

## EPA Confronts Challenges with Nanomaterials

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The Environmental Protection Agency's (EPA's) Office of Inspector General (OIG) recently released a report critiquing the Agency's ability to manage potential risks associated with nanomaterials. Nanomaterials are used in a variety of fields including consumer products, health care, transportation, energy, and agriculture. And while their use continues to expand, the environmental and health risks that may be associated with nanomaterials are still unknown. In particular, there are concerns that nanomaterials, unlike larger particles, may more easily enter the body through absorption, inhalation, and/or ingestion.

OIG found that "EPA has the statutory authority to regulate nanomaterials but currently lacks the environmental and human health exposure and toxicological data to do so effectively." Four major factors contributed to this finding. First, OIG determined that EPA's program offices do not have a formal process to disseminate and utilize data that the Agency may receive through potential reporting requirements. Second, EPA needs to improve its overall message on policy changes and risks of nanomaterials, for example, through a website devoted to nanomaterials. Third, while EPA has proposed to regulate nanomaterials as chemicals, the applicable statutes governing such regulation may not be appropriate for nanomaterials. Specifically, the predictive models used for traditional chemicals under the Toxic Substances Control Act (TSCA) may not be applicable to nanomaterials. And finally, limitations in EPA's ability to actually detect, measure and remove nanomaterials impedes its ability to assess risks and protect environmental and human health.

EPA has authority to regulate nanomaterials under TSCA (permits regulation of nanomaterials during their manufacture, formulation, distribution, use, and disposal), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (permits regulation of nanomaterials in pesticides) and various other statutes (permit regulation of nanomaterials released into the environment).

To date, EPA has proposed to regulate nanomaterials under both TSCA and FIFRA. In October 2010, EPA submitted to the Office of Management and Budget a proposal making any chemical substances from 1 to 100 nanometers subject to TSCA's Significant New Use Rule. And in June 2011, EPA requested comments on how it could use FIFRA to collect information on nanomaterials and proposed a policy classifying any application for a pesticide registration containing nanoscale material as an application for a new active or inert ingredient.

OIG made a single recommendation that the Agency develop a process to ensure dissemination and coordination of relevant nanomaterial information across program offices. EPA has issued a Corrective Action Plan in which it commits to issue a draft document outlining such a process by July 31, 2012.

As use of nanomaterials grows, so do concerns about their unknown effects. Industry will need to closely monitor agency actions over the coming year to stay abreast of developing regulatory requirements.