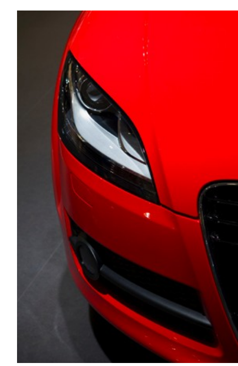
What! EPA is regulating me? Approaches to Managing Industrial Nanoscale Materials

June 22nd, 2010

New England Nanomanufacturing Summit 2010

The Good Stuff



Regulatory challenges to the good stuff?

- 85%-90% of new chemicals are dropped from further review after 20-25 days under the Toxic Substances Control Act (TSCA)
- 100% of potential nanoscale materials (NMs) receive further scrutiny
- The review and ultimate regulation of NMs takes about 6 – 24 months per substance[1]

[1] *Long timelines reflect the period to negotiate regulations, not reach a decision or assess a substance.*

NMs under TSCA

- Chemical substances as defined by the Toxic Substances Control Act (TSCA)

- NMs not on the TSCA Inventory are new chemicals
  - Definition based on molecular identity, not other properties
  - Examples are fullerenes and carbon nanotubes

- NMs on the TSCA inventory are existing chemicals
  - Some metal oxide particles as an example
  - Coated particles or derivatives may require a consultation

- EPA paper on TSCA Inventory status of NMs

NMs under TSCA, cont

- New Chemicals Program for NMs
  - Low release, low exposure exemption (LoReX)
    - Demonstrated low exposures ➔ limited hazard assessment
  - Pre-manufacture notices (PMN)
    - Full risk assessment
    - Limitations on proposed or future activities
    - Data development – Regulatory and voluntary
- Voluntary approach for existing chemicals formally closed January 2010 (Agency still open to collaborations)

NMs under TSCA, cont

- Regulatory approach for existing-chemical based nanoscale materials
  - Current
    - Notices of substantial risk must be submitted
  - Future….
    - Broad nano-SNUR (proposal late 2010): require notification and regulatory review for any “new” nanomaterial of an existing chemical substance
    - Section 8a (proposal late 2010): Data call-in, report use and exposure data for certain nanoscale chemicals
    - Section 4: Mandated testing – first one “announced.” Testing may be needed for certain nanomaterials.

CNT risk assessment challenges

<u>Stage of the RA</u>

- Exposures
  - Occupational
  - Environmental
  - General public
- Hazards
  - Eco
  - Human health

<u>Challenges</u>

- No nomenclature system developed
- Generally, insufficient data to identify relevant properties
- Unclear test methods/relevance of results
- How does material characterization correlate with p-chem

CNT risk assessment challenges

Stage of the RA

- Hazards
  - Eco
  - Human health

Challenges

- Occupational
  - Large agglomerates – do these break down into respirable and inhalable particles that can reach the deep lung
  - How do CNTs disperse in lung/other biological fluids?
  - Interpretation of workplace exposure monitoring reports…

CNT risk assessment challenges

<u>Stage of the RA</u>

- Material Characterization AND P-Chem properties
- Hazards
  - Eco
  - Human health

<u>Challenges</u>

- Environmental
  - Do releases of CNTs escape the POTWs or do they sorb to sludge?
  - If they escape the POTWs, would natural organic matter and sunlight lead to soluble transformation products?

CNT risk assessment challenges

<u>Stage of the RA</u>

- Material Characterization AND P-Chem properties
- Hazards
  - Eco
  - Human health

<u>Challenges</u>

- General public
  - Are CNTs chemically bound in composites or just embedded?
  - Exposures from incineration/landfilling?

CNT risk assessment challenges

Stage of the RA

- Material Characterization AND P-Chem properties
- Exposures
  - Occupational
  - Environmental
  - General public

Challenges

- Eco:
  - No acute effects at saturation due to low solubility?
  - Sample prep/test methods
  - what about the possibility of chronic effects, especially on transformed products?

CNT risk assessment challenges

Stage of the RA

- Material Characterization AND P-Chem properties
- Exposures
  - Occupational
  - Environmental
  - General public

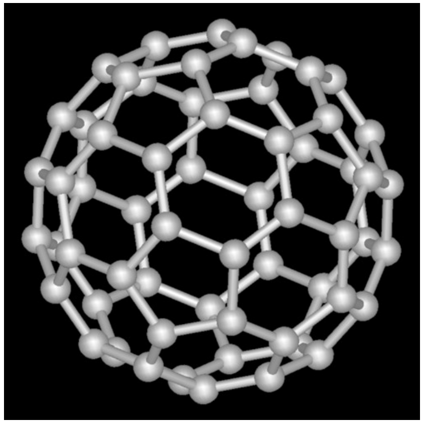
Challenges

- Human health:
  - Relevance of aerosols and material characteristics from tox studies compared to occupational exposures
  - Dose metrics/sample prep
  - What is the right tox paradigm ?

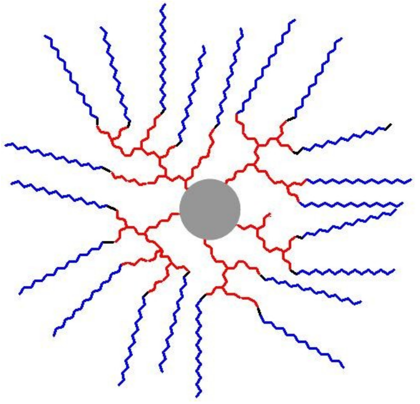
CNT regulatory approach

- Further material characterization
  - Key to chemical identity and risk assessments
- Use restrictions
  - PPE for industrial settings
  - Must be embedded in a polymer/metal matrix for commercial or consumer settings
  - Certain end uses not allowed
- 90-day inhalation tox studies (to date)
- Limit releases to environment AND/OR Fate/Eco testing of CNTs
- Additional testing via other sources

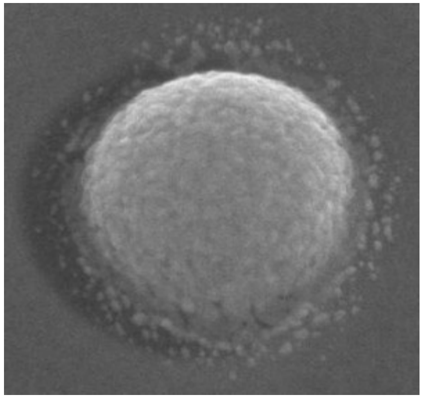
Other NMs that would be "new" chemicals under TSCA



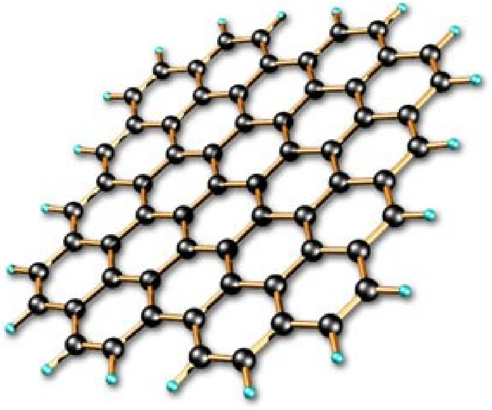
Fullerenes and modified fullerenes



Highly functionalized materials



Coated metal particles



Graphene

Voluntary Program Interim Conclusions

- 2/3 of commercially available chemicals and 90% of NMs were not reported.
- Uncertainty surrounding submitters and submissions
- Companies are not inclined to voluntarily test their NMs

How ORD is Allocating its Nano Resources

50% Sources, Fate, Transport, and Exposure

30% Human Health and Ecological Effects

10% Risk Assessment Methods and Case Studies

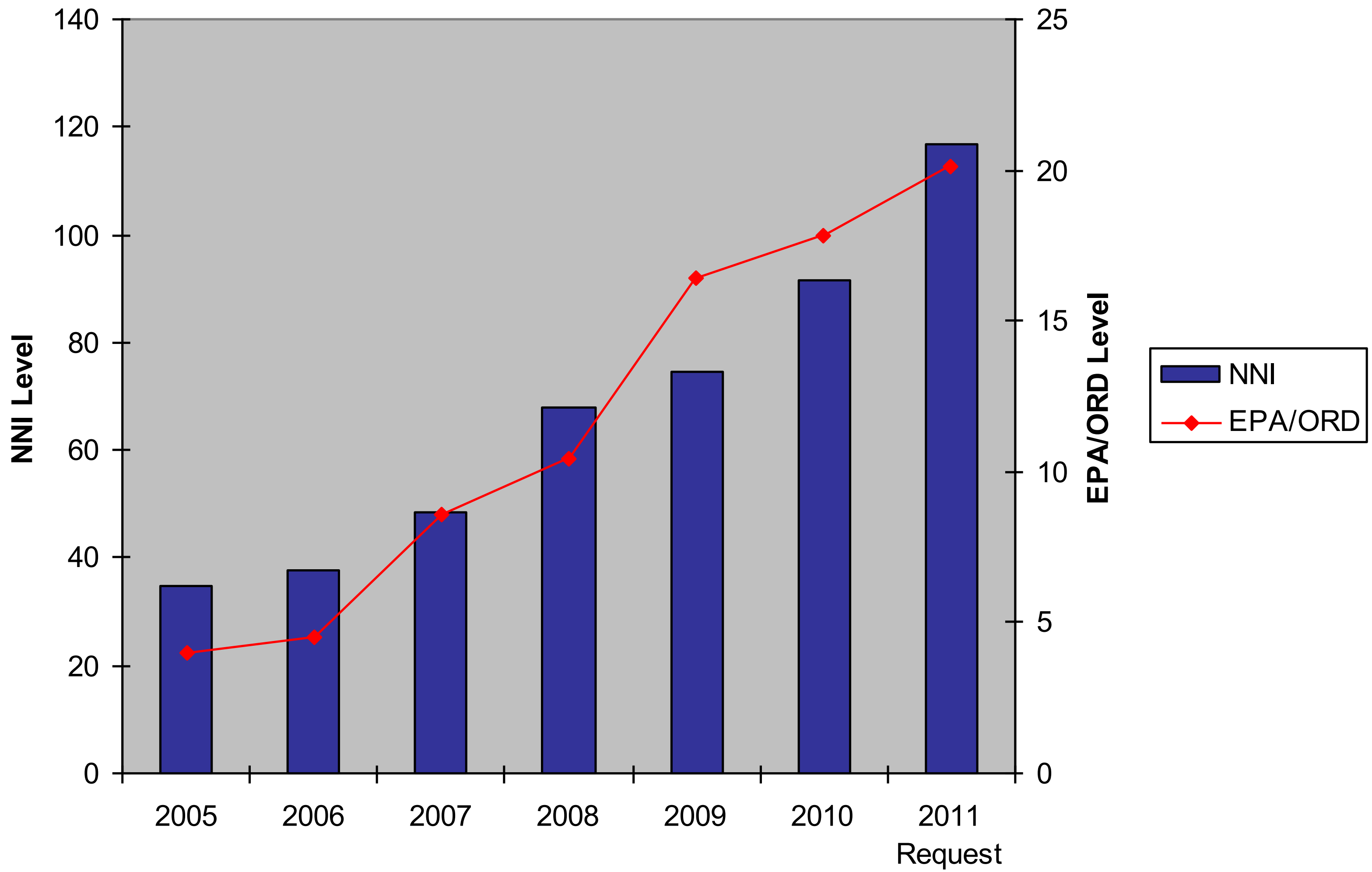
10% Preventing and Mitigating Risks

Challenges:

Potential Release and Exposure: How much of what materials are/will be produced for what uses?

Properties: What properties make a material toxic, mobile, persistent, and bioavailable?

Nanotechnology EHS Budget
Total NNI and EPA/ORD ($ Million)



OECD WPMN Projects

- **Project 1:** Database on Safety Research
- **Project 2:** Research Strategies on Manufactured Nanomaterials
- **Project 3:** Safety Testing of a Representative Set of Manufactured Nanomaterials
- **Project 4 :** Manufactured Nanomaterials and Test Guidelines
- **Project 5:** Co-operation on Voluntary Schemes and Regulatory Programmes
- **Project 6:** Co-operation on Risk Assessment
- **Project 7:** Alternative Methods in Nano Toxicology
- **Project 8:** Exposure Measurement and Exposure Mitigation
- **Project 9:** Environmentally Sustainable Use of Manufactured Nanomaterials

WPMN Project 3: Safety

- "Dataset" – 59 tests
  - Physical-chemical properties
  - Materials characterization
  - Environmental fate
  - Environmental toxicity
  - Mammalian toxicity
  - Safety
- Alternative approaches and methods, including in vitro
- Investigation of different particle sizes, shapes, coatings and/or modifications

Material	Lead sponsor(s)	Co-sponsor(s)	Contributor
Fullerenes(C60)	Japan, US		Denmark, China
SWCNTs	Japan, US		Canada, France, Germany, EC, China, BIAC
MWCNTs	Japan, US	Korea, BIAC	Canada, Germany, France, EC, China, BIAC
Silver nanoparticles	Korea, US	Australia, Canada, Germany, Nordic Council	France, EC, China
Iron nanoparticles	BIAC, China		Canada, US, Nordic Council
Carbon black			Canada, Denmark, Germany. US
Titanium dioxide	France, Germany	Austria, Canada, Korea, Spain, US, BIAC	China, Denmark, Japan
Aluminium oxide			Germany, US, Japan
Cerium oxide	US, UK/BIAC	Australia, Netherlands, Spain	Germany, Switzerland, EC, Japan
Zinc oxide	UK/BIAC	Australia, Spain US, BIAC	Canada, Japan
Silicon dioxide	France, EC	Belgium, Korea, BIAC	Denmark, Japan
Polystyrene			Austria, Korea
Dendrimers		Spain, US	
Nanoclays			Denmark, US

Priority Needs (beyond EPA, beyond R&D) to Better Inform Policy Decisions

- **Green chemistry and life cycle-focused research** that advances sustainable nanotechnology
- New **decision-analysis approaches** to more quickly and effectively use scientific information to inform decisions that weigh the benefits and impacts of technologies across product life cycles
- Better collaborations within and across all sectors: government (including state and local), industry, and academia
  - ➢ **Here is where we have great opportunities, with ECOS, the OECD and others, to enhance information flows in all directions.**

WPMN Project 9: Sustainability

- To enhance the knowledge base about life cycle aspects of manufactured nanomaterials, as well as positive and negative impacts on environment and health of certain nano-enabled applications at their different stages of development.
- Tools and frameworks for life cycle considerations will be developed and applied to some selected cases of nano-enabled applications that demonstrate potential for environmental sustainability.
- To pursue options for a broader initiative focusing on maximising environmental benefits and minimising risks of nano-enabled applications together with OECD partners.

Some final thoughts

- Potential implications for manufacturers/ high-tech downstream users of NMs
  - Potentially longer lead times for NMs to be added to commercial toolkits
  - Increased burden
  - Greater long-term societal acceptance of technology
- Opportunities to establish and capitalize on “greenness” as well as identify problem areas earlier in the innovation cycle

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