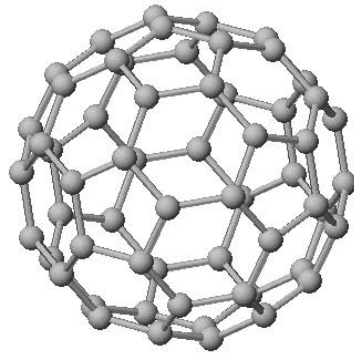


# Nanotechnology for environmental remediation: current issues and guidance for managing occupational and non-occupational health risks of engineered nanoparticles (ENPs)



Ephraim Massawe, Southeastern Louisiana University  
At the American Public Health Association Annual Conference  
141<sup>st</sup> Annual Meeting and Expo, Nov. 2-6<sup>th</sup>, Boston, Massachusetts

# An outline of this presentation

- (a) the evolution of nanotechnologies and how the novel physico-chemical properties of ENPs enable them for various applications, including remediation;
- (b) current applications & practices in environmental clean-up
- (c) framework for exposure assessment strategies and information needs to support local, state and federal government regulatory and oversight functions
- (d) recommendations, based on the available knowledge and information, safe and sustainable methods of handling ENPs, including engineering controls; administrative procedures and personal protective equipment.

# The evolution of nanotechnology and ENPs

## There's Plenty of Room at the Bottom

*An Invitation to Enter a New Field of Physics*



by Richard P. Feynman

Richard P. Feynman presentation made on 12-29-1959 (American Physical Society Annual Meeting at the California Institute of Technology)

Published in Caltech Engineering and Science, Vol. 23:5 February 1960; pp 22-36

"....What I want to talk about is the problem of manipulating and controlling things on a small scale....."

".....Why cannot we write the entire 24 volumes of the Encyclopaedia Britannica on the head of a pin? ....."

".....The theory of chemical processes today is based on theoretical physics. In this sense, physics supplies the foundation of chemistry...."

"...chemistry and chemical processes be described by the physicist..."

The evolution of nanotechnology has led to the need to understand the human health and safety risks of various ENPs

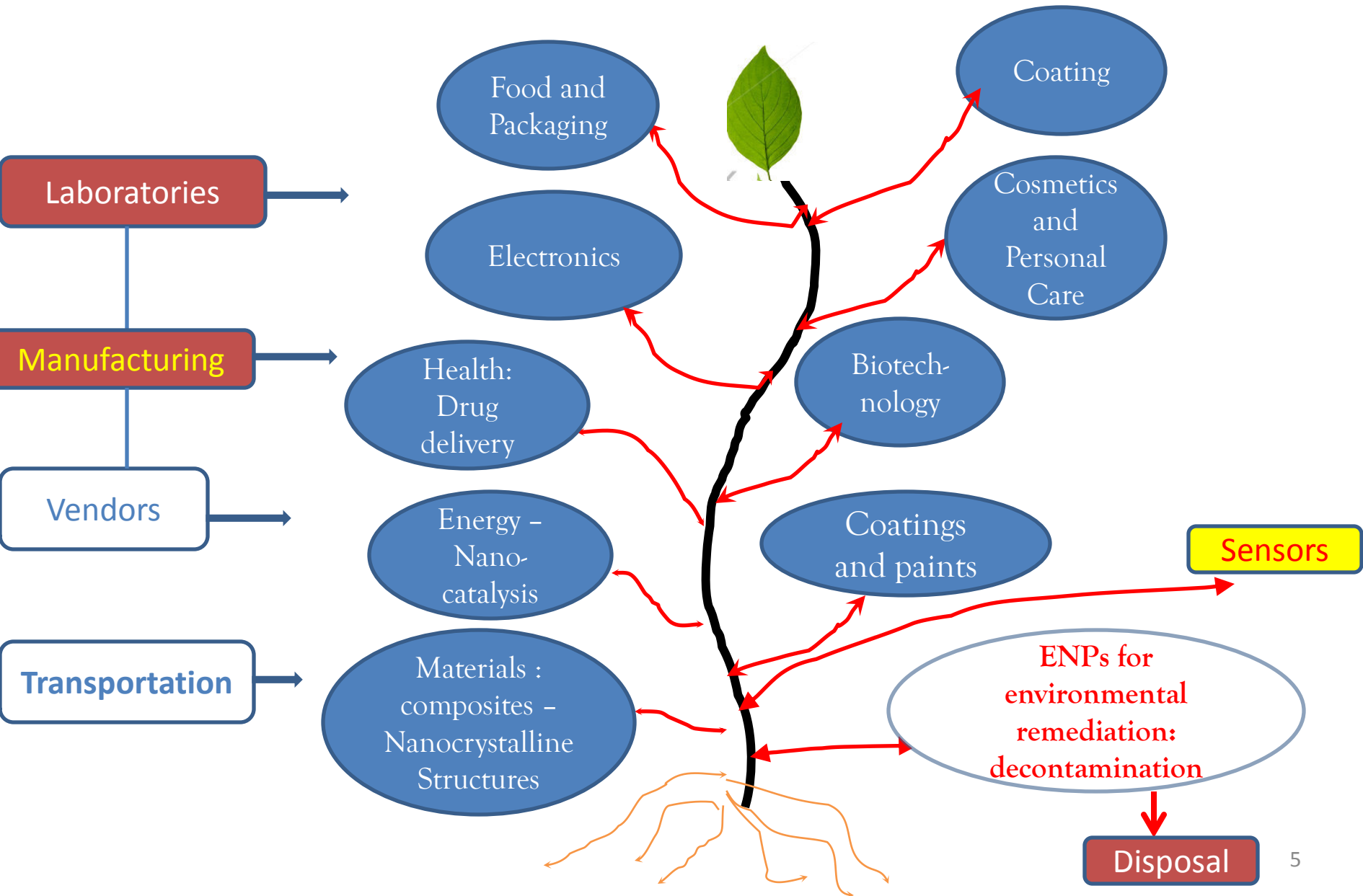
# The evolutionary aspects of nanotechnology: rapid economic and social transformation

- Current estimates of the impact of nanotechnology:
  - about \$1 trillion impact to the global economy,
  - The president's budget this year to support multi-agency R&D alone \$1.766 billion (up by 4% over FY 2012)\*
  - >2 million workers, 1 million of which may be in the U.S.

[Source: Roco and Bainbridge 2001].

- Nanotechnology: *manipulation and understanding of matter at a near-atomic scale to produce new structures, materials, and devices, nanomaterials, engineered nanoparticles* etc.
  - Transformation of many industrial sectors and to be applied in many ways
  - R&D has grown rapidly over the years
  - Applications in many areas now!

# Areas of applications of nanotechnology and ENPs



# Other known areas of application of various ENPs

- Applications – in fuel cells, energy storage, clean energy, and catalysts\*
- Medicine and pharmaceutical - delivery and improved diagnostic capabilities by fullerenes (absorption capability of ENPs)
- \*Consumer products - personal care & cosmetics e.g. sunscreen;
  - # of consumer products containing nanomaterials in the (US) - **54 products** (2006) to **1015 products** (2009)
  - # of consumer products containing nanomaterials on the European market – 6x increase 143 (2007) to 858 (2010)\*
  - \*\*By 2014 – \$2.6 trillion worth of consumer products (**15% in total**) will or may contain nano.
  - By 2020, 60,000 tones of nanomaterials on the market\*\*\*?

**Source:** Nanotechnology Research Directions for Societal Needs in 2020 NSF, WTEC report, September 2010

- \*[http://www.nanowerk.com/nanotechnology/introduction/introduction\\_to\\_nanotechnology\\_6.php#ixzz1x8KHr7aS](http://www.nanowerk.com/nanotechnology/introduction/introduction_to_nanotechnology_6.php#ixzz1x8KHr7aS) \*\*Approaches to Safe Nanotechnology – NIOSH (2012); The Royal Society, Royal Academy of Engineering (2004). Nano-science and Nanotechnology (2004): Opportunities and uncertainties. The Royal Society, Royal Academy of Engineering, London, July 2004
- \*\*\*Maynard, A.D. (2006). Nanotechnology: A Research Strategy for Addressing Risk. Woodrow Wilson International Center for Scholars, Washington, D.C. 6

# Environmental remediation/clean-up and related applications of some selected ENPs

ENPs	Remedial functions
TiO <sub>2</sub>	Pigments, UV-absorber, catalyst
ZnO	Polymer filler, UV-absorber
Au, Fe, Ag	Remediation, clothing
CeO <sub>2</sub> / Ce <sub>2</sub> O <sub>3</sub>	Catalyst (cars), fuel additive
ZrO <sub>2</sub>	Ceramic, catalyst support
Quantum dots; CdSe/ ZnS/ InAs/ InP/InGaP	Medical imaging, drug delivery

# Specific application of nanomaterials in remediation

Nanomaterials	Examples	Remediation Uses
BNPs and Zero-valent Iron	Ni; gold; Pd or Pt; BNPs - Bimetallic Nano Particles; nZVI	Remediation of <ul style="list-style-type: none"> <li>•waters,</li> <li>•sediments or</li> <li>•Soils</li> <li>•(hydrocarbons)</li> </ul>
Metal oxide ENPs	TiO <sub>2</sub> ; ZnO; and Cerium Oxide (CeO)	
Nano Metals	Engineered Nanosilver (Ag)	
Carbonaceous ENPs	Multiwalled Carbon Nanotubes – MWCNTs- <b>much better than activated C</b>	Sorption of metals e.g. Cd; Pb; Cu etc.
	<b>Nanoporous Activated C Fibers (ACFs)</b>	<b>Sorption of BTEX compounds</b>
Nano Clays/ Zeolites	Na <sub>6</sub> Al <sub>6</sub> .Si <sub>10</sub> .12H <sub>2</sub> O	Sorption/Ion Exchange for metals
Carbon-based Dendrimers	<b>Hyper-branched polymers (1-20 nm)</b>	PAHs; Ultra-filtration of heavy metals



## ENPs and the remediation of hazardous sites: the role of the physico-chemical properties of ENPs in the clean-up

- There exists **thousands of hazardous sites** across the U.S. that need clean-up;
  - Many superfund sites regulated by the U.S.EPA under CERCLA;
  - There are hazardous sites regulated by the U.S. EPA under RCRA; and
  - Other hazardous sites are regulated by the DOD; DOE etc.

Site "Owner"	# of Sites	%age
National Priority List <u>superfund sites</u>	740	<1
Other <u>superfund sites</u>	500	<1
States and private companies	150,000	51
Civilian agencies	3,000	1
Department of Energy / DOD	12,000	4
Underground Storage Tanks (UST) contaminated sites	125,000	43
Resource Conservation and Recovery Act (RCRA)	3,800	1
Total # Sites	~ 295,000	100%

## Types of wastes requiring clean-up

Typical Wastes found on the Superfund Sites	
Acetone/Aldrin/Dieldrin/Chlordane	Carbon Tetrachloride
Arsenic/Barium/Nickel /Cadmium/Lead	Chromium/Zinc/Mercury
Chloroform/Cynide	Benzene/2-Butanone
DDT – dichlorodiphenyltrichloroethane	1-1 Dichloroethene
DDE - bis(p-chlorophenyl)ethylene	1-2 Dichloroethene
DDD	Methylene Chloride
Pentachlorophenol	Naphthalene
Trichloroethylene (TCE)/Toluene	Vinyl Chloride/Cynide
Polycyclic Aromatic Hydrocarbons (PAHs)	Polychlorinated Biphenyls (PCBs)
Tetrachlorethylene	Pentachlophenol

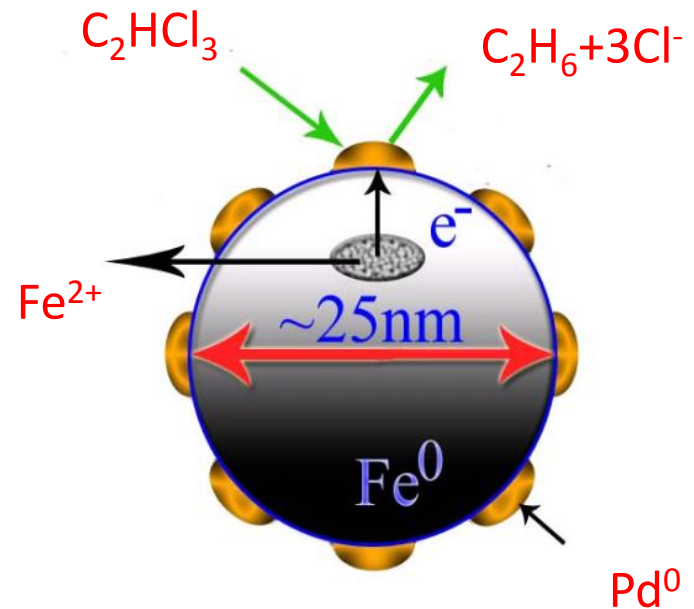
With approximately 300,000 hazardous sites across America (about 1,200 on the EPA's superfund sites or on the National Priority List (NPL) – the task of clean-up is a challenge

# ENPs and the remediation of hazardous sites: the role of the physico-chemical properties of ENPs in the clean-up

- Some hazardous wastes on the Superfund sites are **persistent and toxic; and others can bio-accumulate in the environment (PBT)**
- **Traditional remediation methods: costly, and may take long time**
  - Traditional remediation methods **e.g. pump and treat ~ \$ 5,000, 000**
  - Traditional remediation methods **(PRBs) - 3,400,000**
- **Nano-enhanced remediation methods**
  - e.g. nano-zero valent iron (nZVI) - **\$600,000**
- Thus: traditional methods are seen as **costly.; and it may** take as many as **(40)** years to clean-up all sites across America!

# ENPs and the remediation of hazardous sites: the role of the physico-chemical properties of ENPs in the clean-up

- Reactive surface coatings (e.g. doping with Pd; Pt; Cu; Ni; or Ag)
- High surface areas (e.g., 150 m<sup>2</sup>/gm)
- nZVI Redox is 25-30 x faster than bulk iron
- EPA Superfund sites (30 have used and some site continue to use ENPs)



- At nano-scale range (1-100 nm), ENPs **possess novel properties** significantly different from larger (bulk) particles of similar composition
  - Examples (a) Gold – may change from yellow to red; (b) CNTs (**single-walled** or **multi-walled** can become even stronger\*\*

# Novel physico-chemical properties of matter at the nanoscale: example: Bulk Gold – to- nano-GOLD



Bulk Gold (Au) = Yellow  
Conductive  
Nonmagnetic  
Chemically inert

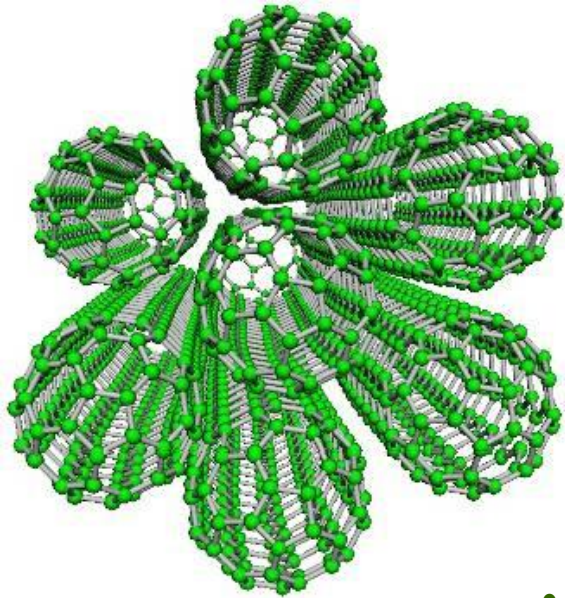
Nano Gold = Red  
Loses conductivity at  $\sim 1-3$  nm  
Becomes magnetic  $\sim 3$  nm  
Explosive and catalytic!

Much of the conventional understanding knowledge about the physico-chemical properties at the atomic or molecular and macroscopic gold tend to disappear at the nano-scale gold

And so the other characteristics of ENPs e.g. biological interactions with the human cells!

# What is known about carbon nano-tubes (CNTs): current knowledge of the CNTs' physico-chemical properties

## Carbon Nanotubes



- Small dimensions of nano-scale
- Carbon nanotubes (CNTs) are chemically stable
  - Carbon nanotubes are mechanically robust
- Carbon nanotubes have high thermal conductivity
- High specific surface area & good adsorbents
- Low resistivity and so high electrical conductivity
- Potential uses: materials, batteries, memory devices, electronic displays, conductors, sensors, medical imaging\*\*.

# Physico-chemical properties of ENPs: during and after use of nano-scale materials

- A list of the physical and chemical properties that can change at the nanoscale: during the synthesis, characterization, use and disposal - each ENP has its set of properties.
  - Color; **Melting temperature**; crystal structure; **chemical reactivity**; electrical conductivity; **magnetism**; mechanical strength; **surface area** ; **potential for conglomeration?** Size
  - are the physico-chemical properties of nanomaterials (and ENPs) that bring the benefits, also responsible for presenting hazardous conditions?
- Uncertainties in predicting the properties of ENPs (diameter/aspect ratios; size, etc. is a challenge to the **regulatory and the oversight of nanotechnology**
  - The ‘new’ properties of ENPs, incomplete information about hazards, varying size distribution, and heterogeneous composition complicate the application of conventional assessment methods
    - e.g. establish OELs based on agreed toxicity testing and safety factors\* (Schulte et al., 2010).

\*Source: Broekhuizen, P. Van., Veelen, W. Van., Streekstria,, W.H. Schulte, P. And Reunders, L. (2012). **Exposure Limits for Nanoparticles: Report of an International Workshop on Nano Reference Values.** *Ann Occup Hyg* (2012) 56 (5): 515-524. doi: 10.1093/annhyg/mes043

# Safety and health issues for consideration

## Progress Toward Safe Nanotechnology in the Workplace A Report from the NIOSH Nanotechnology Research Center

### Steps to Protect Workers Involved with Nanotechnology

### NIOSH Focus

**Hazard  
Identification**  
"Is there reason to believe  
this could be harmful?"

- Toxicologic research
- Health effects assessment
- Safety research

**Hazard  
Characterization**  
"How and under what  
conditions could it be  
harmful?"

- Toxicologic research
- Field assessment
- Epidemiology research

**Exposure Assessment**  
"Will there be exposure in  
real-world conditions?"

- Metrology research
- Field assessment
- Control technology research
- Personal protective equipment  
(PPE) research

**Risk Characterization**  
"Is substance hazardous  
and will there be exposure?"

- Risk assessment
- Dose modeling
- Exposure characterization

**Risk Management**  
"Develop procedures to  
minimize exposures"

- Risk communication
- Guidance development for controls,  
exposure limits, PPE, and medical  
surveillance
- Information dissemination

Adapted from Gibbs, 2006

**Hazard x Exposure**

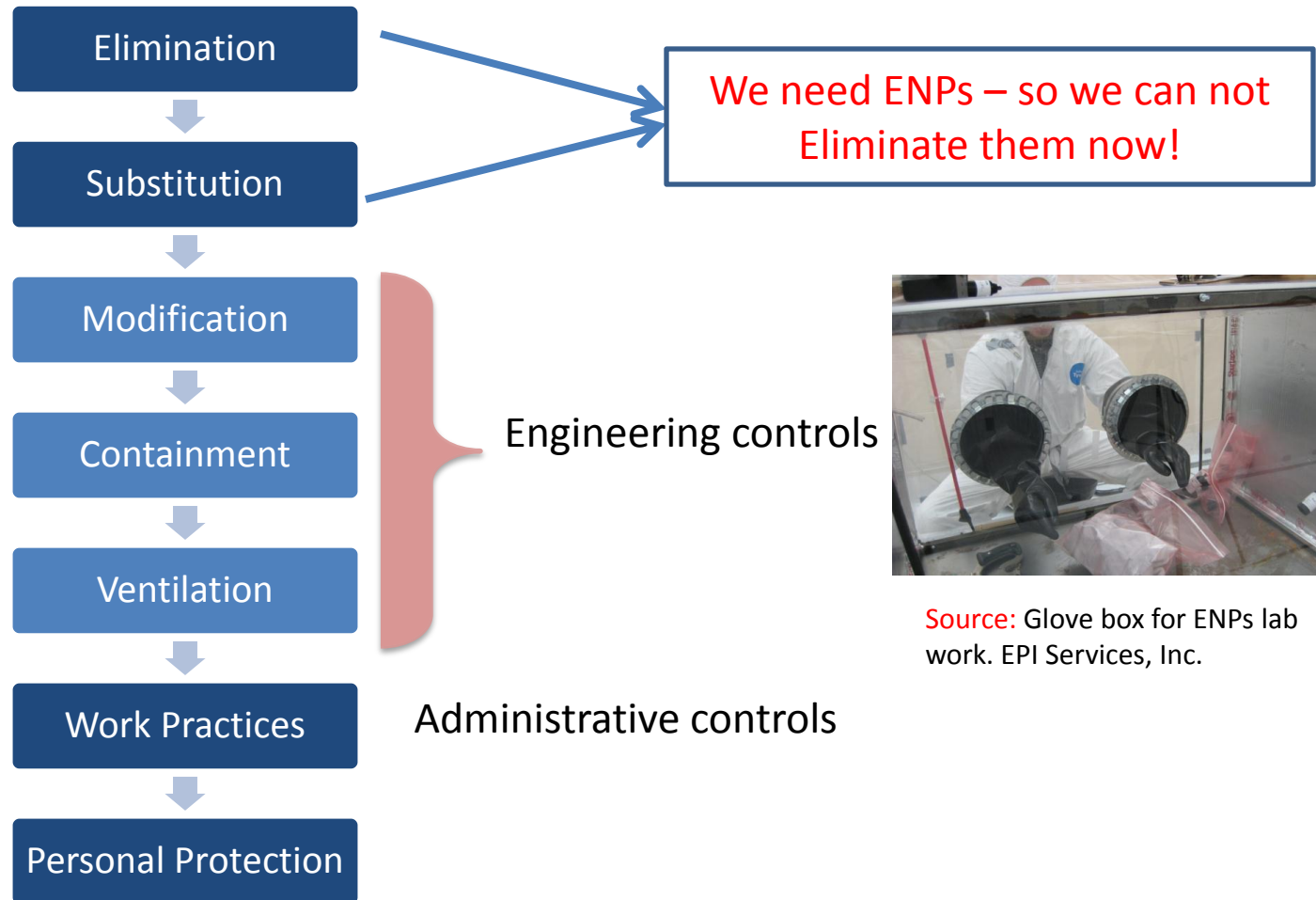
**=**

**Risk**

(Safety/Health and Ecological)

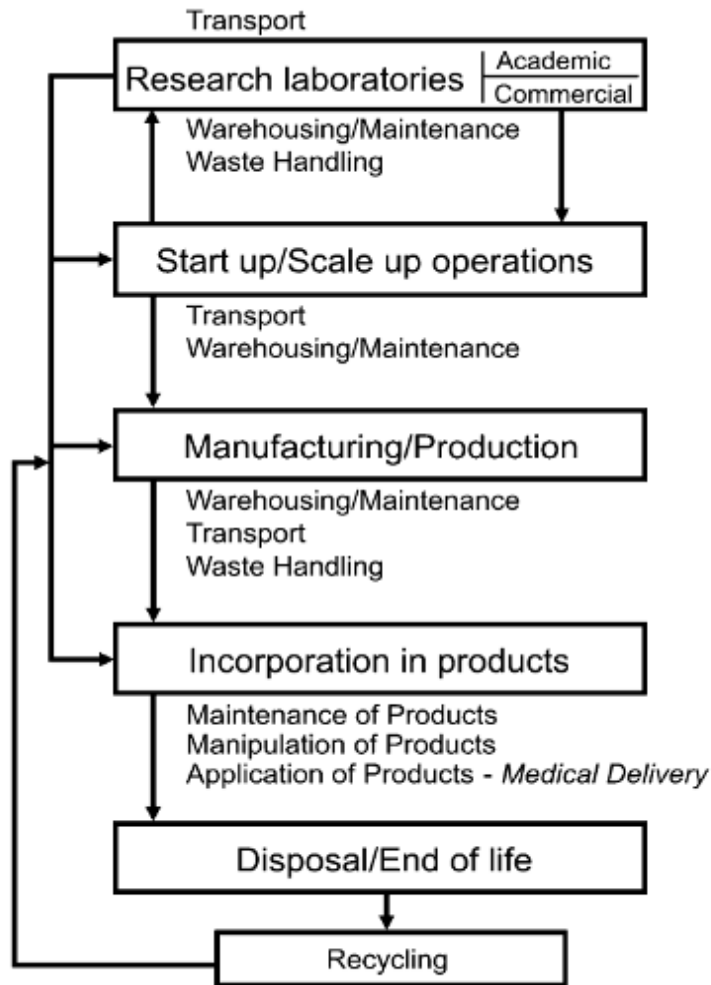


# An industrial hygienists' model for exposure assessment: prevention, control of potential contact, exposure and risks of ENPs



Source: Glove box for ENPs lab work. EPI Services, Inc.

# Handling and the life cycle stages of nanomaterials potential for contact and exposure to ENPs & human health risk



Areas with the potential for  
contact and exposures to ENPs

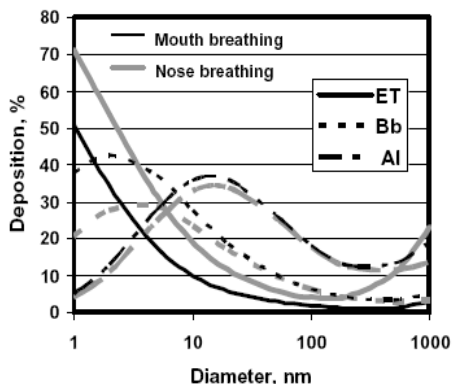
Fig. 5. Range of workplaces that could involve exposure to engineered nanoparticles (adapted from the paper by Schulte et al., 2008a,b).

Source: D.B. Trout, P.A. Schulte (2010). J. Toxicology, Vol 269 pp 128-135

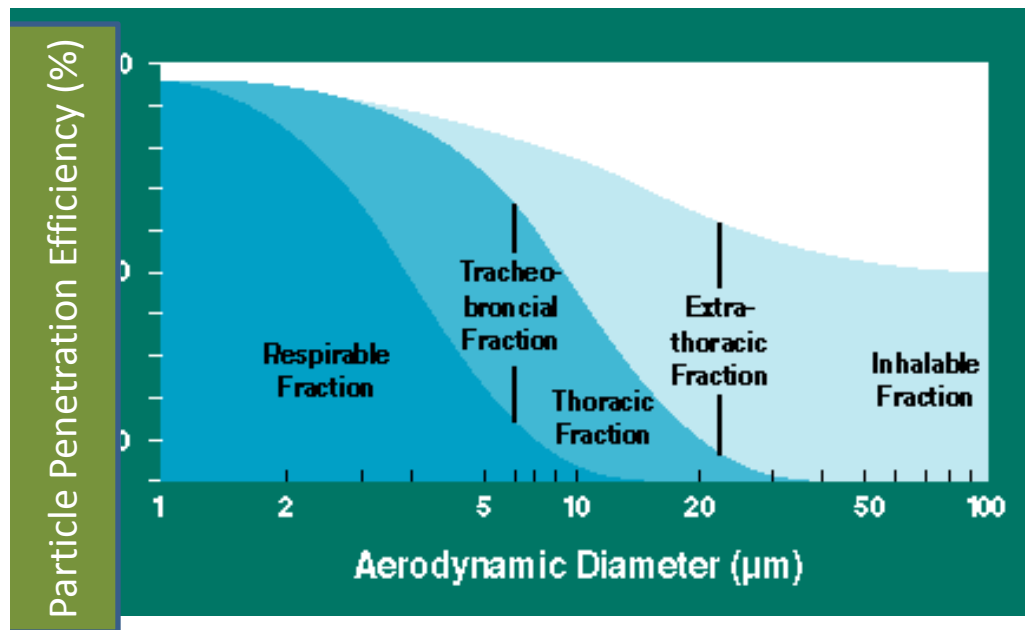
# Handling of ENPs at various life cycle stages: potential for contact, exposure to ENPs & human health risk

Life Cycle of ENPs	Responsibility for Oversight	Laws, Stds and Regs
Research and Development	Various agencies, including academia	HAZCOM (MSDS) RCRA; TSCA?
Manufacturing	Various (profit and non-profit)	Global (GHS; REACH; PIC-Rotterdam & Basel Conventions)
Transportation	DOT/International: air; land; maritime	Right-to-Know HazCom (MSDS) RCRA; TSCA; REACH;?
Application or uses of ENPs	Various consumers (previous slides)	FDA; EPA; OSHA; State agencies?
Disposal	EPA, OSHA etc	HAZCOM (MSDS) RCRA; TSCA?

# Hazard identification step: where would ENPs deposit in the respiratory tract?



**Figure 6**  
Regional deposition of inhaled NP with diameters between 1 nm and 1000 nm for nose and for mouth breathing in the extrathoracic airways (ET), the bronchial airways (Bb) and the alveolar region (Al) during breathing at rest, as predicted by ICRP 66 model (ICRP, 1994).



Nano- ENPs



Micro/Macro

The **respirable** fraction: portion of the inhalable particles to the alveoli (AED<sub>50</sub> = 4 µm)

The **thoracic** fraction: portion of the inhalable particles in the bronchial region AD<sub>50</sub> = 10 µm).

Source: Brown et al. Particle and Fibre Toxicology 2013, 10:12 Page 7 of 12 <http://www.particleandfibretoxicology.com/content/10/1/12>

Source: TSI – Health-Based Particle Size-Selective-Sampling

## Hazard identification step: specific health aspects of ENPs with exposed animals

- largemouth bass to uncoated C<sub>60</sub> i.e. fullerenes (0.5 and 1 ppm) for ~ 48 hrs.
  - There has been an increase in lipid peroxidation of the brain
  - Glutathione depletion in the gull; and
  - Reduced peroxidation in organs such as the liver and gull.

**Source:** Oberdörster (2004). *Environ Health Perspect* 112:1058-1062

- Several studies indicate potential for translocation of ENPs from the blood stream into the bone marrow

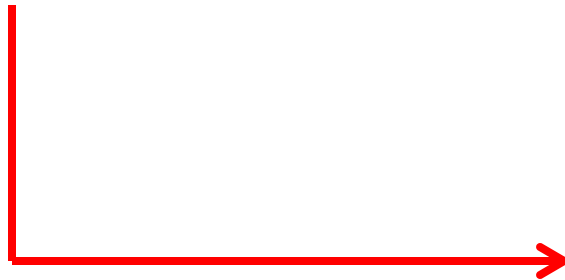


Table 5: Translocation of Nano-sized Particles in the Blood Circulation to Bone Marrow in Mice.

Particle Size	Type	Finding	Reference
~10 nm	PEG-quantum dots	Fast appearance of QDs in liver, spleen, lymph nodes and bone marrow (mouse)	Ballou et al., 2004
<220 nm	Metallo-fullerene	Highest accumulation in bone marrow after liver; continued increase in bone marrow but decrease in liver (mouse)	Cagle et al., 1999
90 – 250 nm	HAS coated polylactic acid nanoparticles	Significant accumulation in bone marrow, second to liver (rat)	Bazile et al., 1992
240 nm	Polystyrene (non biodegradable) polyisohexylecyon-acrylate (biodegradable)	Rapid passage through endothelium in bone marrow; uptake by phagocytizing cells in tissue (mouse)	Gibaud et al., 1996 1998 1994

## Hazard identification step: safety and health aspects of the ENPs

- Nanotechnology and ENPs present many benefits to the society! But what about the risks? Are ENPs hazardous or clean-products?
  - EPAs characterization of a Hazardous Substance Under RCRA :
    - **Ignitability** - a liquid of flash point < 140oF (60oC); or a non-liquid that can cause fire by friction or spontaneous ignition
    - **Corrosivity** - does the product corrode metals – could escape?
    - **Reactivity** - stability when mixed with water?
    - **Toxicity** - this parameter includes leaching and causing harm; pH characteristics etc...

# Hazard identification step: safety and health aspects of the ENPs

Nanoscale zero-valent iron can ignite spontaneously when it comes into contact with air.

**Ignability:** under the U.S.EPA regulatory definition, ENPs (e.g. nZVI)



Potential safety issues and concerns

## Potential Safety Concerns

- Although insufficient information exists to predict the fire and explosion risk associated with powders of nanomaterials, nanoscale combustible material could present a higher risk than coarser material with a similar mass concentration given its increased particle surface area and potentially unique properties due to the nanoscale.

**Source:** Mueller, N.C. And Nowack, B, (2010). Nanoparticles for Remediation: Solving Big Problems with Little Particles. In: *Journal of Elements*, Vol. 6, pp. 395-400 & NIOSH (2011). *Approaches to Safe Nanotechnology. Managing the Health and Safety Concerns Associated with ENPs*

## Exposure assessment step: relevant metrics of assessing exposure to ENPs

- Sampling and measurements of ENPs
  - are they too small to sample or measure?
- Selection of PPE's during sampling or measurements:
  - what type?
- Detection of contamination levels as airborne or waterborne
- Control of contamination to acceptable levels – airborne or waterborne
  - what levels (NIOSH RELs? OSHA PELs? ACGIH TLVs?)



## Hazard assessment step:

what methods to use to conduct assessment in these situations



pouring of nZVI slurry into a water well

**Source:** Mueller, N.C. And Nowack, B, (2010).

Nanoparticles for Remediation: Solving Big Problems with Little Particles. In: *Journal of Elements*, Vol. 6, pp. 395-400 & NIOSH (2011). *Approaches to Safe Nanotechnology. Managing the Health and Safety Concerns Associated with ENPs*



Carbon Nanotubes

**Source:** Michael T. Kleinman  
Department of Community and Environmental  
Medicine University of California, Irvine; pptx slides

## Exposure assessment step: relevant metrics of assessing exposure

- Metrics to evaluate biological effects – what would these be
  - Particle size; shape; oxidant generation; surface functionality & solubility?

These five parameters are believed to be the important determinants of exposure vs. biological response

- Other physical and chemical properties of the ENPs
  - pH etc - - impact to water bodies?
  - What is the dominating chemistry?
- Can these parameters impact the **dose-response relationships?**

	No. of compounds	Chemical composition	Size	Shape	Crystal structure	Surface area	surface charge	Surface chemistry	Solubility	Adhesion
C <sub>xx</sub>	189	100	16	5	2	3	4	2	9	-
MWCNT	31	100	52	32	10	16	-	6	-	-
SWCNT	51	100	37	37	2	16	-	18	-	1
QDs	58	100	66	10	-	-	26	74	-	-
N-metals	207	100	93	29	17	21	16	25	3	-
Others*	182	100	91	14	-	16	26	15	2	-

456 \*) Others include polymers, in-organic nanoparticles, carbon black, and soot

## Exposure assessment steps: need for quantitative measurements to support regulatory and oversight of ENPs

- Limited or lack of established data on occupational exposure limits (OELs) in the workplace to compare to after the assessments
  - OSHA
- Limited or lack of established data on community or general environments exposures to compare to after the assessments
  - EPA
  - FDA

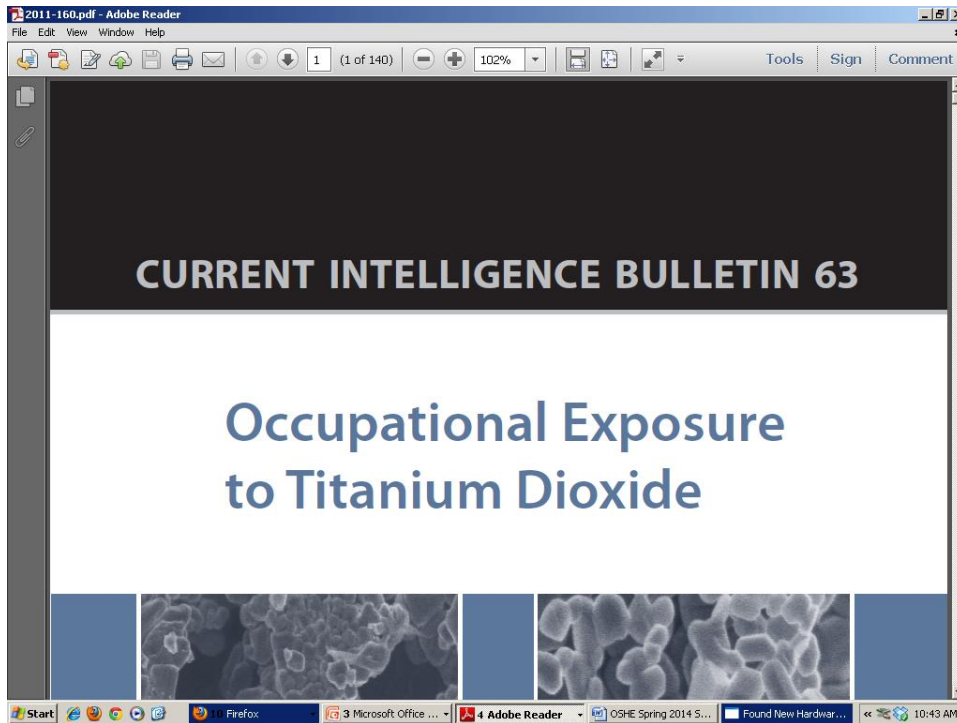
Sources: (a) ECHA (2010) Guidance on derivation of DNEL/DMEL from human data DRAFT (Rev.:2.1). Available at [http://www.echa.europa.eu/documents/10162/13632/r8\\_dnel\\_hd\\_draft\\_rev2-1\\_final\\_clean\\_en.pdf](http://www.echa.europa.eu/documents/10162/13632/r8_dnel_hd_draft_rev2-1_final_clean_en.pdf).

(b) ECHA. (2011) Guidance on the compilation of safety datasheets. Version 1.0, September 2011. Available at [http://guidance.echa.europa.eu/docs/guidance\\_document/sds\\_en.pdf](http://guidance.echa.europa.eu/docs/guidance_document/sds_en.pdf).

# Exposure assessment steps: limited quantitative measurements

- Federal level

- e.g. OSHA (Hazcom and MSDS?) - PELs ; APHA/NEHA/AIHA? - Nanotechnology Working Group ; EPA (TSCA); DOT \*(?) - Current MSDS? Labeling? ETC. **CFR 49 Parts 100 To 185**; NIOSH



Compare with recommended exposure limits of bulk  $\text{TiO}_2$  of  $15 \text{ mg/m}^3$

## 5.2 Recommended Exposure Limits

NIOSH recommends airborne exposure limits of  $2.4 \text{ mg/m}^3$  for fine  $\text{TiO}_2$  and  $0.3 \text{ mg/m}^3$  for ultrafine (including engineered nanoscale)  $\text{TiO}_2$  as TWA concentrations for up to 10 hr/day during a 40-hour work week, using the international definitions of respirable dust [CEN 1993; ISO 1995] and the NIOSH Method 0600

Includes nanoparticles

## Exposure characterization step:

number of people exposed to ENPs (work and community)

Workplace or community characterization  
Does the workplace or community use ENPs? How?

Number of workers potentially exposed (skills, age, gender; work practices etc;  
community settings)?

Potential for ENPs to contaminate Water? Air; Soils?

Preliminary information on physico-chemical characteristics of ENPs

**Risk Assessment and Scoring**



**Risk Management**

# Risk management step: prevention, control and minimize exposure to ENPs



Recommended work practices in the laboratory:  
main focus to prevent potential exposures to ENPs

Source: Bruce Lippy, Ph.D., CIH, CSP; Module 3: Assessing exposure to Nanomaterials in the workplace: Introduction to Nanomaterials and occupational health Photos courtesy of M. Methner, NIOSH



Source: Bruce, L., (-) Introduction to Nanomaterials and Occupational Health, Module 4: Controlling Exposure to Nanomaterials

Use of the glove box during  
research and development



## Burden of regulating conventional pollutants in the U.S.

- EPA –TSCA (1976) covers most conventional toxic chemicals produced and used by industry, commercial/consumer products
  - TSCA based on traditional risk assessment– Hazard ID; evaluation; characterization; and control; RA may not apply to the ENPs
  - Limitations of the risk assessment process – uncertainties
  - At the time of its enactment TSCA grandfathered >> 60,000 chemicals
  - EPA and notice of intent – new uses etc....and the oversight of > than 35,000 chemicals used daily in US industry
- ENPs in drugs, cosmetics, food packaging labeling
  - Regulated by the FDA;
- ENPs use as pesticides
  - Regulated by EPA under FIFRA

# EPA and the Toxic Substances Control Act

## Burden of Regulating Toxic and Hazardous Chemicals in the U.S.

U.S. ENVIRONMENTAL PROTECTION AGENCY

### Pollution Prevention and Toxics

Search: All EPA This Area

You are here: EPA > Chemical Safety & Pollution Prevention > Pollution Prevention and Toxics > Control of Nanoscale Materials under the Toxic Substances Control Act

**The federal government is currently shut down. The EPA website and social media channels will not be updated until the federal government reopens. En la actualidad, el cierre del Gobierno Federal está en vigor. [Message from Administrator McCarthy to EPA employees.](#)**

## Control of Nanoscale Materials under the Toxic Substances Control Act

You will need Adobe Reader to view some of the files on this page. See [EPA's PDF page](#) to learn more.

On this page:

- Nanoscale Materials
- Premanufacture Notifications
- Significant New Use Rule
- Information Gathering Rule
- Test Rule
- Timing of Rules
- International Cooperation on Nanomaterials
- Resources and Related Links

### Nanoscale Materials

Many nanoscale materials are regarded as "chemical substances" under the Toxic Substances Control Act (TSCA). To ensure that nanoscale materials are manufactured and used in a manner that protects against unreasonable risks to human health and the environment, EPA is pursuing a comprehensive regulatory approach under TSCA. This four-pronged approach includes: Premanufacture notifications; a Significant New Use Rule; an information gathering rule; and a test rule.

### Premanufacture Notifications

**Highlights**

February 19, 2010 -- EPA is developing a Significant New Use Rule (SNUR) and other regulations to address potential health and environmental risks from nanoscale materials.

March 15, 2010 -- EPA is for the first time providing free access to the consolidated Toxic Substances Control Act (TSCA) Chemical Substance Inventory on its Web site. Also for the first time the Inventory is available at [Data.gov](#) as a dataset and as an extraction tool, which makes the data easier to manipulate. News release: EPA providing easy access to TSCA Inventory.

U.S. ENVIRONMENTAL PROTECTION AGENCY

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### Premanufacture Notifications

TSCA requires manufacturers of new chemical substances to provide specific information to the Agency for review prior to manufacturing chemicals or introducing them into commerce. EPA can take action to ensure that those chemicals that pose an unreasonable risk to human health or the environment are effectively controlled. Manufacturers are encouraged to [contact EPA](#) if they need assistance determining whether their nanoscale materials are subject to new chemical notification requirements.

Since 2005, EPA has received and reviewed over 100 new chemical notices under TSCA for nanoscale materials, including carbon nanotubes, and that number will increase over time. The Agency has taken a number of actions to control and limit exposures to these chemicals, including:

- limiting the uses of the nanoscale materials,
- requiring the use of personal protective equipment, such as impervious gloves and NIOSH approved respirators,
- limiting environmental releases, and
- requiring testing to generate health and environmental effects data.

EPA has permitted limited manufacture of new chemical nanoscale materials through the use of administrative orders or Significant New Use Rules (SNUR) under TSCA. The Agency has also allowed the manufacture of new chemical nanoscale materials under the terms of certain regulatory exemptions, but only in circumstances where exposures were tightly controlled to protect against unreasonable risks (using, for example, the protective equipment and environmental release limitations discussed above).

### Significant New Use Rule (SNUR)

The Agency is developing a SNUR under section 5(a)(2) of TSCA to ensure that nanoscale materials receive appropriate regulatory review. The SNUR would require persons who intend to manufacture, import, or process new nanoscale materials based on chemical substances listed on the TSCA Inventory to submit a Significant New Use Notice (SNUN) to EPA at least 90 days before commencing that activity. The SNUR would identify existing uses of nanoscale materials based on information submitted under the Agency's voluntary [Nanoscale Materials Stewardship Program \(NMSPP\)](#) and other information.

The SNUNs would provide the Agency with a basic set of information on nanoscale materials, such as chemical identification, material characterization, physical/chemical properties, commercial uses, production volume, exposure and fate data, and toxicity data. This information would help the Agency evaluate the intended uses of these nanoscale materials and to take action to prohibit or limit activities that may present an unreasonable risk to human health or the environment.

- EPA's ability to review toxic or hazardous chemicals and regulate 500-1,000 new chemicals created annually
- 120,000 US establishments create and distribute chemicals
- >20,700 pesticides used in US, and >1.2 billion lbs of pesticides produced annually, with >890 active ingredients, some are toxic!



# EPA and the Toxic Substances Control Act

## Burden of Regulating Toxic and Hazardous Chemicals in the U.S.

**Table 14.2 Estimated Numbers of Chemicals in Commercial Substances during the 1990s**

Type of chemical	Estimated number
Chemicals in commerce	100,000
Industrial chemicals	72,000
New chemicals introduced per year	2,000
Pesticides (21,000 products)	600
Food additives	8,700
Cosmetic ingredients (40,000 products)	7,500
Human pharmaceuticals	3,300

Synthetic  
chemicals  
are  
numerous

Data from Harrison, P., and F. Pearce. 2000. *AAAS Atlas of Population and Environment*. Berkeley, CA: University of California Press.

- EPA has tried in many ways to regulate by prohibiting or restricting:
  - **asbestos** (fiber products which emerged as good insulating agents);
  - **DDT** (a very pesticide which became deadly)
  - **Dioxins**
  - **PCBs**
  - And more than **500 other commercial chemicals**

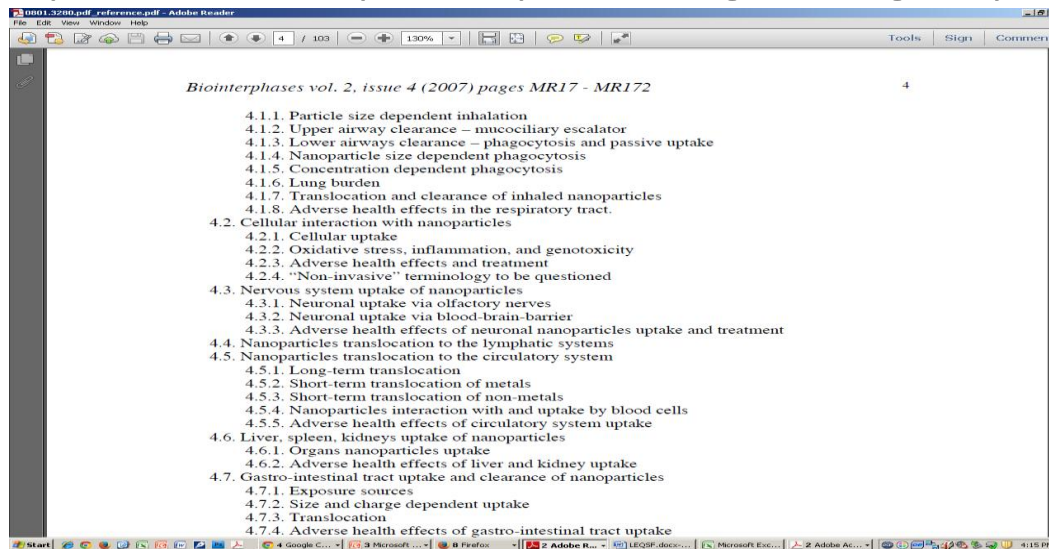
# Packaging, labeling, and storage: use of the conventional placards to transport ENPs by air, land and maritime



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# Nano-informatics project: local government agencies' regulatory and oversight of ENPs

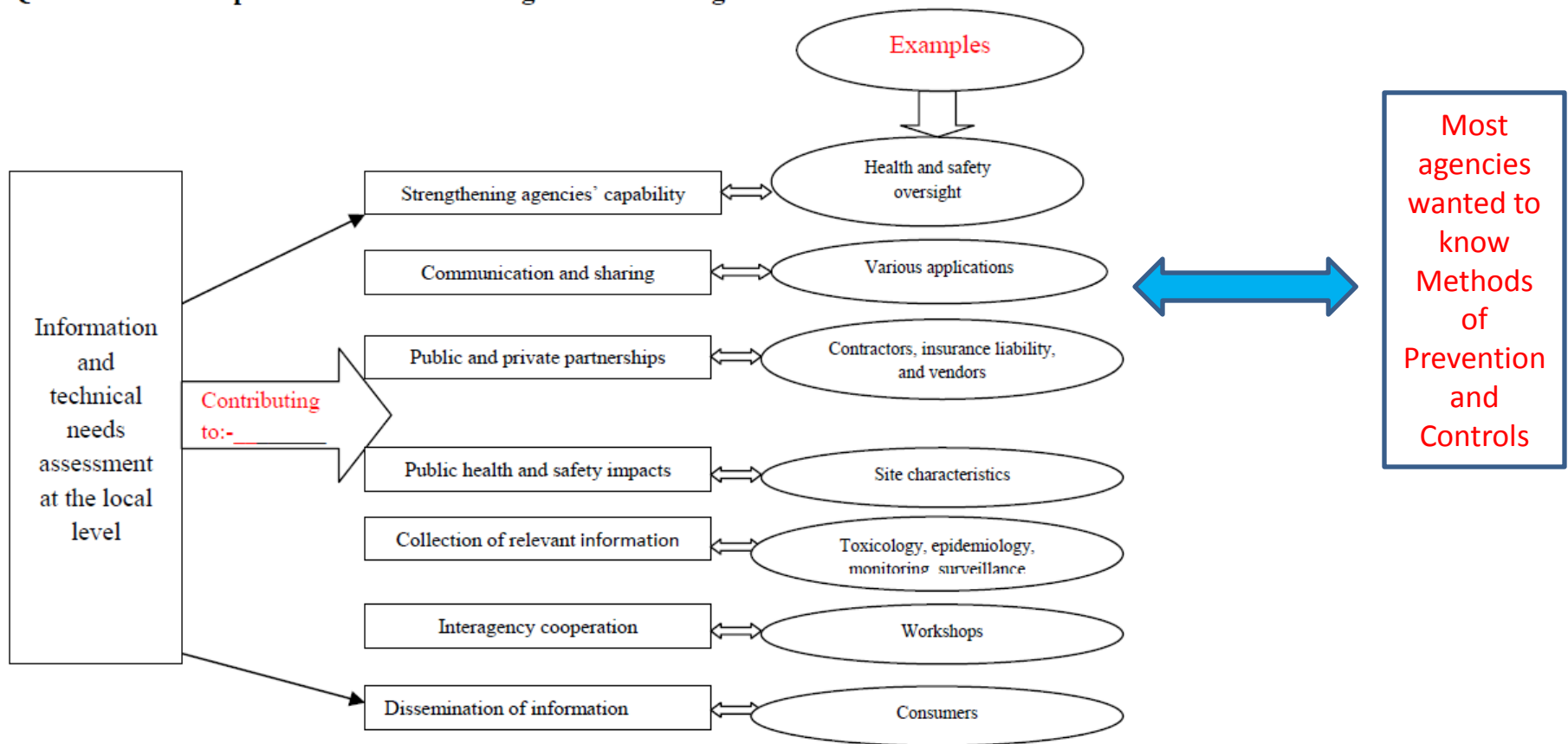
- There are significant occupational and non-occupational health concerns
  - Potential contact/exposure to ENPs may lead to undesired biological effects
- States and local government agencies' key role is to protect human health
  - Through regulatory and oversight mechanisms and lack of information may impede work on permit processing; emergency response etc.



•Source: \*Barbara K et al (2009). Nanotechnology and Insitu Remediation: A Review of the Benefits and Potential Risks. Environmental Health Perspective Vol 117(12) pp 1823-1831) \*\* National Ground Water Association (2008). Environmental Remediation Drilling Safety Guideline <http://www.ngwa.org/ASSETS/4D9F5210FA214110807EE0EC11001446/erdsq.pdf>

# Information and technological needs of the state government agencies for regulatory oversight of ENPs: surveys and preliminary results

**Fig 3**  
**Questions and Responses from the State Agencies and Programs**



## Recommendation for best practices with ENPs

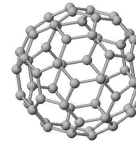
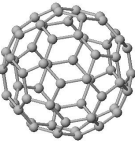
- There is an increase in the number of workers involved with research activities, transportation, use, and disposal of ENPs.
  - Evidence which is currently available suggest that contact with, and exposure to, ENPs can cause health effects in animals!
  - Products which such as DDT; asbestos; and PCBs emerged as “good” for various applications but they have turned out to be deadly
    - We should take bold efforts to avoid repeating this for ENPs!
  - Health and safety of people can be protected if we generate and make appropriate information on the toxicity and hazards of ENPs available and known to government agencies, workers and the communities

## Recommendation for best practices with ENPs

- To start assessments information on ignitability, reactivity, toxicity and flammability is essential to conduct proper hazard identification of ENPs
- There is need to use a rational science-based approach to minimize potential harm that may be caused by ENPs; and if not available,
- precautionary measure should be implemented e.g. Europe has developed **precaution-based nano-reference values (NRVs)\*** to substitute for health-based OELs and derived no-effect levels (DNELs) for ENPs due to lack of appropriate metrics for exposures assessments!

Thank you all for your attention!

Q & A



Dr. Ephraim Massawe,  
Southeastern Louisiana University  
OSHE Program  
SLU 10847, Hammond, LA 70402  
Tel 985-549-2243 Fax 985-549-5532  
Email: [ephraim.massawe@selu.edu](mailto:ephraim.massawe@selu.edu)



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