Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements; Proposed Rule
80 Fed. Reg. 18330 (April 6, 2015)

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The NanoManufacturing Association (NMA) is a new alliance established in 2015 (please see http://www.nanomanufacturingassociation.com/about-1.html). The NMA was established to advocate for a responsible business and regulatory climate for products in which nanomaterials are used or are essential. We want to be a source of good information, contribute information and data as appropriate, and serve as a sounding board for our members.

With respect to identifying chemical substances subject to reporting, this proposal, if implemented, places a heavy and arguably disproportionate burden on the regulated community to figure out what they need to report on to comply because specific chemical identities are not provided and the criteria for determining what a reportable chemical substance (RCS) is are untested. The success of this proposal ultimately depends on the *agency's* ability to define the

information it wants, who it wants it from, and what it wants it on. In plain English, this means don't be confusing, just be clear, avoid broad generalizations, focus on specifics, etc.

The subsequent information obtained must then be useful, and not overly burdensome or impossible for the agency to analyze. How EPA will gauge the success or failure of this program is important to know. The long list of chemical substances in this rulemaking docket is a concept piece, and to some extent, the Nanowerk database that EPA has relied on in the past is similarly speculative. The focus of TSCA and of companies is narrower than either of these approaches, because the focus is on the manufacture of chemical substances *for a commercial purpose*.

The umbrella concept of TSCA is the definition of a chemical substance. Chemical substances are defined by their particular molecular identity. This proposal lumps together all different kinds of *discrete chemical substances.* This is recognized, to some degree, by the exemptions the proposal establishes for certain chemical substances. We think that there are other substances that should be exempt, or clarified as exempt. We would like to call your attention to the Canadian

approach to information collection on nanomaterials in the consultation document that was issued in February 2015. In that proposal, Canada exempts polymers and organic/organometallic pigments and dyes, among other substances. In our written comments, we are going to advocate that the exemption for films be clarified or expanded, as necessary, so that when polymers and coatings are processed, they are treated consistently in North America as exempt from this information collection program. This includes substances that are designed to react to form longer chains or when the chemical substances are embedded upon curing. There are other aspects of the Canadian approach that we will be recommending for consideration. Despite the close cooperation between EPA and Canada through the RCC Program, these two proposals do not look coordinated. Yet, we see no serious roadblocks to having coordinated programs that still serve the agencies' individual purposes well.

With respect to distinguishing between nanoscale forms of a reportable chemical substance, and the concept of a "discrete form" that is set out in the proposed rule, this proposal appears to be trying to expand the statutory definition of a chemical substance, when all EPA is actually interested in is receiving information on physical-chemical properties. The legal obligation to

report a chemical substance under section 8(a) turns on its particular molecular identity, rather than its physical-chemical properties. Therefore, we think that the two concepts need separation in this proposal and we would not support establishing a new regulatory category. We also think that the proposal needs to do better to acknowledge the specific boundaries that Congress established for the types of information that EPA can collect through section 8(a). Similarly, we do not think that a sufficient need has been demonstrated at this time to establish a new and ongoing 135 day notification requirement for existing chemistry, with no sunset, for an entire class of emerging technology. At the very minimum, we hope that EPA will take a more circumspect approach, and resist the urge to ask for information for which there are no established regulatory protocols or suitable record of testing. Surface area and particle size are examples of existing physical-chemical property data which are supported by more researched test protocols and would be more in line with other international information needs for reporting nanomaterials. A narrower set of characteristics is preferred compared to the seven or more characteristics that are currently discussed in the proposal.

Further concerning the proposal to report discrete forms at least 135 days before commencement of manufacture or processing, the agency's proposal would be a very significant change from current EPA guidance which clearly states that the existing TSCA framework will be used to regulate nanomaterials. The White House Office of Science and Technology Policy has clearly communicated in several public, written policy statements that the existing U.S. government frameworks are sufficient to regulate nanomaterials. ABA SEER conducted a thorough analysis of the existing TSCA framework and concluded in a White Paper issued in 2006 that it can sufficiently regulate nanomaterials. This proposed 135 day notification requirement for existing chemistry, on the other hand, would be the most stringent regulatory hurdle of any country compared to the requirements, for example, in Canada, Europe, Australia, Japan, China, and Korea. Contrary to EPA's statements in the proposal, the time between PMN submission and commencing manufacture is a function of the required review period, not the manufacturer's plans for when to begin production. This aspect greatly, and needlessly, expands the already enormous scope of the proposal.

With respect to consideration for EPA's economic analysis, there are differences among manufacturers and processors in terms of the size of the business, the

information the companies can contribute, their experience with filling out a form like the one that is proposed, and the time and resources this entails. These differences do not lend themselves easily to a one size fits all approach. Small business quantity limits have generally served as an important surrogate for potential exposure, and this check is lost under the current proposal. We would like to see EPA to take these concerns under further consideration.

On the topic of electronic reporting, EPA has not provided any mechanism for law firms or consultancies to assist clients in initially making TSCA electronic submissions. We would like EPA to consider ways in which this service might be made available. Looking ahead, we have concerns about the upcoming electronic CDR reporting deadline in 2016 and the implementation of this proposal, as the combination opens the door to an enormous amount of reporting all at the same time. We hope EPA will try to keep that from happening.

With respect to consideration of potential future rulemaking regarding periodic reporting, past section 8(a) rules have generated useful information and resulted in wise regulatory decisions when EPA has asked for manageable kinds and

amounts of information, in reasonable phases, and on a reasonable number of companies and chemicals.

Targeted section 8(a) information collection can lead to fresh insights and more targeted risk assessment and management. This is exactly what nanotechnology needs. Traditionally, EPA has used section 8(a) rules to gather information on specific chemicals and drop other chemicals from further review. The information EPA collects under section 8(a) might also form the basis for significant new use rules (SNURs) for certain chemicals or offer some degree of predictability that other categories of nanomaterials could be assessed as lower risk, and therefore be the subject of reduced testing and/or risk management actions. It would be a significant development if the information we provide allows EPA to lift the current "no release/no exposure" policy that it uses under section 5 for some of the nanoscale chemical substance that are reviewed through the PMN program. Indeed, it is my great hope that all of these potential outcomes come to pass to some extent, because it would mean that the agency is evaluating and regulating these chemical substances like they do any other.

These comments represent a summation of more specific concerns, including the following broad concerns with definitions for reporting:

- We think that the stipulation that the 1 – 100 nm size range must be in at least one dimension must be part of the definition of an RCS for the purposes of improved clarity and precision.
- Are the physical properties for defining a reportable chemical substance and for distinguishing among discrete forms the same or different, or is one a subset of the other? 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. However, EPA should clarify that these properties are not limited to those properties the agency is suggesting for use to distinguish different physical forms.
- What does EPA mean by trace amount? Impurities are already exempt from section 8(a) reporting. We do not think the trace amount concept adds value to this rulemaking. It creates the need to make two ambiguous determinations – what is trace, and whether it contributes to unique and novel properties.
- What kinds of nanoscale substances are “manufactured” as part of a film, only on the surface of the film, or on the surface of something else?

What substances does EPA mean to include in this description of exempt substances? Polymers and coatings should simply be listed as exempt instead, consistent with the Canadian approach.

- Why does EPA believe that it needs to be less-than-transparent about defining a nanomaterial by calling these reportable chemical substances?

There are other areas of clarification that are important concerning distinguishing amongst different nanomaterials by physicochemical properties, for purposes of reporting:

- The terms unique and novel paint an overly exciting/concerning picture about the technology in contrast with the White House direction, and they are problematic when used in standards or regulations because they are purposefully vague. They also are arguably redundant.
- How do the physical and chemical properties EPA is proposing determine the chemical identity of the reportable chemical substances?
- Many of the other physicochemical properties that trigger reporting do not have clear definitions and acceptable protocols, such that generating data for the full set would be challenging at best.

- If used in the final rule to identify substances subject to reporting, the terms sphere, rod, ellipsoid, cylinder, needle, wire, fiber, cage, hollow shell, tree, flower, ring, torus, cone, and sheet must be defined such that one can be clearly distinguished from all others.
- What activities are considered manufacturing, processing, or use of a chemical substance, so that there is more certainty on who should report and what to report? For example, when a chemical substance is formed when a film is dried, this is not manufacturing or processing, it is end use. When a liquid polymer dispersion is purchased to make an article, this is not processing it is use. 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.

Thank you for your consideration of these and NMA's future written comments.