

per day, imprisonment for up to two years, or both.

- **Improper Disclosure.** Any person who knowingly or recklessly discloses protected information—such as a vulnerability assessment, site security plan, or materials developed in their preparation or derived from them—is subject to criminal penalties, including fines and imprisonment for up to one year.

VIII. Preemption

- The bill allows states and localities to enact their own, more stringent, chemical security measures so long as there is no actual conflict between the state or local standard and the federal provisions.

EPA'S NPPTAC RECOMMENDS FRAMEWORK FOR VOLUNTARY NANOMATERIALS PROGRAM

Lynn L. Bergeson

On Nov. 22, 2005, the National Pollution Prevention and Toxics Advisory Committee (NPPTAC) forwarded to the U.S. Environmental Protection Agency (EPA) Administrator Johnson its document entitled *Overview of Issues for Consideration by NPPTAC*. The Overview of Issues document sets forth the NPPTAC's analysis and views on a framework for an approach to a voluntary program for existing engineered nanoscale materials. The framework is intended to complement the approach to the new nanoscale chemicals requirement under the Toxic Substances Control Act (TSCA), and is a must read for those wishing to stay abreast of nano developments. The document can be viewed at www.epa.gov/oppt/npptac/meetings.htm.

Background

EPA formally initiated its nanoscale materials TSCA regulatory explorations on May 10, 2005, when the Office of Pollution Prevention and Toxics (OPPT) issued a *Federal Register* notice announcing its decision to convene a public meeting to assess the feasibility and wisdom of establishing a voluntary program on existing nanoscale materials consisting of chemical substances. 70 Fed Reg. 24,574 (May 10, 2005). In the notice, EPA acknowledged that nanoscale materials consisting of new chemical substances are subject to the notification requirements under TSCA Section 5, and the manufacturer of a new chemical substance must submit a premanufacture notification (PMN), including toxicity and other data, to EPA at least 90 days before production of the chemical is to begin. New chemicals generally are those not listed on the Inventory maintained under TSCA Section 8(b). In the notice, EPA also acknowledged, however, that nanoscale materials consisting of existing chemical substances “may enter commerce without notification to EPA.” 70 Fed. Reg. at 24,574. EPA's notice sought comment on the scope and purpose of a voluntary pilot program for nanoscale



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, James C. Chen, at (202) 637-5713 or jcchen@hhlaw.com.

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materials that are existing chemical substances, the 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 the identification of interested stakeholders.

Comments on these topics, and others, were presented at a June 23, 2005, public stakeholder meeting, the discussion at which generally favored a voluntary program. Following the June 23, 2005, meeting, EPA decided to add “nanotechnology” to NPPTAC’s agenda. NPPTAC is a national advisory body intended to provide advice, information and recommendations on the general policy and operation of programs managed by OPPT in performing its duties and responsibilities under TSCA and the Pollution Prevention Act (PPA).

Much of NPPTAC’s work is conducted through NPPTAC work groups. Presently, NPPTAC has four work groups: HPV Work Group, Pollution Prevention Work Group, Tribal Issues Work Group, and Broader Issues Work Group. Over the summer and fall, the newly created Interim Ad Hoc Nanotechnology Work Group met and discussed issues relevant to the development of a voluntary pilot program on nanoscale materials.

Key Provisions

The Interim Ad Hoc Nanotechnology Work Group prepared the Overview of Issues Document and presented it for discussion at the Sept. 29, 2005, NPPTAC public meeting. Following that public meeting, the document was further reviewed and discussed at the NPPTAC public meeting on Oct. 13-14, 2005. The Nov. 22, 2005, version of the document reflects input from the entire NPPTAC. It was formally offered to EPA for its consideration to facilitate the development of a voluntary program for engineered nanoscale materials referred to as the Nanoscale Materials Voluntary Program (NVP). Key provisions and issues are briefly outlined below.

Overall Goal of the Program—The document provides that the “overall goal of EPA’s program

regarding engineered nanoscale materials should focus on addressing the potential risks of such materials to human health and the environment, thereby giving the public reasonable assurances of safety concerning such materials.”

Scope of the Program—The NVP is intended to encompass engineered nanoscale materials now in or “soon to enter” commerce. The “soon to enter commerce” invited considerable discussion as this description is inherently subjective. After debate, “soon to enter” was defined as “applying to pre-commercial new and existing chemical engineered nanoscale materials for which there is clear commercial intent on the part of the developer, excluding such materials that are only at the research stage, or for which commercial application is more speculative or uncertain.”

Elements of the Program—The Ad Hoc Interim Nanotechnology Work Group consistently expressed its view that program participants should be offered the choice of participating in a “basic” program, or in a more “in-depth” program that includes all the elements of the basic program, and the commitment to generate and report more in-depth information, and implement more in-depth risk management practices. Both of the proposed programs, Basic and In-Depth, are voluntary and participation in either would offer benefits for those willing to provide information and agree to implement appropriate risk management practices. Under the NVP, participants would volunteer one or more specific engineered nanoscale material that they are developing, producing, processing, or using, but need not necessarily volunteer all of their materials. The specific information elements and management practices called for would be clearly identified by the time the voluntary program is announced, but are presently undefined. For each identified information element, participants are expected to provide to EPA all information possessed by the submitter. Information provided by participants relevant to understanding and addressing the potential risks of engineered nanoscale materials will be made publicly accessible, limited as appropriate by protections applicable to confidential business information as described under TSCA.

Basic Program Participation—Participation in the Basic Program would consist of the following three sets of activities for each volunteered engineered nanoscale material: reporting existing (meaning all information possessed by the submitter) material characterization information on the material as well as existing information characterizing hazard, use and exposure potential, and risk management practices; filling in gaps in basic information about material characteristics only; and implementing basic risk management practices.

If elements of a baseline set of material characterization information are missing, voluntary program participants are expected to generate the missing information. The baseline would consist of the following basic material characterization information: chemical composition (including impurities), aggregation/agglomeration state, physical form, concentration, size distribution and/or surface area, and solubility. It is believed that most producers, processors, users and researchers already have this type of information about materials characteristics, and that this commitment would result in only a minimal additional burden.

Participation in the basic program would include a risk management component that consists of a participant's agreement to implement basic risk management practices or other environmental or occupational health protection controls (e.g., worker training; hazard communication (MSDS); use of available engineering controls; provision of personal protective equipment, product labeling, customer training, waste management practices, etc.). Participants are also expected to describe their experience in implementing, and their degree of satisfaction with, Basic Program risk management practices.

In-Depth Program Participation—The In-Depth Program is for organizations, or consortia of organizations and/or entities, that are interested in participating beyond the Basic Program. Participants would agree to generate new information about the hazard and risks (including reduction of risk) of a particular engineered nanoscale material, as well as identifying, implementing and expanding, as needed, risk management measures appropriate for a given life

cycle phase of such substance. Under the In-Depth Program, volunteers would also agree to work to extend application of protective risk management practices identified by EPA along their supply chains, and to conduct monitoring of workplaces, environmental releases, and worker health.

Program Evaluation and Follow-up—An aspect of the NVP that attracted considerable attention was program evaluation. The program is intended to be time-limited and it is expected that EPA will determine a point in time at which it will conduct a full-scale program evaluation to assess at least the following: the degree to which the program is meeting its goals, the rate of participation, the amount and quality of the information generated by the program participants, the adequacy and potential effectiveness of existing risk management practices, and the lessons and conclusions that can be drawn from the program experience. NPPTAC members, and especially Ad Hoc Interim Nanotechnology Work Group members, expressed keen interest in ensuring that the program did not simply get off the ground, but also that it meet the agency's intended goals within a reasonable period of time.

Regulatory Approaches—The NPPTAC envisions a combination of voluntary and regulatory approaches for addressing potential risks of engineered nanoscale materials. The list includes near-term, medium-term and long-term approaches.

Near-Term

1. Defining “new” engineered nanoscale materials, specifying information needed to properly evaluate PMN (and associated exemption) submissions of engineered nanoscale materials.
2. Ensuring public availability of information about environmental health and safety effects of engineered nanoscale materials consistent with TSCA approaches, while addressing confidential business information concerns.
3. Initiating activities to utilize TSCA Sections 8(a) and 8(d) or other authorities to complement the

NVP to ensure that EPA obtains needed information about engineered nanoscale materials to inform the Program Evaluation.

4. Coordinating work/responsibilities between EPA and other agencies (*e.g.*, Food and Drug Administration (FDA) and Consumer Product Safety Commission (CPSC)) to ensure appropriate coverage of engineered nanoscale materials.

Medium-Term

5. Considering whether engineered nanoscale materials added to the Chemical Substances Inventory should be identified as such, and if they should be tracked as a separate category to monitor and enable analysis of the performance of the EPA's engineered nanoscale materials program.
6. Revisiting, and revising as needed, current exemptions (*e.g.*, low volume exemption (LVE), low release and low exposure exemption (LoREX), polymer) and reporting thresholds (*e.g.*, for reporting under the Inventory Update Rule (IUR)) available under TSCA to reflect the novel or enhanced properties of engineered nanoscale materials.
7. Utilizing TSCA authorities, as necessary, to ensure that the Agency obtains needed information about engineered nanoscale materials to inform the Program Evaluation.

Long-Term

8. Possibly developing one or more Significant New Use Rules (SNURs) for new nanoscale uses of existing materials.
9. Promulgating one or more test rules under TSCA Section 4 to obtain further appropriate information needed to evaluate engineered nanoscale materials.
10. Implementing TSCA Section 6 or other risk reduction actions for engineered nanoscale materials found to present an unreasonable risk.

Other measures noted include, but are not limited to, ensuring the development of additional information and implementation of control measures that EPA determines are needed to identify and manage potential risks of engineered nanoscale materials now in or soon to enter commerce.

Scientific Peer Consultation—The NPPTAC encouraged EPA to conduct public scientific peer consultations with specialized scientists to assist in assessing the elements to be included in the Basic and In-Depth Programs, review and consider new scientific developments, and otherwise assess the value and integrity of the NVP.

Implementation Timing—The timing of the NVP is set forth in considerable detail in the Overview Document. The NPPTAC urged EPA to provide additional opportunities to sign up to ensure new entities are included in the program and to include newer materials that may enter commerce. The NPPTAC envisions a 6 to 12-month sign-up period. The NPPTAC also urged EPA to avoid inadvertently rewarding late sign ups by providing for a second sign-up period. Additionally, non-participants in the program are encouraged to submit information on an ongoing basis.

The NVP is a promising, useful step in the responsible development of nanotechnology. The program should be up and running sometime in 2006.

Lynn L. Bergeson is a managing director of Bergeson & Campbell, P.C.



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