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**Chemical Producers and Distributors
Association Annual Meeting**

**Nanotechnology: EPA's Evolving
Nanopesticide Policies**

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Lynn. L. Bergeson
Bergeson & Campbell, P.C.
www.lawbc.com

Overview of Presentation

- Basic Technical Background
- Ongoing Nanotechnology Environmental, Health, and Safety (EHS) Regulatory and Stewardship Initiatives
 - Federal
 - International
 - State
 - Private Sector
- U.S. Governance Coordination Efforts
- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Focus
- Concluding Thoughts

Nanotechnology: What Is It?

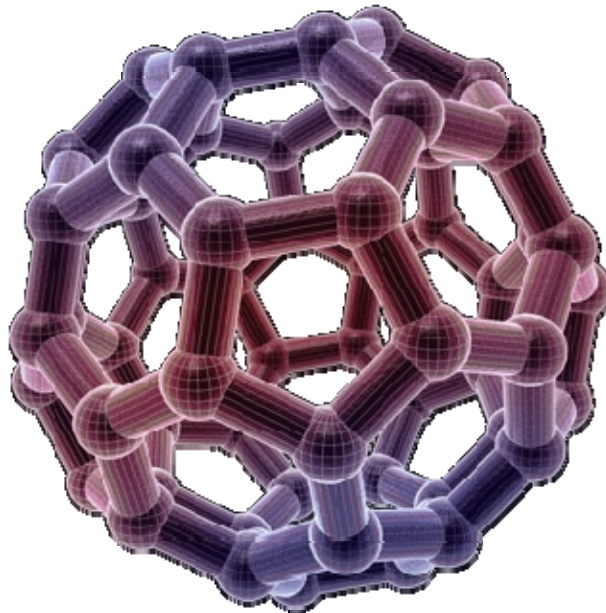
- **National Nanotechnology Initiative (NNI)* -- Defines nanotechnology as:**

Nanotechnology is the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering, and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale. A nanometer is one-billionth of a meter. A sheet of paper is about 100,000 nanometers thick; a single gold atom is about a third of a nanometer in diameter. Dimensions between approximately 1 and 100 nanometers are known as the nanoscale. Unusual physical, chemical, and biological properties can emerge in materials at the nanoscale. These properties may differ in important ways from the properties of bulk materials and single atoms or molecules.

* Source: NNI, <http://www.nano.gov/html/facts/WhatIsNano.html>

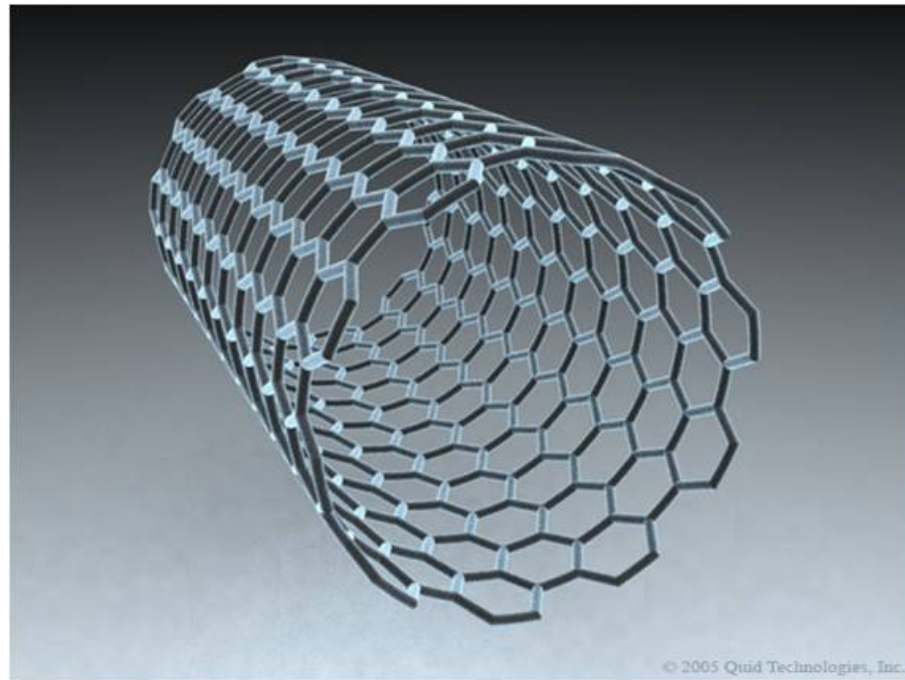
Nanoscale Materials

- Particles -- Nanoscale in three dimensions (buckeyball)



Nanoscale Materials (cont'd)

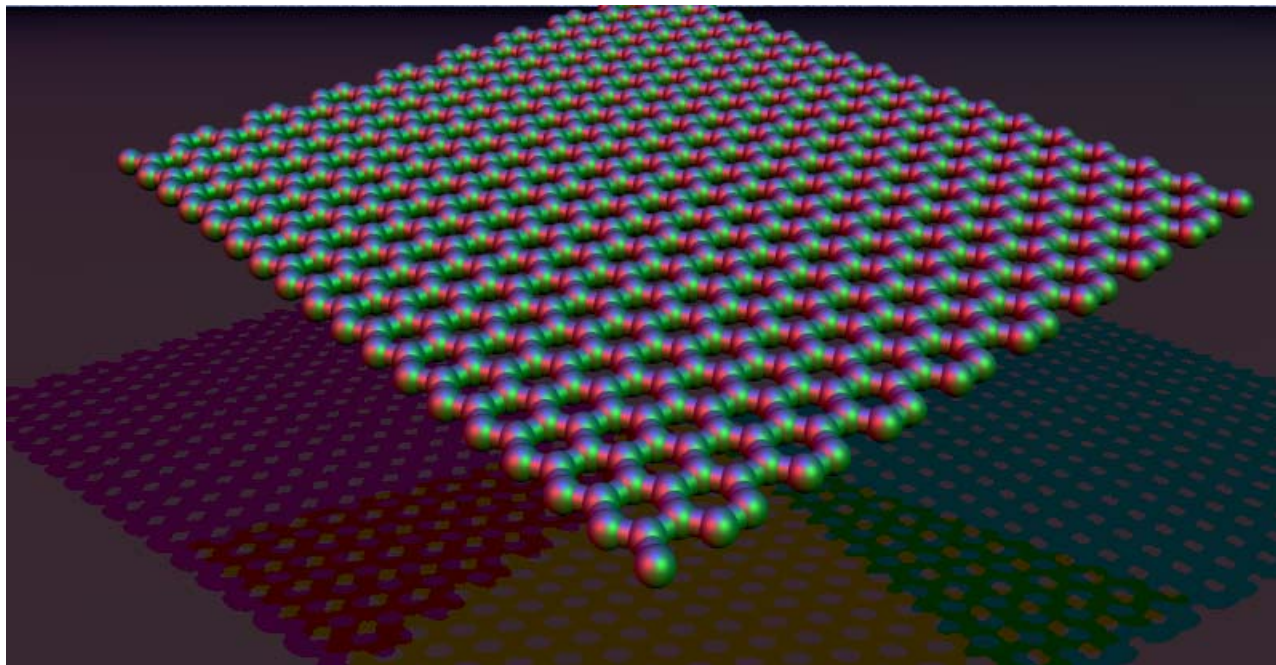
- Tubes -- Nanoscale in two dimensions (single/double wall carbon nanotubes (CNT))



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Nanoscale Materials (cont'd)

- Plates -- Nanoscale in one dimension (nanoribbon)



Definitional Confusion

- NNI definition of nanotechnology is widely cited, but has no regulatory significance
- Fundamental confusion between concept of nanotechnology as a discrete entity and nanotechnology as a constellation of technologies

Definitional Confusion (cont'd)

- U.S. Environmental Protection Agency (EPA) Definitions
 - Office of Pesticide Programs' (OPP) "Working Definition" of Nanoscale Material
 - An ingredient that contains particles that have been intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers

Definitional Confusion (cont'd)

➤ Toxic Substances Control Act (TSCA) Definition of Nanoscale Material

- Materials having structures with dimensions in the nanoscale (approximately 1-100 nanometers (nm)) that may have organizations and properties different than the same chemical substances with structures at a larger scale

Definitional Confusion (cont'd)

- European Parliament (EP) Definitions

- Novel foods -- “any intentionally produced material that has one or more dimensions of the order of 100 nm or less or is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic to the nanoscale”
- On July 7, 2010, the EP voted to ban nanoscale ingredients from food in the European Union until health and environmental risks are better understood

Definitional Confusion (cont'd)

- Cosmetics -- “an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm”
- California Department of Toxic Substances Control (DTSC) Proposed Green Chemistry Initiative Program
 - “Nanoscale” means one or more dimensions of the order of 1000 nanometers or less

Definitional Confusion (cont'd)

- “Nanomaterial” means any form of an engineered chemical, substance or material that is composed of a discrete nanostructure, which has one or more dimensions at the nanoscale

Global Market Forecast

Selection of Global Market Forecasts for Nanotech-Enabled Products, Billion USD

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
LuxResearch (2006, 2008)	30		147							2600	3100
BCC (2008)			12	13			27				
Cientifica (2008)				167				263			1500
RNCOS (2006)						1000					
Wintergreen (2004)											750
MRI (2002)	66					148					
Evolution Capital (2001)	105					700					
NSF (2001)	54										1000

Source: Publicly available information on private market forecast

EHS Implications of Nanotechnology

- “Unique” phenomenon that enables novel applications may cause health/environment risks
- Concern expressed with the paucity of toxicological and ecological effects data and information
- Concern that monitoring and analytical equipment and methodologies are not calibrated to address nanoscale materials
- Concern that existing legal, regulatory, and governance systems are inadequate in some instances to address nanoscale materials

Key EHS Nano Initiatives

Domestic Initiatives

■ Federal

➤ EPA

- Nanotechnology White Paper (<http://www.epa.gov/osa/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf>)
- Nanoscale Materials Stewardship Program
- TSCA -- Regulatory Guidance
- FIFRA -- Regulatory Guidance
- International Center for Technology Assessment (ICTA)
Petition to Regulate Nanosilver Products as FIFRA Pesticides

Key EHS Nano Initiatives (cont'd)

Domestic Initiatives (cont'd)

- Food and Drug Administration (FDA)
 - Nanotechnology Task Force
- ICTA Petition to Regulate Nanoscale Materials
- National Institute of Occupational Safety and Health (NIOSH)
 - Information Exchange
- Consumer Product Safety Commission (CPSC)
 - Position Paper

Key EHS Nano Initiatives (cont'd)

State Initiatives

- California DTSC data call-in (DCI) for CNTs -- DTSC expected to issue DCIs for data on nanometal oxides (nano titanium dioxides and nano zinc oxide) and nanometals (nano silver and nano zerovalent iron)

Key EHS Nano Initiatives (cont'd)

International Initiatives

- Organization for Economic Cooperation and Development (OECD)
 - Approximately 100 countries engaged (member or “active” relationship)
 - Forum for intergovernmental cooperation on environment
 - Working Party on Manufactured Nanomaterials (WPMN) (Chemicals Committee)
 - Working Party on Nanotechnology (WPN) (Committee for Scientific and Technological Policy)

Key EHS Nano Initiatives (cont'd)

International Initiatives (cont'd)

- International Organization for Standardization (ISO)
 - Technical Committee 229 -- Nanotechnologies
- Other
 - United Nations Educational, Scientific and Cultural Organization (UNESCO) Ethics of Science and Technology Program
 - Food and Agricultural Organization of the United Nations (FAO)/World Health Organization (WHO)

Key EHS Nano Initiatives (cont'd)

International Initiatives (cont'd)

■ Mandatory/Voluntary OECD Country Programs

- Canada -- Mandatory DCI for nanoscale materials expected to be implemented soon
- United Kingdom Department for Environment, Food, and Rural Affairs -- Voluntary program (existing data from manufacturer, user, processor, other on nanoscale materials)
- Australia National Industrial Chemicals and Notification and Assessment Scheme -- Voluntary program (chemical importer/manufacturer to report commercial application in Australia)

Key EHS Nano Initiatives (cont'd)

Industry Initiatives

- Environmental Defense Fund/DuPont Nano Risk Framework (<http://nanoriskframework.com>)
- Nanotechnology Occupational Safety and Health (NOSH) Consortium
- Responsible Nano Code (<http://www.responsiblenanocode.org>)
- U.K. Royal Society, Nanotechnology Industries Association, Insight Investment
- Good Nano Guide (<http://www.goodnanoguide.org/>)

U.S. Government Coordination Efforts

■ **Regulatory Policy**

- White House Policy Coordination Group
- Agency-specific groups at EPA and FDA
- Government Accountability Office (GAO) report (issued June 25, 2010)

■ **Science Policy**

- President's National Science and Technology Council Committees and Work Groups
- President's Council of Advisors on Science and Technology
- National Academy of Sciences report



Evolving TSCA Policies

- End of EPA's Voluntary Nanoscale Materials Stewardship Program
- EPA is expected to issue final TSCA Section 5 Significant New Use Rules (SNUR) for certain multi-wall and single-wall CNTs
- EPA is expected to issue a proposed TSCA Section 4(a) test rule to determine the health effects of certain multi-wall CNTs and nanosized clays and alumina

Evolving TSCA Policies (cont'd)

- Possible categorical TSCA Section 5 SNUR for nanoscale chemical substances
- Possible TSCA Section 8(a) rule to establish reporting requirements for “certain nanoscale substances”

Evolving FIFRA Policies

- FIFRA Scientific Advisory Panel (SAP) convened a meeting on nanosilver in November 2009
 - Prompted in part of ICTA Petition
- SAP's report on nanosilver and other nanometal pesticide products issued on February 8, 2010

Evolving FIFRA Policies (cont'd)

- EPA's Background Paper for the SAP notes that the current state of the science lacks sufficient information to determine definitively whether forms of nanosilver particles may cause toxic effects beyond those attributable to the release of silver ions
- SAP largely concluded much data are needed to assess the safety of nanosilver

Evolving FIFRA Policies (cont'd)

- EPA is expected to announce soon:
 - Substitution of a nanoscale active or inert ingredient for a conventionally-sized active or inert ingredient in a product currently registered under FIFRA requires that the registrant submit an application to amend that registration
 - New nanoscale ingredients will be subject to a different registration process

Evolving FIFRA Policies (cont'd)

- EPA has temporarily suspended:
 - Policy change that would require any pesticide registrant that is aware that some constituent of a registered pesticide product is nanosized to submit the information to EPA pursuant to FIFRA Section 6(a)(2)

Evolving FIFRA Policies (cont'd)

- Unclear what EPA will do in response to GAO report, which urged:
 - EPA to modify FIFRA pesticide registration guidelines to require applicants to identify nanoscale material ingredients in pesticides
 - EPA to complete plans to clarify nanoscale material in registered pesticides must be reported to EPA

Concluding Thoughts

- Regulatory uncertainty invites greater risk
- Monitor closely evolving legal/scientific/medical developments
- Advocate relentlessly, seek guidance

Concluding Thoughts (cont'd)

- Work with EPA (FIFRA Office, TSCA Office), NIOSH, others
- Track and comply with evolving industry standards, codes of practice, and risk assessment methodologies
 - ISO Life Cycle Assessment (LCA) Tools
 - EDF/DuPont Nano Risk Framework

Concluding Thoughts (cont'd)

- Assess, develop, and comply with appropriate internal policies and procedures reflecting of nano-specific issues
- Monitor post-sale product complaints, adverse effects reporting and respond appropriately
- Complete all activities reasonably and as appropriate in light of all relevant circumstances

Thank You

Lynn L. Bergeson
BERGESON & CAMPBELL, P.C.
1203 Nineteenth Street, N.W., Suite 300
Washington, D.C. 20036
lbergeson@lawbc.com
www.lawbc.com

THE ACTA GROUP, L.L.C.
1203 Nineteenth Street, N.W., Suite 300
Washington, D.C. 20036
www.actagroup.com

THE ACTA GROUP EU, LTD
Avanta Royal Mills
17 Redhill Street
Ancoats Urban Village
Manchester M4 5BA, UK
www.actagroup.com

