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Client Alert Commentary

Latham & Watkins Chemical Regulation & Contaminated Properties Practice

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# No Small Issue: EPA's Proposed Rule for Nanoscale Material Reporting

***Arguably necessary and long overdue, but not without issues and challenges.***

## Introduction

On March 25, 2015, the U.S. Environmental Protection Agency (EPA or the Agency) issued a Proposed Nanoscale Material (NM) Reporting Rule[1] pursuant to Section 8(a) of the Toxic Substances Control Act (TSCA).[2] Comments on this proposal are due on or before July 6, 2015. EPA also plans to hold a public meeting, at a time and place yet to be announced.

EPA's Proposed NM Reporting Rule has been a long time in the making. Indeed, nearly 10 years ago, EPA initiated public dialogue around a possible voluntary NM reporting "pilot program".[3] Such a voluntary program was then launched in January 2008 and concluded in December 2009.[4] The guiding principle behind this program as well as EPA's other nanotechnology-related activities has been — and remains today — that:

> Nanoscale materials have a range of potentially beneficial public and commercial applications, including medicine and public health, clean energy, pollution reduction and environmental cleanup, and improved products such as stronger, lighter, and more durable or conductive materials. These benefits arise from the distinctive properties of nanoscale materials, in that they are potentially more interactive or durable than other chemical substances. Altering the size of a material from conventional particle size can enhance or produce unique properties that are desirable for a variety of commercial applications. However, these unique and enhanced properties can raise new questions, such as whether the material in the smaller form may present increased hazards to humans and the environment.[5]

## Overview of the Rule

The table below summarizes key features of the Proposed NM Reporting Rule, followed by a discussion of some of the issues the proposal raises.

| Proposed NM Reporting Rule | | | |
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| **Who?** | **When?** | **What Information?** | **Exemptions** |
| Person who either<br><br>(1) Manufactures, imports or processes a "reportable chemical substance" in a "discrete form" within three years of final rule's effective date or<br><br>(2) Proposes to manufacture, import or process a "reportable chemical substance" in a "discrete form" after the final rule's effective date.<br><br>Key Definitions:<br><br>• "*Reportable chemical substance*" means "a chemical substance that is solid at 25 ºC and atmospheric pressure that is manufactured or processed in a form where the primary particles[6], aggregates[7], or agglomerates[8] are in the size range of 1-100 nm and exhibit unique and novel characteristics or properties because of their size. A reportable chemical substance does not include a chemical substance that only has trace amounts of primary particles, aggregates, or agglomerates in | For Person (1): Six months after final rule's effective date<br><br>For Person (2): 135 days prior to commencing manufacture, import or processing | The following information "to the extent that it is known or reasonably ascertainable by the person reporting"[14]:<br><br>(1) The 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.<br><br>(2) Material characteristics including particle size, morphology and surface modifications.<br><br>(3) Physical/chemical properties.<br><br>(4) The maximum weight percentage of impurities and byproducts resulting from the manufacture, processing, use or disposal of each chemical substance.<br><br>(5) Annual production volume for the previous three years before the effective date of the final rule and estimate of the maximum production volume for any consecutive 12-month period during the next two years of | Exempt chemical substances:<br><br>(1) A chemical substance for which a Premanufacture Notification (PMN) was provided on or after January 1, 2005 as long as the PMN covered the substance in its "discrete form."<br><br>(2) Zinc oxide<br><br>(3) Nanoclays<br><br>(4) "Substances manufactured at the nanoscale as part of a film on a surface"<br><br>(5) DNA<br><br>(6) RNA<br><br>(7) Proteins<br><br>(8) Chemical substances which dissociate completely in water to form ions that are smaller than one nanometer<br><br>Exempt persons (defined the same as the current 8(a) regulations with the exception of (1) below): |

| Proposed NM Reporting Rule | | | |
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| **Who?** | **When?** | **What Information?** | **Exemptions** |
| the size range of 1-100 nm, such that the chemical substance does not exhibit the unique and novel characteristics or properties because of particle size."[9]<br><br>• "*Discrete form*"[10] means that the substance "differs from another form of the same reportable chemical substance in that either:<br><br>(1) The change in the reportable chemical substance is due to all of the following:<br><br>(i) There is a change in process to affect a change in size and/or a change in one or more of the properties of the reportable chemical substances identified in (iii);<br><br>(ii) There is a size variation in the mean particle size that is greater than 7 times the standard deviation of the mean particle size (+/- 7 times the standard deviation); and<br><br>(iii) There is a measured change in at least one of the following properties, zeta potential[11], | | production after the final effective date of this rule. Persons who propose to manufacture or process and who are subject to the 135 days prior to commencement reporting requirement, must report the estimated maximum 12-month production volume and the estimated maximum production volume for any consecutive 12-month period during the first three years of production.<br><br>(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.<br><br>(7) Detailed methods of manufacturing or processing.<br><br>(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, descriptions and estimates of any general | (1) Small manufacturers or processors, which would be defined different differently than the current 8(a) regulation to mean "any manufacturer or processor whose total annual sales, when combined with those of its parent company (if any), are less than US$4 million.<br><br>(2) Any person who imports or processes or proposes to import or process a reportable chemical substance solely as part of an article.<br><br>(3) Any person who imports, manufactures, processes or proposes to import, manufacture or process a reportable chemical substance solely as a byproduct.<br><br>(4) Any person who imports, manufactures, processes or proposes to import, manufacture or process a reportable chemical substance solely as an impurity. |

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| specific surface area[12], dispersion stability, or surface reactivity[13], is greater than 7 times the standard deviation of the measured value (+/- 7 times the standard deviation);<br><br>(2) The reportable chemical substance has a different morphology. Examples of morphologies include but are not limited to sphere, rod, ellipsoid, cylinder, needle, wire, fiber, cage, hollow shell, tree, flower, ring, torus, cone and sheet; or<br><br>(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." | | population or consumer exposures.<br><br>(9) Release 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.<br><br>(10) Risk 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 safe handing, transport, use or disposal.<br><br>(11) Existing data concerning health and environmental effects. | (5) Any person who imports, manufactures, processes or proposes to import, manufacture or process a reportable chemical substance solely as a non-isolated intermediate.<br><br>(6) Any person who imports, manufactures, processes or proposes to import, manufacture or process a reportable chemical substance in small quantities solely for research and development.<br><br>Exempt information:<br><br>(1) Information already submitted under the Nanoscale Materials Stewardship Program. |

## Discussion

The Proposed NM Reporting Rule raises a number of issues for public comment. In the Preamble, EPA requests comment on the following specific issues:

- ***Nanomaterial Definition***. Each aspect of the proposed approach for identifying a "reportable chemical substance" in a "discrete form."

- ***Timeframe for Reporting Prior to Commencement***. Whether the 135-day advance reporting timeframe for persons who propose to manufacture, import or process a reportable chemical substance in a discrete form is appropriate.

- ***Costs of Reporting***. Additional data and information pertaining to the cost of the proposed reporting, including "data or other measures of the number of and potential growth in the number of commercial nanoscale materials or firms that might manufacture or process such materials."[15]

- ***Electronic Reporting***. The proposed requirement for electronic reporting, including "feedback on how electronic reporting mechanisms affect reporting entities in terms of reporting time, added efficiencies and potential burden associated with training to use the electronic systems."

- ***Possible Future Periodic Reporting Similar to CDR***. "[T]he possibility of a future rule that would require periodic reporting of chemical substances manufactured at the nanoscale, similar to reporting that occurs under the Chemical Data Reporting (CDR) rule at 40 CFR part 711" but with modifications, such as, for example, with a lower production threshold than the CDR's 25,000 pounds.

In addition to the foregoing specific issues, the Proposed NM Reporting Rule raises additional issues that EPA does not identify, seek comment on or otherwise discuss in the Preamble. A few examples of such additional issues include:

- ***Information Available to Importers and Processors***. Whether importers and processors would normally receive sufficient information to identify nanomaterials that would trigger the reporting requirement and the degree to which these persons can rely on the upstream manufacturer's representations.

- ***"Known" and "Reasonably Ascertainable" Standard***. When is information "known" or "reasonably ascertainable," and in particular, whether the "reasonably ascertainable" requirement would trigger an affirmative obligation to conduct certain types of testing, surveys and other data generation activities.

- ***Confidential Business Information***. Whether the Proposed NM Reporting Rule may raise unique confidential business information issues given the evolving and competitive environment for the development and application of nanotechnology.

## Conclusion

EPA's Proposed NM Reporting Rule, while arguably necessary and long overdue, would have potentially significant implications throughout the nanotechnology value chain. The proposal, if finalized, would establish key definitions of when a material at the nanoscale qualifies as a discrete chemical for regulatory purposes and would provide the vehicle for EPA to collect "known" and "reasonably ascertainable" information on hundreds of such nanoscale materials. EPA plans to use this information to inform its own nanoscale material research programs as well as for risk assessment that could lead to

future regulation. Notably, information would be submitted electronically and made readily available to the public absent a confidential business information claim; therefore, any gaps in information on particular nanoscale materials would become readily apparent not only to EPA, but also to the public. The forthcoming comment period will provide an important opportunity to articulate issues and concerns.

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If you have questions about this *Client Alert*, please contact one of the co-chairs listed below of our Chemical Regulation and Contaminated Properties Practice Group or the Latham lawyer with whom you normally consult:

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**Endnotes**

[1] On March 25, 2015, EPA released a pre-publication version of the Proposed NM Reporting Rule. http://www.epa.gov/oppt/nano/PrepublicationCopy_Nano_8(a)_NPRM_2015-03-23.pdf. The pre-publication version was superseded on April 6 with the publication of the proposed rule in the Federal Register. *Chemical Substances When Manufactured or Processed As Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements*, 80 Fed. Reg. 18,330 (Apr. 6, 2015).

[2] Section 8(a), 15 U.S.C. § 2607(a) grants EPA broad authority to require chemical manufacturers and processors to provide detailed data about all aspects of chemical manufacture and use, including workplace exposure data and disposal-related data. EPA has relied on its Section 8(a) authority

[3] Nanoscale Materials; Notice of Public Meeting, 70 Fed. Reg. 24574 (May 10, 2005).

[4] Nanoscale Materials Stewardship Program; Notice, 73 Fed. Reg. 4861 (Jan. 28, 2008).

[5] Proposed NM Reporting Rule 80 Fed. Reg. 18, 332-33..

[6] "Primary particles are particles or droplets that form during manufacture of a chemical substance before aggregation or agglomerization occurs." Proposed NM Reporting Rule 80 Fed. Reg. 18, 341 (§ 704.20(a)).

[7] "An aggregate is a particle comprising strongly bonded or fused particles where the resulting external surface area may be significantly smaller than the sum of calculated surface areas of the individual components." Proposed NM Reporting Rule 80 Fed. Reg. 18, 340C (§ 704.20(a)).

[8] "An agglomerate is a collection of weakly bound particles or aggregates or mixtures of the two where the resulting external surface area is similar to the sum of the surface areas of the individual components." Proposed NM Reporting Rule (pre-publication version), 80 Fed. Reg. 18, 340 (§ 704.20(a)).

[9] Proposed NM Reporting Rule 80 Fed. Reg. 18, 341C (§ 704.20(a)).

[10] Proposed NM Reporting Rule 80 Fed. Reg. 18, 340C (§ 704.20(a)).

[11] "Zeta potential" means "the electrokinetic potential in colloidal systems. It is measured as the net number of positive and negative charges per unit particle surface area in Coulomb/m2. Proposed NM Reporting Rule 80 Fed. Reg. 18, 341C (§ 704.20(a)).

[12] "Specific surface area means the ratio of the area of the surface of the reportable chemical substance to its mass or volume. Specific surface area by mass is the ratio of the area of the surface of a nanoscale material divided by the mass (m2/kg) and the specific surface area by volume is the area of the surface of the reportable chemical substance divided by its volume m2/m3." Proposed NM Reporting Rule 80 Fed. Reg. 18, 341C (§ 704.20(a)).

[13] "Surface reactivity means the reactivity at the surface of a reportable chemical substance. It is dependent upon factors such as redox potential, which is a measure of the tendency of a substance to lose or acquire electrons, photocatalytic activity, including the potential to generate free radicals." Proposed NM Reporting Rule 80 Fed. Reg. 18, 341C (§ 704.20(a)).

[14] Proposed NM Reporting Rule 80 Fed. Reg. 18, 341C (§ 704.20(d)).

[15] Proposed NM Reporting Rule 80 Fed. Reg. 18, 337-38.