Society for Risk Analysis
New England Chapter

2015-2016 Event Series

MEETING ANNOUNCEMENT
Wednesday, April 20, 2016
Refreshments: 5:30 pm – 6:00 pm
Presentations: 6:00 pm – 6:45 pm
Questions and Discussion: 6:45 – 7:00 pm

TOXICOLOGY AND RISK ASSESSMENT OF NANOSCALE MATERIALS

PRESENTATION 1
JOEL COHEN, SCD
GRADIENT

PRESENTATION 2
JO ANNE SHATKIN, PHD
VIREO ADVISORS, LLC

Location
Health Effects Institute (HEI)
75 Federal St., Suite 1400
Boston, MA 02110

Please RSVP by Monday, April 18th to Heather Lynch (hlynch@gradientcorp.com).

Space is limited, so reserve your seat today. For more information on SRA-NE, please go to: **sra.org/sra-ne**

Society for Risk Analysis
New England Chapter

PRESENTATION 1

OVERVIEW AND CURRENT CHALLENGES IN NANOMATERIAL TOXICOLOGY AND RISK ASSESSMENT

The growing number of engineered nanomaterials (ENMs) utilized in a wide variety of consumer products and biomedical applications is accompanied by increasing concerns of environmental and occupational exposures. Regulatory agencies in the U.S. (EPA, FDA) are currently trying to understand and manage potential risks to human health and the environment, though no nano-specific regulation yet exists. Meanwhile, nano product registries and mandatory reporting practices are emerging in Canada, France, Belgium, and other EU nation states, intending to facilitate monitoring and prevent potential hazards. Evidence suggests exposure to ENMs may cause a variety of pulmonary and cardiovascular effects, although the underlying toxicity mechanisms are not currently well understood. Discrepancies in the nanotoxicology literature may be partly due to a lack of standardized nanomaterial dispersion protocols, and a lack of consideration for particle transformations in liquid suspension and the subsequent impacts on particle settling and dosimetry. Recent reports demonstrate how dosimetric considerations can greatly impact interpretation of dose-response data and hazard ranking for large panels of ENMs. Tools for addressing such challenges are currently available, and are slowly being integrated in nano toxicity studies. Still, major data gaps exist regarding the hazards and risks associated with consumer level exposures to nanoscale-releases from nanotechnology enhanced consumer products (NEPs). In light of such data gaps, recent nanotoxicology research aims to 1) accurately characterize the physicochemical properties and exposure levels of such releases across various life-cycle stages (consumer-use, end of life and waste disposal, etc), and 2) apply recently developed dosimetry methods to bring *in vivo* and *in vitro* exposure concentrations onto the same scale as expected human level exposures.

ABOUT THE PRESENTER

Dr. Joel Cohen is a Senior Toxicologist at Gradient in Cambridge, MA, specializing in human health toxicology and risk assessment. He is trained in particle and inhalation toxicology, with particular expertise in the environmental health and safety of nanomaterials. At Gradient, his primary responsibilities include review of toxicology and epidemiology data for consumer product risk assessment, evaluation of regulatory safety assessment frameworks for chemicals in consumer products, particulate matter inhalation exposure assessment and dose modeling, and human health risk assessment. Before joining Gradient, Dr. Cohen earned his doctoral degree at the Harvard School of Public Health, where he investigated particle-cell interactions using various *in vitro* models for nanomaterial toxicity, cellular uptake, and particle translocation. He developed a newly patented method for characterizing a critical particle parameter that drives transport in liquid suspension, enabling accurate estimation of delivered-to-cell doses for in vitro studies. He has authored several peer-reviewed articles and presented his work in the field of nanotoxicology to academic and general audiences.

Society for Risk Analysis
New England Chapter

PRESENTATION 2

ADVANCING RISK ANALYSIS FOR NANOSCALE MATERIALS – AN OECD/SRA COLLABORATION ON ALTERNATIVE TESTING STRATEGIES FOR READ ACROSS AND RISK ASSESSMENT GUIDANCE

The Organisation for Economic Co-operation and Development (OECD) Working Party on Manufactured Nanomaterials (WPMN) SG-AP Project (#4), "Advancing the practice of risk assessment with alternative testing strategies: State of the science for read across and risk assessment guidance" coordinated several efforts related to risk analysis of nanoscale materials. This effort culminated in a 2014 workshop organized by the SRA Emerging Nanoscale Materials Specialty Group to develop recommendations on how to advance the use of alternative testing strategies for nanomaterials in risk assessments. The project team surveyed the state of the science in alternative test strategies (ATS) from a "multiple models" perspective to show areas of common findings from differing approaches, areas of greatest uncertainty, and priorities for follow up in applied research toward risk management of manufactured nanomaterials (MNs). Experts from academia, industry, public interest groups, and government researched, analyzed, and discussed how alternative models could be used to advance the risk analysis of MNs. The objectives were to identify how ATS could be used in a risk analysis context to inform human health, ecosystem health, and exposure needs for MN in the near term and longer term, and research needs to support the development of these strategies in the near future. Efforts included organizing and producing a symposium, a case study on alternative methods in safety testing, a State of the Science report and three white papers, each used as background materials for discussion in a September 2014 workshop that developed recommendations to advance knowledge and fill key gaps in understanding.

Workshop deliberations revealed that ATS are now being used for screening, and that, in the near term, ATS could be developed for use in read-across or categorization decision making within certain regulatory frameworks. Participants recognized that leadership is required from within the scientific community to address basic challenges, such as standardization of materials, techniques and reporting, designing experiments relevant to realistic outcomes, as well as coordination and sharing of large-scale collaborations and data. The recommendations will aid the proper development and implementation of relevant ATS for MN testing that will expedite the ability to identify high-risk MNs, and lead to more rapid, cost-effective, and reliable MN safety testing for specific risk management decision contexts.

ABOUT THE PRESENTER

Dr. Jo Anne Shatkin is an environmental health scientist and recognized expert in environmental science and policy, human health risk assessment, emerging contaminants policy and environmental aspects of nanotechnology. She is President of Vireo Advisors, LLC, a woman-owned business based in Boston, Massachusetts focused on sustainability strategies for new and nano-technology development and innovation. She has extensive experience in working with entrepreneurs to guide responsible product development and commercialization. Prior to joining Vireo, Jo Anne was CEO of CLF Ventures, where she worked with early stage and large organizations on new technology introduction strategies, including business planning, environmental impact assessment, and networking for financing.

Since 2005, Jo Anne has provided leadership on the responsible development of nanotechnology, and on approaches for decision making under uncertainty. She served as an expert to several international committees on nanotechnology safety, including the joint WHO/FAO Expert Panel on Nanotechnology in Food, the Canadian Council of Academies, and the US/Russia Bilateral Commission for Science and Technology Nanotechnology Environmental Health and Safety Panel. She serves as EHS Advisor to P3Nano, the US public private partnership to advance commercialization of nanocellulose. She pioneered the use of life cycle thinking in risk analysis for nanomaterials, collaborating with the U.S. Environmental Protection Agency to develop several case studies that informed EPA's risk analysis, research agenda and policies for nanomaterials. Jo Anne developed and uses NANO Life Cycle Risk Analysis to inform safe development strategies for nanomaterials, described in her book, Nanotechnology Health and Environmental Risks Second Edition (CRC Press 2012). She founded the Emerging Nanoscale Materials Specialty Group of the international Society for Risk Analysis, where she is a Fellow and served as councilor, and in 2015 received the Outstanding Practitioner Award. She serves on the board of the Center for Environmental Policy at American University and the University of Maine Forest Bioproducts Research Institute and was a Switzer Environmental Fellow. She is leading efforts to develop methods and standards for environmental health and safety for TAPPI and participates in the US Technical Advisory Group to ANSI on EHS Standards Development for nanocellulose.

Jo Anne received an Individually Designed Ph.D. in Environmental Health Science and Policy and her MA in Risk Management and Technology Assessment from Clark University, Worcester, Massachusetts and possesses a Bachelor of Science degree from Worcester Polytechnic University in Molecular Biology and Biotechnology.

GETTING TO THE EVENT

MBTA (Red Line):

Take the MBTA Red Line inbound toward Ashmont/Braintree. HEI is about a 0.3 mi walk from the Downtown Crossing stop. After exiting the station, head southeast on Summer St. toward Hawley St. Turn left onto Hawley St., walk about two blocks, then turn right onto Franklin St. After about three blocks, take a right onto Federal St.; the building will be on your right. HEI is located on the 14th floor of the 75-101 Federal St. building.

By Bus:

The 93 and Silver Line (SL4) bus routes stop nearby.

Driving Directions:

From I-90E: Take exit 24 A-B-C toward Atlantic Ave. Continue onto Atlantic Ave. for 0.2 mi and turn left onto Summer St. Turn right onto High St., then make a left onto Federal St.

Parking is available in the garage at 75/101 Federal St.