Nanotechnology

Pesticide Program Dialogue Committee

November 9, 2006

Scope of Presentation

- Definition
- Applications of nanotechnology
- Potential concerns
- Federal government's role
- EPA's role
- What OPP is doing
- Summary

Definition

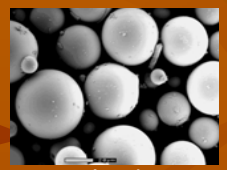
- Three part:
  - **Size**: Approximately 1 – 100 nm in any dimension
  - **Properties**: Unique phenomena enabling novel applications
  - **Control**: Deliberately engineered.

The Scale of Things -- Nanometers and More

Things Natural

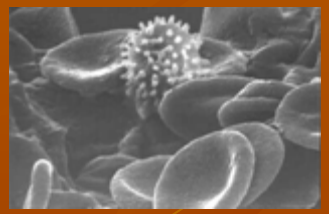
Dust mite
200 μm

Ant
~ 5 mm



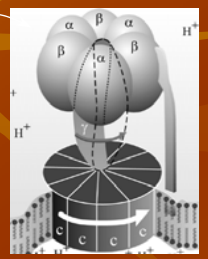
Fly ash
~ 10-20 μm

Human hair
~ 10-50 μm wide

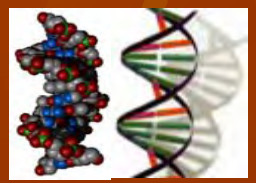


Red blood cells
with white cell
~ 2-5 μm

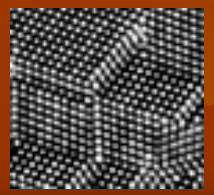
~10 nm diameter



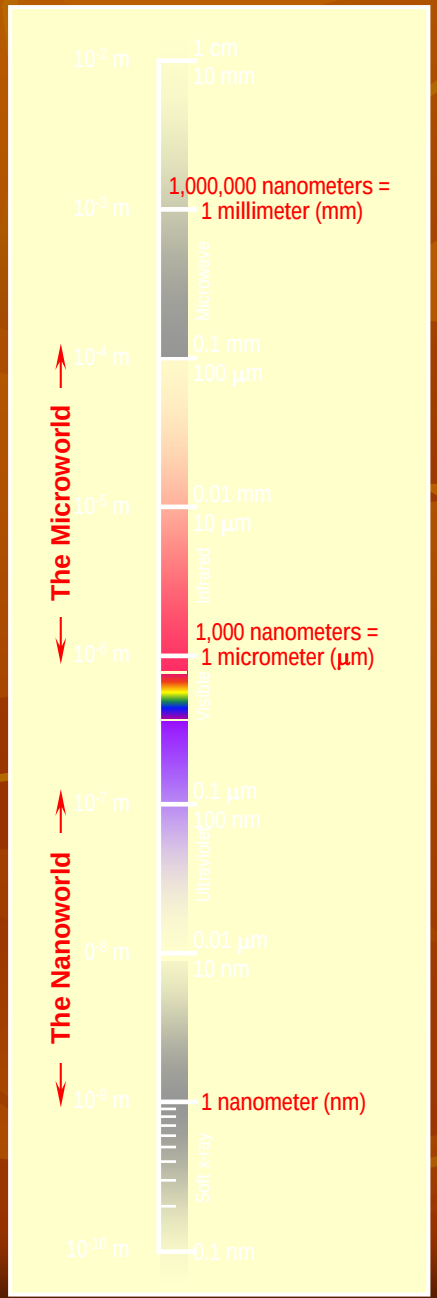
ATP synthase



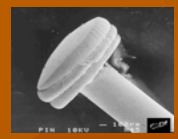
DNA
~2-1/2 nm diameter



Atoms of silicon
spacing ~tenths of nm

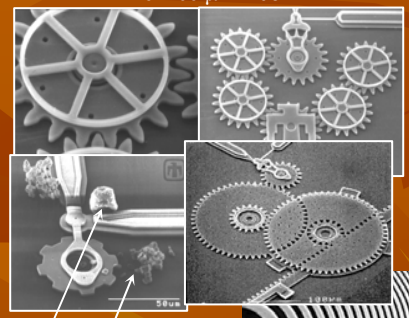


Things Manmade

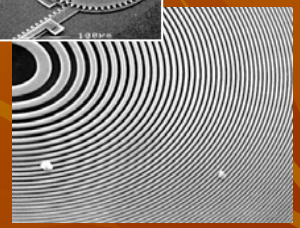


Head of a pin
1-2 mm

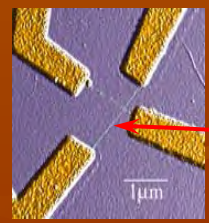
MicroElectroMechanical devices
10 -100 μm wide



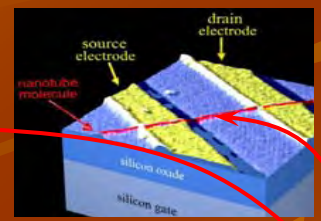
Red blood cells
Pollen grain



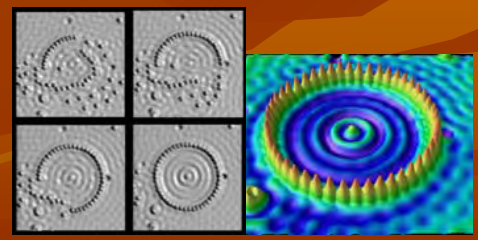
Zone plate x-ray "lens"
Outermost ring spacing
~35 nm



Nanotube electrode

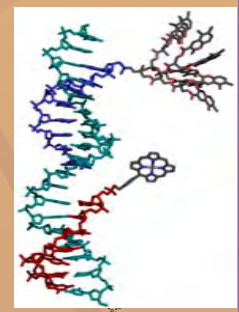


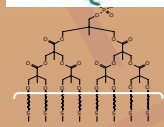
Nanotube transistor



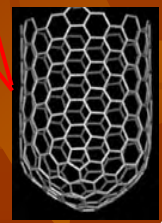
Quantum corral of 48 iron atoms on copper surface
positioned one at a time with an STM tip
Corral diameter 14 nm

21st Century Challenge





Combine nanoscale building blocks to make novel functional devices,



Carbon nanotube
~2 nm diameter

Office of Basic Energy Sciences
Office of Science, U.S. DOE
Version 03-05-02

The Scale of Things

Object	Size nm
Width of Hair	50,000
Red Blood Cell	7,000
Bacterium	1,000
Virus	100
Width of DNA	2.5
Carbon Nanotube	2
Aspirin Molecule	1

Current Applications

Health and Fitness	Electronics and Computers	Home and Garden	Food and Beverage
•Wound dressing •Pregnancy test •Toothpaste •Golf club •Tennis Racket •Skis •Antibacterial socks •Waster and stain resistant pants •Cosmetics •Air filter •Sunscreens	•Computer displays •Computer games •Computer hardware	•Paint •Antimicrobial pillows •Stain resistant cushions	•Non-stick coatings for pans •Antimicrobial refrigerator •Canola oil

Future Applications

- Biological sensors
- Targeted drug delivery systems
- Energy generating coatings and films
- Novel robotic devices
- Food packaging
- Pesticides

Questions and Potential Concerns

- Size facilitates exposure and could increase toxicity
  - Human health concerns (both local and systemic effects):
    - Inhalation –inflammatory and fibrogenic responses observed to specific NMs
    - Dermal – toxic response including oxidative stress and loss of cell viability and potential immune system effects

Questions and Potential Concerns

- Ecological concerns:
  - Uptake and accumulation in fish and wildlife
  - Formation of byproducts and degradates which are novel
  - Toxicity to aquatic and terrestrial ecosystems (both acute and chronic)

What is the Federal Government Doing?

- December 2003 – 21st Century Nanotechnology Research and Development Act signed
- Required implementation of a national nanotechnology program
- Now called the National Nanotechnology Inititiative (NNI)

National Nanotechnology Initiative

- Establishes R & D goals and priorities for the federal government
- Invests in federal R & D programs
- Provides interagency coordination of federal nanotechnology programs

Federal Budget

- Federal Government Spending
  - $464 million in 2001
  - Almost $1.3 billion in 2007
  - Spending in two major areas
    - Environmental health and safety issues
    - Education and research on broad implications
  - EPA - $5 million in 2006 and $9 million requested for 2007

What is EPA Doing?

- In 2004, the Science Policy Council (SPC) created a cross-Agency workgroup to develop a white paper
- ORD and OPPT co-chaired, all major programs represented
- Describes the potential environmental benefits of nanotechnology; identifies risk assessment issues and research needs; and provides recommendations for next steps
- Public and peer review comment and revision, approved by the SPC on September 25 and is being prepared for publication

White Paper

- Key recommendations:
  - **Pollution Prevention, Stewardship, and Sustainability**
  - **Research**
  - **Risk Assessment**
  - **Collaboration and Leadership**
  - **Cross-Agency Workgroup**
  - **Training**

Other EPA Offices

- OAR – reviewing an application for registration of a nanosized diesel fuel additive under the Clean Air Act

- OSWER – workshop held in July 2006 on nanotechnology and waste management practices

OPPT and Nano

- Many nanoscale materials (NMs) are chemical substances as defined by TSCA
- NMs not on the TSCA Inventory are new chemicals and a Pre-Manufacture Notice (PMN) is required before commencement of manufacture
- There is presently no similar requirement for NMs that are existing chemicals, i.e. already on the TSCA inventory

OPPT and Nano

- Program needs include:
  - A mechanism to collaboratively generate data needed to provide a sound scientific foundation for assessments
  - An appropriate interim approach to obtain better informed decision-making on new chemicals and realize oversight of “existing” chemical NMs
  - An appropriate degree of industry stewardship in the manufacture and use of new and existing chemical NMs

OPPT and Nano

- PMN submissions are being received and reviewed on NMs but most have not met other elements of NNI definition -- unique properties or deliberately engineered
  - To date, one low release, low exposure exemption has been granted (carbon nanotube)
- There have been several recent company meetings on pending new chemical NMs
- General approach has been to permit limited manufacture of nanosized new chemicals under appropriate controls via use of consent orders and Significant New Use Rules (SNURs)

OPPT and Nano

- OPPT held a public meeting in June 2005 on how it might best fill its role in assessing and managing the risks of NMs
- National Pollution Prevention and Toxics Advisory Committee (NPPTAC) requested to provide additional input via a public process
- NPPTAC “Overview Document” forwarded to EPA in Nov, 2005
- Agency Workgroup established in May 2006 to explore the concept of a stewardship program using the above to inform discussion

OPPT and Nano

- Stewardship Program:
  - Participation is voluntary
  - Complements new and existing chemicals regulatory approach
  - Increases experience with risk assessment/ mitigation of NMs and provides insight on what test data needs to be developed
  - Accelerates generation of test data to provide sound scientific basis for decision-making

Case Studies

- Lead by ORD and OPPT with most EPA offices involved
  - Goals
    - Identify research needs
    - Identify needs for conducting risk assessment
  - Titanium dioxide and carbon nanotubes
  - Targeting Spring timeframe

OPP and Nano

- FIFRA requires a finding of “no unreasonable adverse effects”
  - This finding must be made regardless of size and whether or not is engineered or naturally occurring (i.e., all pesticide products are held to the same standard)
  - Consideration of both active and inert ingredients

OPP and Nano

- Currently registered nanopesticides
  - None that we are aware of
  - Some have claimed to be nano but are not
  - We have had discussions with some companies regarding potential future submissions

OPP Nano Challenges

- How to adequately assess the health and safety of nano-scale pesticides
- Are the current testing requirements adequate?
- Identifying nanomaterials
- Making decisions based on sound science

OPP Workgroup

- Nanotechnology workgroup formed
  - Charged with development of a regulatory framework for nanopesticides
  - Representatives from most divisions as well as OGC
  - The workgroup will be both proactive and reactive:
    - Wide range of expertise to help form policies and testing requirements
    - Workgroup will be used to assess applications for nanopesticides as they are submitted

OPP Workgroup

NAME	ORG.	EXPERTISE
Betty Shackleford	AD	Chair
Jack Housenger	HED	Chair
1. Bill Jordan	IO	Policy
2. Nancy Whyte	AD	Microbiologist
3. Najm Shamim	AD	Chemist
4. Ben Chambliss	AD	Regulatory
5. Jenny Tao	AD	MD/Toxicologist
6. Stephanie Irene	EFED	Toxicologist, Ecological
7. Nathanael Martin	FEAD	Policy
8. Matthew Crowley	HED	Exposure
9. Timothy Dole	HED	Industrial Hygienist
10. Ayaad Assaad	HED	Toxicologist (inhalation)
11. Deborah Smegal	HED	Toxicologist/Risk Assessor
12. Elissa Reaves	HED	Toxicologist
13. Tamue Gibson	RD	Regulatory
14. Tara Chandgoyal	BEAD	Plant Pathologist
15. Alaa Kamel	BEAD	Chemist
16. Lance Wormell	SRRD	Regulatory
17. Don Sadowsky	OGC	Legal
18. Chris Kaczmarek	OGC	Legal

OPP Workgroup

- Areas of emphasis for the workgroup
  - Policy/Regulation
  - International Activities
  - Hazard (human health and ecological)
  - Exposure (fate, dietary, worker, aquatic, terrestrial, etc)
- Training and education

Workgroup Goals

- Developing the framework:
  - Work with and learn from other agencies within the government and internationally in figuring out the best way to evaluate potential risks to nanomaterials
  - Be in the best position to evaluate a nanopesticide submission when it is received
  - Provide information to the public on how the Agency is assuring the safety of future nanopesticides
  - Provide clear guidance to pesticide registrants of any additional data needs for nanopesticides as soon as possible
  - Provide a scientifically sound and transparent process

Industry

- What industry can do
  - Engage early in the process
  - Share plans on future submissions
  - Identify nanomaterials - preferably before submission

The Public

- What the public can do
  - Share information and concerns
  - Provide comment/input

OPP and Nanotechnology

- Summary
  - We will be proactive in communicating and identifying our needs as we progress
  - We will work with other agencies, countries, public interest groups and the industry to identify a health protective and efficient way of evaluating nanopesticides
  - Development of a clear, transparent and scientifically sound framework