

Gradient CORPORATION EH&S Nano News

Volume 1, No. 9

www.ehsnanonews.com

October 2006

Guest Contributor

ABA SEER'S Review of Existing Laws and Nanotechnology

By Lynn L. Bergeson ¹

Earlier this year, the American Bar Association (ABA) Section of Environment, Energy, and Resources (SEER) offered to brief representatives of the US Environmental Protection Agency's (EPA) Office of General Counsel on legal and regulatory issues arising in connection with the application of existing statutory and regulatory authorities to engineered nanoscale materials. SEER prepared briefing documents on each statute, and a separate briefing document on innovative governance mechanisms. Each document identifies the legal and regulatory issues EPA will likely encounter as it considers how best to address issues arising in connection with nanotechnology. All seven briefing documents, which are solely the product of SEER and do not purport to represent the opinions of EPA, are available at http://www.abanet.org/environ.

These papers provide the first comprehensive review of these federal statutes with a view toward assessing their utility in addressing the legal and regulatory issues presented by nanotechnology. The papers conclude that these core environmental statutes provide EPA with broad legal authority to address the challenges EPA is encountering as it assesses the potential risks and benefits associated with engineered nanoscale materials.

The briefing document that has generated the most interest is the paper on the Toxic Substances Control Act (TSCA). This briefing document concludes that nanomaterials include chemical substances and mixtures that EPA has authority to regulate under TSCA, that if a new chemical substance is manufactured at the nanoscale, it is subject to TSCA Section 5 premanufacture notification (PMN) requirements applicable to any new chemical substances, and that EPA may regulate nanomaterials as existing chemical substances under its TSCA Section 5(a)(2) authority to issue significant new use rules (SNUR).

Shortly after the briefing documents were posted on-line, Environmental Defense (ED) responded to the paper with its own paper dated August 31, 2006, which is available at the SEER website noted above. ED's comments reiterate its position that TSCA distinguishes "molecular identity" from "chemical structure" and that "EPA has long considered more than chemical structure where that alone is insufficient to define a substance." The SEER document notes that distinguishing between chemically similar materials on the basis of morphology presents challenges, and notes that "the discussion of EPA's legal authority under TSCA to regulate nanomaterials, whether as "new" or "existing" ... should be conducted with an understanding of the technical difficulties in distinguishing between nanoscale and conventional-sized materials of the same molecular identity." The SEER briefing document and ED's response (and additional papers referenced in each document) are not intended to resolve the thorny issues with which EPA's TSCA office is now struggling to resolve. They provide, however, much needed detail and thoughtful consideration of these issues. Readers are urged to review and consider all sides of this interesting debate, and be prepared to provide comment to EPA when (and if, as promised) it issues guidance on the regulation of engineered nanoscale materials under TSCA.

¹ Lynn L. Bergeson is managing director of Bergeson & Campbell, P.C., a Washington, D.C. law firm focusing on conventional and engineered nanoscale chemical, pesticide, and other specialty chemical product approval and regulation, environmental health and safety law, chemical product litigation, and associated business issues, and President of The Acta Group, L.L.C. and The Acta Group, EU, Ltd. with offices in Washington, D.C. and Manchester, UK. Ms. Bergeson served as Chair of the ABA SEER when the Nano Project was completed.



Gradient

Publication Staff:

Editorial

Barbara D. Beck, Ph.D., DABT Christopher M. Long, Sc.D. Noelle M. Cocoros, M.P.H.

Production

Melissa Motta Melissa Marieb Ruth Buchman

Contact Us:

Gradient Corporation 20 University Rd Cambridge, MA 02138

t: 617.395.5000 f: 617.395.5001

email: ehsnanonews@gradientcorp.com website: www.gradientcorp.com

Copyright © Gradient Corporation 2006. Photocopying for personal use is permitted.