Challenges in Addressing Nanotechnology Commercialization Implications - What Have We Learned?

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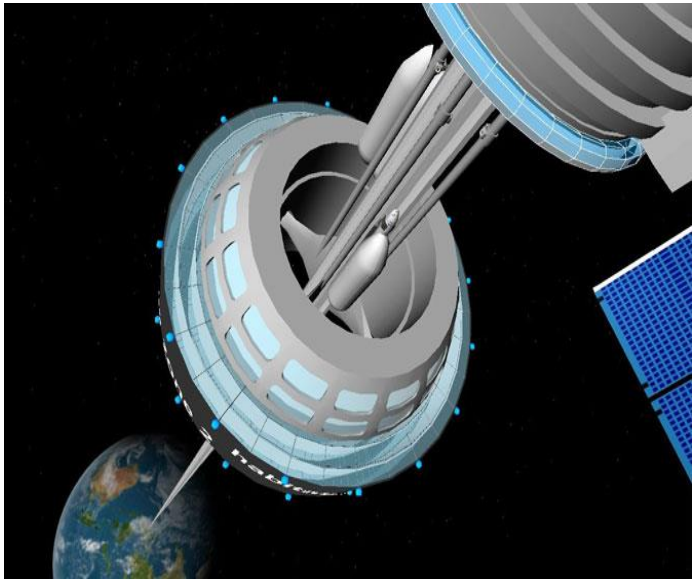
U.S. Consumer Product Safety Commission
Office of Hazard Identification and Reduction (EXHR)
Sustainable Nanotechnology Organization (SNO) Conference
November 11, 2016

Outline

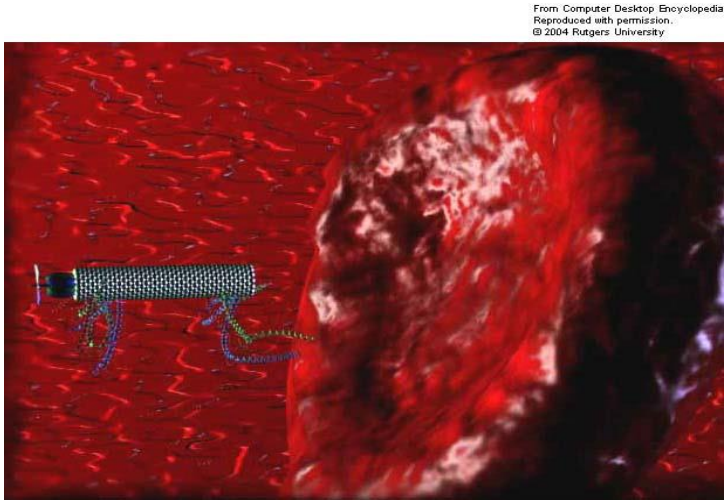
- Expected benefits to society
- Public perception and stakeholder concerns
- The National Nanotechnology Initiative (NNI)
- Consumer nano-enabled product implications
- Research to address product implications
- State of the science for exposure assessment

Expected Nanotechnology Societal Benefits

- Early 2000's
  - The National Nanotechnology Initiative (NNI) was established in 2001
    - Federal support the sustainable development of nanotechnology
- Considerable attention on the potential benefits
  - Elevator to space made with nanotechnology
  - Array of new smart products
    - Smart and stain resistant clothing, electronics, sunscreens
  - Nanobots to cure disease and repair cells

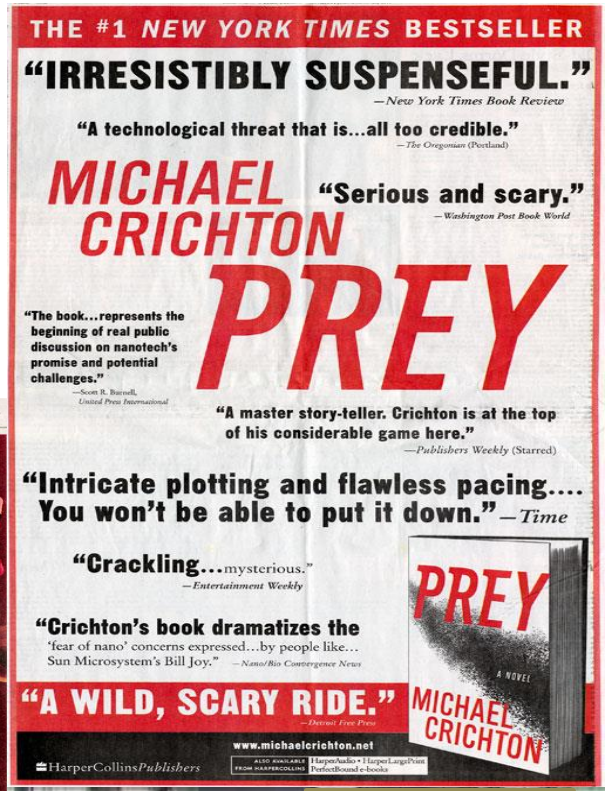


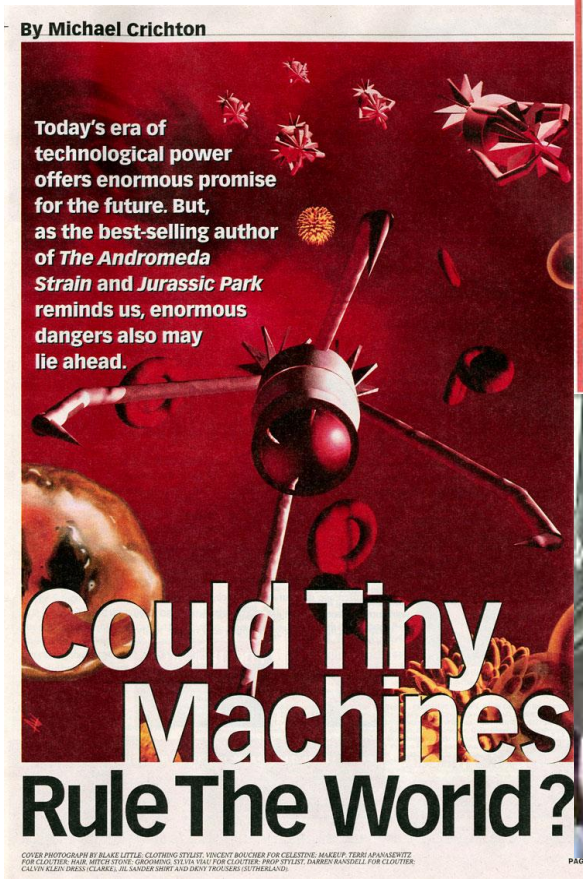
Source -news.discovery.com



Nanotechnology Concerns

- Exaggerated fears expressed by the public
- Protests
- Media
  - Killer Nanoparticles
    - Book “Prey” by Michael Crichton



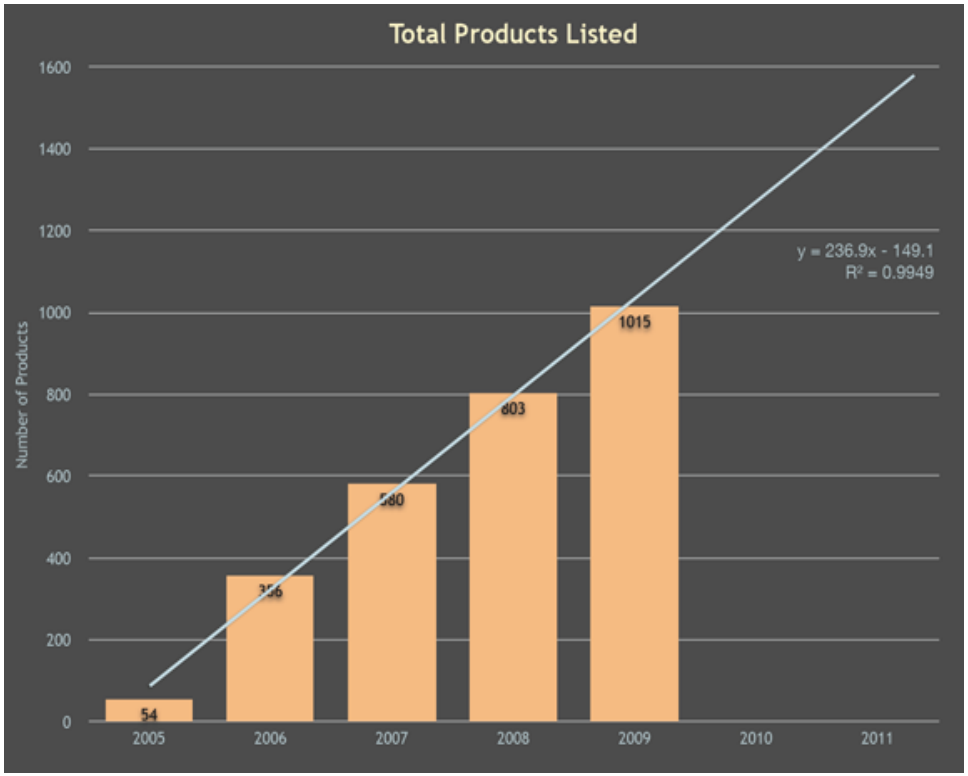


Sources – Parade Magazine, November 24, 2002;

- http://nanotechnologies.weebly.com/against.html

Stakeholder Perspectives on the Commercialization of Nanotechnology

Consumer Products Containing Nanomaterials



Courtesy of the Woodrow Wilson Center Project on Emerging Nanotechnologies

- Stakeholder group activities
  - Database of nano-enabled products
  - Reports on regulatory authority
    - Are federal agencies prepared to address nanotechnology implications?

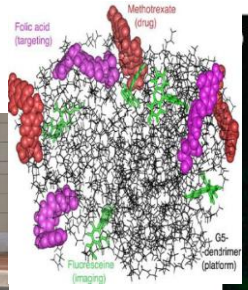

NIH
OSTP
OMB
NSF
DOE
NIST
DOD
FDA
NASA
NIOSH
USDA/NIFA
National Nanotechnology Initiative
Collaborative, Multi-agency, Cross-cut Program
Among 25 Federal agencies
USDA/FS
DOS
EPA
Ensures US Leadership in fundamental R&D to advance understanding and control of matter at nanoscale for:
DOTr
NRC
• National economic benefit
DOT
USPTO
• National security
USGS
ITIC
• Improved quality of life
DOL
DOJ
DOC BIS
DHS
CPSC
ITC
DOEd

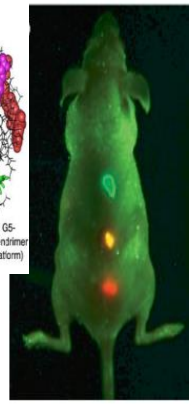
www.nano.gov

NNI Vision

A future in which the ability to understand and control matter at the nanoscale leads to *a revolution in technology and industry that benefits society.*







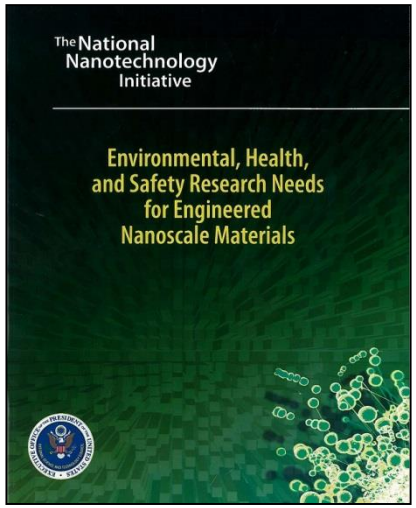




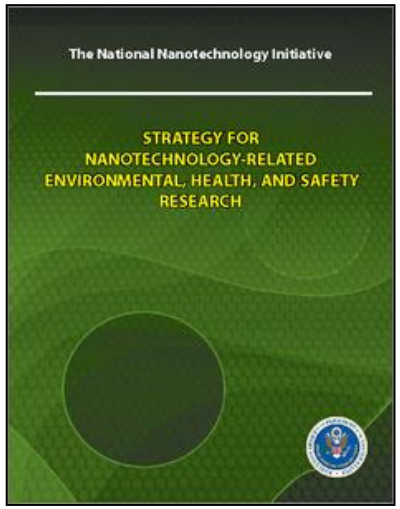
The 2011 NNI Environmental, Health, and Safety Research Strategy

- Serves as a comprehensive and more detailed follow-up to a prior initial strategy (2008) and identification of research needs (2006)
- Provides guidance to Federal agencies on research activities, priorities, and program planning

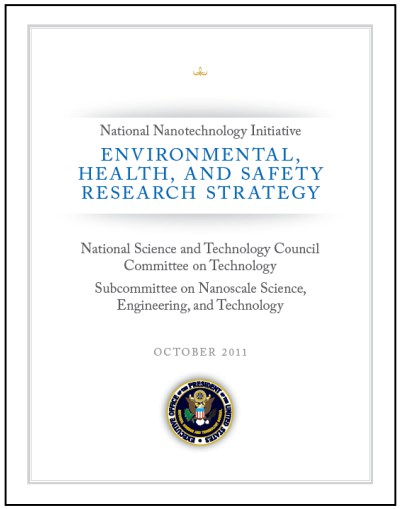
2006
(published 2007)



2008



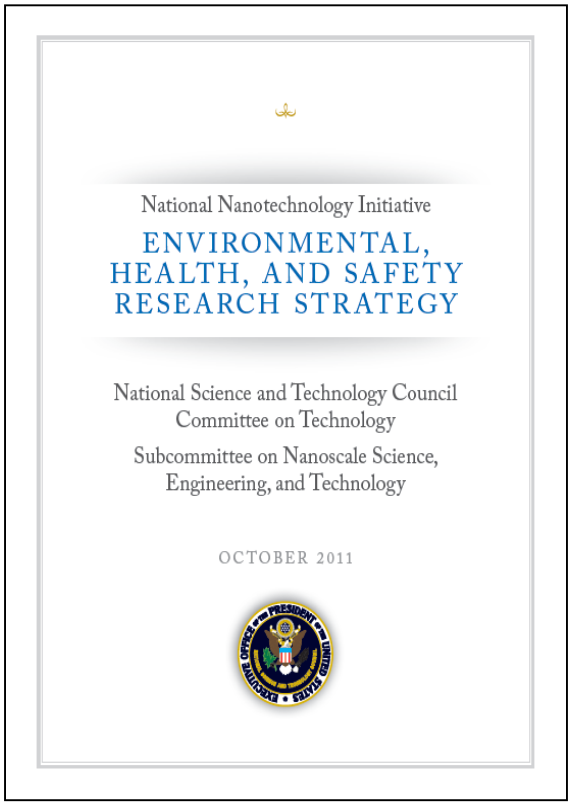
2011



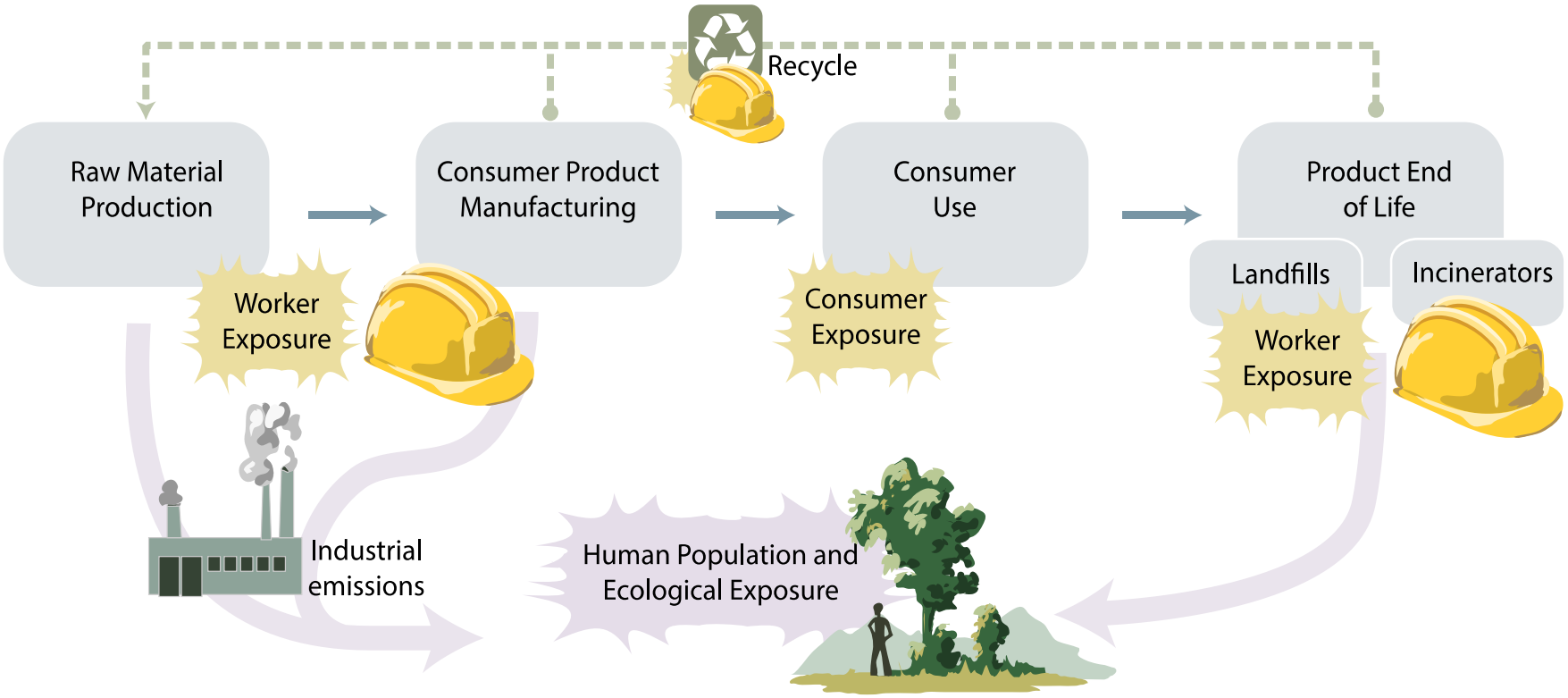
The 2011 NNI Environmental, Health, and Safety Research Strategy

The NNI Environmental Health and Safety Mission

- Engage stakeholders through workshops for input
- Employ science-based risk analysis and risk management
- Protect public health and the environment
- Foster technological advancements that benefit society

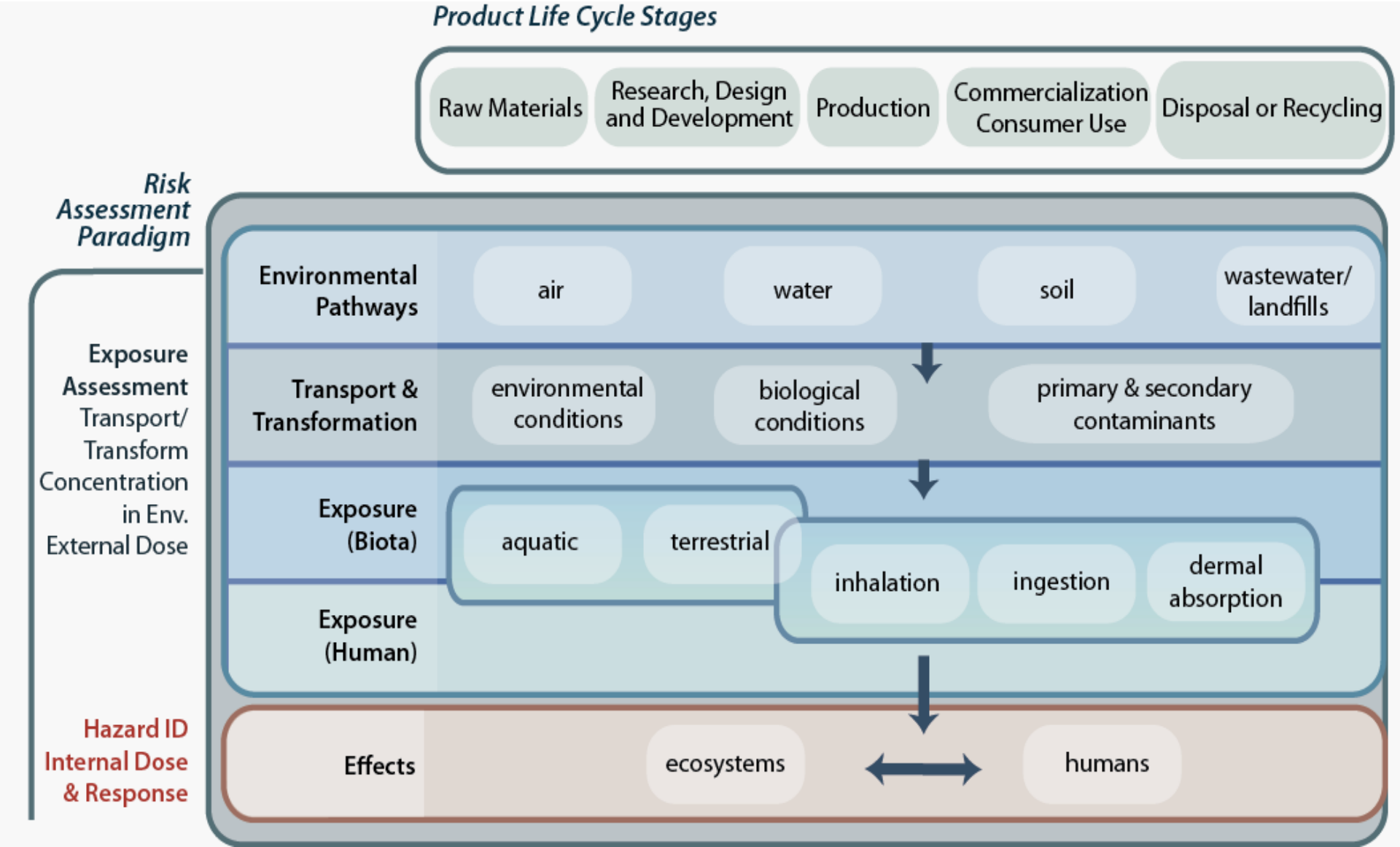


The 2011 NNI EHS Strategy: A conceptual framework that incorporates risk-assessment, risk management, and life cycle analysis to inform specific research principles



Source: EPA

Nano.gov
U.S. National Nanotechnology Initiative



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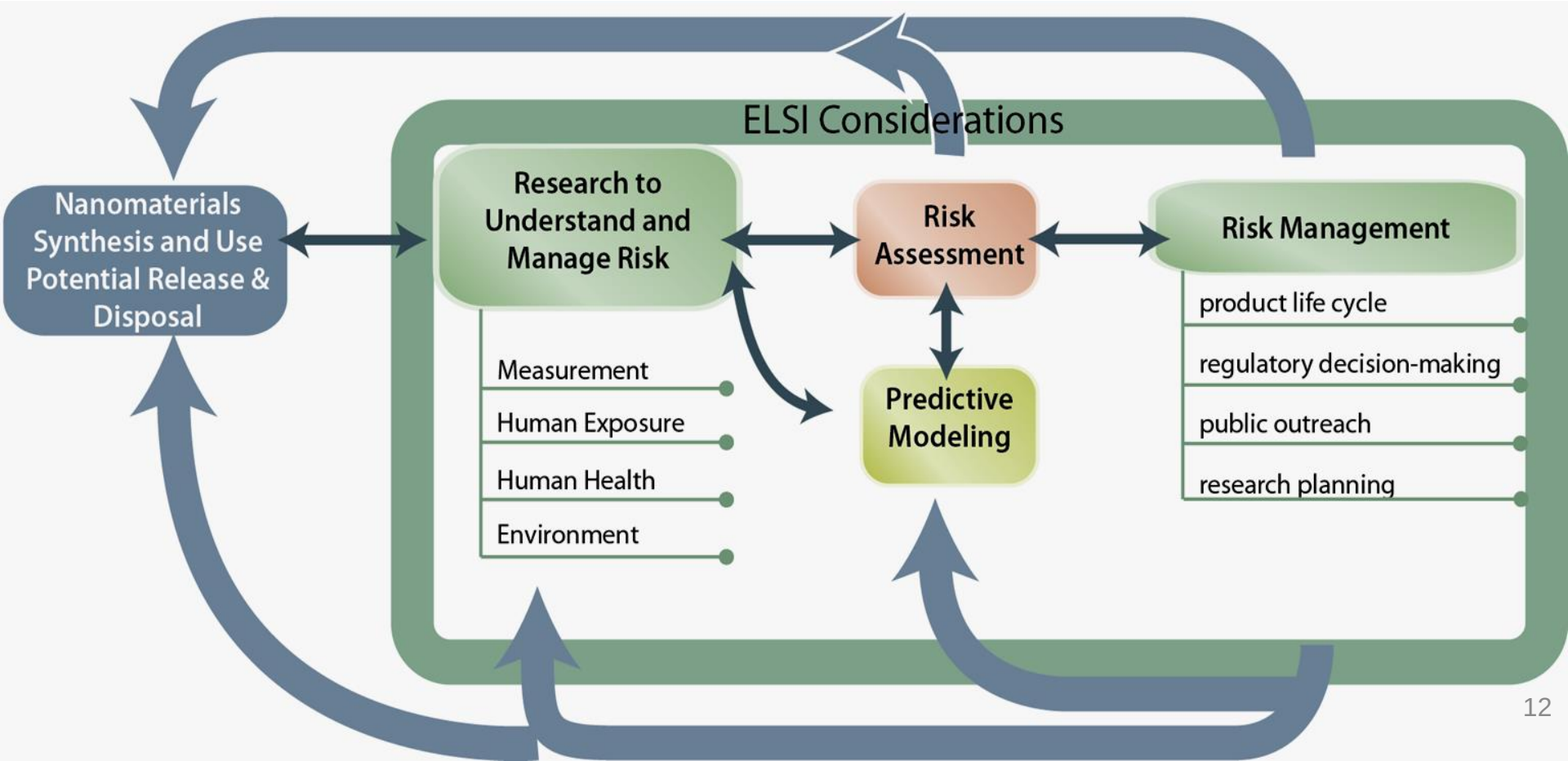
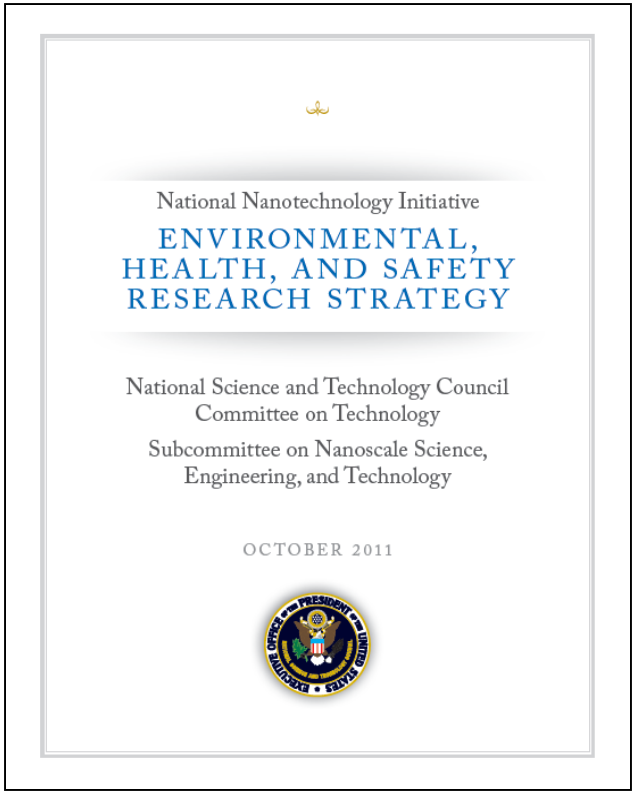


Risk-Based Framework for Addressing Nanotechnology Health and Safety Implications

- 2011 National Nanotechnology Initiative (NNI) Environmental, Health, and Safety (EHS) Research Strategy
  - Employ science-based risk analysis and risk management
  - Research Needs
    - Understand processes and factors that determine exposures to nanomaterials
    - Identify population groups exposure to engineered nanomaterials
    - Characterize individual exposures to nanomaterials
    - Conduct health surveillance of exposed populations



Framework for Addressing Nanotechnology Health and Safety Implications

- 2011 Office of Science and Technology Policy (OSTP) "Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials"
  - "A fundamental element of these risk-based approaches is to examine those characteristics and properties of a material that are relevant to considerations about human and environmental safety-such as **exposure**, biodistribution…"
    - **Best available science**

Addressing Nano-enabled Product Implications

- Are nanomaterials actually used in manufactured products?
  - Are robust analytical methods available?
- How will federal agencies regulate nano-enabled products?
- Can traditional toxicology testing approaches be used for nanomaterials
- Do methods exist to characterize and quantify nanomaterial releases from products
- Can traditional risk assessment approaches be applied?

U.S. Consumer Product Safety Commission

- Independent federal agency
- Established in May 1973
- Responsible for consumer product safety including imported consumer products
- Five Commissioners, appointed by the President and confirmed by the Senate

What is a Consumer Product?

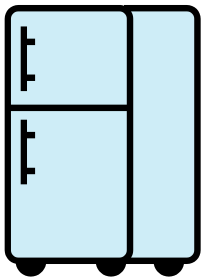
- Thousands of different types of products sold or distributed to consumers for personal use in or around the household or school and in recreation

". . . any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise…"[1]

Section 3(a)(5) of the Consumer Product Safety Act, 15 U.S.C. § 2052 (a)(5)

Laws that Give CPSC Authority Over Consumer Products, Imported and Domestic

- Consumer Product Safety Act*
- Federal Hazardous Substances Act*
- Flammable Fabrics Act
- Poison Prevention Packaging Act
- Virginia Graeme Baker Pool and Spa Safety Act
- Children's Gasoline Burn Prevention Act
- Refrigerator Safety Act
- Drywall Safety Act
- Child Nicotine Poisoning Prevention Act



*Amended by the Consumer Product Safety Improvement Act of 2008

Federal Hazardous Substances Act (FHSA)

- Covers articles that are or contain a “hazardous substance ,” 15 U.S.C. § 1261(f)
  - Any substance or mixture which is toxic, corrosive, an irritant, a strong sensitizer, flammable or combustible, or generates pressure through decomposition, heat or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.
  - self-administering statute
  - considers exposure
  - requires case-by-case hazard assessment

CPSC Nanomaterial Statement

- Released in 2005
- The potential safety and health risks of nanomaterials can be assessed under existing CPSC statutes, regulations, and guidelines.
- CPSC staff assesses a product's potential chronic health effects to consumers under the Federal Hazardous Substances Act (FHSA).
- The analysis may require unique exposure and risk assessment strategies.

Identified Data Needs for Nano-enabled Product Exposure and Risk Assessments

- Determination of consumer products that contain nanomaterials and the specific nanomaterials that are incorporated into these products.
- Exposure studies that quantify the releases of nanomaterials from products.
  - Into a variety of media including air and liquids (e.g., surrogate sweat and saliva).
- Estimates of potential human exposure and uptake of released nanomaterials.
- Development/validation of risk assessment approaches to estimate potential health effects

Development of the CPSC Nanotechnology Research Program

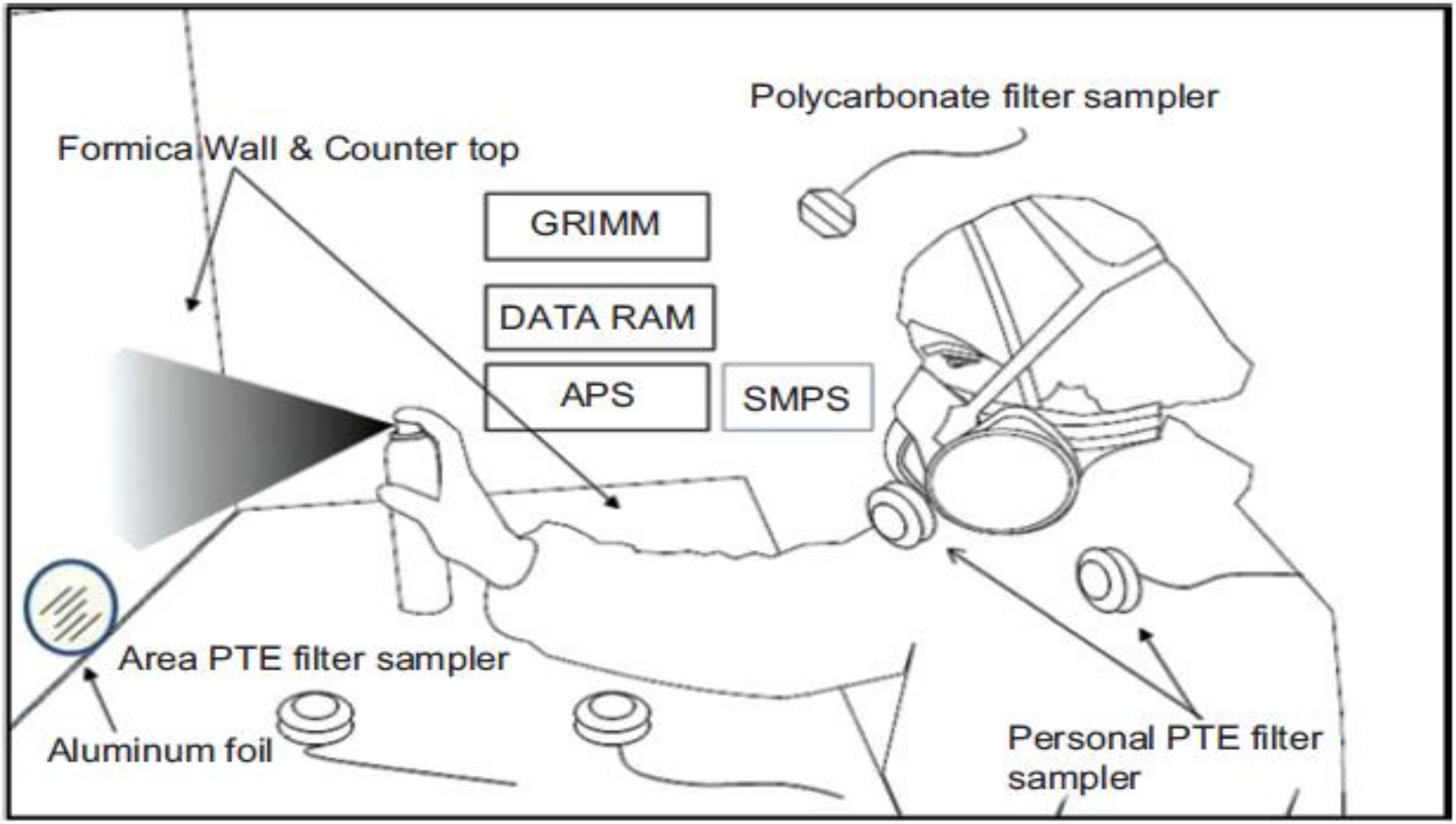
- Formal research program established in 2011
- Approximately $2M annual budget
- Interagency agreements with federal partners
  - EPA, FDA, NIST, NIOSH, NSF
    - Several academically-based research contracts
  - ILSI Nanorelease project
- Reports and publications in peer-reviewed journals
- Voluntary standards

Characterization of an Aerosol Generated during Application of a Nano TiO_2-Enabled Antimicrobial Spray Product to a Surface

- Interagency agreement between CPSC and NIOSH
- Verify presence of nanomaterials and develop methods for air emissions
- Procedures
  - Operator 24 inches from wall
  - Spray can held 8 inches from wall
  - Spray back and forth for 2.5 minutes
  - Sample in the breathing zone
- Sampling conducted in exposure chamber with electronic “finger”

Chen et al. Inhal. Toxicol. 22: 1072-1082, 2010

Realistic Exposure Scenario



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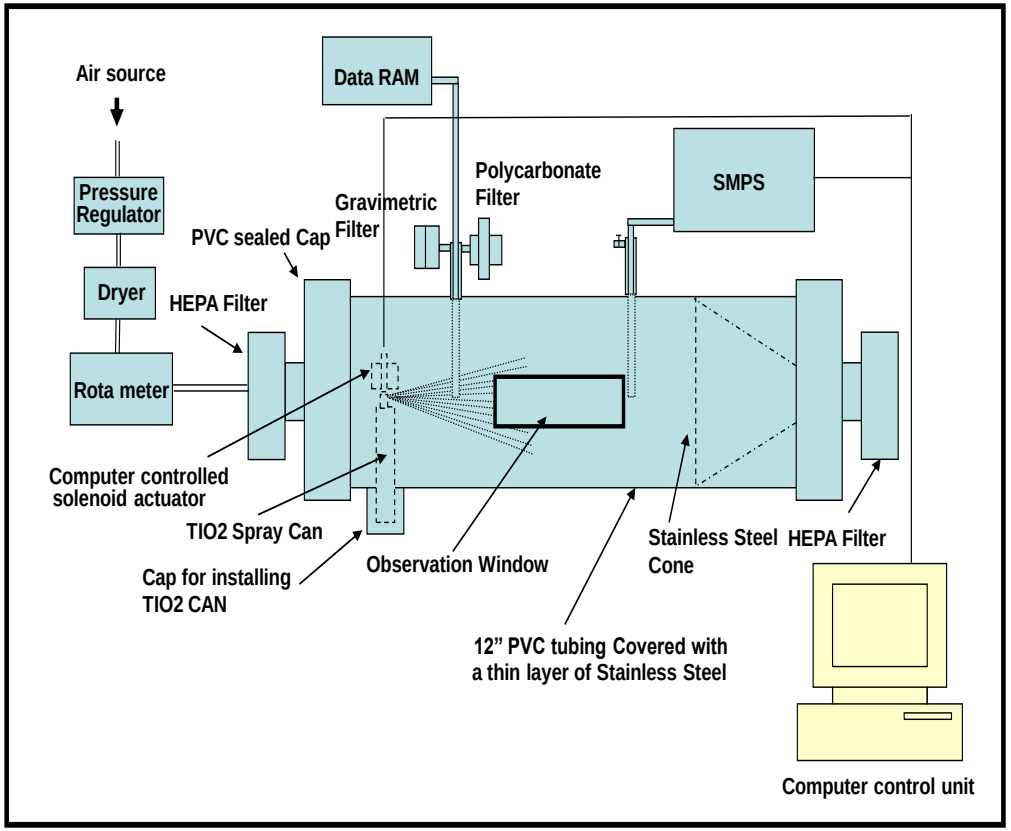
Chamber Testing



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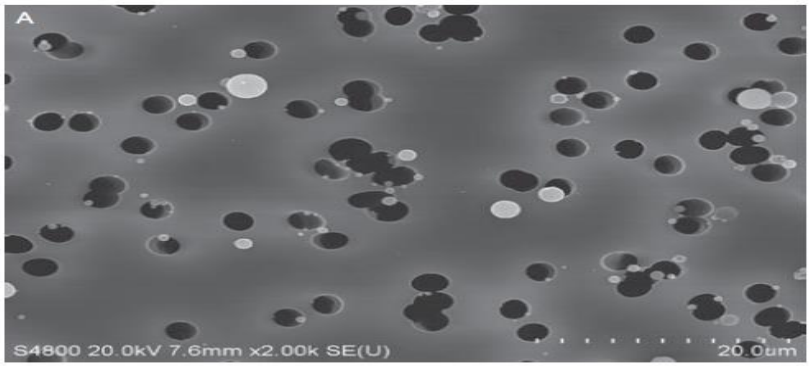
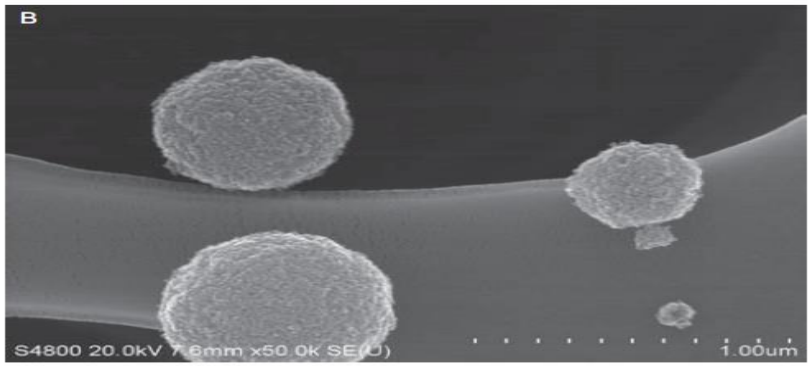
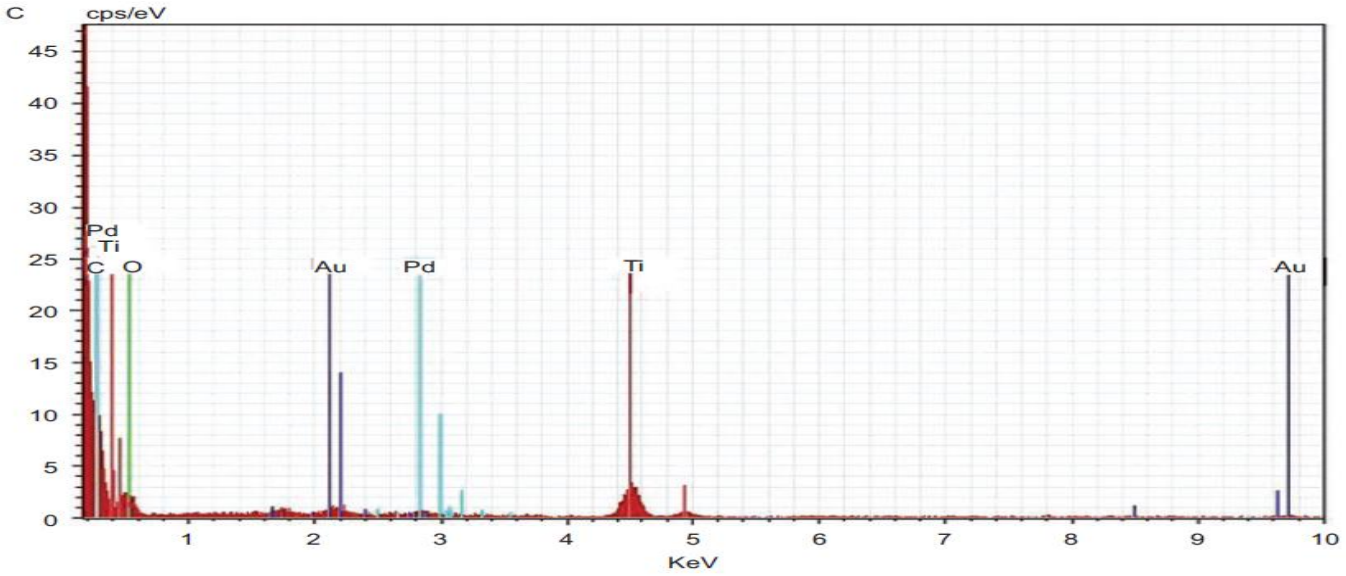
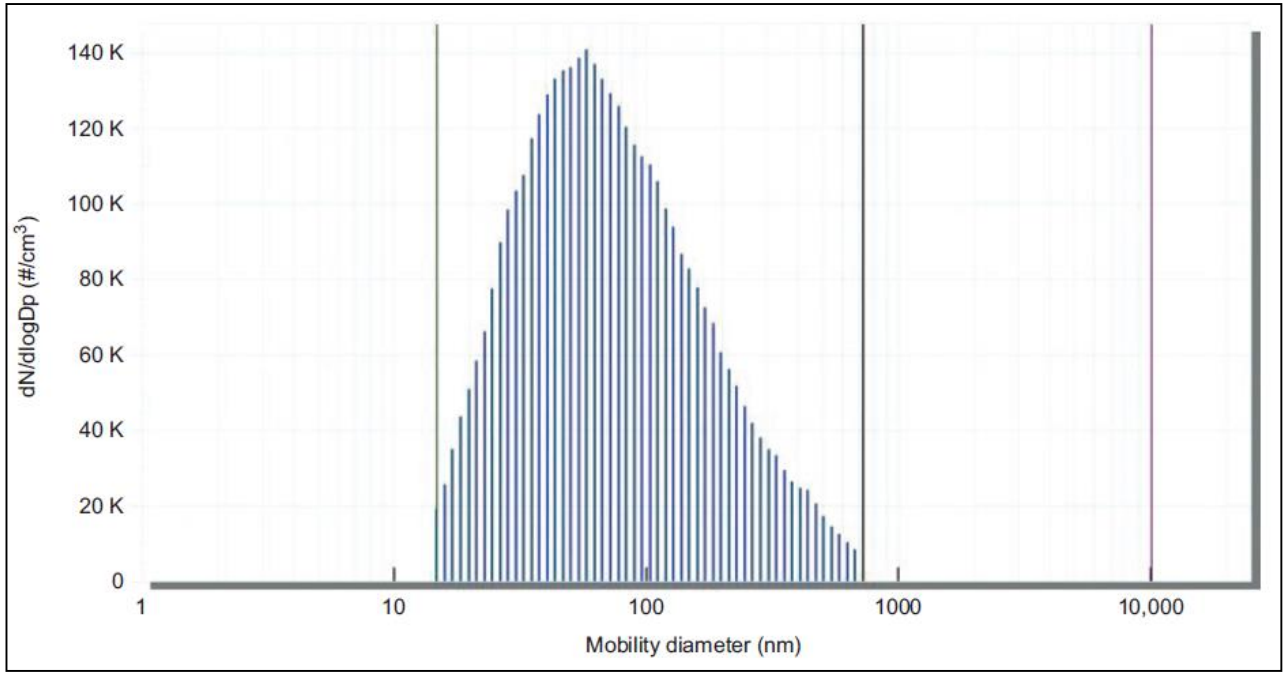
Particle Morphology, Size, and Composition (SEM & EDX)







Particle Number and Size



- APS/SMPS
  - Total particles: 1.6 x 10^5 p/cm^3
  - Count median diameter = 75 nm
  - Nanoparticles = 1.2 x 10^5 p/cm^3

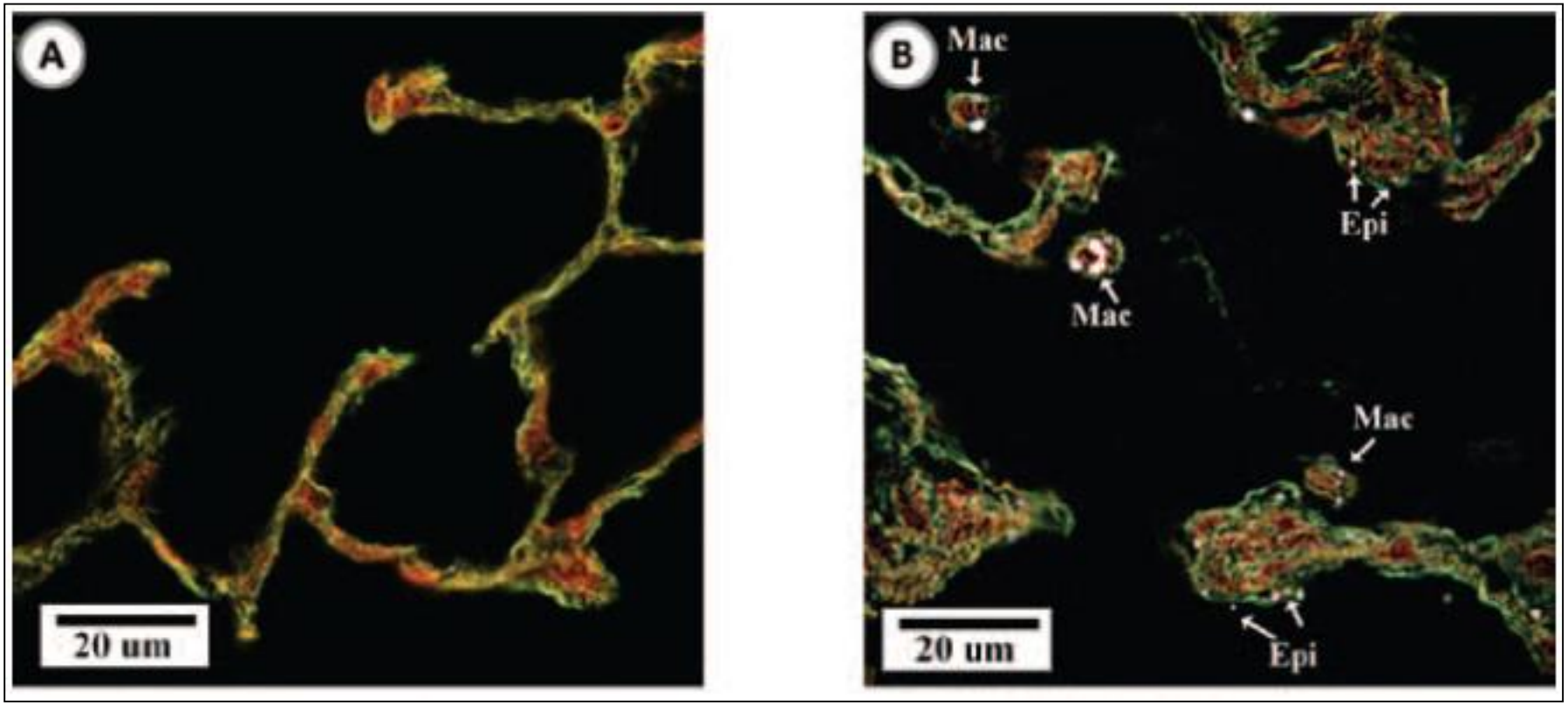
V. Castranova, WVU

Inhalation Exposure of Rats to Nano TiO_2-Enabled Antimicrobial Spray Aerosol

- Pulmonary exposures result in low, medium, and high lung burden
- Monitor responses 24 hr. post-exposure
  - Pulmonary (breathing rate, inflammation, and cell injury)
  - Cardiovascular (vascular responsiveness)
- Relate to consumer risk

McKinney et al. Inhal. Toxicol. 24:447-457, 2012

Pulmonary Deposition of Nano TiO_2

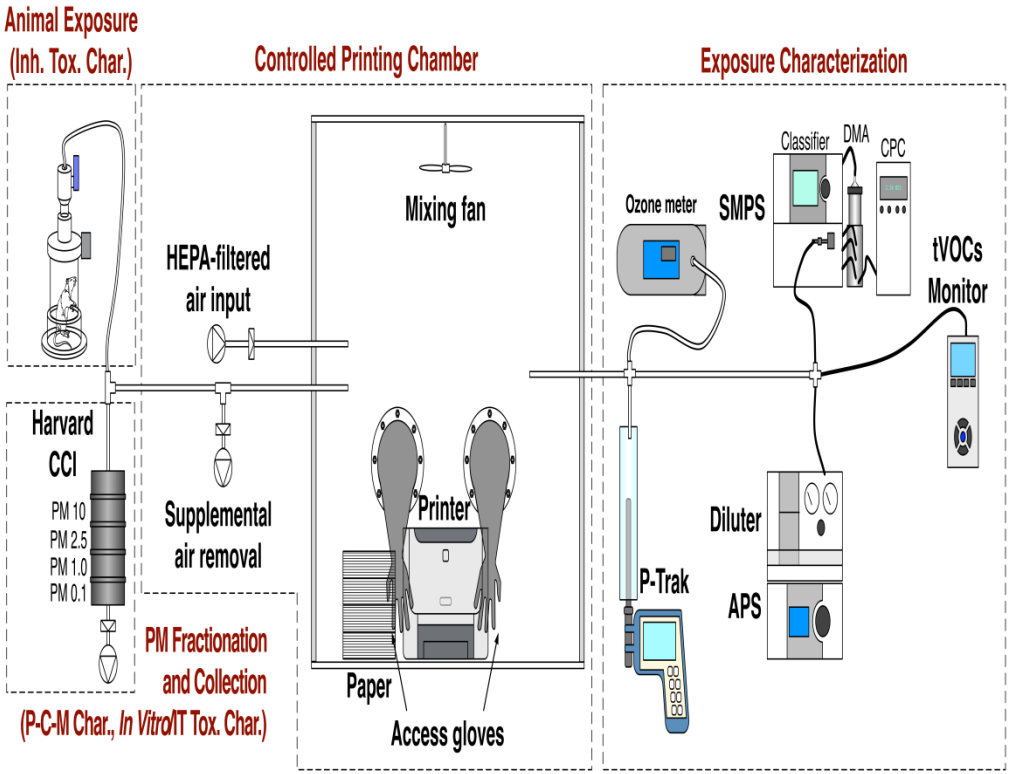


V. Castranova, WVU

Results

- From exposure measurements during application, human alveolar burden would be 0.075 µg TIO_2/m^2 of alveolar epithelium/minute = 0.03 µg/rat lung/minute.
- Rat alveolar depositions were 3.74 µg, 9.83 µg, and 43.31 µg.
- These lung burdens would be achieved in 2, 5 ½ , and 24 hours of application, respectively.
- Therefore, expected consumer use would result in an alveolar lung burden below the NOEL in this rat study.

Exposure Platform for Laser Printer Particles



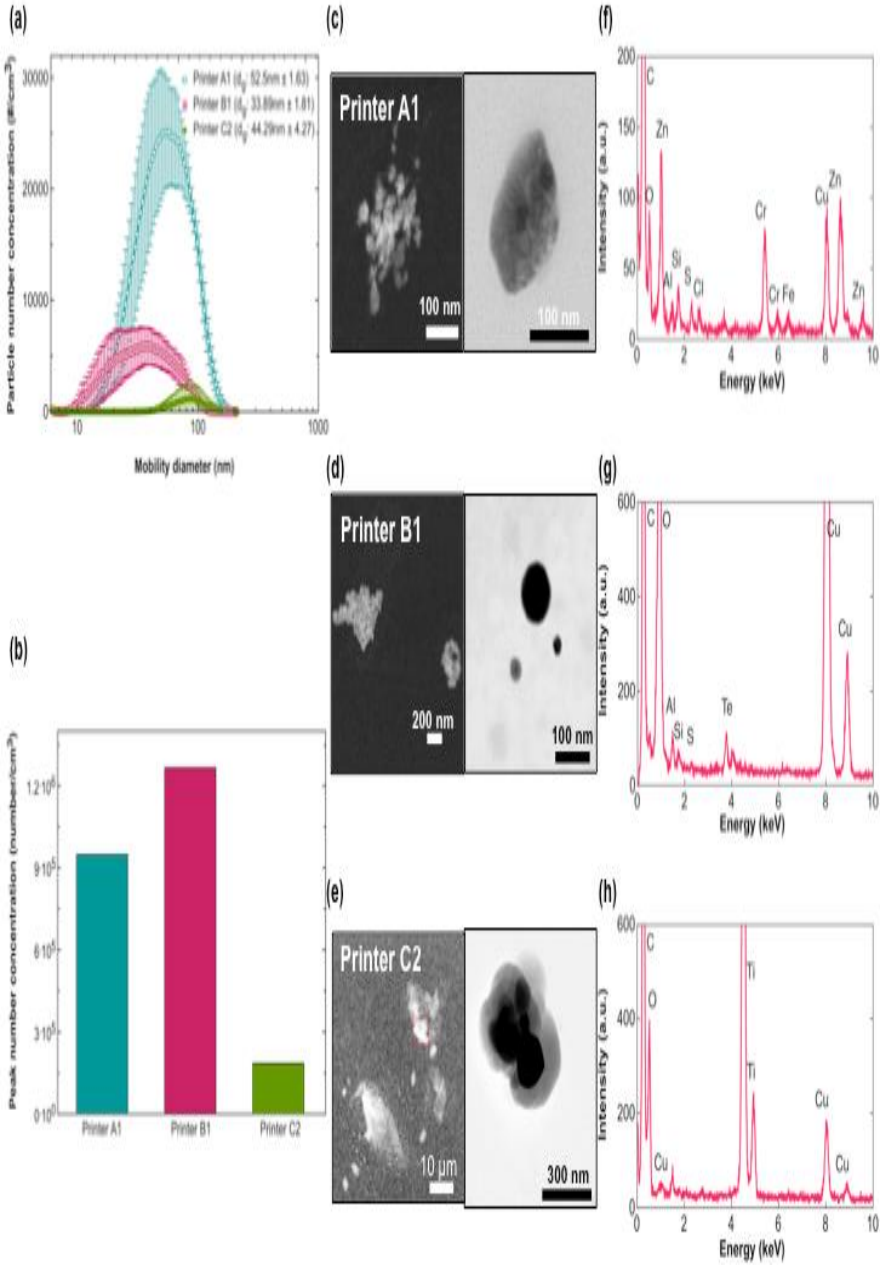
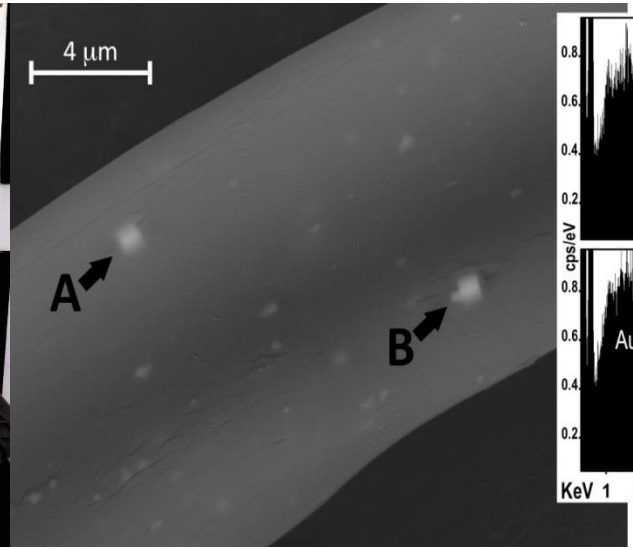


FIGURE 2. Characterization of PEPs from three printers of different manufacturers: Printer A1, B1 and C1. (a) Size distribution of airborne PM emitted during the first ten minutes after printing started. (b) Peak particle number concentration achieved in the first ten minutes after printing started. (c,d,e) Scanning transmission electron microscopy images of PEPs from three printers and their respective EDX spectrum (f,g,h).

Pirela et al., CPSC and NIOSH (Harvard SPH)

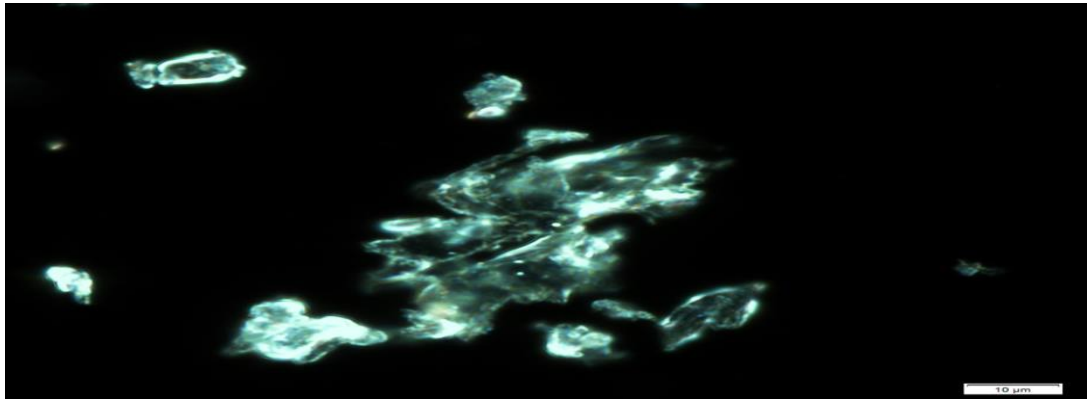
Nanoparticle Concentrations in Various Matrices

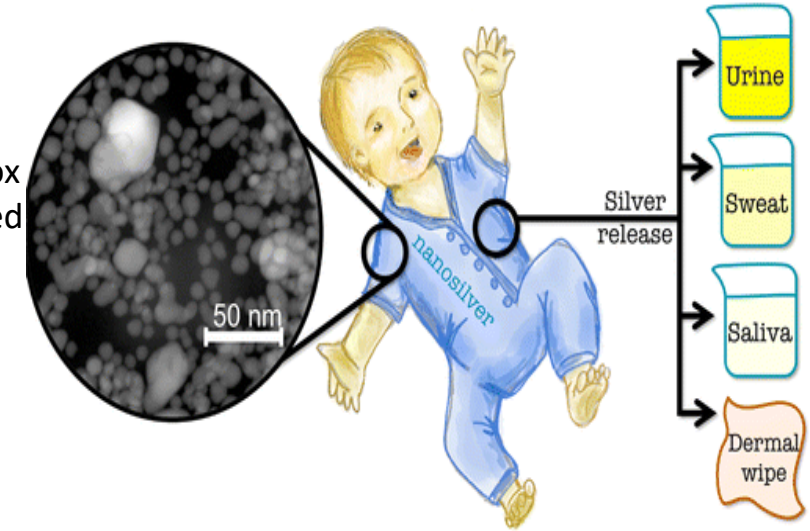


Wood Dust Generation (Sanding Dust)

A belt disc sander (Skil, model 3376-01, 4”×36”) with 240 grit aluminum oxide sanding belt (Powertec, 110200) was installed in a closed glove box (Cleatech LLC, 2100-2-B, 35”W × 24”D × 25”H). Wood dust was generated and dusts around the sander were collected for animal exposure.

J Sisler, A Hecht et al., CPSC and NIOSH





Silver particles (A and B) inside polyester fibers observed in backscattered mode by SEM (left) and EDS spectra from particles A and B (right)

M Vance et al., 2013 UVA (CPSC and EPA)

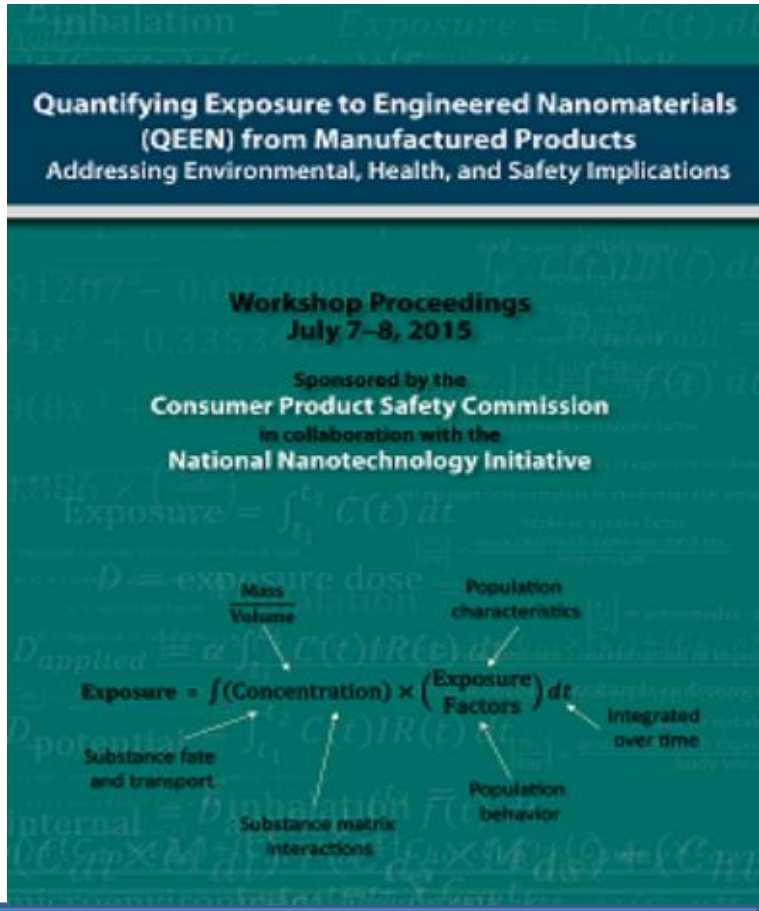
Call to Action for Exposure Science and NanoEHS Communities

Quantifying Exposures to Engineered Nanomaterials (QEEN) Workshop

July 7-8, 2015, Rosslyn, VA

- Co-sponsored by CPSC and NNI
- Bring together and engage stakeholders
- Focus on lifecycle exposures: from production, use and disposal
- Identify methods and approaches from various media
- Understand global efforts for exposure science
- Re-invigorate US – EU Communities of Research (COR)

QEEN report released March 28, 2016 nano.gov



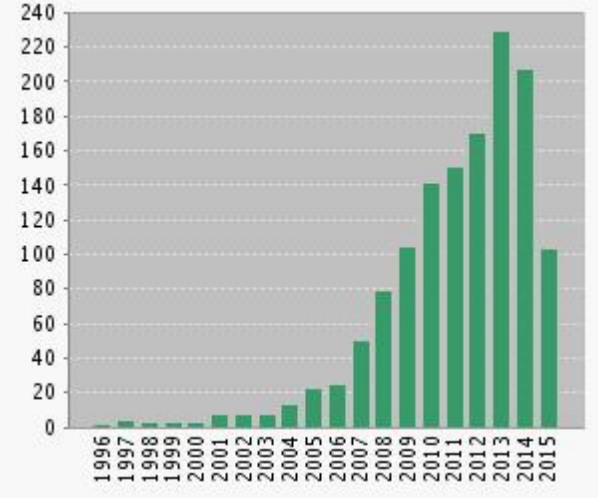
United States Consumer Product Safety Commission

State of the Science

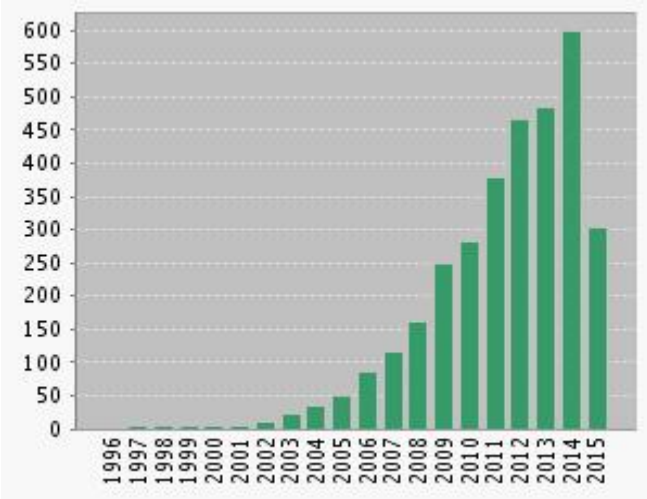
- Analysis of publications
  - Number of publications with “nano” is increasing
  - Fewer publications with “exposure” than with “toxic”
    - More emphasis on “toxicity” and “hazard” than exposure
  - Occupational exposures better understood than exposures to general population from consumer products
  - More information needed for consumer exposures from products

Publication Trends: What's in a Title?

Nano* + Exposure (n=1375)



Nano* + Toxic* (n=5,270)



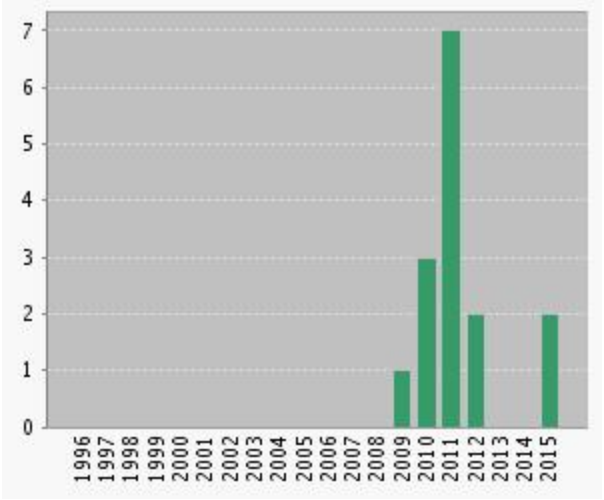
Focus on workers (most prior to 2012)

None related to consumers

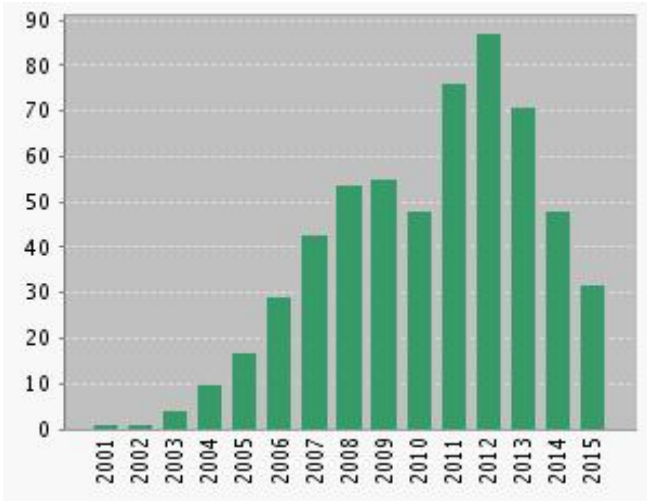
One provocative hypothesis title:

Type 1 diabetes epidemic in Finland is triggered by zinc-containing amorphous silica nanoparticles

Nano* + Epidem* (n=16)



Nano* + Risk (n=576)



Presented by Paul Westerhoff QEEN (2015)

Exposure Assessment Challenges

Mechanically induced MWCNT release from nanocomposites

Characterization of intact nanocomposite materials

- Raman, SEM & TEM
- Commercial materials often have carbon fibers as well as MWCNTs – additional analytical challenges

Mechanical release - cutting, sawing, abrasion

- Released particle collection and analysis
  - Passive collection, MOUDI, electrostatic precipitator, filtering
  - Real-time particle analysis – CPC, SMPS
  - Release particle analysis – Raman, SEM/STEM, LM

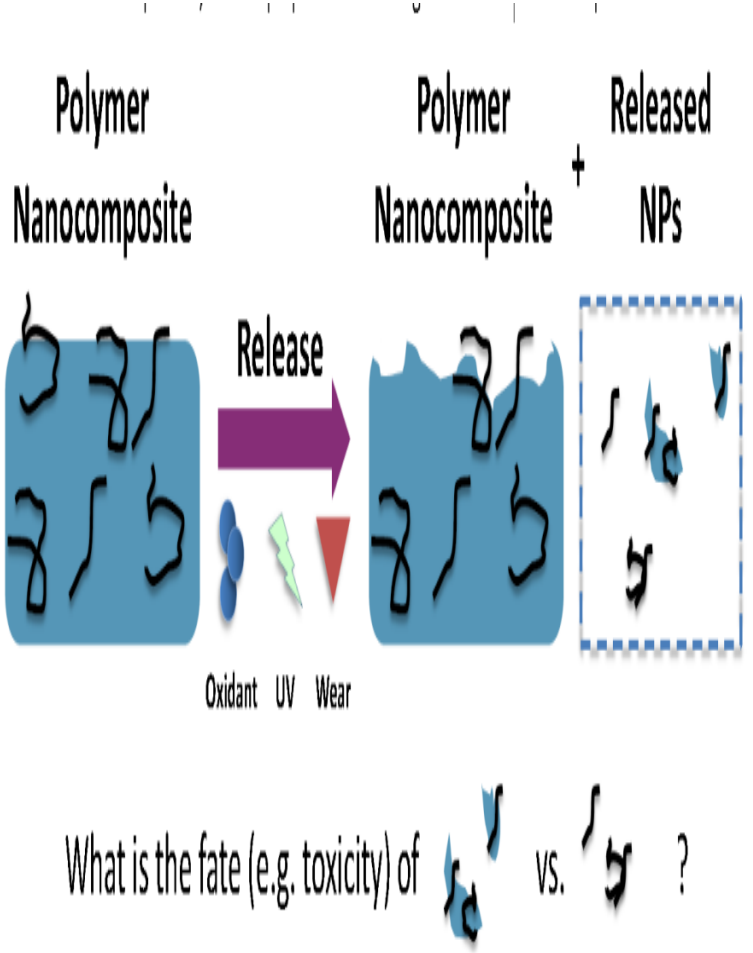
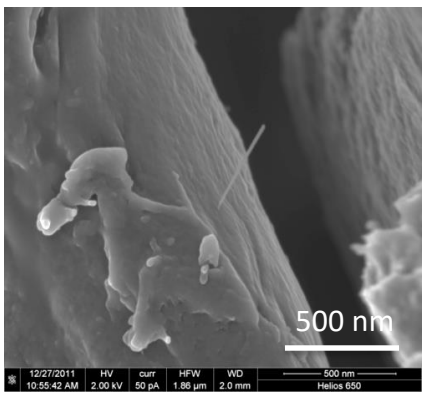


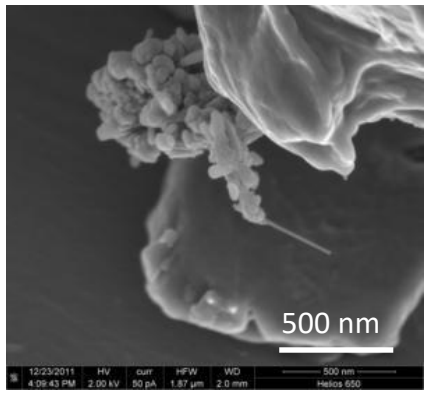
Figure 5.1 Concept of carbon nanotubes released from polymer nanocomposite. (Source: H. Fairbrother.)

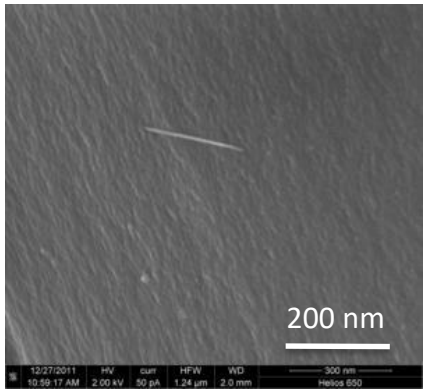
Presented by Jeff Stevens and Elijah Petersen QEEN (2015)

Nanoparticles from cutting debris

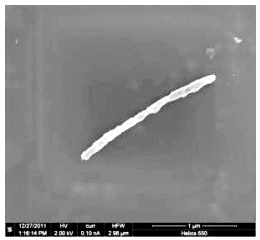
- *What do we mean by released MWCNT?*
  - Partially embedded
  - Attached
  - Loose

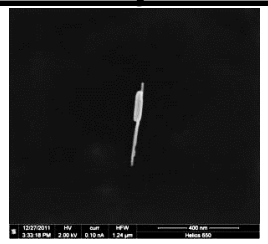


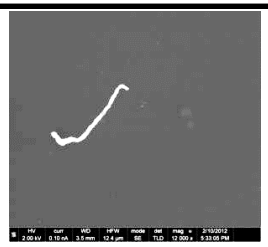


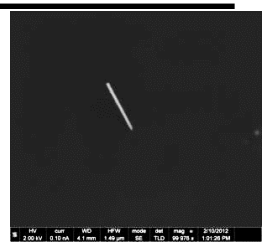


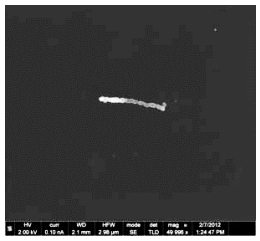
- *Are rod-shaped particles MWCNTs?*











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Exposure Assessment State of the Science

- Instrumentation and methods are currently available to measure and characterize worker or consumer exposure to nanoparticles.
- It is possible to construct generation systems that closely mimic real-world exposures.
  - Use of exposure systems to generate nanoparticles, capturing the interactions of mixed exposures
- Hazard assessment, using *in vitro* and *in vivo* test systems
  - Use exposure doses and structure sizes that reflect actual human exposures.

Exposure Assessment State of the Science

- Need to adequately assess health implications of nanomaterials incorporated into manufactured products
  - Develop robust exposure assessments

- Develop less expensive and easier-to-use techniques.
  - Rapid and high-throughput screening for environmental and occupational samples
    - Promote good stewardship in industry, particularly in smaller companies

- Develop and maintain substantive private–public collaboration, partnership and knowledge sharing.

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