



Nanotechnology
Coalition

Presentation to Office of Information and Regulatory Affairs

November 1, 2016

Comments on Proposed Rule:

Chemical Substances when Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements; EPA-HQ-OPPT-2010-0572

The Nanotechnology Coalition is an independent trade association composed of nanomaterial producers, users and other stakeholders that focus on environmental, health, and safety issues to promote the safe development of nanomaterials, communicate industry positions to regulatory agencies, address standards and definitions in nanotechnology, and promote development of nanotechnology stewardship programs.

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Overview of Comments

- The Proposed Rule:
 - Bypasses statutory minimum criteria for imposing moratoria on nanoscale material manufacturing and processing
 - Diametrically opposed to White House “*Policy Principles*” for oversight and regulation of nanomaterials (June 9, 2011) and international counterparts
 - Creates arbitrary results (data collection and enforcement)
 - Imposes needless economic and regulatory burdens
 - Deficiencies cannot be cured without re-proposal



Proposed Rule Bypasses Statutory Minimum Criteria for Imposing Moratoria on Nanoscale Material Manufacturing and Processing

- Moratorium on future manufacture, import and processing of existing substances on the TSCA inventory that are reportable nanoscale materials unless companies complete a pseudo-PMN and 135-day EPA review period (40 CFR §704.20(f)(2))
 - Precautionary: EPA will use this period to do risk assessment and propose SNUR where deemed warranted
 - Unstated EPA assumption of inherent unusual risk of significant harm for reportable nanoscale materials -- different than all other chemicals – underline this extraordinary pre-emptive review procedure
- Functional equivalent to imposing a SNUR, but more burdensome and unfair
 - Longer review period
 - Side-steps required threshold risk findings and rulemaking procedures
 - Imposes moratorium & ‘PMN’ process on all new users of existing nanoscale materials chemicals (not just new uses or new chemicals)
 - Moratorium will be to no end/benefit in most cases (only fraction will be “new uses” susceptible to a SNUR)
 - Similar to withdrawn SNUR Notice of Proposed Rulemaking



Proposed Rule Bypasses Statutory Minimum Criteria for Imposing Moratoria on Nanoscale Material Manufacturing and Processing (cont.)

- Unlawful under TSCA
 - Unprecedented action; no authority for imposing manufacturing or use moratoria under §8
 - Moratoria are authorized by TSCA §6 (risk evaluation), §5(a) (SNUR) and §7 (imminent hazard), each subject to predicate risk findings and procedural protections, which the proposed rule would by-pass
 - Risk finding cannot be made for nanoscale materials as a class of substances; SNUR component dropped from original (2010) rule proposal
 - TSCA §8 is not designed to provide an on-going reporting obligation for companies; this sets a precedent for EPA to circumvent §6 for any other existing chemical regardless of risk
- Stifles Innovation
 - Example: New potential customer for existing, previously reported nanoscale materials. After deciding to try the material must (1) prepare ‘PMN’ (1-3 months, \$) and (2) wait out review period (4+ months) until it knows whether EPA will seek to ban or restrict; (3) final conditions of use may not be settled for years during SNUR rulemaking



Proposed Rule is Diametrically Opposed to White House “Policy Principles” for Oversight and Regulation of Nanoscale Materials and With International Counterparts

- Key “policy principles” in this context
 - No presumptions of risk or safety concerns
 - Decision-making based on science, and on specific risks identified scientifically
 - No decision-making on scientifically unfounded generalizations
 - Use standard oversight approaches to assess & manage risks consistent with law
 - Agencies should use legal means to obtain risk information where needed to evaluate and act on risk
 - Consider potential benefits and potential costs of proposed oversight
 - Transparent/open decision-making; ample opportunity for public input
 - EPA rejection of Canadian reporting approach to defining reportable nanoscale materials and asking for comparable information demonstrates a failure of cooperation and disregards the RCC relationship
 - In managing risks, use flexible, evidence-based approaches that avoid wherever possible hindering innovation and trade



Proposed Rule Will Create Arbitrary Results

- Arbitrary applicability determinations and reporting
 - Adds no risk benefit while holding nanoscale materials to a higher standard of reporting than any other existing materials
 - Based on ambiguous and/or subjective applicability criteria
 - Based on different test methods for same physical criterion
 - Based on different levels of existing company knowledge
 - No scientific basis for the particular criteria selected
 - Affects both applicability and exclusion criteria in the rule
- Arbitrary results in who reports and what is reported (front end)
- Unenforceable! Arbitrary non-compliance determinations by enforcement staff and citizens (back end)
- Resulting chaos and uncertainty creates injustice, unwarranted regulatory cost, commercial stigma, and hinders innovation
- Identifying nanoscale materials as a special class of chemical substances implies special safety concerns which are unproven resulting in a chilling effect on innovation and marketplace acceptance



Proposed Rule Imposes Needless Economic and Regulatory Burdens

- Unnecessary or duplicative reporting
 - Materials already subject to risk management orders/SNURs
 - Materials (not submitters) that have completed PMN review as nanomaterials
 - Inconsistent with Canadian approach
- Unwarranted permanent reporting scheme (vs. one time)
 - Creates a stand-alone program for regulation of nanoscale materials without a risk finding
- Unwarranted burden on “small businesses” (as defined)
 - Premature to revise standard for “small business manufacturer or processor” in light of requirement for EPA, in consultation with SBA and after public notice and comment, to make a determination whether changes to the standard are warranted
 - Moratorium and 135-day reporting requirement for new manufacturers and processors exceeds chemical reporting requirements in Canada, Europe, China and Japan



Proposed Rule Imposes Needless Economic and Regulatory Burdens (cont.)

- No opportunity for full exemption of large volume “legacy” materials
 - Standard previously used by EPA to identify engineered nanomaterials (2011 Joint Memorandum for the Heads of Executive Department Agencies)
 - Canada and the United States have consistently incorporated this standard in working definitions for engineered nanomaterials to exclude legacy products in commerce
 - Legacy materials have not been identified by EPA, Environment Canada, Health Canada or the Regulatory Cooperation Council as engineered nanomaterials which warrant mandatory reporting
 - Many of the chemical substances covered by this proposed rule have been in commerce for decades
 - A significant economic burden would be placed on legacy industries, such as inks, paints, coatings, pigments, plastics and rubber, which include many small businesses, without the existing unique and novel standard



Summary

- Proposed rule is inconsistent with the Policy Principles
 - Arbitrary reporting applicability criteria/results will breed chaos and regulatory uncertainty for the future development of nanotechnology in the U.S.
 - Applicability criteria based on unfounded generalizations, not tied to risk
 - “135-day” future reporting rule is non-standard oversight approach, contrary to law, based on unwarranted generalizations, without articulation of benefits or assessment of costs
 - Finalizing the rule without more dialog and re-proposal on gaps filled in the proposal denies the agency and community adequate public review and input
 - Rejection of Canadian approach and cooperation unnecessarily increases burden and cost
 - Economic analysis based on stale information
 - Ongoing reporting burden of proposed rule stigmatizes nanoscale materials and hinders innovation and trade



Proposed Rule Deficiencies Cannot Be Cured Without Re-proposal

- Public comments identified many data and information gaps in the proposal necessary for developing and rationally supporting a reporting rule
 - Necessary for the public to evaluate whether the Agency had considered all relevant factors in decision-making
 - In some respects, Agency has proposed an “empty vessel”; public can’t comment on important aspects of the rule that are “missing”
- Concerned that EPA may fill the identified “gaps” without further public input on new substantive additions it makes and rationales it newly develops or newly articulates
 - Filling voids with wholly new substantive matter is not “logical outgrowth” of proposal
 - Public denied opportunity to develop evidence on the record on new controversial and/or technical terms and rationales



Recommendations

- Withdraw or re-open proposal to engage the public on practicable and transparent applicability criteria
- Alternatively, EPA can use the reset of the TSCA inventory to capture information on nanoscale materials which would allow the agency to best use its resources and provide timely information on nanoscale materials.