

Pesticides, Chemical Regulation, and Right-to-Know Committee Newsletter

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August 2007

FROM THE CHAIR

Lynn L. Bergeson
Bergeson & Campbell, P.C.
lbergeson@lawbc.com

The Pesticides, Chemical Regulation, and Right-to-Know Committee has been very active these past several months. Since our last newsletter, our Committee sponsored three Quick Teleconferences (QT) as part of our Nanotechnology Track: (1) *Nanotechnology and the Toxic Substances Control Act (TSCA)* (May 24, 2007); (2) *Nanotechnology and Environmental Governance* (June 21, 2007); and (3) *RCRA, CERCLA, and Nanotechnology* (July 11, 2007). The July QT concluded the Nano QT Track, which the committee and others regard as a big success. Our thanks to the many speakers and moderators who offered their time and expertise to discuss this important emerging technology and the U.S. Environmental Protection Agency's (EPA) authority under the core environmental statutes to address potential risks posed by nanotechnology applications.

The committee is looking forward to the new ABA year, which begins immediately after the ABA Annual Meeting in San Francisco in early August. The committee will continue to address substantive legal, regulatory, and science policy issues germane to our charter, and will extend our reach to include several developing areas of the law, including the new U.S. Department of Homeland Security rules pertinent to chemical plant security, food safety issues, and new

developments in the regulation of biotechnology. We urge anyone who is interested in the many issues on which our committee focuses to join our committee and get involved.

Here is a brief rundown of committee activities in which the committee engaged this year, in addition to the Nanotechnology Track discussed above, and a few others the committee sponsored. We invite you to let us know if you wish to become involved in any of these activities, or wish to suggest additional activities that you believe may interest committee members:

- **Keystone**—The committee sponsored a session at the 36th Annual Conference on Environmental Law at Keystone, Colorado, on nanotechnology entitled *Making Way for the Super Tiny: Are Emerging Legal and Regulatory Frameworks for Nanoscale Materials Adequate?* The discussion featured: Michael T. Lesnick, Ph.D., Senior Partner, Meridian Institute, Nashville, Tennessee; Lynn L. Bergeson, Bergeson & Campbell, P.C., Washington, D.C.; Norine Kennedy, Vice President, Environmental Affairs, U.S. Council for International Business, New York; Pat Mooney, ETC Group, Washington, D.C.; and Donald Sadowsky, Office of General Counsel, EPA, Washington, D.C.
- **ABA Annual Meeting**—The committee sponsored a session at the ABA Annual Meeting in San Francisco entitled *The Role of the Legal Profession in the Responsible*

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James C. Chen, Editor**

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Development of Nanotechnology. Panel members included: Christine L. Peterson, Foresight Nanotech Institute; Scott W. Cummings, Buchanan Ingersoll & Rooney, P.C.; Mark N. Duvall, The Dow Chemical Company; and Thomas A. Kalil, University of California, Berkeley. The panel discussed a wide range of issues including: nanotechnology and human health and the environment right to privacy and Fourth Amendment searches, intellectual property protection for nanotechnology innovations, and the ethical implications of nanotechnology.

- **Section Fall Meeting**—The committee is sponsoring a session at the 15th Section Fall Meeting in Pittsburgh entitled *Think Globally, Act Locally: The Proliferation of State and Local Toxics Regulations*. The panel consists of Sarah Brozena, American Chemistry Council; Daryl Ditz, The Center for International Environmental Law; and Kyle Holifield, Wal-Mart Stores, Inc. Lynn Bergeson will serve as moderator.

In this issue of the newsletter, we offer substantive information on a range of topics, including articles on: EPA's draft list of chemicals for initial endocrine disruptor screening, recent clarification of the U.S. Department of Agriculture Animal and Plant Health Inspection Service's policy toward genetically engineered plant material, EPA's request for public comment on proposed enhancement to its self-audit policy, and a summary of EPA's recently rolled out notices on the Nanoscale Materials Stewardship Program.

Committee members are urged to get involved. If you think a subject merits discussion and/or wish to organize a QT or other programs, please let Program Vice Chair Larry Culleen or me know. If you are interested in contributing an article to the newsletter, please let Vice Chair Jim Chen know.

Thanks for your interest and thanks for all of your wonderful ideas and help. We look forward to continuing our success in the new ABA year.

RECENT CLARIFICATION OF APHIS POLICY TOWARD GE PLANT MATERIAL

**Lawrence E. Culleen
Allison Carroll
Arnold & Porter LLP
Washington, D.C.**

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) recently issued a notice in the *Federal Register* clarifying its policy for handling situations in which regulated genetically engineered (GE) plant material becomes mixed, at low levels, with commercial seeds and grains. 72 Fed. Reg. 14,650 (Mar. 29, 2007).

Among other things, APHIS is responsible for overseeing the importation, movement, and field testing of regulated GE material in the United States, in order to ensure appropriate confinement of such material in field tests. In conjunction with the U.S. Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA), APHIS provides regulatory oversight of the development of GE materials consistent with the Coordinated Framework for Regulation of Biotechnology, adopted in 1986. FDA has primary responsibility for ensuring the safety of food, including food for animals. EPA regulates pesticides to ensure public safety from the use of pesticides, including the residue of pesticides on food.

Since August 2002, all three agencies have been working to strengthen controls and prevent low levels of regulated GE materials from entering commerce before appropriate safety standards have been met. For its part, APHIS strengthened its field testing requirements and initiated a process to amend its biotechnology regulations under 7 C.F.R. 340. 67 Fed. Reg. 50,578 (Aug. 2, 2002). APHIS also has developed a policy based on current regulations for responding to low level presence (LLP) of regulated GE materials in commercial seeds and grain—the same policy that recently has been clarified in the *Federal Register* notice. At a future date, APHIS intends to consider establishing new criteria to determine whether low levels of regulated GE materials would be acceptable in commercial seeds and grain based on

known risks to plant health, public health, and the environment.

APHIS's current regulations require that an authorization be obtained before the introduction of a new GE plant. Thus, APHIS employs a process for reviewing permits, applications, and notifications to minimize the likelihood of LLP incidents from facilities that might be sources of GE materials. Under the Plant Protection Act (PPA), APHIS is empowered to take appropriate remedial steps when it determines that a PPA LLP incident has occurred and could pose a risk to plant health or the environment. In the event remediation is necessary, APHIS has the authority to hold, seize, quarantine, treat, apply other remedial measures to, and destroy or otherwise dispose of regulated GE materials. APHIS has concluded that its requirements and policies developed in recent years continue to ensure that such occurrences will continue to be unlikely. Even if remediation is not required, APHIS's recent notice makes clear that the agency might take enforcement action against a company or individual for regulatory violations in the event of a failure of containment of GE materials. APHIS coordinates closely with EPA and FDA on investigations, risk evaluations, and the determination of what remediation measures, if any, will be necessary. However, the notice does not discuss how issues within the jurisdictions of those other agencies would be addressed (such as foods that might contain unintentionally present GE materials that might be present in the commercial and consumer food supplies).

The announcement by APHIS clarified the circumstances in which remedial action under the PPA is not necessary in the event of non-containment. The first would be when the regulated material is derived from plants that meet all of the criteria to qualify for APHIS' notification process. This includes the majority of GE plants field tested under APHIS regulations. The second situation in which APHIS may opt not take remedial measures is if the GE plant in question is similar to another GE plant that has already been deregulated with respect to both plant genotype and any novel protein expressed. Notwithstanding APHIS's recent interpretation, the notice emphasizes

that even though remedial measures would not generally be applied in these two situations, applicants field testing these types of plants still must be authorized through notifications or permits and must follow all pertinent APHIS requirements.

This clarification comes in the wake increased international comment and concern regarding LLP incidents and the presences of GE plant materials in commercial seeds and grain.

*This article was prepared by **Lawrence E. Culleen** (attorney) and **Allison Carroll** (legal assistant) of the Washington, D.C. office of **Arnold & Porter LLP**.*

EPA SOLICITS PUBLIC COMMENTS ON PROPOSED ENHANCEMENT TO SELF-AUDIT POLICY

Lawrence E. Culleen
Allison Carroll
Arnold & Porter LLP
Washington, D.C.

EPA is considering making significant changes to its “Self-Audit” Policy to take into account circumstances which arise when businesses change hands and environmental compliance problems are unearthed and might be disclosed. Thus, on May 14, the Environmental Protection Agency (EPA) published a notice in the *Federal Register* signaling its intent to consider offering tailored incentives for new owners of regulated facilities voluntarily to self-report violations they identify pursuant to the current Audit Policy. 72 Fed. Reg. 27,116.

The “Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations,” was issued in its current form on April 11, 2000. 65 Fed. Reg. 19,618. The purpose of the Self-Audit Policy is to enhance protection of human health and the environment by encouraging regulated entities to voluntarily discover, disclose, correct, and prevent the recurrence of violations of federal environmental law. Companies that make disclosures in keeping with the terms of the Self-Audit Policy may receive limited and even complete mitigation of penalties for the violations disclosed, including a reduction in civil penalties and a determination not to recommend criminal prosecution. EPA does not intend specifically to amend the policy but will explore ways to enhance its implementation and encourage its greater use among new owners of regulated facilities.

EPA’s interest in encouraging increased use of the Self-Audit Policy among new owners stems from recent experience negotiating corporate auditing agreements with companies following a merger or acquisition. Although the existing policy has been generally successful, more than half of the over 3,000 violations disclosed pursuant to the policy may not produce significant reductions in pollutant emissions. It is the

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agency's goal to increase the number of self-disclosures that have the potential to yield significant environmental benefits while effecting compliance with federal environmental requirements. EPA believes that new owners of regulated facilities may be particularly well-situated and highly-motivated to conduct self-audits of their new facilities and achieve significant improvement in environmental protection by correcting any violations discovered (especially those that contribute to unlawful emissions). The agency recognizes that a major disincentive for new companies to voluntarily disclose violations may be uncertainty regarding how EPA will penalize companies that offer such self-disclosures. To that end, EPA's notice professes that it is the agency's goal to provide greater overall certainty and consistency in the implementation of the Self-Audit Policy and to explore the desirability of offering tailored incentives to new owners that opt to self-disclose.

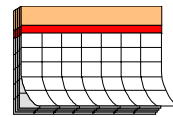
The agency believes that any enhancement of the current Self-Audit Policy should have four main objectives: (1) to increase the number of self-audits and disclosures that yield significant environmental benefits; (2) to be transparent and straightforward; (3) efficient administration; and (4) to minimize transaction costs for participating entities.

In its recent request for comment, EPA has requested that public comments focus on several key issues. First, whether EPA should offer tailored incentives to encourage new owners to discover, disclose, correct, and prevent environmental violations. Second, how the agency should determine who is a new owner. Third, what types of incentives should be available to new owners that self-audit. Fourth, how the agency should determine the extent to which new owner self-audits are achieving significant improvements to the environment. The comment period closed on July 13, 2007.

*This article was prepared by **Lawrence E. Cullen** (attorney) and **Allison Carroll** (legal assistant) of the Washington, D.C. office of **Arnold & Porter LLP**.*

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15th Section Fall Meeting

Sept. 26-30, 2007

Pittsburgh

The Basic Practice Series

Sept. 28-29, 2007

Pittsburgh

37th Annual Water Law Conference

Feb. 21-22, 2008

San Diego

37th Annual Conference on Environmental Law

March 13-16, 2008

Keystone, Colorado

Eastern Water Resources

May 1-2 2008

Charlotte, North Carolina

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EPA ISSUES DRAFT NMSP CONCEPT PAPER AND TSCA INVENTORY PAPER

**Lynn L. Bergeson
Bergeson & Campbell, P.C.
Washington, D.C.**

On July 12, 2007, the U.S. Environmental Protection Agency (EPA) published in the *Federal Register* three separate notices related to the long-awaited Nanoscale Materials Stewardship Program (NMSP) under the Toxic Substances Control Act (TSCA). See 72 Fed. Reg. 38,079-38,085 (July 12, 2007). All of the notices and accompanying documents are available at <http://www.epa.gov/opptintr/nano/nmspfr.htm>. The first notice announces the availability of, and solicits public comment on, EPA's proposed Information Collection Request (ICR) under the Paperwork Reduction Act, including the draft form that NMSP participants would use to submit data to EPA; the second announces an Aug. 2, 2007 public meeting on the NMSP; and the third announces the availability of, and seeks public comment on, two draft documents: (1) the "Concept Paper for the Nanoscale Materials Stewardship Program under TSCA" (NMSP Concept Paper); and (2) the "TSCA Inventory Status of Nanoscale Substances—General Approach" (TSCA Inventory Paper). The latter document addresses an issue of significant interest to TSCA practitioners, namely the regulatory status under TSCA of existing nanoscale materials that consist of chemical substances listed on the TSCA Inventory. Written comments on these documents, as well as on the ICR, must be submitted to EPA no later than **September 10, 2007**.

Draft NMSP Concept Paper

EPA developed the NMSP Concept Paper and its accompanying Annexes "to outline [EPA's] initial thinking on the design and development" of the NMSP, which will "complement and support [EPA's] new and existing chemical efforts on nanoscale materials" and "help address some of the issues identified in EPA's Nanotechnology White Paper." EPA states that the NMSP has the following specific objectives:

- Help EPA assemble existing data and information from manufacturers and processors of existing chemical nanoscale materials;
- Identify and encourage the use of risk management practices in developing and commercializing nanoscale materials;
- Encourage the development of test data needed to provide a firmer scientific foundation for future work and regulatory/policy decisions; and
- Encourage responsible development.

The NMSP will include, but not be limited to, engineered nanoscale materials manufactured or imported for commercial purposes within the meaning of 40 C.F.R. Section 720.3(r). Importantly, EPA explains that participation in the NMSP "would not relieve or replace any requirements under TSCA that a manufacturer, importer, or processor of nanoscale materials may otherwise have."

Annex A of the NMSP Concept Paper (Description of Nanoscale Materials for Reporting) contains "clarifications and descriptions" of various key terms used throughout the Concept Paper, including "engineered," "nanoscale," "engineered nanoscale material," and "nanotechnology."

With respect to participation in the NMSP, EPA foresees involvement by persons or entities that do or intend to do any of the following, with the corresponding intent to offer a commercially available product: manufacture or import engineered nanoscale materials, physically or chemically modify an engineered nanoscale material, physically or chemically modify a non-nanoscale material to create an engineered nanoscale material, or use engineered nanoscale materials in the manufacture of a product.

Both "new" and "existing" (for purposes of TSCA Section 5) engineered nanoscale materials can be included in the NMSP. Annex A also provides examples of materials that EPA believes would and would not be appropriate for inclusion in the program.

Consistent with the National Pollution Prevention and Toxics Advisory Committee Interim Ad Hoc Work Group on Nanoscale Materials' recommendations, EPA is considering a two-part NMSP: (1) a "basic" program that would request the reporting of "all known or reasonably ascertainable information regarding specific nanoscale materials," and (2) an "in-depth" program in which additional data would be developed and submitted to EPA over a longer timeframe. NMSP Concept Paper at 3. Annex B (Data Elements) delineates the types of data that participants in the basic program would be expected to report. Submitters would be encouraged, but not required, to submit their data through a data submission form that EPA has prepared. Data claimed as confidential business information (CBI) will be protected "in the same manner as CBI submitted under TSCA in accordance with procedures in 40 CFR parts 2 and 720" (*id.* at 13), and EPA encourages NMSP participants both "to give careful consideration to what they will and will not claim [as] CBI" and "to make as much data as possible available to the public."

As part of the "basic" program, NMSP participants would agree to implement a risk management program, as well as "agree to consider information provided by EPA that is relevant to [nanoscale material] risk management . . . and to provide information about the risk management practices and other aspects of their risk management program that are relevant to nanoscale materials."

The "in-depth" program would be informed by the basic program's results, and would involve a subset of the information reported under the basic program "in a greater amount of detail." *Id.* at 5. EPA states that "[i]n-depth data development would likely apply to a smaller set of representative nanoscale materials designated for further evaluation by mutual agreement of EPA and participants, with input from stakeholders." *Id.*

EPA will use the data from the NMSP "to gain an understanding of which nanoscale materials are produced, in what quantities, how they are used, and the data that is available for such materials." *Id.* The data will assist EPA scientists in making human health and environmental risk determinations, and may be

used to "[i]dentify the data that are missing to conduct an informed risk assessment of a specific nanoscale material" and "[i]dentify nanoscale materials or categories of nanoscale materials that may not warrant future concerns or actions, or should otherwise be treated as a lower priority for further consideration." *Id.* at 6. Significantly, EPA explains that if data submitted by an NMSP participant "indicates that the participant is manufacturing a nanoscale material that is reportable under [TSCA] section 5 . . . as a new chemical substance, EPA will immediately inform the participant of that situation and the applicable TSCA requirements." *Id.*

Roughly one year after commencement of the basic program, EPA will publish an interim report summarizing "the types of data available, the reasons some data were reported as not being available, additional data that would be needed for a better risk assessment and any activities for which data are being used." Two years after the launch of the NMSP, EPA will issue a more detailed evaluation of the program and simultaneously "determine the future direction of the basic reporting phase as well as in-depth data development."

Annex C of the NMSP Concept Paper (OPPT TSCA Framework) contains a brief summary of the TSCA regulatory framework, while Annex D (Issues and Challenges) discusses various issues and challenges regarding nanotechnology and nanoscale materials that the Office of Pollution Prevention and Toxics (OPPT) in particular, and EPA more generally, faces.

Draft TSCA Inventory Paper

The TSCA Inventory Paper "describes how EPA currently determines whether a nanoscale substance is a 'new' chemical only for the purposes of the [TSCA] Inventory." TSCA Inventory Paper at 1. EPA cautions that its approach to the "new" versus "existing" chemical distinction, which is so crucial to the premanufacture notice (PMN) requirement set forth in TSCA Section 5(a), does not "establish[] a precedent on how nanotechnology issues arising under other EPA programs, other Federal Government agencies, or other federal statutes will be addressed."

Initially, EPA stresses that this paper “informs the public of the approach EPA has historically taken under TSCA in evaluating whether chemical substances are new, and further informs the public of EPA’s intention to follow this approach for nanomaterials that are chemical substances.” EPA explains that the determination of whether a chemical substance is a new or existing chemical turns solely on “whether the chemical substance has the same molecular identity as a substance already on the Inventory. A chemical substance with a molecular identity that is not identical to any chemical substance on the TSCA Inventory is considered to be a new chemical substance (*i.e.*, not on the Inventory); a chemical substance that has the same molecular identity as a substance listed on the Inventory is considered to be an existing chemical substance.” Specifically with respect to nanoscale substances, EPA states:

Although a nanoscale substance that has the same molecular identity as a non-nanoscale substance listed on the Inventory differs in particle size and may differ in certain physical and/or chemical properties resulting from the difference in particle size, EPA considers the two forms to be the same chemical substance because they have the same molecular identity. The Inventory listing in this case is considered to represent both the nanoscale and non-nanoscale forms of the substance and, as such, does not distinguish between two forms having the same molecular identity that differ only in particle size and/or physical/chemical properties resulting from the difference in particle size.

Id. at 6. In the paper, EPA outlines for the first time precisely how it construes the term “molecular identity.” EPA indicates that it “views molecular identity as being based on such structural and compositional features as the types and number of atoms in the molecule, the types and number of chemical bonds, the connectivity of the atoms in the molecule, and the spatial arrangement of the atoms within the molecule,” and that “chemical substances that differ in any of these structural and compositional features . . . have different molecular identities.” EPA offers the following examples of when substances are deemed to have different molecular identities:

- When they have different molecular formulas, *i.e.*, they have the same types of atoms but a different number of atoms, *e.g.*, ethane (C₂H₆) and propane (C₃H₈), or they have the same number of atoms but different types of atoms, *e.g.*, bromomethane (CH₃Br) and chloromethane (CH₃Cl), or they differ in both the types and numbers of atoms.
- When they have the same molecular formulas but have different atom connectivities, *i.e.*, they have the same types and number of atoms but are structural isomers (*e.g.*, n-butane and isobutane) or positional isomers (*e.g.*, 1-butanol and 2-butanol).
- When they have the same molecular formulas and atom connectivities but have different spatial arrangements of atoms, *e.g.*, they have the same types, number, and connectivity of atoms but are isomeric (*e.g.*, (*Z*)-2-butene and (*E*)-2-butene).
- When they have the same types of atoms but have different crystal lattices, *i.e.*, they have different spatial arrangements of the atoms comprising the crystals, *e.g.*, anatase (atoms arrayed tetragonally) and brookite (atoms arrayed orthorhombically) forms of titanium dioxide.
- When they are different allotropes of the same element, *e.g.*, graphite (carbon atoms arranged in hexagonal sheets with each atom bonded to three other atoms in the plane of a given sheet) and diamond (carbon atoms arranged in a tetrahedral lattice with each atom bonded to four other atoms).
- When they have different isotopes of the same elements.

Specifically with respect to nanoscale substances, EPA reiterates that “[a] chemical substance with a molecular identity that is not identical to any substance on the TSCA Inventory is considered to be a new chemical,” and points out that “[a] nanoscale substance might not

have a non-nanoscale counterpart with the same molecular identity (e.g., nanotubes and carbon fullerenes), or a substance might be found in both nanoscale and non-nanoscale forms, but if the substance has not been reported previously to EPA and placed on the Inventory in either form, it is considered a new chemical.” On the subject of adding a nanoscale substance to the Inventory, EPA states as follows:

Systematic chemical nomenclature conventions may not exist for all nanoscale substances identified as new chemicals. In these cases, EPA will likely need to apply new nomenclature conventions to fully, uniquely, unambiguously, and consistently identify and name these new chemical substances for the purposes of the TSCA Inventory. As with existing nomenclature conventions, EPA expects that new nomenclature conventions developed for Inventory listing of these novel substances will include data elements necessary to describe and distinguish their unique molecular identities but will not describe different physical forms (e.g., particle sizes) of these new substances. In the interim, EPA intends to describe new chemical substances (including new substances that exist in nanoscale forms) to the best of its ability for listing these substances on the Inventory, recognizing that names assigned to these substances and even their Inventory status may change once nomenclature conventions are developed. As necessary, EPA will provide interim guidance on molecular identity data elements that could be used by the notifier and [EPA] to identify and name these new chemical substances for listing on the Inventory.

Id. at 5-6. EPA concludes the TSCA Inventory Paper by urging manufacturers or importers of nanoscale substances “to contact the [OPPT] New Chemicals Program to arrange a pre-notice consultation or to submit a request for an Inventory search under the *bona fide* intent to manufacture provision in 40 CFR [Section] 720.25.”

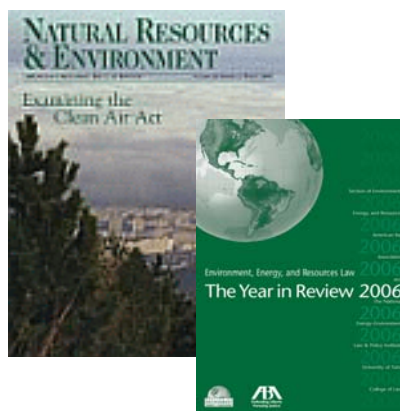
Lynn L. Bergeson is managing director of *Bergeson & Campbell, P.C.*, a Washington, D.C. law firm focusing on conventional and engineered

nanoscale chemical, pesticide, and other specialty chemical product approval and regulation, environmental health and safety law, chemical product litigation, and associated business issues, and is president of The Acta Group, L.L.C. and The Acta Group EU, Ltd with offices in Washington, D.C. and Manchester, UK.

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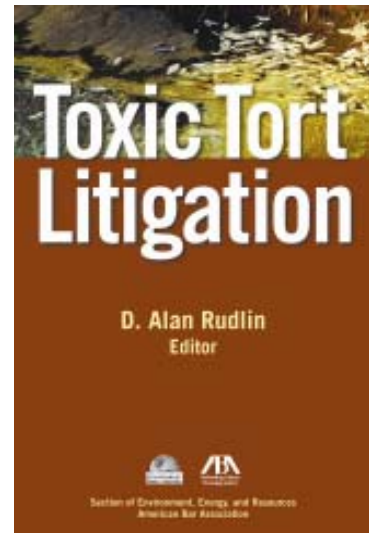


NEW FROM ABA PUBLISHING AND THE SECTION
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Toxic Tort Litigation

D. Alan Rudlin, Editor

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