GAO Recommendations

To improve EPA's ability to assess the health and environmental risks of chemicals, the Report recommends that Congress consider amending TSCA by: (a) providing explicit authority to enter enforceable consent agreements under which chemical companies are required to conduct testing; (b) giving EPA authority to require manufacturers and processors to develop test data based on substantial production volume and necessity for testing; and (c) authorizing EPA to share confidential business information with states and foreign governments, subject to procedures which would protect the information from unauthorized disclosure.

The Report also contains four recommendations for executive action. It recommends that EPA (a) develop a methodology for using the information obtained through the HPV program to prioritize chemical reviews and obtain risk information, (b) require that companies provide EPA with copies of health and safety studies that they submit to foreign governments, (c) develop a strategy for improving and validating the models that EPA uses to assess risks, and (d) revise its regulations to require companies to reassert claims of confidentiality.

AMERICAN BAR ASSOCIATION
SECTION OF ENVIRONMENT, ENERGY, AND RESOURCES

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24th Annual Water Law Conference
Feb. 23-24, 2006
San Diego, California

35th Annual Conference on Environmental Law
March 9-12, 2006
Keystone, Colorado

TSCA AND NANOSCALE MATERIALS UPDATE

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The U.S. Environmental Protection Agency (EPA) issued on May 10, 2005, notice of its much anticipated stakeholder meeting on nanotechnology, which occurred on June 23, 2005, in Washington, D.C. The public meeting, which was well-attended, was convened to "discuss a potential voluntary pilot program for certain nanoscale materials and the information needed to adequately inform the conduct of the pilot program." EPA's Office of Pollution Prevention and Toxics is well-along in this process. This column provides a short update on key activities in this regard.

Background

Nanoscale materials are chemical substances containing structures in the length scale of approximately 1 to 100 nanometers and may have different molecular properties than their bulk counterparts. Nanoscale materials are generally grouped in three categories: naturally-occurring, byproduct/incidental (particulate from diesel combustion) and engineered nanoscale materials. EPA's regulatory initiative focuses on engineered, or intentionally produced, nanoscale materials.

According to EPA, some nanoscale materials are new chemical substances and thus are subject to notification under Toxic Substances Control Act (TSCA) Section 5. As such, EPA reviews these substances for potential human health and/or environmental risks before they are manufactured. Other nanoscale materials, according to EPA, "are existing chemical substances that may enter commerce without notification to EPA. EPA is considering a potential voluntary pilot program for such nanoscale materials."

In this regard, EPA specifically sought comment on:

- The scope and purpose of a voluntary pilot program for nanoscale materials that are

existing chemical substances;
- Kinds of information that are relevant to the evaluation of potential risks from exposure to nanoscale materials;
- Chemical characterization and nomenclature of nanoscale materials for regulatory purposes; and
- Identification of interested stakeholders.

EPA believes comment on the following issues would be "particularly helpful":

- Feasibility and value of a voluntary pilot program;
- Scope and design of a voluntary pilot program, including elements such as: purpose, *(e.g.*, research and development, use involving environmental release, commercial use), administration, outcomes, duration and next steps;
- Information useful for the evaluation of potential effects on human health and the environment;
- Size, dimensions and shapes of chemical substances that should be considered nanoscale materials;
- Types of information that would be useful to provide;
- Manufacturing processes for nanoscale materials and how they relate to identities of the products from the nanoscale manufacturing sector; and
- Identification of interested stakeholders.

EPA believes strongly that information derived from a pilot program "will allow EPA and the affected industry to better understand the issues with respect to potential risks and for EPA to gain experience in the evaluation of such types of chemical substances." In this regard, EPA expects that certain parameters will be important in the context of a potential voluntary pilot program. These are:

- What should be the scope of a voluntary program?
- What information should be included in a voluntary program, and what information regarding the properties of the particular nanoscale material would be relevant to consider?
- How long should a voluntary program last?
- How should participants in a voluntary program be identified?
- What should trigger a voluntary submission under the program?
- How likely would it be for companies to volunteer for such a program, and what should be the incentive structure to encourage participation?
- Should participation in a voluntary pilot program have TSCA Inventory consequences?

While the June meeting addressed some of these issues, time did not allow robust comment on many of them. To help it obtain additional views on these subjects, EPA announced recently that is has created an *ad hoc*, interim nanotechnology workgroup as part of its National Pollution Prevention and Toxics Advisory Committee (NPPTAC), a Federal Advisory Committee Act (FACA) created to advise EPA on matters specific to TSCA and related chemical regulatory initiatives. The *ad hoc* workgroup is charged with considering four topics: (1) options for possible elements of a voluntary pilot program for existing engineered nanoscale materials;
(2) approaches that may be appropriate for putting such a voluntary pilot program in place;
(3) consideration of issues that may be relevant to the review of new chemical nanoscale materials under TSCA; and (4) consideration of other relevant issues raised in stakeholder input provided at EPA's June 23, 2005, public meeting, as well as written comments submitted to the docket.

The NPPTAC is scheduled to offer recommendations to EPA in this regard in October. To assist both the workgroup and NPPTAC, EPA is considering convening a second public meeting on **September 29, 2005**, in Washington, D.C. The public meeting will continue to seek comment and public discourse on many of the issues raised initially in the June public meeting. EPA hopes to roll out its voluntary engineered nanoscale materials program later this year.

EPA is keenly aware of the cross-media implications of nanotechnology, and its interests go far beyond TSCA. EPA's Science Policy Council is preparing a white paper on issues pertinent to nanotechnology and the environment, and is expected to release the white paper later this year or early next.

Lawyers and interested others should stay tuned, monitor and participate in this exciting and evolving area of law and science.

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

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The Pesticides, Chemical Regulation, and Right-to-Know Committee welcomes the participation of members who are interested in preparing this newsletter. If you would like to lend a hand by writing, editing, identifying authors or identifying issues, please contact the editor, Lynn Bergeson, at (202) 557-3801 or lbergeson@lawbc.com.

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MAKING A SPLASH: APPLICATION OF REGISTERED PESTICIDES AND THE REQUIREMENT FOR NPDES PERMITS UNDER THE CLEAN WATER ACT

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Pesticides have, in the past, triggered questions about conflicts between the primary statute regulating pesticides, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136 et seq. and other environmental statutes. For example, in 1977, the U.S. Environmental Protection Agency (EPA) dealt with the issue of statements on registered pesticide labels that prohibit discharge into lakes streams and ponds and National Pollutant Discharge Elimination System (NPDES) permits issued under the Clean Water Act (CWA), 33 U.S.C. § 1251 et seq., that have allowed such disposal. EPA addressed this conflict in a series of guidance documents (*see e.g.*, *EPA Policy and Criteria Notice 2180.1*, June 18, 1977; *PR Notice 93-10*; *PR Notice 95-1*), which fairly well settled the issue through amendment of pesticide labels. Through those notices, EPA required label statements on registered pesticides, noting that pesticide disposal was prohibited *except* in accordance with an applicable NPDES permit. In an interesting twist to the issue, courts have recently looked at the opposition situation, where a pesticide label has directions for use allowing application of the pesticide onto waters of the United States, but for which no corresponding NPDES permit exist. This article examines the case history that developed from these situations, EPA's attempt to address the issue through a series of interpretative guidance documents, and the current status of the law today.

Case Law

The issue of the need for NPDES permits for application of a registered pesticide first arose in the case *Headwaters, Inc. v. Talent Irrigation Dist.*, 243 F.3d 526 (9th Cir. 2001). In that case, the Talent Irrigation District applied an aquatic herbicide, Magnacide H, to its canals without an NPDES permit. The active ingredient in Magnacide H is acrolein, a