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TSCA Compliance Opportunities/ Strategies for Nanoscale Materials

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The Goal: Consistent Regulatory Compliance and Exemplary Product Stewardship

- Regulatory Compliance -- avoids adverse consequences, including business interruption, fines, enhanced regulatory scrutiny, negative media attention, compromised “brand,” related harms
- Exemplary Product Stewardship -- helps ensure business stakeholders are upholding “best practices” standards against which corporate behavior will be measured as legal, regulatory, policy standards evolve

Achieving/Monitoring Compliance

- Key elements of a Compliance Management System
 - Management commitment -- tone at the top
 - Compliance procedures -- written Standard Operating Procedures (SOP) for TSCA regulatory requirements
 - Information management -- establish a process for regular evaluation, management, and communication of potential risks
 - Include potential risks across product life-cycle
 - Ensure the process is informed by new scientific information and evolving industry standards and practices (EDF/DuPont Nano Risk Framework www.NanoRiskFramework.com, Responsible Nano Code www.responsiblenanocode.org)

Achieving/Monitoring Compliance (cont'd)

- Document the system
 - Essential for compliance verification, best practices, auditing
 - Train often and regularly, using widely available resources
 - Industry trade associations, government resources, including EPA, NIOSH, FDA
 - Webinars
 - Trusted Internet sources
- Work with regulatory agencies
 - EPA
 - NIOSH
 - FDA

Concluding Thoughts

- Resources available through EPA OPPT offer great value to nano innovators in helping to achieve and maintain TSCA compliance
- Important to develop an effective management system to document, maintain, and monitor TSCA compliance and exemplary product stewardship
- Essential to stay abreast of evolving legal, regulatory, and industry practices to ensure compliance

Thank You.

Questions from Webinar participants.

