

NANOMATERIALS:

Health and Policy Considerations



Jennifer Sass, Ph.D.

Definition:

Nanomaterials are mainly chemicals manipulated to alter their physico-chemical properties by altering their size.

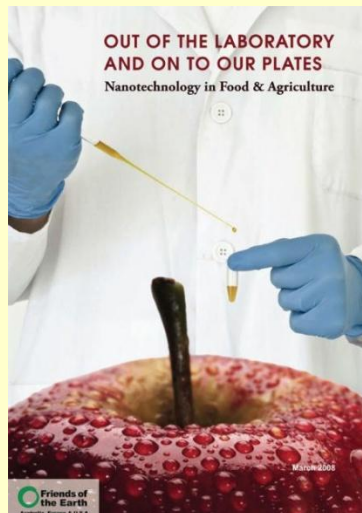
Altered physico-chemical properties are likely to also alter their toxicology/hazard profile.

NANO-ENABLED PRODUCTS

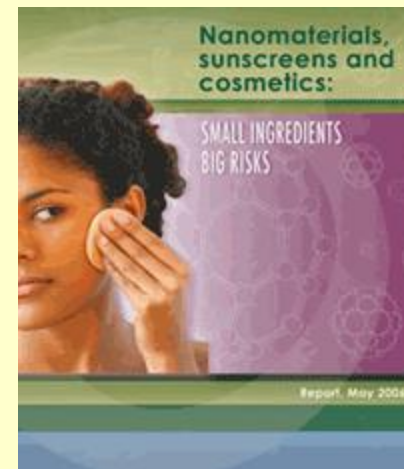
800+ consumer products using nanotechnologies, according to manufacturer

Estimates predict 15% of goods globally, worth \$2.6 trillion by 2014 will be nano-enabled

Every sector, and every Fortune 500 company is invested



SASS



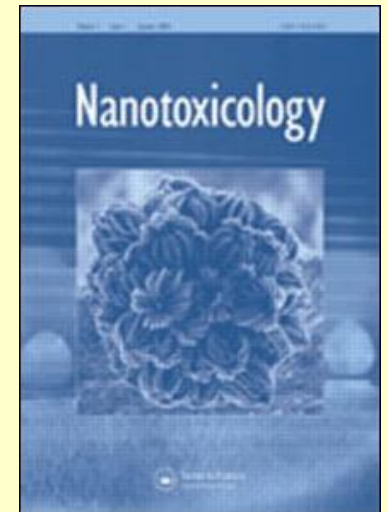
NANOTOXICOLOGY: basic assumptions

Small size facilitates easier access to the lungs, passage through cell membranes, and possibly skin penetrance.

Once inside the body, they seem to have access to all tissues and organs, including the brain and fetal circulation.

Animal studies suggest that some nanomaterials cause inflammation, damage brain cells and cause pre-cancerous lesions.

Ultrafine (nano) air pollution, is associated with size-dependent reduced lung function and increased likelihood of asthma, respiratory disease, and deaths from lung and heart disease.



NANO TITANIUM DIOXIDE

When TiO₂ nanoparticles were fed to mice in drinking water (300-3,000 µg/day for five days), they showed DNA damage. (Trouiller et al, 2009)



When pregnant mice were injected under the skin with TiO₂ (0.1 mg at 3, 7, 10, and 14 days postcoitum) the nanoparticles were found in the offspring and caused reduced sperm production and brain cell death in the male offspring. (Takeda et al, 2008).

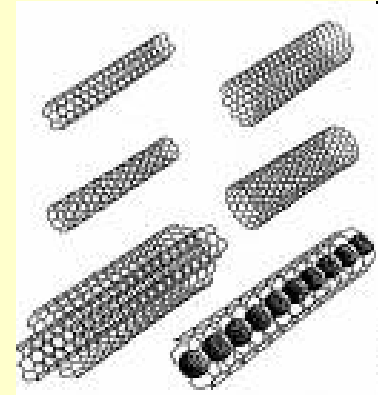
CARBON NANOTUBES: the new asbestos?

Both are long, rigid, fiber-like tubes.

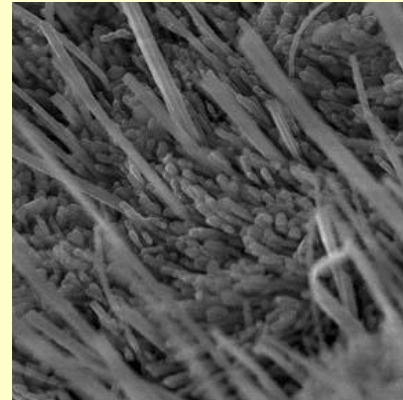
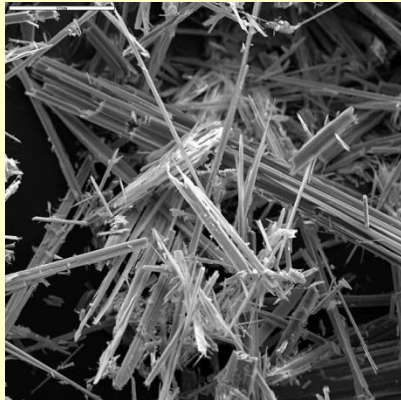
Both have a diameter of about 100-200 nm.

Both cause cytotoxicity, DNA damage, mutation.

Both cause size-dependent inflammation, granulomas, fibrosis



Review by Jaurand et al, 2009. <http://www.biomedcentral.com/content/pdf/1743-8977-6-16.pdf>





Carbon Nanotubes (CNT) under TSCA

- October 31, 2008 CNT Federal Register Notice regarding chemical identity questions and enforcement
- Allotropes of carbon such as CNT are considered “new”
- CNT consent orders
 - 90 day inhalation toxicity studies
 - 1 gram sample – screening testing
 - Material characterization
 - Embedded in a polymer/metal matrix
 - Personal protective equipment for workers

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Examples

- Carbon-, Silica-, Titania- derivatives are handled on a case-by-case basis
 - Personal protective equipment
 - Use/formulation limitations
 - Fractional restrictions on particles <100nm
 - Require testing
 - Aligned with standing new chemicals policy for respirable poorly soluble particulates
- EPA has received PMNs for fullerenes and modified fullerenes
- Emerging complex nanomaterials in the <<one gram production volume range

EPA Publishes Proposed SNURs for 17 Chemicals, Including CNTs and Fullerenes – December 28, 2011

Under TSCA Section 5(e) - required to notify EPA at least 90 days before commencing manufacturing, producing, importing.

EPA determined that nano SNURs may present and unreasonable risk of injury to human health. EPA requiring PPE – gloves, chemical protective clothing, respirators - and some workplace monitoring.

Comments are being prepared by unions and environmental groups including:

ICWU- International Chemical Workers Union

AFL-CIO – Am Fed Labor and Congress of Industrial Org

UAW – Int Union United Auto, Aerospace and Ag Workers

USW- United Steelworkers

BGA – Blue Green Alliance

The regulation should have proposed engineering, administrative, and other controls as the initial protections, Bill Kojola, director of safety and health at the AFL-CIO, and Michael J. Wright, director of health, safety, and the environment for the United Steelworkers, told Bloomberg BNA Jan. 31.

“The best way you can control a hazard is at its source. If you can keep a toxic material out of the air in the first place, that's better than putting a respirator on a worker,” Wright said.

EPA Announces Conditional Registration of Nanosilver Pesticide Product | Pesticide News Story | - Windows Internet Explorer

US EPA http://www.epa.gov/oppfead1/cb/csb_page/updates/2011/nanosilver.html

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Pesticide News Story: EPA Announces Conditional Registration of Nanosilver Pesticide Product

For Release: December 1, 2011

EPA is conditionally registering a pesticide product containing nanosilver as a new active ingredient. The antimicrobial pesticide product, HeiQ AGS-20, is a silver-based product for use as a preservative for textiles. As a condition of registration, EPA is requiring additional data on the product to confirm EPA's assessment that the product will not cause unreasonable adverse effects on human health or the environment, the general standard for a registration under the Federal Insecticide, Fungicide, and Rodenticide Act.

By way of background, on August 12, 2010, EPA posted a Proposed Conditional Registration to the docket for public comment. EPA received 45 public comments, and responses to these comments along with the decision document to conditionally register the product can be found at www.regulations.gov in Docket ID # EPA-HQ-OPP-2009-1012. A description of the additional studies and timeline when the data must be submitted is also available in the docket.

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Compliance | NRDC Sues EPA Over Nanosilver | Chemical Processing - Windows Internet Explorer

http://www.chemicalprocessing.com/articles/2012/nrdc-sues-epa-over-nanosilver NRDC lawsuit nanosilver

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NRDC Sues EPA Over Nanosilver

Lawsuit challenges approval of product before all required data are submitted.

By Lynn L. Bergeson

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On January 26, 2012, the [Natural Resources Defense Council](#) (NRDC) sued the U.S. [Environmental Protection Agency](#) (EPA) for approving a pesticide product containing nanosilver under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This article summarizes the lawsuit, explains what's at stake, and discusses the lawsuit's implications.

NRDC's Objections

HeiQ, a company headquartered in Bad Zurzach, Switzerland, filed an application in 2008 for HeiQ AGS-20, a materials preservative in textiles. After considerable administrative review and an EPA Scientific Advisory Panel (SAP) review, EPA proposed to approve the registration conditionally and requested comment on its proposal. Importantly, as part of the conditional approval, EPA would require that HeiQ conduct certain studies during a 4-year period following issuance of the conditional registration. The required tests include route-specific toxicity studies for occupational exposure scenarios, as well as product characterization and stability tests to determine if nanosilver breaks away from AGS-20.

“Lawsuit is likely to cause commercial uncertainty for the nano community.”

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NNI FEDERAL BUDGET 2010-2011 (dollars in millions)

DOE	380
HHS/NIH	456
DOD	415
EPA	17
NIOSH	9
FDA	7

**CONCLUSION – E/OHS TESTING IS NOT
KEEPING UP!**