NanoManufacturing Association

COMMENTS OF THE NANOMANUFACTURING ASSOCIATION

ON THE

PROPOSED INFORMATION COLLECTION RULE; *CHEMICAL SUBSTANCES WHEN MANUFACTURED OR PROCESSED AS NANOSCALE MATERIALS; TSCA REPORTING AND RECORDKEEPING REQUIREMENTS*

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EXECUTIVE SUMMARY OF COMMENTS

The NanoManufacturing Association (NMA) appreciates this opportunity to provide comments on the U.S. Environmental Protection Agency's (EPA) proposed reporting requirements pursuant to section 8(a) of the Toxic Substances Control Act (TSCA) (15 U.S.C. § 2607(a)) for certain chemical substances manufactured, imported, or processed at the nanoscale.[2] NMA has a number of recommendations based on input by representatives from the industries we represent. The input they have provided seeks to improve the rule to make the information gathered more meaningful for EPA, ensure the proposed requirements stay within the scope of EPA's TSCA authority, and provide industry with much needed clarity on what must be reported.

NMA supports a phased approach for reporting that requires information from manufacturers and importers first and then calls upon processors to fill information gaps. Also, absent an explicit and supported finding that information regarding such mixtures is necessary to effectively enforce the statute—a need that would, in most instances, not arise until EPA elects to regulate a given chemical—mixtures should not be subject to separate reporting. In addition, NMA thinks it is reasonable to expect that the chemical identities of substances selected for reporting are identified by rule, rather than express the threshold for reporting solely in terms of a substance's size and properties. Currently, the proposed rule places the burden entirely on manufacturers and processors to identify and decide whether or not a chemical substance should be reported.

These comments provide NMA's rationale for why the proposed exemptions should be harmonized with the February 2015 Canadian approach for collecting information on nanoscale chemical substances and other parts of TSCA. NMA supports exemptions for polymers (including

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[1] Proposed Rule; *Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements*; 80 Fed. Reg. 18,330 (Apr. 6, 2015).

[2] The NMA is an alliance of private companies and trade associations established to advocate for a responsible business and regulatory climate for products in which nanomaterials are used or are essential. For more information, visit our website at: http://www.nanomanufacturingassociation.com/about-1.html

polymer dispersions), substances embedded in polymer matrices, pigments and dyes, certain naturally occurring substances, mixtures (including surface treatments), substances for which there are low or no pulmonary exposure, and small manufacturers and processors. It is critical that EPA recognize longstanding agency determinations that certain chemical substances and mixtures are low risk due to low exposures and/or low hazards. Furthermore, NMA believes that the proposed small business exemption requires adjustment for inflation to better reflect the financial resources these companies have available to comply.

Because section 8(a) reporting is required only for chemical substances as defined by TSCA, NMA believes that the provisions in the proposed rule that would require separate reports to be filed for each discrete physical form of the same chemical substance are outside the scope of the law. Moreover, surface treatments that impart reactivity cause the surface treated substance to be regarded as a new substance subject to premanufacture notification (PMN). The proposed rule exempts new substances subject to PMN reporting. Other surface treatments will be considered part of a mixture and subject to a heightened threshold before reporting is required. Therefore, surface coatings should be removed from the list of criteria for describing discrete forms entirely. The statute contemplates a single reporting form on a *per chemical substance* basis, which is solely determined by the substance's molecular identity.

Since validated regulatory protocols for the most of the physical-chemical properties discussed in the proposed rule are still under development, it is not yet possible to reliably distinguish and report on the basis of this information. Information collection on properties must qualify as one of the specific items of information listed in section 8(a)(2), and must have established, well-defined measurement protocols. Therefore, NMA recommends that EPA convene an appropriate process to identify the most relevant physical-chemical properties and develop appropriate protocols for testing such properties.

NMA strongly urges the Administration to drop the proposed implementation of an ongoing reporting program 135 days prior to commercialization of existing chemicals from further consideration. The agency has not undertaken this kind of program under section 8 before for even the most hazardous substances in commerce. Such an extraordinary measure must be well-grounded by need based on a scientifically sound risk assessment. EPA does not offer such support in the proposed rule.

As proposed, this rule calls for a significant time and resource commitment, and potentially would require companies to hire new staff. The current estimate of 200,000 hours (over 8,000 days) for all companies seems to significantly underestimate the time that will be needed to first identity chemical substances subject to reporting, locate the information, and complete a lengthy PMN-type form for each discrete form.[3] EPA should consider whether to extend the reporting timeframe in order to receive high quality submissions, and reconsider the estimated time commitment and scheduling for this rule so that it does not coincide with 2016 Chemical Data Reporting.

Considering the significant changes needed to establish a fair and workable program on information collection, NMA believes that EPA should re-propose this rule.

[3] 80 Fed. Reg. at 18,339.

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I. Introduction

The NanoManufacturing Association (NMA) respectfully submits these comments on the U.S. Environmental Protection Agency's (EPA) proposed reporting requirements pursuant to section 8(a) of the Toxic Substances Control Act (TSCA) (15 U.S.C. § 2607(a)) for certain chemical substances manufactured, imported, or processed at the nanoscale.[4] These comments draw upon certain key principles that in our experience are closely associated with the implementation of section 8(a) of TSCA. First, section 8(a) authorizes EPA to collect information on chemical substances, and specifies seven items of information that can be required through an information collection rulemaking. Second, rules issued under section 8(a) of TSCA must be reasonable, and must not be unnecessary or duplicative. As reflected by the basic nature of the information EPA is authorized to collect (*e.g.*, chemical identity and the like), information reported pursuant to section 8(a) should be readily known and available to those from whom the information is being sought. Third, and fundamentally, the definition of "chemical substance" under TSCA is controlling in the context of a section 8(a) rulemaking. Reports can be required for each discrete chemical substance that is in the scope of a particular information rule, as distinguished by their particular molecular identity. The stated purpose of this proposed rule is to gather information on nanoscale chemical substances to understand whether additional regulatory actions are warranted. As explained in the sections that follow, NMA thinks that certain aspects of the proposal do not align with the aforementioned principles and go beyond what is reasonable and necessary to accomplish this goal.

II. Aligning the Proposal with the Boundaries of Section 8(a) Reporting

TSCA section 8(a) authorizes EPA to collect information on "chemical substances", as that term is defined by TSCA. The threshold for asking for information on discrete chemical substances is "as the Administrator may reasonably require."[5] The statute lists the types of information that EPA may require. The information that may be required is as follows:

> (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.

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[4] The NMA is an alliance of private companies and trade associations established to advocate for a responsible business and regulatory climate for products in which nanomaterials are used or are essential. For more information, visit our website at: http://www.nanomanufacturingassociation.com/about-1.html

[5] 15 U.S.C. § 2607(a)(1)(A).

> (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.

Section 8(a)(2) provides EPA with authority to require records and reports for the above information "insofar as known to the person making the report or insofar as reasonably ascertainable."

In contrast to chemical substances, *per se*, the ability to require reporting for mixtures and small quantities used in research and development is more circumscribed. Under Section 8(a)(1)(B)(ii) of TSCA, reporting requirements that apply to manufacturers and processors of R&D chemicals must be "necessary for the effective enforcement of this chapter."[6] While the proposed rule would require reporting for mixtures, EPA proposes to exempt from reporting persons who manufacturer or process a chemical only for research and development (R&D) purposes.[7] NMA supports the proposed R&D exemption. R&D substances are exempt from most TSCA information collection requirements and it is unlikely that any information gathered via section 8(a) for R&D substances would be used by EPA to take further action under TSCA for those substances. Thus, the proposed R&D exemption is appropriate.

The statute goes further to instruct that "[t]he Administrator may not require in a rule promulgated under this paragraph the maintenance of records or the submission of reports with respect to changes in the proportions of the components of a mixture unless the Administrator finds that the maintenance of such records or the submission of such reports, or both, is necessary for the effective enforcement of this chapter."[8] In section 8(a)(1) and (a)(3), EPA is instructed to exempt small manufacturers and processors from having to submit section 8(a) reports except in the case of regulated

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[6] 15 U.S.C. § 2607(a)(1)(B).

[7] 80 Fed. Reg. at 18,341 (to be codified at 40 C.F.R. § 704.20(c)(3)).

[8] 15 U.S.C. § 2607(a)(1).

chemicals or for purposes of compiling the initial TSCA Inventory. Section 8(a)(2) specifically directs that, to the extent feasible, EPA shall not require "any reporting which is unnecessary or duplicative."[9]

A. Discrete Physical Forms Are Not "Chemical Substances" Subject to Reporting under Section 8(a)(1)

As explained by these comments, the proposed approach of designating each physical form of a chemical substance to be a "reportable substance" exceeds the authority provided by the statute. Section 8(a)(1)(A) directs that:

> each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a *chemical substance* shall maintain such records, and shall submit to the Administrator such reports . . . *(emphasis added)*

For EPA to require in the proposed rule substance-by-substance reporting under section 8(a) of TSCA on any basis other than their molecular structure is improper. As explained above, the required reports are to be submitted on a "chemical substance". TSCA defines the term "chemical substance" as any "organic or inorganic substance of *a particular molecular identity*, including – (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (ii) any element or uncombined radical."[10]

NMA respectfully submits that section 8(a) rules are controlled by the principle that molecular identity is used to distinguish a chemical substance for the purpose of notification and reporting. This principle has long guided the way in which EPA administers the TSCA program. EPA's regulations identify the information that needs to be provided to establish a chemical substance's particular molecular identity in premanufacture notices (PMNs) submitted under section 5 of TSCA. This information primarily consists of the Chemical Abstracts Service (CAS) Index Name, associated CAS Registry Number (CASRN) for the substance if one exists, and a structural diagram.[11] PMN submitters are instructed to obtain formal chemical names from the CAS Inventory Expert Service (IES).[12] Indeed, CAS nomenclature is central to the identification of a "chemical substance": CAS nomenclature, which relies on molecular structure as the basis for the systematic chemical nomenclature, is relied on by

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[9] 15 U.S.C. § 2602(2)(A).

[10] 15 U.S.C. § 2602(2)(A) (emphasis added).

[11] 40 C.F.R. § 720.45(a).

[12] *See also,* U.S. Environmental Protection Agency, Instruction Manual for Reporting under the TSCA §5 New Chemicals Program at 26, *available at* http://www.epa.gov/opptintr/newchems/pubs/tscaman2.pdf.

government and industry for complying with TSCA, in order to distinguish one discrete chemical substance from another.[13]

CAS nomenclature, in turn, is based unequivocally on the principle of molecular structure. The *CAS Name Selection Manual* emphasizes the critical role of chemical structure as the basis for CAS index nomenclature:

> A second difference between index nomenclature and commonly used nomenclature is that for the former there must only be one unique name for a structure. Names used by the general chemical public in scientific publications, trade literature of the like, tend to reflect a particular point of interest, such as reactivity and biological activity, rather than similarity in basic structure.[14]

CAS instructs that "from the structure of the compound," one first determines the highest compound class to which it belongs on which an index name may be based. In a subsequent step, one should "[n]ame the structural fragments to be cited as substituent prefixes."[15] With regard to inorganic compounds, the *CAS Name Section Manual* states that "[t]he names selected for inorganic compounds are based on United States usage, the IUPAC rules…and the representation of chemical structure."[16] For example, CAS has adopted "Fullerene" as a class name and to it are added ring sizes, number of carbon atoms, and point group symmetries to name specific members of the class. In the name [5,6]Fullerene-C_{60}-I_h, '[5,6]' indicates the presence of ring sized 5 and 6, 'C_{60}' the number of carbon atoms, and 'I_h' the point group symmetry.[17]

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[13] For a published discussion on chemical nomenclature development needs for nanoscale chemical substances, see ISO/TR 14786 "Nanotechnologies - Considerations for the development of chemical nomenclature for selected nano-objects" (2013).

[14] Principles of General Index Nomenclature, Volume I, *Chemical Abstract Services Chemical Name Selection Manual* ("CAS Name Selection Manual"), Introduction, Volume I, Washington, D.C., 1982, at A-005.

[15] CAS Name Selection Manual, Volume I at A-006.

[16] CAS Name Selection Manual, Volume III at IN-1. With few exceptions, physical properties are not used to establish a single molecular entity, *i.e.*, to define molecular identity (the rutile and anatase form of titanium dioxide and the crystalline and amorphous forms of silica are exceptions to the rule). They are, in a minority of cases, incorporated into supplemental Chemical Substance Definitions (CSDs) for a subcategory of Class 2 materials encompassing the most poorly-defined Class 2 materials, *i.e.*, substance of unknown or variable compositions, complex reaction products, or biological materials (UVCBs). However, these exceptions to the general rule do not form a sufficient basis for wholesale adoption of the agency's proposed concept of establishing a discrete physical form as a separate "chemical substance" for which reporting is required under section 8(a).

[17] Chemical Abstracts Service, Naming and Indexing of Chemical Substances for Chemical Abstracts (2007 ed.) at 34.

As a canon of statutory construction, where Congress uses technical words or terms of art, they are to be implemented by reference to the art or science to which they are appropriate.[18] In this respect, "molecular structure", "physical properties" (including form), and "chemical properties" are technical terms that Congress used which have independent meanings in the field of chemistry. The way in which the term "molecular" is defined by the Oxford English Dictionary illustrates this point:

> Relating to or consisting of molecules. A molecule is defined as a group of atoms chemically bonded together, representing the smallest fundamental unit of a compound that can take part in a chemical reaction.[19]

The common understanding, reflected in the language above, underscores that physical and chemical properties are separate concepts from the one that is used by TSCA – molecular identity – to define a chemical substance. It is not reasonable to indirectly prescribe meanings to "particular molecular identity" that chemistry and the English language directly ignore.

Finally, it is inconsistent to single out coated reportable chemical substances for separate reporting given their status as new chemicals or mixtures. Under the proposed rule, nanoscale forms of a particular chemical substance that are coated with different chemical substances would be considered discrete forms for each chemical coating.[20] However, chemical substances that are manufactured or processed in a nanoscale form solely as a component of a mixture, encapsulated material, or composite are otherwise required to be reported.[21] Coated reportable chemical substances (RCS) will either be reacted with the coating (and therefore exempt from the proposed rule because they are subject to premanufacture notification) or, alternatively, will be considered a mixture. It is not clear why EPA has decided to separately and redundantly address coated RCS's in this way.

The use of molecular identity to identify all substances subject to TSCA must be applied in the same way to nanoscale chemical substances. Any other approach is inconsistent with EPA's stated policy on how nanoscale substances are identified and named for complying with TSCA.[22] NMA

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[18] *Corning Glass Works v. Brennan*, 417 U.S. 188, 201 (1974). *See also*, Norman Singer, Sutherland Statutory Construction § 47:29 (6th ed. 2000) ("In the absence of legislative intent to the contrary, or other overriding evidence of a different meaning, technical terms or terms of art used in a statute are presumed to have their technical meaning. If a term is connected with and used with reference to a particular trade, the term will have the meaning given [by] experts in the particular trade.").

[19] *Compact Oxford English Dictionary of Current English*, Third Edition.

[20] 80 Fed. Reg. at 18,341 (to be codified at 40 C.F.R. § 704.20(a)).

[21] 80 Fed. Reg. at 18,335.

[22] U.S. EPA, TSCA Inventory Status of Nanoscale Substances – General Approach (Jan. 23, 2008) at 5, *available at:* http://www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf ("In determining whether a nanoscale substance is a new or existing chemical, the Agency intends to continue to apply its current Inventory approaches based on molecular identity, rather than focus on physical attributes such as particle size.").

respectfully asks EPA to drop those aspects of the proposal that call for filing separate discrete chemical substance reports for different physical or coated forms of nanoscale chemical substances.

B. Proposed Information Requests Are Outside the Statute

Section 8(a)(2)[23] of TSCA, in contrast to other sections of the Act,[24] sets out a closed list of information. This understanding stems from careful parsing of the legislative history. The legislative history describes this list as illustrative or as providing examples,[25] but not in the manner intended to convey that the enumerated items are not an exhaustive list. Rather, taken in context, Congress gave EPA the discretion to select one or more items that it wishes to pursue from the entire list: the agency must select its topics for information collection from the list, but it is not required to include *all* of the enumerated topics each time that it seeks to collect information under section 8(a)(2). This is neatly illustrated by EPA's apparent decision in the proposed rule to not require information authorized by section 8(a)(2)(G) on changes in the manner or method of disposal.

NMA agrees that the following information requirements in the proposed rule align well with the agency's authority in this section of TSCA:

- Proposed 40 C.F.R. 704.20(d)(1), with respect to "[t]he common or trade name, the specific chemical identity including the correct Chemical Abstracts (CA) Index Name and available Chemical Abstracts Service (CAS) Registry Number, and the molecular structure of each chemical substance or mixture";[26]
- Proposed 40 C.F.R. 704.20(d)(4), concerning "[t]he maximum weight percentage of byproducts resulting from the manufacture, processing, use, or disposal of each chemical substance";[27]
- Proposed 40 C.F.R. 704.20(d)(5), concerning annual production volumes;
- Proposed 40 C.F.R. 704.20(d)(6), use information describing the category of each use by function and application, estimates of the amount manufactured or processed for each category of use, and estimates of the percentage in the formulation for each use; and

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[23] 15 U.S.C. § 2607(a)(2).

[24] In comparison, elsewhere in TSCA Congress employed phrases like "including by not limited to, each of the following," "consider all relevant factors, including . . . ," "shall extend to all things within the premises," "shall contain such information as the Administrator shall require, including . . . ,".

[25] H.R. Rep. No. 1679, 94th Cong., 2nd Sess. 78 (1976).

[26] 80 Fed. Reg. at 18,341.

[27] *Id.*

- Proposed 40 C.F.R. 704.20(d)(8), exposure information with estimates of the number of individuals exposed in their places of employment, descriptions and duration of the occupational tasks that cause such exposure.

However, some of the information EPA requests in the proposed rule from manufacturers, importers, and processors exceed the authority of the statute because they are not part of the enumerated list authorized for collection under Section 8(a).[28] For example, material characteristics including particle size and morphology in proposed 40 C.F.R. § 704.20(d)(2) and other physical and chemical properties in proposed 40 C.F.R. § 704.20(d)(3) are not explicitly listed, and cannot be considered part of the statutory definition of chemical identity for data collection under section 8(a)(2)(A) for the reasons explained above. Also, NMA is unable to find support for the proposed use of section 8(a) to collect information on weight percentage of impurities and detailed methods of manufacturing. While EPA may feel this information offers insights on chemical identity under section 8(a)(2)(A) or perhaps aids in understanding the structure of substances subject to reporting, these items are not part of the existing reporting structure under section 8(a). They are not chemical substance identity, *per se*. As such, it is not appropriate to seek this information under this rule.

Section 8(a)(2)(F) of TSCA authorizes EPA to collect information on "[t]he 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."[29] However, in proposed 40 C.F.R. § 704.20(d)(8), required information would include descriptions and estimates of any general population or consumer exposures as well. In proposed 40 C.F.R. § 704.20(d)(9), it is also suggested that "[r]elease information with estimates of the amounts released, descriptions and duration of the activities that cause such releases, and whether releases are directly to the environment or to control technology" be provided.[30] As written, this description invokes potential releases into the environment rather than

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[28] It is axiomatic that a federal agency's regulatory authority is limited by the powers delegated to it by Congress, even where the agency believes in good faith that a proposed action outside its authority would otherwise constitute effective public policy. *See, e.g.*, *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374-75 (1986) ("[W]e simply cannot accept an argument that the FCC may nevertheless take action which it thinks will best effectuate a federal policy. An agency may not confer power upon itself. To permit an agency to expand its power in the face of congressional limitation on its jurisdiction would be to grant to the agency power to override Congress. This we are both unwilling and unable to do."); *Succar v. Ashcroft*, 394 F.3d 8, 10 (1st Cir. 2005) ("Viewing the larger statutory context [in a case involving an Immigration and Naturalization Service regulation], we find Congress has also been explicit about where the Attorney General has been granted discretion and where he has not. By contrast with other areas, there is no explicit grant of discretion to redefine eligibility to apply for adjustment of status of parolees to exclude those in removal proceedings. Congress did not place the decision as to which applicants for admission are placed in removal proceedings into the discretion of the Attorney General, but created mandatory criteria.").

[29] 15 U.S.C. § 2607(a)(2)(F) (emphasis added).

[30] 80 Fed. Reg. at 18,342.

exposures in the workplace. Based on a plain reading of the statute, section 8(a) cannot be used to gather the general population exposure, consumer exposure, and environmental release information.

The proposed rule also seeks information on "[r]isk management practices describing protective equipment for individuals, engineering controls, control technologies used, any hazard warning statement, label, safety data sheet, customer training, or other information which is provided to any person who is reasonably likely to be exposed to this substance regarding protective equipment or practices for the safe handing, transport, use, or disposal of the substance."[31] This is yet another category of information that is not identified for data collection by the section 8(a)(2) list.

Because the information listed in the statute represents the total amount of information that EPA may seek under section 8(a), the aforementioned areas should be dropped from further consideration. Furthermore, since the proposed rule indicates that the information it collects will facilitate the assessment of risks and risk management, EPA should seek scientific evidence allowed within the parameters of TSCA because, as of now, there is little scientific evidence included in the type of information that EPA would request under this proposed rule. If EPA's goal is to further understand the potential risks associated with nanomaterials, much of the information it is requiring to be reported is unlikely to lead to risk management decisions based on scientific evidence.

C. Phased Reporting for Processors and Mixtures

NMA respectfully urges EPA to defer a decision on information needs from processors and for mixtures until after the agency has received and reviewed information from manufacturers. There are a number of reasons that NMA supports this approach.

1. Processor Considerations that Support a Phased Approach

Given the potentially large number of affected products and processors covered by the proposed rule, a high number of responses can be expected. Staggered reporting helps to manage the volume and flow of information that is received. In addition, processors have more limited access to the information required by section 8(a). While processors can contribute trade names, categories of use, disposal, and worker exposure, other information EPA is seeking is not readily known and may not be available. The information EPA proposes to request on nanoscale chemical substances that may not be readily known or available to processors includes: chemical identity (molecular structure), physical properties, byproducts, impurities, general population exposure information, and health effects data. For these data, processors will have to go back to their suppliers. In many instances, this kind of information is considered proprietary by their suppliers. By collecting section 8(a) information from manufacturers and importers first, EPA will be able to better guide processors on the substances,

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[31] Proposed 40 C.F.R. § 704.20(d)(10); 80 Fed. Reg. at 18,342.

information, and activities that subject them to reporting, and to ensure that their reporting obligation is reasonable.

NMA asks EPA to recognize that processors are not as experienced as manufacturers with TSCA reporting, and consider whether the 6-month reporting deadline after the effective date of the final rule should be extended. For these businesses, the number of reports they will need to file could be on par with those for manufacturers, and they face a high degree of complexity associated with reporting irrespective of the number of reports they file. EPA is likely to receive higher quality submissions if the reporting deadline is extended. NMA is concerned that processors may need to hire additional staff in order to meet the 6-month deadline. In the proposed rule, EPA estimates that each form will take 137 hours to complete.[32] However, for a processor that has a combination of 100 "discrete" forms of nanoscale chemical substances and mixtures, this means 13,700 hours of reporting for a single company. NMA thinks that the current estimate of 200,000 hours (over 8,000 days) for the entire reporting community underestimates the time needed to comply.[33] For these reasons, NMA urges EPA to adopt a phased reporting approach for processors.

2. Considerations Supporting a Phased Approach for Collecting Information on Mixtures

Because the business of processors is centered on mixtures, the two are inextricably linked. As previously noted in these comments, TSCA section 8(a)(1)(B) specifies that EPA may require reporting for mixtures "only to the extent the Administrator determines the maintenance of records or submission of reports, or both, is necessary for the effective enforcement of this chapter." Congress clearly intended for section 8(a) to be used in a more limited way insofar as mixtures, and by implication, processing activities, are concerned. The phrase "effective enforcement" reflects a narrowing of EPA's authority under which it must affirmatively determine that information on mixtures is essential to assure that manufacturers and processors are complying with TSCA.

TSCA's legislative history explains that the scope of reporting and recordkeeping under section 8(a)(1) is more limited for mixtures. The House Report states:

> The Administrator also is authorized to promulgate rules under which manufacturers and processors . . . of mixtures shall maintain records and submit reports, but only to the extent the Administrator determines is necessary for the effective enforcement of the bill.[34]

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[32] 80 Fed. Reg. at 18,339.

[33] *Id.*

[34] H.R. Rep. No. 1341, 94th Cong., 2nd Sess. 41 (1976).

The House Report discusses the rationale for this circumscribed approach as follows:

> The Committee has specified a different standard for requiring reporting for manufacturers or processors of mixtures . . . because the Committee anticipates that in implementing its regulatory functions the need for information from such manufacturers and processors will not be as great as it will be with respect to other manufacturers or processors.[35]

As explained above, it was deliberate on the part of Congress that EPA should carry out its regulatory mission without creating unnecessary economic barriers to technological innovation. Congress anticipated that, in many cases, section 8(a) information collection on mixtures would be overly burdensome. Reporting for mixtures turns on whether it is "necessary for the effective enforcement" of TSCA so that EPA would take a "hard look" at the need for this information. "Enforcement", for example, means "[t]o compel observance of or obedience to" or "to make sure that people do what is required by (a law, rule, etc.)."[36] For enforcement to be "effective" means it must be successful in producing a desired or intended result. The standard presupposes that there is something to enforce, such as where a manufacturer or processor of a chemical substance could conceivably be in violation of TSCA.[37]

However, this proposed rule is not tied to an announced enforcement initiative or perceived noncompliance. Absent an explicit and supported finding that information regarding such mixtures is necessary to effectively enforce the statute—a need that would in most instances not arise until EPA elects to regulate a given chemical—mixtures should not be subject to reporting in this rule.

Finally, as mentioned in Section II.A of these comments, the finding of need for mixtures applies to the surface coated substances proposed for reporting at 40 C.F.R. § 704.20(a).[38] EPA's guidance states that surface treatments that impart reactivity cause the surface treated substance to be regarded

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[35] *Id.*

[36] http://www.thefreedictionary.com/enforcement.

[37] While not clearly the case here, a less stringent reading of the statute, pursuant to section 2(b) of the Act, would still places a higher level of scrutiny on the agency to demonstrate "effective enforcement" of TSCA by establishing for the record how reporting information on complex formulated mixtures is required to develop adequate data with respect to the effect of these chemical substances and mixtures on health and the environment, to regulate on chemical substances and mixtures that present an unreasonable risk of injury to health or the environment, and how this can be done in a manner that does not create unnecessary economic barriers to technological innovation. Without a risk based finding, it would be insufficient alone for this purpose to require information on mixtures simply because they contain individual chemical substances subject to reporting under this rule.

[38] 80 Fed. Reg. at 18,340-41 ("A discrete form of a reportable chemical substance differs from another form of the same reportable chemical substance in that . . . (3) 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.").

as a new substance; a new substance subject to PMN reporting is exempt from this proposed rule. However, other surface treatments will be regarded as part of a mixture that includes the substrate and the surface treating chemical. Such combinations should be treated like any other mixture under the rule and, indeed, should be exempted from reporting.

D. Activities Which Constitute Manufacturing, Processing and Use

The TSCA definitions for manufacture, process, and use raise complex and important issues that require careful consideration. The proposed rule should acknowledge and explain these different concepts.[39] For example, based on the definition of a chemical substance under TSCA and the manner in which TSCA defines a mixture as comprised of two or more discrete substances, if an activity at a facility alters the particular molecular identity of a substance, then the activity is not processing of the original substance but the use of that substance in the manufacture of another substance.

Section 3(10) of TSCA defines the various ways in which a chemical substance or mixture can be processed. It states that to process is "the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce -- (A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (B) as part of an article containing the chemical substance or mixture."[40] Because a change in form or physical state is defined as processing by EPA, these activities cannot be taken to include a change in molecular identity. Otherwise, these activities would be considered manufacturing.

Section 3(11) defines the term "processor" as "any person who processes a chemical substance or mixture."[41] According to the statutory definition, processing requires the "the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce."[42] To satisfy this definition, the chemical substance or mixture must not only undergo a preparation step but the preparation of the substance or mixture must be for "distribution in commerce."[43] Unlike the definition of manufacture, processing within the meaning of TSCA does not including preparing chemical substances or mixtures for on-site use. Although EPA has rarely opined on the distinction between processing and use with the TSCA context, the agency has had occasion to consider the distinction between processing and otherwise use within the meaning of section 313 of the Emergency Planning and Community Right-To-Know Act (EPCRA). 40 C.F.R. § 372.3 of the EPA's regulations implementing

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[39] 40 C.F.R. § 704.3.

[40] 15 U.S.C. § 2602(10).

[41] 15 U.S.C. § 2602(11).

[42] 15 U.S.C. § 2602(10).

[43] 15 U.S.C. § 2602(4) and § 2602(3), respectively.

EPCRA section 313 defines "process" in the same operational way as it is defined under TSCA.[44] In the EPCRA section 313 context, EPA has stated that:

- Storage is not a processing activity (Q. 9 EPCRA Section 313 Questions and Answers, Addendum to the Revised 1998 Version);
- The addition of an acid to wastewater to neutralize the wastewater prior to discharge is not processing (Q. 19);
- Residuals of a solvent used to produce a product distributed in commerce are not processed because the residual solvent does not function as a component of the product (Q. 22);
- Chemicals not incorporated into products distributed in commerce are not processed but are otherwise used (Q. 23 & 24); and
- A chemical used only for wastewater treatment is not considered processed because its function (to treat wastewater) is such that it is not intended to be incorporated into a product distributed in commerce (1998 Revised EPCRA Section 313 Questions and Answers (Q. 127)).

Consequently, it is appropriate and necessary for EPA to provide additional guidance to identify relevant activities as manufacturing, processing or use.

E. Exemption for Small Businesses

Section 8(a) rules must provide an exemption for small manufacturers per section 8(a)(3)(B) of TSCA.[45] EPA has defined small processors on a rule-by-rule basis using the same two standards established for small manufacturers.[46] In this case, the agency is proposing to eliminate production volume as a relevant consideration and exempt only those companies with less than four million dollars in annual sales, including those of the parent company.[47]

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[44] "Process means the preparation of a toxic chemical, after its manufacture, for distribution in commerce: (1) In the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance, or (2) As part of an article containing the toxic chemical. Process also applies to the processing of a toxic chemical contained in a mixture or trade name product." 40 C.F.R. § 372.3.

[45] 40 C.F.R. §§ 704.3, 704.5(f) (originally promulgated in *Reporting and Recordkeeping Requirements; Small Manufacturer Exemption Standards*, 49 Fed. Reg. 45,425 (Nov. 16, 1984); amended in *Comprehensive Assessment Information Rule*, 53 Fed. Reg. 51,717 (Dec. 22, 1988)).

[46] *See, e.g.*, 40 C.F.R. §§ 704.25(a)(7), 704.33(a)(4), 704.104(a)(3).

[47] 80 Fed. Reg. at 18,335-36.

NMA urges EPA to update this proposal to be ten million in total annual sales to reflect inflation. Over 20 years ago, EPA expressed concern that relying on an annual sales or "resource" parameter alone would prevent some relatively small firms from qualifying for an exemption[48] and that production volume was judged to "best approximate exposure potential."[49] NMA applauds the agency's recognition and use of these important screening tools, which are equally relevant today. However, low exposure and the capacity to respond in a timely manner are not captured here. The resource parameter of the small business exemption should be an accurate indicator of the financial resources available for compliance with reporting and recordkeeping requirements. In this respect, EPA has already recognized the need to account for inflation as part of maintaining this exemption.[50] In today's dollars, four million in total annual sales is a mere fraction of the total annual sales they represented twenty years ago.[51] Using the BLS Producer Price Index for Chemicals and Allied Products that is referenced into the agency's definition of small manufacturer or importer in 40 C.F.R. § 704.3, four million dollars in 1984 is worth slightly under ten million dollars in 2015.[52]

EPA also should implement a different, higher annual sales figure for small business processors in this rule. Because EPA has historically defined a small processor for purposes of section 8(a) on a rule-by-rule basis, NMA thinks EPA is able to consider an alternative approach. For these companies, a nanoscale chemical substance is but one component of a multi-component product and the cost of nanoscale raw materials are often higher than competing products. The need to recapture this cost, in part, in sales of the processed product can result in annual sales figures that will easily exceed the proposed small business threshold of four million dollars for an otherwise small business processing operation.

III. Appropriate Exemptions Must Be Provided for Products and Practices Long Considered to Be Low Risk by EPA under TSCA

Many researchers have explored the public's underlying perception of risk associated with nanotechnology as an enabling platform for developing or improving commercial and consumer products.[53] The Administration has recognized the societal benefits from nanotechnology and the

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[48] 49 Fed. Reg. at 45,427.

[49] *Id.*

[50] 49 Fed. Reg. at 45,428.

[51] EPA should consider whether its small entity impact analysis under the Regulatory Flexibility Act, Docket Document No. EPA-HQ-OPPT-2010-0572-0002, needs to be revised to account for inflation. *See also* 80 Fed. Reg. at 18,339-40.

[52] *See* Databases, Tables & Calculators by Subject: Producer Price Index-Commodities, Chemicals and Allied Products, *available at:* http://data.bls.gov/timeseries/WPU06?data_tool=XGtable.

[53] Steyn, W. (2009), "Potential Applications of Nanotechnology in Pavement Engineering", *Journal of Transportation Engineering*, Vol. 35, No. 10, 764-772.

importance of taking a science-based approach to risk management.[54] In the case of formulated products such as paint, paving, and other materials where nanoparticle components are embedded in a matrix and there is limited to no exposure, these benefits can and should be supported by affirming negligible health and/or environmental risks. Similarly, EPA has consistently acknowledged that polymers are a low risk class of substances. By extension, these beneficial uses need not be subject to expanded and unnecessary regulatory reporting.

NMA welcomes EPA's acceptance that there are nanoscale chemical substances that do not rise to the level of information collection and therefore are exempted under the proposed rule.[55] As explained in this section, there are additional groups of materials and activities that also should be exempt due to low risk (low exposures and/or low hazards). It is important that this rule reflects a basic understanding of low risk, low exposure scenarios involving nanoscale chemical substances and the safeguards employed. As discussed in previous sections, TSCA Section 8(a)(2) specifically directs that EPA shall not require "any reporting which is unnecessary or duplicative". It is consistent with this mandate to avoid unnecessary reporting for EPA to provide additional exemptions and clarify proposed exemptions from reporting. Indeed, NMA believes that EPA would be wise to more closely coordinate this rule with the Canadian approach in the consultation document that was issued in February 2015.[56] In addition to polymers, Canada proposed to exempt organic/organometallic pigments and dyes, naturally occurring/incidentally produced nanomaterials, and certain biological materials. The final Canadian rule that was just issued on July 25, 2015, remains consistent with that approach. It requires information collection for a list of specific substances, an approach recommended elsewhere in these comments for this proposed rule.[57] NMA believes that these classes of materials should be treated consistently across the U.S. and Canada as exempt from information collection on nanomaterials when processed. This includes substances that are designed to react to form longer chains and chemical substances embedded in a polymer matrix upon curing.

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[54] Executive Office of the President, Memorandum for the Heads of Executive Departments and Agencies: Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Nanotechnology and Nanomaterials (June 9, 2011) at 2, *available at:* http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf.

[55] 80 Fed. Reg. at 18,341 (to be codified at 40 C.F.R. § 704.20(c)).

[56] Environment Canada and Health Canada, *Proposed Approach to Address Nanoscale Forms of Substances on the Domestic Substances List (February 2015)*, *available at* http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=1D804F45-1.

[57] Canada Gazette, 2015; Part I, vol. 149, No. 30, p. 1942, July 25. Although the list includes a very small number of specified polymers of particular interest to the Canadian government, these are exceptional cases, and polymers are otherwise absent from Canada's list.

A. The Proposed Exemption for Films Should Be Clarified and Expanded as Necessary to Exempt Polymer Dispersions

With respect to the proposed exemption for substances formed as part of a film, NMA respectfully requests clarification that EPA clearly interprets this proposed exclusion to apply to polymers and polymer dispersions (emulsion polymers) used for formulate in coatings, adhesives, and sealants. NMA believes the proposed film exemption also should be clarified as applying to formulated latex paints and coatings, which may contain nano-pigments embedded in a polymer matrix, as well as pigment dispersions (colorants).[58] The manufacturing of polymer dispersions is a well-established technology which has proven to be safe for decades – long before the means to even measure particle size was commercially available to industrial quality control laboratories and before any public dialogue on nanoscale chemical substances began. Polymers, emulsion polymers, latex paints, and coatings are well-characterized, and in many cases they or their components have undergone review by the EPA. NMA believes that existing federal information and regulatory programs for these substances are meeting current needs. To require reporting on these materials would be unnecessary and duplicative.

Polymer dispersions are used as binders in most (low VOC) waterborne coating, adhesive and sealant applications, *e.g.*, paper and wood glue, carpets and flooring adhesives, non-woven fabrics, paints and coatings, paper and paperboard coatings, plasters and textile finishing agents. Polymer dispersions technology has been used successfully for more than 50 years and has contributed to a significant reduction in VOC emissions from these product categories.[59] For these products, the particles in that size range are part of a liquid matrix and represent tails in a Gaussian distribution. These products should not be drawn into characterization as nanoscale chemical substances, particularly because historically they have not been considered to be nanotechnology and they have the same chemical structure as "bulk" materials. It is true that some polymer dispersions include particles designed to be less than 100 nm. Nevertheless, these substances, even when intentionally processed, should also be exempt because they are still polymer dispersions that form larger chains, and as explained below, present a low risk of nanoparticle exposure.

Polymer dispersions are liquids consisting of water and polymer particles, manufactured by emulsion polymerization or mechanical dispersion. The particle size can widely vary between < 100 nm (0.1 µm) and 10 µm, depending on the intended use of the polymer dispersion. The polymer particles

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[58] The proposed rule exempts "Chemical substances manufactured at the nanoscale as part of a film on a surface." 80 Fed. Reg. at 18,341 (to be codified at 40 C.F.R. § 704.20(c)(1)(iii)).

[59] *See, e.g.*, South Coast Air Quality Management District 2007 Air Quality Management Plan, Appendix III – Base and Future Emissions Inventories at Tables A-1 and A-2 (showing a decrease in VOC emissions from architectural coatings and related solvent from 48.58 tons per day in 2002 to 38.79 tons per day in 2005), *available at:* http://www.aqmd.gov/home/library/clean-air-plans/air-quality-mgt-plan/2007-air-quality-management-plan; Paint Quality Institute, "Water-based vs Solvent-based", *available at:* http://www.paintquality.com/en/understanding-paint/water-based-vs-solvent-based.

are dispersed in water and cannot be isolated by simple separation techniques. On application polymer dispersions are converted to a dry film, the properties of which usually determine the performance of the final product. The water evaporates until the particles form a dense packing and the polymer particles agglomerate. The polymer particles deform and coalesce to produce a continuous and pore-free polymer-film. When set, the polymers are hard and insoluble, and are no longer discrete particles (nanoscale or otherwise). Further fusion by inter-diffusion of macromolecules from adjacent particles imparts mechanical strength. Consequently, the release of isolated nano-particles – if present at all – is very unlikely. Nano-scale particles are not added with the intention of being isolated or released. Individual particles lose their identity during the application process (film formation) and would no longer be detectable as discrete particles. The polymer particles in polymer dispersions – including those on the nano-scale – are not individually available during their lifecycle. In these systems, the polymer is manufactured in water and delivered to users as such. When applied (rolled or sprayed), the polymers react to form larger particles and ultimately coalescence to form a (polymer) film on the surface.

Exposure of humans and the environment to polymer dispersion particles cannot totally be excluded during production and processing. However, standard practice has always been to run emulsion toxicity and exposure studies using the full distribution of particle sizes. Consequently, there is an extensive set of evidence that indicates that polymer dispersions have no unusual risk or hazard. Furthermore, a release of isolated polymer particles, and consequently any human or environmental exposure to isolated particles, is highly unlikely. Therefore, no additional risks due to nano-particles in polymer dispersions are anticipated in the life cycle of polymer dispersions or in the application of waterborne products based on polymer dispersions. When the potential risk is as low for a class of chemicals as it is for polymer dispersions, it is both unnecessary and unreasonable to require reporting.

B. Polymers and Formulated Products Which Embed Nanoscale Substances into Polymer Matrices Such as Paints and Coatings Should Be Exempt

Paints, coatings, and other polymers also have a long history of safe use, as do the organic and organo-metallic pigments and dyes that have been used in these and other applications. Among other substances, Canada proposed to exclude biological materials, polymers and organic and organo-metallic pigments and dyes, unless they are intentionally manufactured to exhibit one or more nanoscale properties;[60] the final Canadian rule follows this approach by largely excluding such substances from the list of substances.[61] NMA notes that EPA has consistently, throughout the history of TSCA, considered

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[60] Environment Canada and Health Canada, *Proposed Approach to Address Nanoscale Forms of Substances on the Domestic Substances List (February 2015)* at 8-9, *available at* http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=1D804F45-1.

[61] Canada Gazette, 2015; Part I, vol. 149, No. 30, p. 1942, July 25.

polymers among the safest chemical substances as a class.[62] EPA is to be commended for acknowledging that, as a class, many polymers may be exempted from the PMN requirement with post-manufacture reporting under 40 C.F.R. § 723.250. A reference point for purposes of defining the exemption from this rule could be the polymer exemptions in the TSCA Chemical Data Reporting rule, which is another section 8 reporting rule. In general, polymers are exempt from CDR reporting unless they are regulated by TSCA rules or orders. In addition, NMA thinks that exempting processors of nanoscale chemical substances which are stably embedded into a polymer matrix is an appropriate reflection of EPA's favorable experience with many nanoscale chemical substance and polymer submissions. There is further precedent for this approach in EPA consent orders and Significant New Use Rules (SNURs) that exempt nanoscale substances from these requirements when embedded in a polymer matrix.[63]

Nanoscale chemical substances including, but not limited to, carbon nanotubes, silica, and pigments are frequently processed as part of liquid formulations and are subsequently cured and embedded into polymer matrices, and their embedded forms are recognized as low risk when reviewed by EPA.[64] Studies available in the literature support this approach. In one study, for example, two thermoplastics were amended with carbon nanotube and silica nano-fillers; these materials were then subjected to mechanical, chemical, and weathering forces to examine if nanomaterials were released. No free nano-fillers were detected and *in vivo* instillation testing done to compare the abraded matrix with and without nano-filler found no differences in hazards.[65] These results were confirmed by independent *in vivo* studies done by the Danish National Research Center for the Working Environment. In further support of the low risk nature of nanomaterials added to polymers, it was found that multi-walled carbon nanotubes which were added to elastic thermoplastic polyurethane also released no detectable free carbon nanotubes, following abrasion and weathering.[66] Again, no additional toxicity was associated with the presence of CNTs associated with released materials.

Specific to the paint and coatings industry, the milling of pigments has been occurring in the paint and coatings industry for decades.[67] Generally speaking, paint formulators buy pigments in bulk

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[62] *See, e.g.*, *Premanufacture Notification Exemptions; Exemptions for Polymers*, 49 Fed. Reg. 46,066 (Nov. 21, 1984).

[63] *See, e.g.,* section (I)(b)(1) in Consent Order for PMN P-08-0177 (exemption from consent order requirements for completely reacted or cured quantities of a carbon nanotube), *available at:* http://www.nanolawreport.com/EPA%20Premanufacture%20Notice%20Number%20P-08-0177.pdf.

[64] *Id.*

[65] W. Wohlleben *et al.* (2011), "On the Lifecycle of Nanocomposites: Comparing Released Fragments and their In-Vivo Hazards from Three Release Mechanisms and Four Nanocomposites," *Small* 7(16):2384–95.

[66] W. Wohlleben *et al.* (2013), "Elastic CNT–polyurethane nanocomposite: synthesis, performance and assessment of fragments released during use," *Nanoscale* 5(1):369–80.

[67] These pigments include, but are not limited to, crystalline silica, titanium dioxide, and carbon black.

quantity and size and mill the pigments to increase the dispersion of the pigment into the mixture. The final particle size of the pigment ranges, but often falls below 100 nm. Based on the proposed rule, the milling of pigments could be considered manufacturing or processing nanoscale chemical substances. After milling, these pigments are then added into the paint mixture under extensive engineering controls to protect workers. When the paint or coating is ultimately applied, the pigments are embedded in the polymer matrix. The low exposure to these pigments, after introduction into a paint formulation, has been well characterized. In fact, California's Office of Environmental Health Hazard Assessment (OEHHA) issued a safe use determination[68] for crystalline silica in paints under Proposition 65. Further, a consortium of European-based research centers has compared the dust released from epoxy and paints nanocomposites with conventional (*i.e.*, no nanomaterial content) products during sanding and sawing.[69] In their research, which involved rigorous sampling and analysis using scanning electron microscopy (SEM), they observed no significant differences in the particle size distributions between the two categories of products. They go on to stress that the analysis found any observed nanoscale chemical substances were enclosed or partly enclosed in the underlying matrix. Similarly, a comprehensive literature review of occupational exposure studies on nanotechnology workplaces, defined as those where nano-size materials are utilized, has affirmed very low concentrations of nanoparticulates in paint and coating application operations, with observed nanoscale chemical substances embedded in the sampled matrix.[70] Given the low exposure and low risk of these applications, EPA should exempt these substances from the reporting requirements.

C. Applications Which Result in Low or No Significant Pulmonary Exposures to Isolated Nanoscale Chemical Substances Should Be Exempt

Where the use pattern results in little or no significant pulmonary exposure, it is both appropriate and necessary for EPA to exempt such substances from reporting. In this regard, a number of reviews and regulatory decisions further support the proposition that reporting on nanoscale

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[68] *Issuance of a Safe Use Determination for Crystalline Silica in Interior Flat Latex Paint* (Dec. 26, 2003), available at: http://oehha.ca.gov/prop65/CRNR_notices/safe_use/sylicasud2.html.

[69] V. Gomez *et al.* (2014), "Comparison of dust release from epoxy and paint nanocomposites and conventional products during sanding and sawing," *Annals of Occupational Hygiene*, 58(8): 983-94. *See also* G. Hunt *et al.* (2013), "Towards a consensus view on understanding nanomaterials hazards and managing exposure; knowledge gaps and recommendations," *Materials,* 6:1090-1117; I. Koponen *et al.* (2009), "Sanding dust from nanoparticle-containing paints; physical characterization," *J Phys Conf Ser*, 151:012408; and A. Norgard *et al.* (2009), "Release of VOC's and particles during use of nanofilm spray products," *Environmental Science and Technology*, 43:7824-30.

[70] T. Kuhlbusch *et al.* (2011) "Nanoparticle exposure at nanotechnology workplaces: A review," *Particle and Fibre Toxicology*, 8:22. *See also* M. Vorbau, Hillermann L., Stinz M. (2009) "Method for characterization of abrasion induced nanoparticle release into air from surface coatings," *Journal of Aerosol Science*, 40(3):209-17; and L. Hsu, Chein H., (2007) "Evaluation of nanoparticle emissions for TiO2 nanopowder coatings materials," *Journal of Nanoparticle Research*, 9(1):157-63.

substances that are incorporated into polymer coatings should not be considered a high priority for this TSCA 8(a) rule because there is low to no concern for exposures to nanoscale chemical substances incorporated into polymeric coatings. As this section explains, other materials are also low exposure and should be exempt.

A recent literature review identified 54 studies where releases of nanoscale chemical substances from formulated products were evaluated.[71] The investigators categorized the finding in four groupings: the first where releases were in the form of large particles of the product matrix itself (most prevalent), second where the nanomaterial was partially embedded in the matrix (second most prevalent), and (quite rarely) the third and fourth categories which represent various forms of the nanomaterial itself. The authors stress that the potential for exposure (or lack thereof) is a valid consideration in a risk assessment. More importantly, the review incorporated studies that addressed releases derived from a wide variety of industrial processes that reflect likely end uses in commerce including machining, weathering, UV exposure, aqueous impact, repeated washing, dermal contact, sweating, medical applications, collisions, and incineration. The review concluded that the release of dissociated nanoscale chemical substances is rare, and most materials released are either matrix material such as polymer or matrix material with embedded nanoscale chemical substances.

This lack of significant exposures to isolated nanoscale chemical substances further decreases the concern for reporting on nanoscale substances that are incorporated into polymer coatings as a high priority for the TSCA 8(a) rule. A number of the more recent studies cited indicated that, using more advanced detection techniques and improved protocols than many early studies cited, stronger conclusions could be drawn. For example, Wohlleben *et al.* tested a thermoplastic polyurethane containing CNTs for release due to use, machining, and outdoor weathering.[72] The release of free CNTs was not detected under any condition, and (as noted earlier in this document), a preliminary risk assessment indicated that the material is safe in workplace and consumer settings. Similar risk assessment work done by Wohlleben *et al.* in 2011 produced a similar lack of concern for CNTs and silica which were incorporated into both plastics and cement.

In further support of eliminating reporting on nanoscale substances incorporated into polymers, at least two regulatory bodies have indicated low to no concern for such nanoscale chemical substances based on low exposures. As previously discussed, painting related exposure data developed by the National Paint and Coatings Association (NPCA, now the American Coatings Association or ACA) were

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[71] Frogett S., Clancy S., Boverhof D., Canady R. (2014), "A review and perspective of existing research on the release of nanomaterials from solid nanocomposites", *Particle and Fibre Toxicology*, 11:17. *See also* Kaegi R., Ulrich A., Sinnet B., Vonbank R., Wichser A., Zueeg S., Simmler H., Brunner S., Vonmont H., Burkhardt M., Boller M., (2008) "Synthetic TiO_2 nanoparticle emission from exterior facades in an aquatic environment", *Environmental Pollution,* 156:233-239.

[72] W. Wohlleben *et al.* (2013), "Elastic CNT–polyurethane nanocomposite: synthesis, performance and assessment of fragments released during use," *Nanoscale* 5(1):369–80.

submitted to the California Office of Environmental Health Hazard Assessment (OEHHA) as part of a "Safe Use Determination" (SUD) for crystalline silica administered by that agency under its "Proposition 65" regulations. In its report affirming safe use in small particle (respirable) size crystalline silica in latex paint formulations, OEHHA noted that the lack of respirable crystalline silica detection in the collected air samples under field testing conditions "reasonably approximated normal spraying activity" and on whole likely resulted in overestimates of exposure levels from the average use of interior flat latex paint. Similar categorical assertions of low or no exposure conditions to nanoscale chemical substances embedded in a matrix have been issued in the International Agency for Research on Cancer (IARC) Monographs. Specifically, in the IARC Monograph on carbon black, a widely used material in formulated products, IARC notes "[e]xposure to carbon black does not occur during the use of products in which carbon black is bound to other materials, such as rubber, printing ink or paint."[73] Such conclusions track the current EPA risk management approach under TSCA, which places lower concern on nanoscale chemical substances that are incorporated into hard polymer matrices: the assumption is that any exposures resulting from such articles are of low risk.

In addition to the nanoscale chemical substances noted above, nanocrystalline cellulose (NCC), is a naturally-sourced, primary structural building block of trees and other plants, at least one form of which has been assessed as low risk by Environment Canada, and should therefore not be considered for TSCA section 8(a) reporting at this time.[74] NCC is that portion of the cellulose polymer chain in plants that is derived from glucose units and which is condensed into rigid straight chains due to hydrogen bonding, thus giving rise to areas of high crystallinity in the plant's cellulosic structure. These crystalline sections are simply extracted from the surrounding material using acid hydrolysis. This high-value nanomaterial can be used as a dispersion agent in fluids, to manufacture films, and enhanced strength for applications such as packaging and coatings.

The incorporation of NCC into liquid matrices results in low or no exposure to the nanoscale form of the chemical substance, *per se*. NCC safety data for both ecotoxicity and human health endpoints indicate that it is nontoxic.[75] Once released, it is biodegradable. As a result, in 2012 a sulfuric acid-derived NCC was granted unrestricted manufacture and importation in Canada following Health Canada and Environment Canada reviews; it was the first nanomaterial to be added to the Canadian DSL, without restrictions.[76] NCC is stable in water and hence can be spray-applied to surfaces. While

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[73] IARC Monographs Volume 93, *Carbon Black*, at 185, http://monographs.iarc.fr/ENG/Monographs/vol93/mono93-6.pdf.

[74] B. O'Conner *et al.* (2014), "Commercialization of Cellulose Nanocrystal (NCC) Production: A business case focusing on the importance of proactive EHS management," *Nanotechnology Environmental Health and Safety*, 10: 225-246; T. Kovacs *et al.* (2010), "An ecotoxicological characterization of nanocrystalline cellulose," *Nanotoxicology*, 4(3):255-270.

[75] *Id.*

[76] Canada Gazette, 2012; Part II, vol. 146, No. 24, p.2457, Nov. 21, 2012.

release of NCC is unlikely prior to spraying in a liquid form, there was found to be very low levels of exposures during spray application: the overall measured particulate level in the workplace was 50 ug/m^3 with no presence of particles in the nanoscale; average diameter was approximately 17 um, which is above the respirable size range. Further, the TLV-TWA for cellulose is 10 mg/m^3,[77] which is 200 times higher than the measured ambient concentrations of NCC. Despite this, and data from a subacute inhalation study, the risks of long term exposure to workers is not yet fully characterized. However, standard PPE equipment is adequately protective, considering the larger size range of the NCC particle, and application information demonstrate that this chemical substance is considered to be of low risk with low likelihood of exposure when embedded into polymer matrices.

Another type of nanocellulose, nanofibrillated cellulose (NFC), has a risk profile that is similar to that of NCC and thus likewise should not be considered for TSCA 8(a) reporting at this time. NFC is a highly crystalline and rigid material composed of nano-sized cellulose fibrils with a high aspect ratio (length to width ratio). NFC is produced mechanically by disintegrating wood pulp. A high shear zone is formed during the disintegration to delaminate multilayer cell walls of wood fibers and separate fibril while minimizing cutting and entangling. The typical lateral dimensions of NFC are 5-20 nanometers and longitudinal dimension ranges from 500-2,000 nanometers. NFC is often supplied in the form of a slurry and not as loose dry fibers.

Similarly to NCC, NFC that is incorporated into liquid matrices or polymers will result in low or no exposure to the nanoscale form of the chemical substance. The available toxicity data to date suggest no evidence of significant environmental or health effects, although inhalation of high doses may induce pulmonary inflammation.[78] As with NCC, the risks of long term exposure to workers is not yet fully characterized; however, with the use of appropriate PPE, the inhalation risk for the worker is mitigated.

As is clear from the preceding discussion, it would be "unnecessary or duplicative" to require reporting on substances that have a history of safe use, that do not result in significant pulmonary exposure, or that have been recognized as low risk by EPA and other regulatory bodies. Consistent with the requirement under section 8(a)(2) to abstain from such requirements, exemptions should be provided for these substances.

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[77] Per the American Conference of Governmental Industrial Hygienists and the National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit.

[78] *See* L. Alexandrescu *et al.* (2013), "Cytotoxicity tests of cellulose nanofibril-based structures," *Cellulose* 20:1765–75; K.-S. Hannukainen *et al.* (2012), "Genotoxicity of nanofibrillated cellulose in vitro as measured by enzyme comet assay," *Toxicology Letters* 211:S1–S174; K. Hua *et al.* (2014), "Translational study between structure and biological response of nanocellulose from wood and green algae," *RSC Adv* 4:2892–2903.

IV. The Proposed Elements for Reporting Discrete Forms Are Arbitrary and Capricious Because They Cannot Be Reliably Measured[79]

The proposed rule is based on reporting those nanoscale chemical substances considered "discrete forms" of a "reportable chemical substance".[80] To be an RCS, EPA is proposing that a chemical substance must be in the size range specified and exhibit a unique or novel property.[81] According to the proposed rule, differences in at least seven physical-chemical properties can lead to reporting a nanomaterial as a "discrete form" of an RCS: (1) mean particle size; (2) zeta potential; (3) specific surface area; (4) dispersion stability; (5) surface reactivity; (6) morphology; and (7) presence of coatings of a different chemical substance or mixture.[82] Beyond these variations in properties that trigger reporting under Section 8(a), other unidentified "unique and novel characteristics or properties, because of particle size" may trigger reporting of an RCS.[83] NMA believes that the vagueness of this terminology will inevitably sweep unintended substances into the rule or, perhaps more problematically, lead to noncompliance.

NMA is concerned that the proposed rule effectively compels companies to conduct tests on these or other physical-chemical properties to determine whether they must report, many of which are not required or commonly performed. In the context of section 8(a), which limits reporting to information "known to the person making the report or insofar as reasonably ascertainable,"[84] this is entirely inappropriate. EPA can require testing under section 4 of TSCA, but only after making the requisite risk-based finding. Further, most of these properties are not accompanied by test methods that have been identified and/or validated in a regulatory context, leaving manufacturers and processors to simply guess as to what will (or will not) constitute compliance under the rule. Therefore, the proposed properties that trigger reporting are arbitrary, difficult to measure, and unnecessarily

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[79] Pursuant to section 19(c)(1) of TSCA, a final section 8(a) rule is judicially reviewed under the arbitrary and capricious standard. *See also* 5 U.S.C. § 706. Aspects of EPA's proposal that should be reconsidered in light of this standard of review are discussed in this section and throughout these comments.

[80] 80 Fed. Reg. at 18,334.

[81] As noted in the definitions of nanoscale and nanotechnology developed by ISO with respect to the size range from approximately 1 nm to 100 nm, properties that are not extrapolations from a larger size will typically, but not exclusively, be exhibited in this size range. *See* ISO/TS 27687:2008, definition 2.1; ISO/TS80004-1:2010, definition 2.3. For such properties the size limits are considered approximate. After due technical deliberation, ISO specifies that the defining properties of interest are size-and structure-dependent, and distinct from those associated with individual atoms or molecules or with bulk materials. NMA hopes that the Agency will take these clarifying concepts under consideration.

[82] 80 Fed. Reg. at 18,340-41 (to be codified at 40 C.F.R. § 704.20(a)).

[83] 80 Fed. Reg. at 18,341 (to be codified at 40 C.F.R. § 704.20(a)).

[84] 15 U.S.C. § 2607(a)(2).

burdensome.[85] The resulting data may be too uncertain and unreliable to be used as the basis for regulatory decision making.

Consider, for example, the measurement of zeta potential.[86] This is a value generated in an instrument that uses a variety of models inherent to the instrument to measure the electric potential at the boundary between the surface charge of the particle and the thin layers of ions of opposite charge that are attracted from the medium to the surface charge of the particle. It is considered to be predictive of colloidal stability. Instruments measure the velocity of particles in an electric field (electrophoretic mobility) and then use a mathematical model to predict the zeta potential. Various instruments integrate different models, which largely are based on particles with spherical shapes. Factors that greatly affect the calculated zeta potential include the pH of the solution, the ionic strength of the medium, the ionic composition of the medium, the instrument and model used in the estimation, the size and shape of the nanoparticle, and the coating on the nanoparticle. For certain nanoparticles, the measurement of zeta potential has no rigorous meaning, as it is affected in addition by properties of the coating including layer thickness, layer permeability, and frictional drag.[87] There are no accepted regulatory guidelines, or other clear standard methods, that standardize testing approaches for zeta potential across particles, coatings, instruments, and test conditions.

The other physicochemical properties given regulatory significance in the proposed rule have similar or greater difficulty in terms of their measurement using standardized protocols and raise significant questions for how responsible parties should approach them. For example, how should surface reactivity be measured, and should this occur in biological fluids or in environmental matrices or in some controlled media that is representative of one or more of these milieu? With regard to morphology, how should responsible parties distinguish different morphologies for purposes of

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[85] As our comments in this section and elsewhere demonstrate, the vagueness of multiple aspects of the proposal fails to meet requirement under TSCA that section 8(a) rules not be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. *See* 15 U.S.C. § 2618(c)(1)(B); 5 U.S.C. § 706. Moreover, the proposed rule's lack of direction implicates due process concerns. *See, e.g.*, *FCC v. Fox Television Stations, Inc.*, 132 S.Ct. 2307, 2317 (2012) ("A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required. . . .This requirement of clarity in regulation is essential to the protections provided by the Due Process Clause of the Fifth Amendment. It requires the invalidation of laws that are impermissibly vague. . . . Even when speech is not at issue, the void for vagueness doctrine addresses at least two connected but discrete due process concerns: first, that regulated parties should know what is required of them so they may act accordingly; second, precision and guidance are necessary so that those enforcing the law do not act in an arbitrary or discriminatory way.").

[86] R. Hunter (1981), "Zeta potential in colloid science: principles and applications, Academic Press, New York; Louie *et al.* (2012) "Parameter identifiability in application of soft particle electrokinetic theory to determine polymer and polyelectrolyte coating thickness of colloids," *Langmuir*, 28:10334-47.

[87] Hotze, *et al.* (2014), "Nanoparticle core properties affect attachment of macromolecule-coated nanoparticles to silica surfaces," *Env. Chemistry*, 11:257-67.

reporting (*e.g.*, the fibers, rods, and needles listed in the proposal)? EPA must provide significantly more direction on this critical issue.

Even if measurable, justifications for why these seven properties are the necessary and sufficient properties to trigger reporting are not contained in the EPA preamble of this proposed rule. Further, other authorities have selected different physicochemical properties of importance for characterizing nanoscale chemical substances in a regulatory context. The Organization for Economic Cooperation and Development (OECD), for example, considered a broader list of physical-chemical properties as important when developing characterization information on commercial nanoscale chemical substances which it subjected to testing as part of the OECD Sponsorship Programme: structural formula/molecular structure; composition (including impurities and additives); basic morphology; known catalytic activity; agglomeration/aggregation state; water solubility/dispersability; crystalline phase; dustiness; crystallite size; particle size distribution (dry and in relevant media); specific surface area; zeta potential; surface chemistry; photocatalytic activity; pore density; porosity; octanol-water partition coefficient (where relevant); redox potential; radical formation potential; flammability; explosivity; and incompatibility.[88] The OECD has not yet identified a subset of these characteristics that would be critical to characterizing nanoscale chemical substances; it also has not yet identified the best methods to determine these characteristics.[89]

Beyond the problematic measurement of the selected properties themselves, the concept of "unique and novel properties or characteristics" created by these properties creates further problems. For example, a change in dispersion stability imparted by a change in particle size may not reach seven standard deviations in magnitude (assuming dispersion stability can be measured with such precision). However, such a change in dispersion stability might create unique properties. EPA must clarify how these concepts are intended to fit together. An overemphasis on unique or novel properties could cause all waterborne polymers, latex paints, and waterborne coatings to require individual reporting.

Similar issues with standardization and relevance of physicochemical properties arise in the context of the exemptions in the proposed rule. The proposed rule would exempt "[c]hemical substances which dissociate completely in water to form ions that are smaller than 1 nanometer."[90] Again, under what exact conditions – test medium components, duration, etc. – would such a

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[88] OECD Environment, Health and Safety Publications Series on the Safety of Manufactured Nanomaterials (No. 27), List of Manufactured Nanomaterials and List of Endpoints for Phase One of the Sponsorship Programme for the Testing of Manufactured Nanomaterials: Revision (Dec. 1, 2010) at 14-16, *available at:* http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2010)46&doclanguage=en.

[89] *See also* TR 13014, Nanotechnologies — Guidance on physicochemical characterization for manufactured nano-objects submitted for toxicological testing (2011).

[90] 80 Fed. Reg. at 18,341 (to be codified at 40 C.F.R. § 704.20(c)(1)(vii)).

determination be made? Tantra *et al.* note that no universal method exists for the measurement of dissociation and that standardization is needed in terms of several factors, including the following: pH, presence of dissolved ligands, surface tension, particle size, mass of particles and aggregation/agglomeration state, hydrodynamic conditions, and presence of salts.[91] The OECD is working on a dissociation test guideline, but it is not yet complete.

Size and surface area also lack standardized measurement protocols. However, information on these two properties may be more readily available than other properties discussed in the proposed rule. It may make more sense, if these data could be characterized as existing data concerning the environmental and health effects of a RCS, to limit physical chemical data requests to these properties. This is supported by an expert study in 2012 which found that measurement methods are available for these two parameters, although certain types of materials are challenging and overall dedicated guidance documents will have to be provided for specific materials and sectors.[92] Associating reporting with these two properties would also be beneficial for companies that market in both the US and the EU, although particle size is best based on weight percent. It is the task for industry to evaluate its individual commercial chemicals, but it is the role of the U.S. government to provide standardized guidance and test guidelines to enable such testing so that the data generated are acceptable in a regulatory context. It may make sense for the EPA (and its Office of Research and Development, along with other U.S. government agencies like NIST) to cooperate with the European Joint Research Centre (JRC) and/or OECD to complete the needed guidance on these two more broadly tested physicochemical parameters for nanomaterial reporting.

If physicochemical characteristics are to be used to distinguish nanomaterials that are subject to 8(a) reporting (which is contrary to how EPA has historically identified chemicals for reporting, as noted earlier in Section II.A) then NMA supports a workshop, or series of workshops, to further explore the appropriate physicochemical parameters and protocols that would be suitable for use in 8(a) reporting. These workshops must, of course, be held prior to reporting requirements being finalized.

Canada has also directly defined the term “nanomaterial” for regulatory reporting of nanoscale chemical substances, and selected a single specific parameter to identify such materials for proposed reporting (if they are already in commerce in Canada): materials that are manufactured at or within the

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[91] R. Tantra, *et al.* (2015), “Suitability of analytical methods to measure the solubility for the purpose of nanoregulation,” *Nanotoxicology,* online.

[92] T. Linsinger, *et al.* (2012), “Requirements on measurements for the implementation of the European Commission definition of the term ‘nanomaterial’,” *available at:* http://publications.jrc.ec.europa.eu/repository/handle/JRC73260.

nanoscale (1-100 nm, inclusive), or have internal or external surface structures at the nanoscale.[93] In the proposed rule Canada also has proposed a workshop, in part, to discuss these definitional issues.

Even if the seven physicochemical properties identified by EPA were appropriate for distinguishing RCSs under section 8(a), the methods for determining these properties would have to be available for manufacturers and processors to comply with the reporting requirements. Even for the limited parameters of size and surface area that are part of the EU definition of what constitutes a nanomaterial, the European Commission's JRC determined that none of the currently available methods can be used to measure these parameters for all potential nanoscale chemical substances.[94] The JRC further concluded that dedicated guidance documents will have to be provided for specific nanoscale chemical substances that specify relevant particle size measurement methods and test conditions; it is likely that several methods will be needed for sufficient assessments. Beyond these more fundamental measurements which are still lacking in appropriate protocols, the EPA proposal calls out additional measurement parameters which will likely require even more standardization. For example, under what conditions (*in vivo*, *in vitro*, in which milieus, for what ranges of milieus properties) should surface reactivity be measured, and what specific units of reactivity should be reported? Similar questions exist for dispersion stability and zeta potential. EPA provided limited guidance in this area in the preamble, noting that all physicochemical parameters could be evaluated in the same medium. For morphology, how would manufacturers and processors distinguish between the different morphologies identified in the proposed regulatory text: what definitions would distinguish for example a rod from an ellipsoid, needle, wire, and/or fiber as these shapes could be considered on a continuum? For all of the seven properties identified by EPA, which specific protocols should be used to measure the properties such that they would be acceptable in a regulatory context?

Beyond the individual seven parameters, EPA also identifies how much variance in the parameters is sufficient to consider the material a new discrete form, thus requiring new reporting. It notes that a measured change in zeta potential, specific surface area, dispersion stability or surface reactivity that is greater than seven times the standard deviation of the "measured value" triggers reporting.[95] The scientific basis for the use of seven standard deviations as a cutoff for reporting is not presented in the proposed rule. Therefore, it should either be justified or supplanted with a justified cut-off. The use of standard deviation as a measure of confidence in statistical conclusions is generally useful. It is assumed that the measured value is the mean of the values measured, although this is not

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[93] Environment Canada and Health Canada, *Proposed Approach to Address Nanoscale Forms of Substances on the Domestic Substances List (February 2015)*, *available at* http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=1D804F45-1. *See also* Canada Gazette, 2015; Part I, vol. 149, No. 30, p. 1942, July 25.

[94] T. Linsinger *et al.* (2012), "Requirements on measurements for the implementation of the European Commission definition of the term 'nanomaterial'," available at: http://publications.jrc.ec.europa.eu/repository/handle/JRC73260.

[95] 80 Fed. Reg. at 18,341 (to be codified at 40 C.F.R. §§ 704.20(a)(1)(ii), 704.20(a)(1)(iii)).

stated. Also, is this cut-off of seven times the standard deviation for physicochemical values assumed to be based on a normal distribution? The preamble to the proposed rule also notes that changes in particle size of ten percent or greater would be a trigger for reporting.[96] As NMA understands, this is an error in the proposal because it conflicts with the proposed rule language; in any case, EPA provides no justification for why ten percent should constitute sufficient variance to trigger reporting.

More generally, because EPA does not have the authority under section 8(a) to require testing, as acknowledged in the proposal, EPA cannot go forward with these properties as a basis for reporting because they are not routinely tested for in the context of TSCA for traditional chemicals that are notified under Section 5 of TSCA. These properties are also not sufficiently defined within the context of nanoscale chemical substances, there are not appropriate protocols available to test for these properties, and the degree of variation between measurements of individual properties has not been justified. As previously noted, it is therefore difficult at best for companies to conduct testing to determine whether they are subject to the rule in the first place. It is misleading to the public for EPA to characterize information upon which compliance with this proposal is predicated, and for which EPA can compel by law for applicable substances under section 4, as a "voluntary" submission under section 8(a).

V. A Pre-Commercialization Reporting Requirement for Existing Chemicals is not Reasonable or Necessary

The proposed reports and 135 day waiting period with no sunset, for an entire class of emerging technology, would establish a notification program for existing chemicals that takes longer, and is more burdensome, than for new chemical substances under section 5. NMA does not agree with EPA's determination that this aspect of the proposal is consistent with existing Administration policy,[97] and urges its withdrawal entirely. NMA has reviewed EPA's existing guideline for reporting nanoscale substances to the TSCA Inventory,[98] and two policy statements issued by the White House Office of Science and Technology Policy. These policy statements have concluded that the U.S. regulatory framework as it exists today is sufficient to regulate nanomaterials.[99]

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[96] 80 Fed. Reg. at 18,334.

[97] 80 Fed. Reg. at 18,330.

[98] U.S. EPA, TSCA Inventory Status of Nanoscale Substances – General Approach (Jan. 23, 2008) at 5, *available at:* http://www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf.

[99] Executive Office of the President, Memorandum for the Heads of Executive Departments and Agencies: Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Nanotechnology and Nanomaterials (June 9, 2011), *available at:* http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf. *See also* Executive Office of the President, Memorandum for the Heads of Executive Departments and Agencies: Principles for Regulation and Oversight of Emerging Technologies (March 11, 2011). Moreover, in a White Paper issued in 2006, the American Bar Association (ABA) Section on Energy, Environment and Resources (SEER) concluded that EPA's existing programs

Previous section 8(a) rules have not used the form EPA is proposing to use. In past section 8(a) rules, EPA has required ongoing reporting in very limited circumstances. In one case, EPA promulgated a section 8(a) rule for one specific use of hexachloronorbornadiene (HEX-BCH, CASRN 3389-71-7) concurrently with a SNUR on all other uses.[100] This rule requires companies to report within 30 days after making the management decision to manufacture, import, or process the substance for the single use that was not subject to the SNUR.[101] Another example is the section 8(a) rule EPA promulgated for anthraquinone, which applied to manufacturers only.[102] This rule was promulgated concurrently with a section 4 test rule. The rule required annual reporting under section 8(a) so that EPA could determine if total U.S. manufacturing exceeded 3 million lbs., a threshold that EPA had determined raised the risk level and called for a second tier of section 4 testing.[103] In each of these cases, the ongoing 8(a) reporting requirement was narrowly targeted to a specific chemical with established hazards and was necessary to implement other ongoing management measures implemented by EPA under other sections of TSCA. EPA has made no such finding for nanoscale chemical substances.

Congress could not have envisioned that section 8(a) would be used to subject existing chemicals to on-going reporting equivalent to a PMN submission under section 5, with an even longer review period than it deemed appropriate for new substances. The amount of information EPA is requiring, and the proposed form, create the expectation that this reporting obligation is a form of premanufacture notification. Because a compliance requirement is established, this notification operates as a new form of regulation upon which lawful commercialization is conditioned. It will therefore serve to operate as a restriction and a potential barrier to commerce. As a result, several associated and disproportionate burdens are likely to arise. For example, the acrylic polymers made via emulsion polymerization, waterborne dispersions of polyurethane, and alkyd polymers are often cleared for TSCA under the 1995 Polymer Exemption. If this 135 day pre-notice requirement is finalized, the advantage of the polymer exemption is eliminated for these polymers. For this reason, they should be exempt from this requirement. Additionally, this degree of reporting would impede imports by creating a barrier in trade due to TSCA if companies have to file a notice and wait 135 days to import certain forms of a chemical substance but not others. Competing existing chemical products would not be subject to the same requirement.

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can be used to regulate nanomaterials. *Regulation of Nanoscale Materials under the Toxic Substances Control Act*, American Bar Association Section of Environment, Energy, and Resources (June 2006) at 11.

[100] *Hexachloronorbornadiene; Submission of Notice of Manufacture, Import, or Processing and Determination of Significant New Use*, 50 Fed. Reg. 47,534 (Nov. 19, 1985).

[101] 40 C.F.R. § 704.102(e)(2).

[102] *Anthraquinone; Final Reporting and Recordkeeping Requirements and Test Rule*, 52 Fed. Reg. 21,018 (June 4, 1987).

[103] 52 Fed. Reg. at 21,022.

The corresponding benefits of having this information to making future regulatory decisions under other sections of TSCA seem small in comparison to the significant commercial uncertainty and resource burden this proposal would create. It is not clear why the agency believes it has to take additional reporting steps at this stage. A program of this magnitude would need to be supported by risk-based findings in order to be reasonable, yet the agency states numerous times that no risk-based findings are established by the proposed rule.[104] It seems duplicative to require companies to report to EPA over and over for the same chemical substances. It is simply not clear that this approach would yield any significant new information on a routine basis.

NMA's first preference is that an ongoing reporting requirement be dropped from further consideration entirely. However, if this reporting approach is maintained against NMA's recommendation, EPA must clarify that manufacturing or processing can begin as soon as a company is notified by EPA or once the 135 day period has elapsed, whichever is earlier. Since EPA is under no mandatory time limit to review the data, it is critical to have certainty on when commercialization can begin.

VI. Other Areas for Which Clarification is Respectfully Requested

A. Solids at 25 °C

The focus on materials which are solids at 25 °C makes sense in that most manufactured nanoscale chemical substances under TSCA present as solids, with limited to no dissolution potential. Regarding the definition of a solid, many materials perceived as solids are actually very viscous (thick) liquids. The most notable one is glass, but polymers could also be considered viscous liquids rather than solids. The ambiguity may make some polymer manufacturers choose to not report and while others will. With respect to dissolution potential, EPA should indicate how dissociation is measured (duration, conditions, etc.), and indicate how dissociation is interpreted relative to silver and other elements commonly associated with nanoscale chemical substances. If a material is soluble immediately, then it likely behaves more like its conventional equivalent chemical such that there are no unusual attributes.

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[104] *See, e.g.,* 80 Fed. Reg. at 18,331 ("This proposed rule and the discussion of the potential risks do not conclude and are not intended to conclude that nanoscale materials as a class, or specific uses of nanoscale materials, necessarily give rise to or are likely to cause harm to people or the environment."); 80 Fed. Reg. at 18,331 ("This proposed rule is not intended to indicate restrictions or conclusions about the risks of chemical substances manufactured at the nanoscale in general.") (supporting that the rule is not intended to establish any risk-based findings); and 80 Fed. Reg. at 18,332 ("Consistent with the June 9, 2011 memorandum on the Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials, this proposal is not making any finding about the potential risks of nanoscale materials in general or any specific nanoscale materials.").

B. Trace Amount

The proposed definition of RCS "does not include a chemical substance that has only trace amounts of primary particles, aggregates, or agglomerates in the size range of 1-100 nm, such that the chemical substances does not exhibit the unique or novel characteristics or properties because of particle size."[105] Elsewhere the agency noted that it was interested in receiving comments on whether reporting under its proposed approach "would be focused on those nanoscale forms with potential for significantly different physical or chemical characteristics or properties."[106]

The exclusion of trace amounts seems to be designed to parallel the exemption for impurities and unintentionally manufactured materials, which separately applies based on the incorporation of the standard exemptions for impurities and byproducts in 40 C.F.R. § 704.5(b) and (c).[107] Indeed, section 8(a) reporting is limited to chemical substances as defined by TSCA that are intentionally manufactured. NMA suggests that it may be preferable to define a numeric threshold that determines whether a nanoscale component is present in trace amounts. A trace amount cutoff is desirable because the current language is inadequate for determining whether the trace amounts are relevant when (1) the properties at issue are not well understood; (2) the sensitivity of testing is insufficient to adequately detect or characterize small amounts; and (3) it is not technically feasible to test these properties over a range of concentrations to determine at which point "unique and novel" properties are no longer exhibited.

C. Use of the Preliminary Assessment Information Rule (PAIR) Form

The PAIR form was expressly designed to provide the information authorized by section 8(a).[108] In contrast, the voluntary Nanoscale Materials Stewardship Program (NMSP) form contains areas of information that EPA is not authorized by section 8(a) to require. Inclusion of these items, even with the stipulation that the information only needs to be provided on a voluntary basis, circumvents the statute. It is "unnecessary" under section 8(a) for EPA to require reporting using the section 5 reporting form. The proposed form is almost indistinguishable from EPA's mandatory premanufacture notification form under section 5. The form is long and many processors are unfamiliar with it, and there is already a section 8(a) form established for this purpose. This is not a section 5 rule and therefore the use of the PMN form is not appropriate. The use of a modified PMN form for the voluntary NMSP is clearly distinguishable in that this is a mandatory program that must follow the instructions provided by

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[105] 80 Fed. Reg. at 18,341 (to be codified at 40 C.F.R. § 704.20(a)).

[106] 80 Fed. Reg. at 18,338.

[107] 80 Fed. Reg. at 18,341 (to be codified at 40 C.F.R. § 704.20(c)(3)).

[108] EPA Form 7710-35.

statute. Because the information on the proposed form goes beyond section 8 of TSCA, the existing section 8 reporting form should be used instead.

D. Clarifications Related to Reliance on Existing Information

In this proposal, EPA references a number of databases which are available in some form to the public, purportedly as representative of the potential universe of chemical substances that could be subject to reporting.[109] Reliance on these resources as a metric for gauging the success of this information collection rule would be highly troublesome, and EPA should clarify that it is not the agency's intention to do so.[110] NMA's concern stems from the fact that there is no objective basis to confirm whether the listed substances are intentionally manufactured, imported, and processed in the United States for non-exempt commercial purposes at the nanoscale or exhibit specific properties associated with the nanoscale. Indeed, as EPA stated in the Interim Report on the NMSP, "many of the products included in [these databases] may be excluded from or exempted under TSCA regulation (cosmetics, pesticides, R&D chemicals, etc.)."[111] NMA further questions their inclusion as part of this rulemaking on the basis that there is no rationale correlation or examples offered to demonstrate that these substances meet the proposed rule's RCS criteria.

Some of these databases are expressly designed to capture companies and substances that are at the exempt R&D stage, or are not doing business in the United States, or are simply conceptual at this time. Therefore, to present these databases as authoritative or current compilations of RCSs in the United States is misleading. Their continued use as part of this rulemaking could drive the agency or the public to mistakenly conclude that substantial non-reporting has occurred if many of them go unreported. Fundamental fairness dictates that these references either be withdrawn or their limited relevance, when compared to the actual reports submitted by U.S. manufacturing and processing operations, should be acknowledged.

In addition, it is notable that many of the scientific references cited in the proposal date from 2006 to 2009. The state of the science on nanoscale materials has advanced since that time. EPA has reviewed over 170 chemical substances through the new chemicals program under TSCA[112] and the agency has obtained information on nanoscale chemical substances through a variety of means.

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[109] Docket Document No. EPA-HQ-OPPT-2010-0572-0020, Docket Document No. EPA-HQ-OPPT-2010-0572-0021, Docket Document No. EPA-HQ-OPPT-2010-0572-0025, Docket Document No. EPA-HQ-OPPT-2010-0572-0023, Docket Document No. EPA-HQ-OPPT-2010-0572-0022, Docket Document No. EPA-HQ-OPPT-2010-0572-0059.

[110] U.S. EPA, Nanoscale Materials Stewardship Program Interim Report (January 2009) at 14-17, *available at*: http://www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf.

[111] *Id.* at 14.

[112] 80 Fed. Reg. at 18,335-36.

Although EPA issued an Interim Report on the NMSP, a final report was never issued and the proposal does not describe the information received by EPA through the NMSP nor does the proposal exempt information that is duplicative. Instead, the proposal merely exempts companies who submitted some or all of the required information for a reportable chemical substance under the NMSP from resubmitting that same information. This approach is unnecessary and likely to be duplicative for processors, whose reportable chemical substances may have already been the subject of voluntary reports to EPA under the NMSP by the manufacturer.

EPA also participates in the OECD WPMN Sponsorship Programme, which is designed to test 13 manufactured nanomaterials. EPA could review this program to better identify specific chemical substances and describe information needs in this proposal. As with the NMSP, and the scientific publications upon which the proposed rule relies, EPA should publicly identify the information made available through the Programme and exempt this information from reporting. More generally, the PMN program has provided EPA with significant information on chemistries, uses, and exposures. EPA may be able to rely on these reviews to further tailor this rule to exempt certain substances and activities from reporting. It would be beneficial for advancing this rulemaking for EPA to clarify ways in which it is making reasonable use of the information it already has on hand.

E. Undefined Terms

If used in the final rule to identify substances subject to reporting based on morphology, the terms sphere, rod, ellipsoid, cylinder, needle, wire, fiber, cage, hollow shell, tree, flower, ring, torus, cone, and sheet must be defined.[113] EPA must clarify the basis for its understanding that these are commercially relevant features. It is not clear whether these are commercially available forms of nanoscale chemical substances or research concepts.

F. Reconciling the Proposed Regulatory Text with the Preamble

Areas in which the proposed rule and preamble must be reconciled are as follows:

- The preamble notes a change in mean particle size of $\geq$10% and changes greater than 7 standard deviations triggers RCS reporting. The language of the proposed rule is controlling and needs to include these criteria if they become part of the final rule.
- The definition proposed for a discrete form needs to reflect the preamble discussion that a change in both size and property is required, if this becomes part of the final rule.
- The preamble states that EPA's intent is for covered substances to include chemical substances in the size range of 1 – 100 nm in 1, 2, or 3 dimensions. The definition of reportable substance should be clear on whether all or one dimension must be nanoscale, if this becomes part of the final rule.

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[113] 80 Fed. Reg. at 18,341 (to be codified at 40 C.F.R. §704.20(a)).

VII. Considerations for a Workable Program

Nanotechnology has a critical role in the U.S. as a platform for continuous product improvement, with many desirable and essential uses in industrial applications subject to TSCA. The Obama Administration has been a champion of nanotechnology, recognizing its societal benefits and the importance of taking a science-based approach to risk management.[114] NMA respectfully requests that the Administration and EPA remain clearly committed to working within the existing TSCA framework.

Currently, the proposed rule places too great a burden on manufacturers and processors to determine whether or not a chemical substance should be reported based on criteria that are not well-defined. The proposed rule cuts a wide swath across many industries and the number of companies subject to reporting is likely to be substantial. Previous section 8(a) rules have clearly stated the chemical identities of the substances subject to reporting.[115] If EPA is determined not to follow the historical precedent, EPA must at least provide an equivalent level of certainty on whether a company must report and for what substances. The information required must be clearly authorized by the authority granted in section 8(a) of TSCA on which this rule is based.

EPA's regulation of nanoscale chemical substances – indeed of all chemical substances – is grounded in TSCA's definition of a chemical substance and the Agency's risk assessment policy expressed in foundational EPA policy documents. EPA indicates that the information collected by this rule will facilitate the assessment of risks and risk management. Unfortunately, there is little in the way of reliable scientific evidence included in the type of information that EPA is requesting. If EPA's goal is to further understand the potential risks associated with nanomaterials, much of the information it is requiring to be reported is unlikely to lead to risk management decisions based on scientific evidence.

The proposed 135 day notification period for an already existing nanomaterial represents the most stringent regulatory hurdle faced by these materials in any developed economy, when compared to the regulations for nanoscale chemical substances in Canada, Europe, Australia, Japan, China, and South Korea. This aspect of the proposal undermines the established reporting structure of TSCA. It represents little gain compared with the delays it would create for innovation, and greatly expands the already enormous scope of the proposal.

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[114] Executive Office of the President, Memorandum for the Heads of Executive Departments and Agencies: Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Nanotechnology and Nanomaterials (June 9, 2011) at 2, *available at:* http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf.

[115] Indeed, NMA is not aware of a single section 8(a) rule that was finalized that did not specifically identify the substances covered by the rule using a chemical identity and CASRN.

Despite these concerns, NMA thinks this information collection rule under TSCA section 8(a) can provide the agency and the public with fresh insights, providing the recommendations in these comments are followed. To summarize:

- A phased approach is needed to require information from manufacturers and importers first and then call upon processors to fill information gaps.

- Absent an explicit and supported finding that information regarding such mixtures is necessary to effectively enforce the statute—a need that would in most instances not arise until EPA elects to regulate a given chemical—mixtures should not be subject to separate reporting.

- Expressing the threshold for reporting solely in terms of a substance's size and properties places too great a burden on manufacturers and processors to identify and decide whether or not a chemical substance should be reported.

- The proposed exemptions in this rule should be harmonized with the February 2015 Canadian approach for collecting information on nanoscale chemical substances and other parts of TSCA. This includes exemptions for polymers (including polymer dispersions), substances embedded in polymer matrices, pigments and dyes, certain naturally occurring substances, mixtures (including surface treatments), substances for which there are low or no pulmonary exposure, and small manufacturers and processors. It is critical that longstanding agency determinations that certain chemical substances and mixtures are low risk due to low exposures and/or low hazards continue to be recognized.

- Separate reports for each discrete physical form of the same chemical substance are outside the scope of the law and surface treatments should be removed from the list of criteria for a discrete form entirely. The statute contemplates a single reporting form on a *per chemical substance* basis, which is solely determined by the substance's molecular identity.

- Since validated regulatory protocols for the most of the physical-chemical properties discussed in the proposed rule are still under development, it is not yet possible to reliably distinguish and report on the basis of this information. It is not permissible under the circumstances to base compliance on testing for these properties. A series of workshops is likely necessary to develop such protocols.

- NMA strongly urges the Administration to drop the proposed implementation of an ongoing reporting program 135 days prior to commercialization of existing chemicals from further consideration.

- The time and resources commitment for completing the form EPA has proposed is substantial. EPA should reconsider using this form, consider whether to extend the reporting timeframe, and adjust the proposed small business exemption for inflation and for processors.

Toward this end, and considering the significant changes needed to establish a fair and workable program on information collection, EPA should re-propose this rule. NMA appreciates consideration of these comments, and would be happy to engage in further dialogue on this rulemaking. Please do not hesitate to contact us with questions, requests for clarifications, or comments on this submission.

Respectfully submitted:

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