materials for toxicologic assessment; (4) Linsiger, T. et al. 2012. Requirements on measurements for the implementation of the European Commission definition of the term "nanomaterial." JRC Reference Report EUR 25404 EN. (5) ISO/TS 12805:2011–Nanotechnologies—Materials specifications—Guidance on specifying nano-objects.
[40] Proposed 40 C.F.R. § 704.20(a)(3).
[41] Proposed 40 C.F.R. § 704.20(f)(2).

that perceptions of specific nanomaterials are based on scientific evidence rather than unsupported generalizations."[42]

3.2. The 135-day pre-commencement period is inconsistent with the TSCA framework. The 135-day pre-commencement period imposes a requirement not unlike a Significant New Use Notice (SNUN) under TSCA § 5. Such a requirement is a significant departure from EPA's TSCA § 8(a) authority, which does not include the imposition of review periods, regulatory approval, or notice of commencement. TSCA § 5 constructs should not be imposed on existing chemicals.

3.3. The 135-day reporting requirement is arbitrary. EPA has not explained why it needs such an advance period; what it will do with the information received; and what might be the potential impact to the reporting entity. Without a clearer, defensible, risk-based statement of need and explanation of process, combined with the pejorative nature of the proposal, the Panel strongly opposes the 135-day pre-commencement requirement.

4. CONSIDERATIONS FOR THE AGENCY'S ECONOMIC ANALYSIS

4.1 EPA has greatly underestimated the number of discrete forms of nanoscale materials that individual companies may have to report. Some Panel members have anecdotally mentioned that they may have dozens or more potentially reportable discrete forms of nanoscale substances, not the approximately 5 per company estimate in the EPA's economic analysis of the Proposed Rule.[43] An ACC Nanotechnology Panel Member Company could not definitively and confidently apply the proposed criteria to discern the number of "discrete forms" of a specific substance it places on the US market. Based on their uncertain understanding of the proposed definition, the Member Company believes the number of potentially reportable discrete forms may be in the range of 10 to 20 for one substance. In addition, the Member Company notes that the number of discrete forms calculated for this specific substance changes depending on the property selected as the basis of comparison. The Panel will take this opportunity to emphasize that the "discrete forms" concept has many flaws and strongly urges EPA to consider a clearer alternative (see 2. 3 above).

4.2 EPA has apparently not considered several important factors in the economic analysis. Important factors missing from EPA's economic analysis include the time and effort that would be required by companies to review and analyze physicochemical property information to determine whether a material is a discrete form and, more significantly and developing additional physical chemical data to understand whether or not there is a reporting obligation. The need to develop data may be particularly burdensome for processors, who may not typically receive the data necessary to make a discrete form determination.

[42] Executive Office of the President. Memorandum for the Heads of Executive Departments and Agencies. June 9, 2011. Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials.

[43] Economic Analysis for the TSCA Section 8(a) Proposed Reporting Requirements for Certain Chemical Substances as Nanoscale Materials, RIN 2070-AJ54.U.S. EPA/OPPT. March 12, 2015. *"EPA therefore estimates a current average of 5.06 nanomaterials . . . with commercial relevance per reporting business"* (p. 2-7).

4.3. The Panel would also like to emphasize the economic impact of the 135-day notification period, both in terms of sending a negative signal to the market and not allowing companies to respond quickly to customer requests. See our comments in Section 3 above.

4.4. The proposed rule could potentially qualify as a "significant regulatory action" as described in Executive Order 12866.[44] The Panel believes that many factors could combine to make the Proposed Rule a "significant regulatory action." The relevant factors are: the amount of time and effort required to interpret the rule to determine which of a company's products are covered (see Section 1 above); novel legal/policy interpretation of "chemical substance" under TSCA (see Section 2 above); significantly larger number of discrete forms per entity (see Section 2 & 4 above); the potential market consequences of the proposed 135-notification period (see Section 3 above); the inclusion of processors who are not familiar with TSCA reporting rules; and the complexities around electronic reporting (see 5.1 below). The Panel feels strongly that EPA needs to provide a more accurate and reasonable estimate of the burden and explain how the proposed rule does not raise novel and conflicting legal and policy issues (a trigger for a significant regulatory action) in the context of the TSCA framework.

5. ELECTRONIC REPORTING

5.1. EPA should not claim electronic reporting as a factor that reduces the burden of compliance. In principle, the Panel supports the concept of filing information electronically. However, it is the Panel's experience that what should be a relatively simple process of completing an electronic form through CDX is not. Panel members cite problems with CDX that have taken weeks to resolve. Until problems with EPA's electronic reporting tools are addressed to make them more efficient and reliable, electronic reporting should not be considered a factor that reduces regulatory burden.

6. CONSIDERATION OF POTENTIAL FUTURE RULEMAKING REGARDING PERIODIC REPORTING

6.1. The Panel does not support consideration of future rulemaking regarding periodic reporting at this time. The Panel believes the Proposed Rule is a step toward better understanding (a) what nanoscale materials are in commerce; (b) the volumes and uses of those materials; and (c) whether some materials in commerce may have properties that warrant an additional tier or step of targeted information gathering. The information collected under this Proposed Rule will help determine if there are benefits to additional rules. There may not be. For example, the results of reporting under the first year of the French registry produced rather predictable results.[45] Should EPA obtain similarly unsurprising results, the need for a new, on-going reporting rule would be questionable and unnecessary. The Panel will take this opportunity to note that nanoscale forms of many existing substances are already captured in the CDR.

[44] Executive Order 12866. Regulatory Planning and Review. 56 Fed. Reg. 51735 (October 4, 1993).
[45] Éléments issus des déclarations des substances à l'état nanoparticulaire: Rapport d'étude. November 2013. Available at http://www.developpement-durable.gouv.fr/IMG/Rapport_public_format_final_20131125.pdf (last accessed June 3, 2015).

7. WHAT MUST BE REPORTED

7.1. EPA must explain more clearly the basis of authority for requesting information that does not fall within the scope of the clear statutory authority of TSCA § 8(a). Congress clearly articulated the totality of information EPA can request under TSCA § 8(a):

> *(2) The Administrator may require under paragraph (1) maintenance of records and reporting with respect to the following insofar as known to the person making the report or insofar as reasonably ascertainable:*
>
> *(A) The common or trade name, the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required.*
>
> *(B) The categories or proposed categories of use of each such substance or mixture.*
>
> *(C) The total amount of each such substance and mixture manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.*
>
> *(D) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture.*
>
> *(E) All existing data concerning the environmental and health effects of such substance or mixture.*
>
> *(F) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure.*
>
> *(G) In the initial report under paragraph (1) on such substance or mixture, the manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such manner or method.*
>
> *To the extent feasible, the Administrator shall not require under paragraph (1), any reporting which is unnecessary or duplicative.*[46]

The statutory language is definitive and not merely illustrative. It dictates unambiguously the finite set of information elements from which EPA can choose when developing a regulation under TSCA § 8(a). There is no language that gives EPA the authority to expand the list (i.e., a phrase such as "including, but not limited to" or other language that gives the Administrator discretion to expand the list). The Proposed Rule would expand EPA's TSCA § 8(a) authority significantly by incorporating information requested under TSCA § 5 as well as information that was included in the voluntary NMSP. The Panel notes that the NMSP does not create precedent for exceeding clearly defined statutory authority.

[46] 15 U.S.C. § 2607(a).

8. OTHER COMMENTS

8.1. EPA should use the CDR reporting form as the basis for reporting under the Proposed Rule. The Panel finds the proposed reporting form unnecessarily complicated and burdensome.[47] Moreover, the form only creates more questions about what EPA wants reported and whether the agency will receive comparable data. Where possible, EPA should specify appropriate methods and conditions. For example:

8.1.1. Aspect Ratio. The aspect ratio measured in a sample of particles will exist as a distribution of aspect ratios. Therefore, EPA should clarify whether it want the mean or median aspect ratio. If the intent is to identify fiber-like particles, the Panel suggests it would be more efficient to ask whether or not the material has an aspect ratio greater than a particular threshold. It may be more efficient for EPA to ask for the average fiber length.[48]

8.1.2. Porosity. Does EPA want micro or macro porosity? What is the preferred metric? EPA should clarify what it is asking for in the "porosity" field.

8.1.3. Surface-to-Volume Ratio. Does the agency want the internal or external ratio? The form is not clear on what information would be most useful and does not provide a way to distinguish between approaches.

8.1.4. Fate and Transport. The properties requested in this section will be media dependent. Reporting should include a field for the media in which the measurement was taken. Otherwise, data submitted across reporting entities may be difficult to compare.

8.1.5. Risk Management Practices. EPA should clarify what information should be reported. Does EPA want copies of safety data sheets? Is it sufficient to generally describe a company's safety practices?

8.1.6. Existing Health and Environmental Effects Data. Does the obligation apply only to previously unreported or unpublished health and safety data? The Panel believes it should. The Panel also believes that companies should not be required to report information available in the scientific literature. It is as available to EPA as it is to industry. Finally, Panel member experience with past Section 8 rules has shown the importance of clearly defining the scope of human health and environmental data that the Agency seeks to collect.

8.1.7. Neat Substances. The proposed data submission form requests analyses for the 100% neat substance. Doing so may not be possible for all materials, such as nanomaterials manufactured in solution and never isolated from that solution or mixtures as defined in the proposed rule. How does a reporting entity handle this contradiction?

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[47] Proposed Data Submission Form for TSCA 8(a) Reporting for Chemical Substances Manufactured and Processed as Nanoscale Materials. Available at www.regulations.gov, Docket# EPA-HQ-OPPT-2010-0572. Posted April 6, 2015. ID: EPA-HQ-OPPT-2010-0572-0042.

[48] *For example*, a nanoparticle could have an aspect ratio >3:1 but still be <100 nm in all dimensions. According to Schinwald et al (2012) only fibers longer than about 4 microns have the potential to cause nanofiber-induced pathogenicity in the lung pleura. *See* Schinwald, A. et al. (2012). The threshold length for fiber-induced acute pleural inflammation shedding light on the early events in asbestos-induced mesothelioma. Tox. Sci. 128, 461-470.

8.1.8. **State of Matter.** If the proposed rule indicates that the nanomaterial must be a solid at room temperature, then why are metrics associated with gases and liquids being requested for the neat substance?

8.2. EPA should use the familiar Form-U as a basis for designing a reporting form for this 8(a) rule. Given the clear Congressional direction regarding the types of information that can be collected under TSCA 8(a) (see Section 7 above), the Panel recommends that EPA base the reporting form on the much simpler, clearer, and familiar Form-U that was used for CDR reporting before electronic reporting became mandatory.[49] Doing so will reduce the regulatory burden by reducing the learning time required to understand the significantly more complicated and vague proposed reporting form.

[49] See http://www.epa.gov/cdr/pubs/formu_revisions_rule.pdf (last accessed July 7, 2015).