

EPA Seeks Big Help with Nanomaterials Data

Chemical Processing, October 2008

By Lynn L. Bergeson

It's time to give the agency the nanoscale materials information it needs

The nominal deadline to submit basic information on nanoscale materials under the Nanoscale Materials Stewardship Program (NMSP) of the U.S. Environmental Protection Agency (EPA) was July 28. While the deadline has passed, EPA is encouraging entities to submit information on an ongoing basis. The program objectives and how EPA will use the information to assess additional regulatory steps applicable to nanoscale materials deserve some attention.

TWO PROGRAMS TO PARTICIPATE IN

EPA's Office of Pollution Prevention and Toxics (OPPT) is at the forefront in addressing regulatory and risk assessment challenges that nanoscale materials may pose. Using its authority under the Toxic Substances Control Act (TSCA), OPPT has for years been reviewing the regulatory status of nanoscale materials that consist of chemical substances, assessing risk management practices for nanoscale materials, and addressing its TSCA obligations. EPA launched a public process to design and develop a stewardship program in October 2006 to obtain information on nanoscale materials, and convened several meetings in 2007 to gain public input on the elements and design of such a program.

EPA launched the NMSP on January 28. The NMSP is in two parts: a "basic" program, where participants report all known or reasonably ascertainable information on specific nanoscale materials, including risk management practices; and an "in-depth" program, where participants consider committing to develop needed data. EPA will use data received to prepare the interim report on the NMSP. Participants in the basic program may continue to submit new data that become available.

Under the in-depth program, participants develop a plan and consider submitting data over a longer period. EPA intends to conduct both programs over the next two years, "although it may make adjustments or decide on future steps or direction of the program at an earlier point as sufficient experience is gained." EPA asks that entities who want to participate in the in-depth program notify EPA. As soon as EPA identifies potential sponsors, it will coordinate the process for in-depth data development. To avoid duplication of testing, EPA will coordinate the in-depth program with its research program, other federal testing and research programs, and internationally through the Organization for Economic Cooperation and Development's Working Party on Manufactured Nanomaterials. EPA also will coordinate with the Canadian government to encourage participation of Canadian companies and participation of American companies in Canadian data development activities that will allow joint development and sharing of data by both countries.

EPA also invites basic program participants to submit available data on risk management practices for nanoscale materials they manufacture, import, process, or use. Participants who have already developed a risk management plan should include it as part of their submission under the basic program. Participants who don't have a risk management plan should "consider developing one," says EPA.

As of late August, EPA's NMSP Web site (epa.gov/oppt/nano/stewardship.htm) notes that 22 organizations covering more than 93 nanoscale materials have submitted information under the basic program, with 10 additional commitments to submit information and three commitments to participate in the in-depth program.

EPA will use NMSP data "to gain a better understanding of the nature of nanoscale materials that are produced; the quantities in which they are produced; how they are or will be used; any hazards, exposures, or releases associated with those materials; and how these hazards are being addressed." EPA scientists will use the data in determining how and whether certain nanoscale materials or categories of nanoscale materials may present risks to human health and the environment.

EPA intends to publish an interim report approximately one year after announcement of the NMSP. The report would describe participation in the basic program during its first six months, and would summarize, to the extent possible considering confidential business information claims, who reported, the types of data available, the reasons some data were reported as being unavailable, additional data that would be useful to improve risk assessment, and any activities for which data are being used.

EPA's launching of the NMSP is an important component in identifying and managing potential risks associated with this promising and evolving technology. Those with nanoscale material interests should participate in the NMSP to assist EPA's ongoing efforts to build a sustainable nanoscale stewardship program.

Lynn is managing director of Bergeson & Campbell, P.C., a Washington, D.C.-based law firm that concentrates on chemical industry issues. The views expressed herein are solely those of the author. This column is not intended to provide, nor should be construed as, legal advice.