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US EPA Asks Nanomaterial Firms to Submit Hazard and Exposure Data Within Six Months--Voluntary Program Raises Strategic and Practical Issues for Firms Using Nanomaterials

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After more than two years in development, US EPA recently launched its Nanomaterials Stewardship Program (NMSP), 73 FR 4861 (Jan. 28, 2008). This initiative asks **every** firm and research organization manufacturing, importing, purchasing, processing or otherwise using engineered nanoscale materials to voluntarily submit all existing information and data they have or can obtain concerning (1) their nanoscale material's chemical and physical properties; (2) hazard information for the material, including any health or safety studies; (3) the extent of worker or other human exposure to the material through its expected life cycle; (4) the nature and extent of any releases of the material to the environment; and (5) the risk management (i.e., exposure minimization) practices currently used. The Agency has asked to receive this information by July 28, 2008. EPA has made available several guidance documents that describe the kinds of data it seeks, provide an optional reporting form and identify the subset of materials of greatest interest to the Agency (excluding, e.g., biological materials, organic dyes, to-be-applied thin films that do not contain nanoscale particles and materials regulated only by the FDA). Firms have the option to submit most of the requested data as confidential business information (CBI) (including chemical and company identity) to protect it from public disclosure, but they must follow prescribed procedures to do so.

In addition to submissions of available data (the Basic Program), the Agency also is seeking a smaller number of firms (or consortia) to voluntarily sponsor new environmental and human health-related testing of particular nanomaterials over the next two years (the In-Depth Program). EPA proposes to negotiate with the sponsors regarding the particular materials, endpoints and test methods to develop a program to complement past nanomaterial studies, EPA's ongoing nanomaterial research programs and the OECD's current program to test a representative set of nanomaterials already in commerce. (The OECD is also seeking industry volunteers to sponsor testing. Complementing its testing program, OECD steering groups also are assessing the suitability of existing environmental and human health-related test methods for evaluating nanomaterials and defining and prioritizing testing endpoints.) In-Depth Program testing likely would be designed to meet the needs of both initiatives.

Purpose of the Data Collection

The NMSP represents an effort by EPA to systematically and comprehensively collect available information relevant to the potential environmental, health and safety risks of the various nanomaterials currently (or soon to be) in commerce, including details of risk management practices. The information sought largely mirrors the information EPA requires of chemical manufacturers prior to permitting the manufacture or import of new chemicals for commercial purposes--the Pre-Manufacture Notice (PMN) review under §5 of the federal Toxic Substances Control Act (TSCA). In that context, EPA performs a kind of lifecycle risk assessment for the new chemical; the Agency has the authority to impose a variety of substance-specific exposure control obligations on manufacturers and users where its review indicates regulatory controls are warranted. An analogous review can be expected for the NMSP data, which will provide EPA with better, broader and more robust baseline information on health and environmental effects, exposures, risks and management practices than the anecdotal and speculative information that is currently available. It offers the prospect of a more informed (and thus rational) basis for future action by EPA and others in properly identifying, assessing and managing risks related to particular nanoscale materials in particular use contexts. EPA will issue an interim report in early 2009 assessing the information received by the July 28 deadline. The In-Depth Program is likely to run beyond two years.

Industry's Common Interest in Successful NMSP

Like all other chemical substances, nanomaterials already are subject to the full range of existing chemical control laws, and the Agency evaluates them in the ordinary regulatory context. EPA so far has resisted demands to treat all "nanomaterials" as a unitary class of substances and to enact regulations specific to that "class" on the basis of perceived potential class risk. While acknowledging these potential risks, the Agency has properly deflected such calls, citing the substantial sufficiency of existing laws and the need for better information for sound policymaking-sorting out where any real and **unique** risks lie, how they may be controlled as a practical matter and whether additional authorities are necessary to do so. The NMSP is an effort to obtain, on a voluntary basis, real information concerning what is known about the materials in commerce today, and how those materials are used and controlled.

EPA anticipates that a significant percentage (25-50%) of the approximately 600 large and small firms that it estimates are involved in manufacturing or applying nanoscale materials will participate in the NMSP. The United Kingdom's voluntary nanomaterials reporting program, initiated in 2006, however, has generated only nine submissions in its first 16 months. There is a very real risk, alluded to by the Agency in its NMSP announcement, that low participation rates in the voluntary NMSP may result in a more burdensome, mandatory information disclosure rule under §8(a) of TSCA. Indeed, poor participation may serve to undermine claims that firms working with nanomaterials are already exercising good risk management practices, and that any nanospecific regulations that may be warranted should be deferred pending development of good information identifying where the risks lie (e.g., particular materials and uses), and then tailored to the particular risks. Poor participation also may spur further Congressional action (e.g., Congressman Albert Wynn's announcement earlier this year of his intent to hold hearings on "the serious gaps in the

current statutory and regulatory framework" for nanomaterials), and bolster pressure on state and local governments to act on their own, as Berkeley, California, did and Cambridge, Massachusetts, is considering. In light of the potentially serious adverse consequences that could flow from any of these alternatives, it is in the best interests of industry generally to support EPA's efforts to both (a) base its policy on sound information and (b) use voluntary means to collect it. The NanoBusiness Alliance and the American Chemistry Council's Nanotechnology Panel are both working with members to encourage participation. Given the relatively small universe of potential participants, there is little room for "free riders."

Companies also should consider whether participation may become important from the public relations or commercial reputation perspective. Participation in the NMSP may come to be accepted as a marker of "responsible development," and, like ISO 9000 certification, a de facto requirement for downstream customers with progressive sourcing policies. Indeed, nanomaterials suppliers need to be prepared to respond to requests from customers who wish to participate in the NMSP themselves for their own reasons. And, even for companies with strong risk management policies and practices, NMSP participation may be an effective practical reassurance tool for insurers, underwriters, curious local authorities and concerned neighbors.

Common Benefit, Individual Risks

While broad participation in the NMSP would generally benefit firms across the spectrum of industries using or planning to apply nanotechnologies, at the individual company level, participation in the NMSP, even in the "Basic Program," presents both burdens and risks that should be evaluated in deciding whether and/or how to submit information. EPA estimates that a typical firm will need to devote 150 hours per material to understand the background of the NMSP, assemble the available information, and prepare the submittal; actual time will depend on a variety of factors, including the extent to which the information is readily available or CBI protections are claimed, and other individual considerations.

One consideration that should cause individual firms to spend additional time responding to the NMSP is the sensible precaution of reviewing and/or reconsidering their current nanomaterial risk management practices prior to describing those practices to EPA. Like NIOSH, EPA encourages firms to use exposure mitigation practices for nanoscale materials, and although it may have particular views, the Agency has not prescribed any particular practices. The NMSP does not require that participants reconsider or justify their current practices; however, EPA's expectation (characterized by EPA as an indirect benefit of the NMSP) is that participating firms will, as a practical matter, conduct such reviews in light of relevant best management practices that may have been developed since any prior review (e.g., NIOSH's Interim Guidance and ASTM's Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings (E2535-07)), and, prior to their NMSP submittal, will voluntarily make any adjustments appropriate to their circumstances.

If EPA's review of individual NMSP submissions indicates that potential risks may exist for a specific nanoscale material in a particular context, it may identify additional risk management practices for the participant to consider, and, where warranted, work more actively with the participant to determine possible actions to avoid, reduce or mitigate potential risks, and persuade the submitter

to apply appropriate changes. Viewed most favorably, the NMSP presents an opportunity for firms to obtain an informed, independent and largely informal review of the sufficiency of their nanomaterials risk management practices given the state of current knowledge.

Participation in the NMSP may not be without risk. It is possible that information submitted to NMSP may reveal a firm's failure to comply with applicable rules. Perhaps the most significant of these would be EPA's determination, based on an NMSP submission, that a particular material represented a "new" (as opposed to "existing") chemical substance manufactured (or imported) for a non-exempt purpose and for which a TSCA §5 Pre-Manufacture Notice should have been submitted. For some companies, there may be significant uncertainty concerning the TSCA status of their nanomaterial. Coincident with the NMSP, the Agency has updated its TSCA status determination guidance regarding nanoscale substances. Other potential TSCA violations that might be discovered (and inadvertently disclosed) include operations that unintentionally exceed the bounds of the TSCA research and development exemption; failure to timely report (under TSCA §8(e)) unpublished health studies or other information indicating that a material may present a substantial risk; or failure to timely submit required TSCA Inventory Update data. Beyond TSCA, and depending on the characteristics of the material, hazardous waste management and/or occupational safety violations also may be disclosed. EPA has broad authority to impose substantial penalties, and, in appropriate cases, to halt manufacturing and seize product in the hands of the of the violator and its customers.

EPA declined requests, made during NMSP development, to provide penalty mitigation or other "safe harbor" for violations revealed by NMSP submissions. And while it does not appear that EPA has taken any TSCA enforcement actions respecting particular nanomaterials, Agency enforcement attorneys were present at the last NMSP development public meeting, and in December 2007 the Agency reportedly told the House Subcommittee on the Environment and Hazardous Materials that PMN violations were occurring with respect to nanomaterials. Thus, any company considering participation in the NMSP would be well advised to audit its TSCA compliance prior to submitting NMSP information. Although there is no NMSP "safe harbor," other EPA penalty mitigation policies may apply. For example, EPA's "Audit Policy" provides for a waiver of penalties for violations discovered in the course of a compliance audit and promptly disclosed and corrected (and meeting certain other conditions). For some companies, a pre-submission audit may be an effective means to confirm compliance status to resolve with EPA any ambiguities that may be discovered with minimal penalty exposure.

Participation in the NMSP presents both potential benefits and risks. Firms weighing participation need to understand these considerations as they may apply to their individual circumstances, and make decisions and develop a strategy based on an evaluation of how they may play out to support or hinder broader commercial goals and objectives. Indeed, even in the absence of the NMSP, the management issues raised by the program--sufficient worker and environmental protection, sound legal compliance and regulatory strategy, and good commercial and public relations--are all matters for which firms working with nanomaterials should have a coordinated strategy.

The authoring attorneys are part of the Environmental Department and Nanotechnology Practice

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