

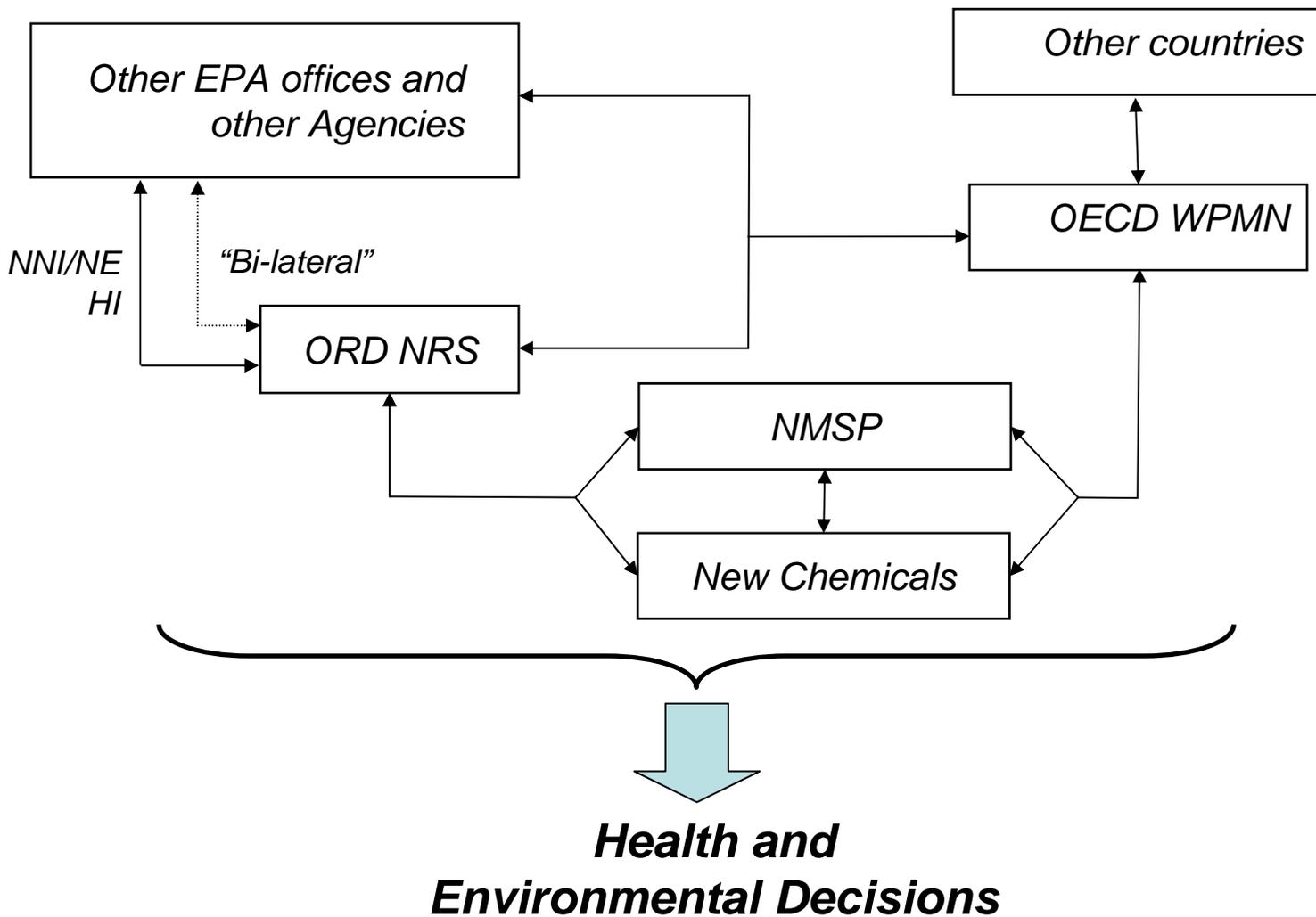
EPA Progress And The Emerging Regulatory Role For Industrial Nanoscale Materials

March 19th, 2009

Office of Pollution Prevention and Toxics



Context of work on nanoscale materials





NMs under TSCA

- Address new and existing chemical-based nanoscale materials through regulatory and voluntary components
- New Chemicals Program
 - Significant New Use Rules (SNURs)
 - Consent orders where needed
 - Potential to participate in NMSP In-depth Testing program



NMs under TSCA, cont

- Voluntary approach for existing-chemical based nanoscale materials
 - Basic reporting and In-depth Testing program
- Regulatory approach for existing-chemical based nanoscale materials
 - Current
 - Section 8(e) – notices of substantial risk (8 received to date)
 - Future....
 - Section 8(a) – report use and exposure data
 - Section 4 test rules
 - Targeted SNURs (Sec. 5(a)) for NMs/categories



NMs under TSCA, cont.

- 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 novel carbon allotropes
- 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
- Different tools available depending on whether a chemical is “new” or “existing”.



New Chemicals Program

- PMN information: chemical identity, use, anticipated prod. volume, exposure and releases, existing available test data
- Review of PMNs to determine if need to prohibit or limit manufacturing, processing or use pending development of needed information
- Following EPA review, if manufacturing or importing commences:
 - EPA must be notified (NOC)
 - Chemical is added to the inventory



New Chemicals Program, cont

- Exemptions
 - With a full 90+-day standard review
 - **Low volume exemption (LVE)**: very few cases
 - **Low release and exposure exemption (LoREX)**
 - **Test market exemption (TME)** – no nano's to date
 - With record-keeping requirements only
 - **Polymer exemption** – based on limited bioavailability;
 - Monomers must be on the TSCA inventory
 - **R&D exemption**
- Over 60 new nanoscale chemical notifications since January 2005.



CNTs under TSCA

- Allotropes of carbon such as CNTs are considered “new”
- Oct. 2008 CNT Federal Register notice regarding chemical identity questions and need for new chemical notification;
⇒ outreach to CNT producers.
- Focus on CNT compliance began in March 2009.



CNTs under TSCA, cont

- CNT consent orders
 - 90-day studies (inhalation toxicity to date)
 - Material characterization properties
 - Necessary for chemical identity and risk assessments
 - Use restrictions
 - Personal protective equipment for industrial settings
 - Must be embedded in a polymer/metal matrix for commercial or consumer settings
- Similar approach for other carbon allotropes



Other New NMs

- EPA has received the first PMNs for fullerenes and modified fullerenes
- Silica-, titania-, etc. derivatives/coated compounds are handled on a case-by-case basis (SNURs, Consent orders)
 - Personal protective equipment
 - Use/formulation limitations
 - Fractional restrictions on particles $<100\text{nm}$
 - Testing as appropriate



Future policy directions of new chemicals

- Development of new chemical categories for NMs
- Integration of test data into PMN reviews
 - PMNs and consent orders
 - TSCA 8e data
 - Academic research
 - ORD and NNI data
 - International (OECD) integration

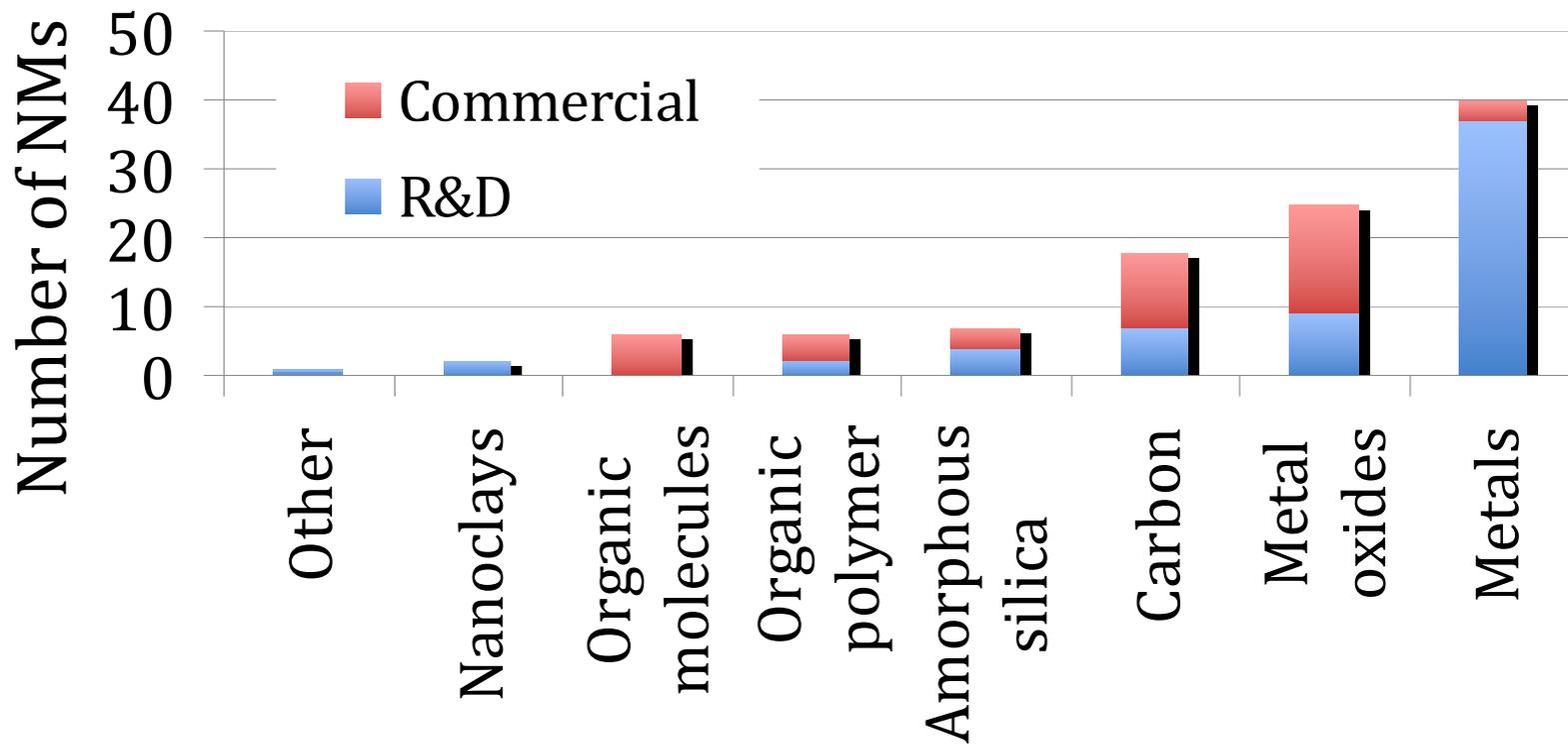


Existing Chemicals - Nanoscale Materials Stewardship Program

- Complements and informs regulatory approach
- Increases experience with risk assessment/ mitigation
- Provides insight on test data to be developed
- Generation of test data to provide sound scientific basis for decision-making
- Encourages risk management practices

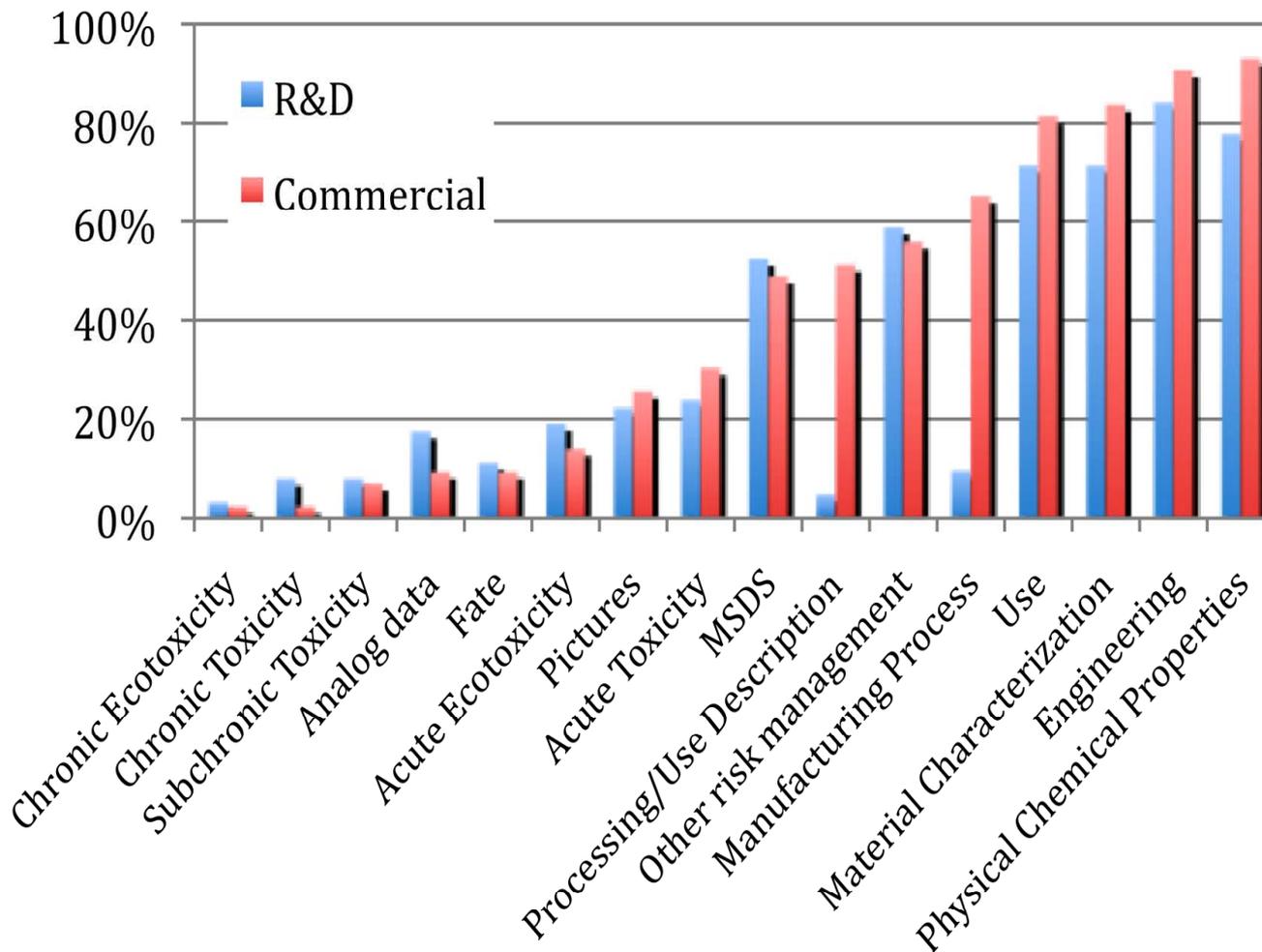


NMs by Chemical Subfamily





NMs by Data Element



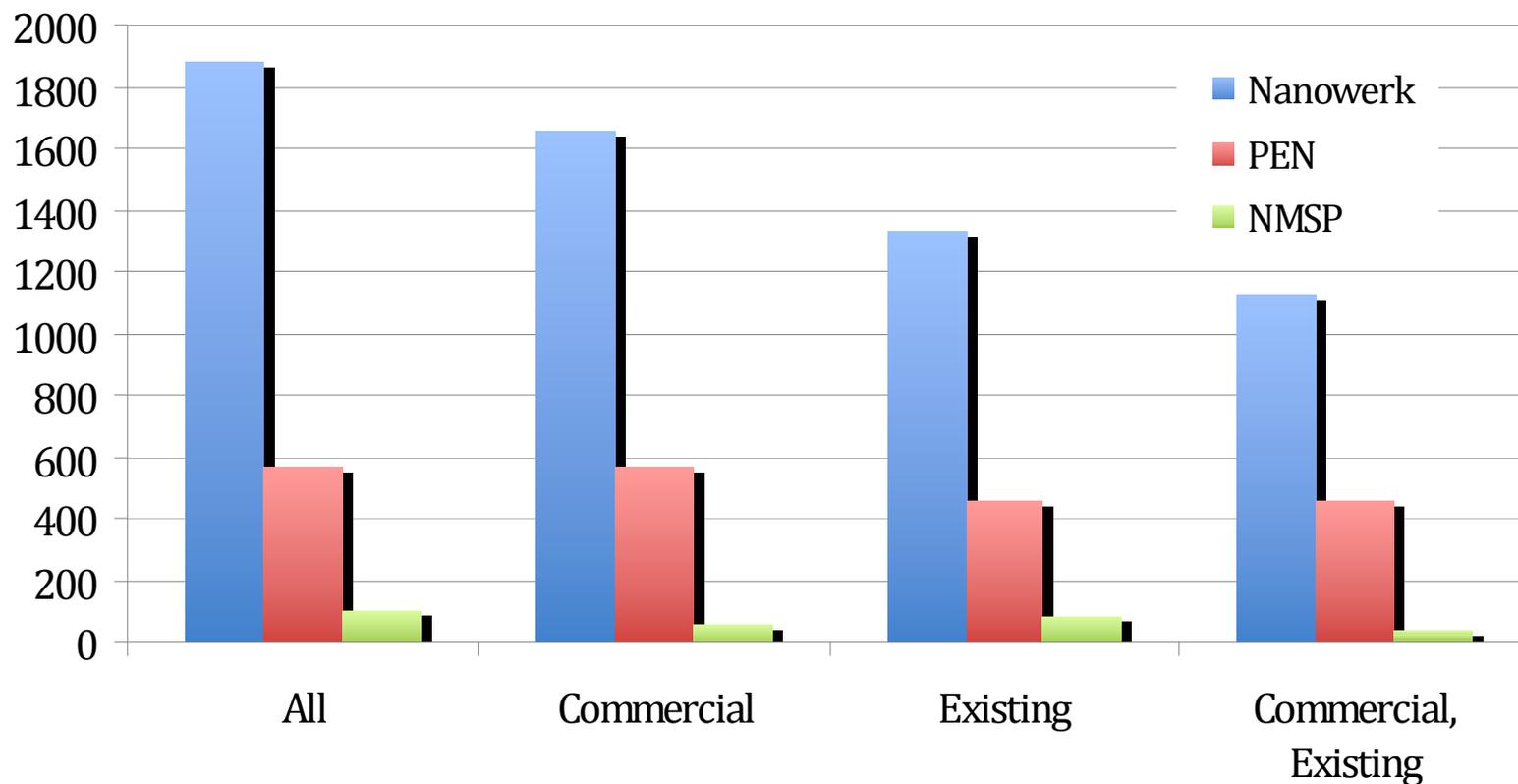


NMSP Analytics

- Comparison to the “universe of NMs”
 - Nanowerk Database of NMs
 - Wilson Center Inventory of NMs in Consumer Products
 - Individual company publications/websites
 - Scientific literature
 - Inventories from other sources
- Classification by chemical/shape where possible
- Link up databases to prioritize



Comparison of nanoscale materials

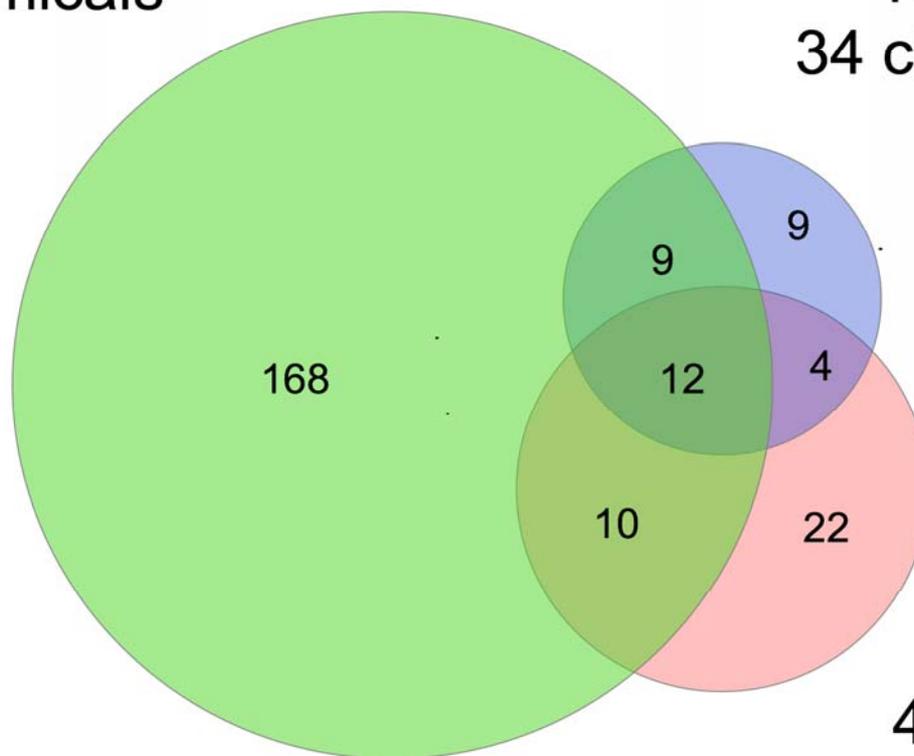




Overlap: existing chemicals

Nanowerk
199 chemicals

NMSP
34 chemicals



PEN
48 chemicals



In-Depth Program

- Sponsors would develop data on a smaller set of representative nanoscale materials
- Entities or consortia with an interest in developing data should notify EPA.
- EPA will facilitate data development process
- EPA will begin in-depth follow-up with interested stakeholders after they identify themselves
- 4 in-depth participants, 3 for CNTs

<http://www.epa.gov/oppt/nano/nano-contact.htm>



NMSP Interim Conclusions

- Submissions from 29 companies covering 58 TSCA chemicals and 123 NMs complements 60+ new nano chemicals.
- Improved EPA's understanding of NMs and the NM industry.
- Contributed to EPA's engagement with other agencies and international bodies.
- Informed next steps on regulatory and research issues.



NMSP Interim Conclusions, cont

- 2/3 of commercially available chemicals and 90% of NMs were not reported.
- Uncertainty whether submitters provided data on all NMs they produce. Not all relevant data provided.
- Companies are not inclined to voluntarily test their NMs
- Need additional progress towards addressing NPPTAC's considerations...



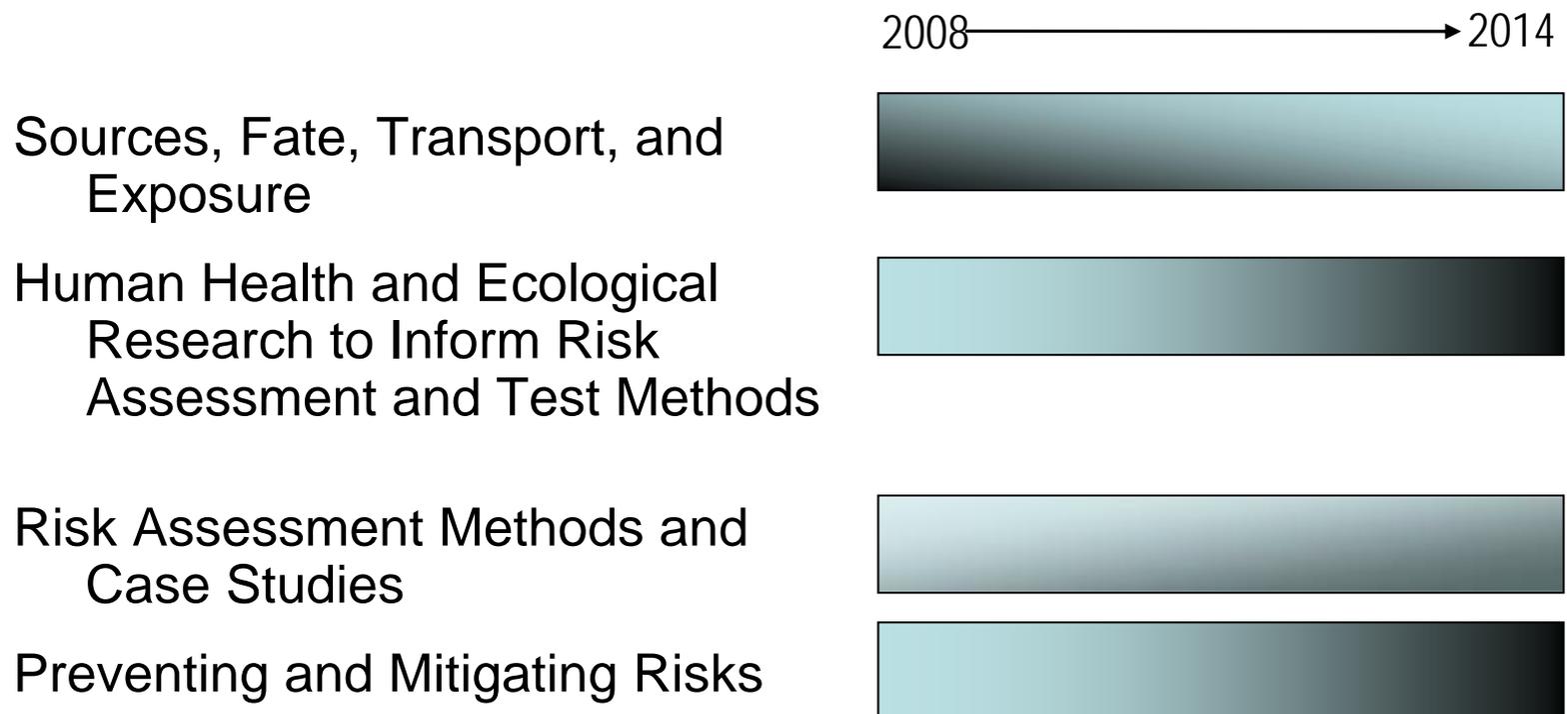
NMSP next steps

- Accept submissions till January 2010
- Review submissions on hand; contact companies with follow-up questions
- Develop test plans with In-Depth participants
- “consider how to best apply regulatory approaches under TSCA...”
- Final report to integrate NMSP and PMN lessons-learned on nano



ORD - Integration of Research and Regulation

Resource Allocation Changes Over Time*



*Darker shading indicates greater relative emphasis.



ORD Research Activities

Extramural Grants

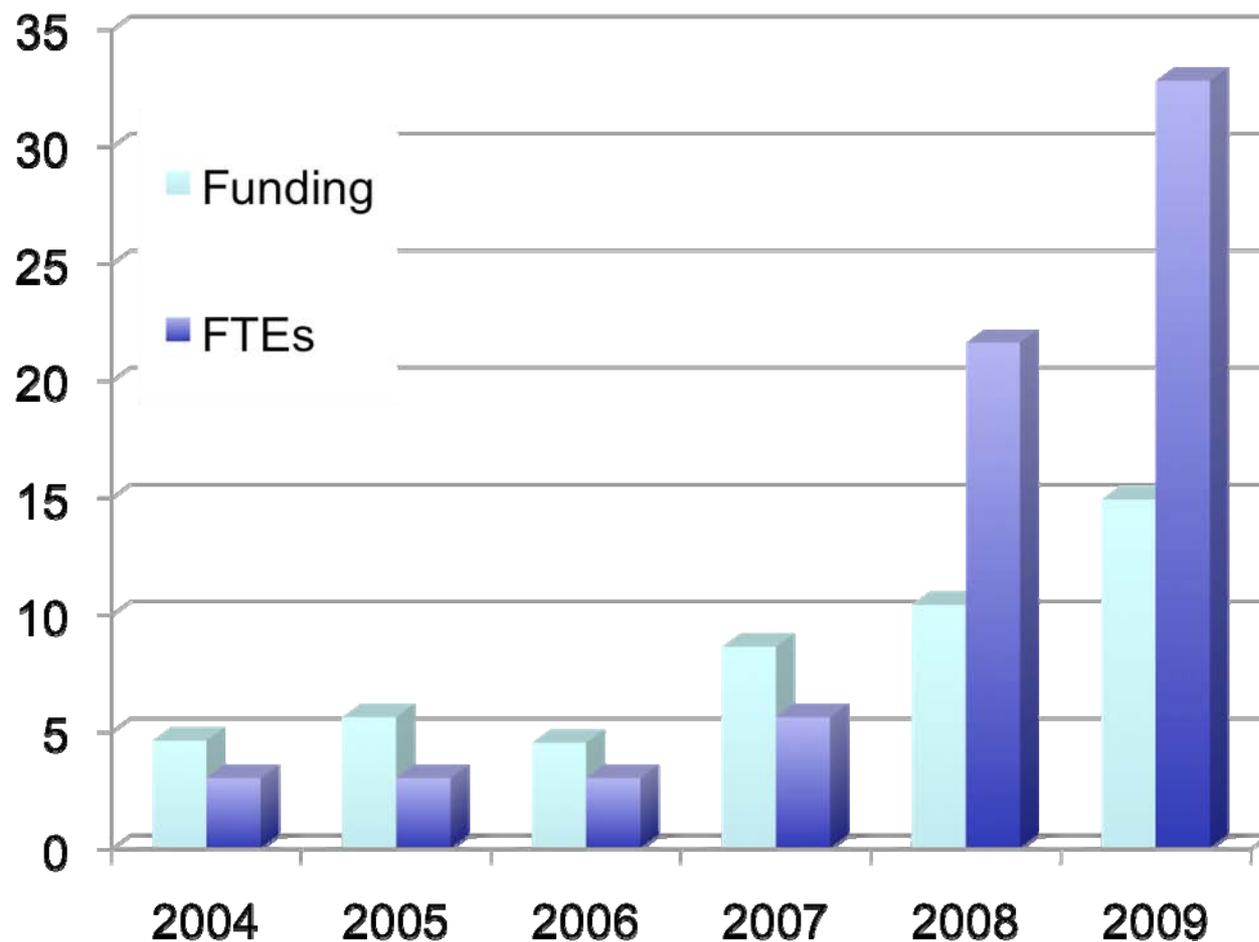
- Through 2007, 86 grants awarded for approx. \$30 million
- Information available online at www.epa.gov/ncer/nano

In-house Research

- EPA's scientists have done research on toxicity of ultrafine particulate matter and are gathering info on various environmental applications.
- Budget proposal for 2009 provides funding for EPA in-house research



ORD NM Budget History, FY '04 - FY '09 (Proposed)





ORD - Issues, Path Forward

- *Near Term*
 - Implementing our research strategy (final peer review comments due 10 Dec. 2009)
 - Interagency coordination
 - International coordination; OECD involvement
 - Providing near-term decision support
- *Longer Term*
 - Capacity building
 - Evolving the research program as needs change
 - Developing an integrated, multidisciplinary nanotechnology research team



OECD WPMN

- Established in September, 2006
- Objective: *To promote international co-operation in health and environmental safety related aspects of manufactured nanomaterials, in order to assist in their safe development*
- Works through the implementation of 9 projects via “Steering Groups”



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



WPMN Project 3: Safety

- “Dataset” – 59 tests covering:
 - 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
- End product of Phase 1 is a “dossier” with supporting data; task groups developing a guidance manual and review process
- Sponsorship workshop - Busan Korea, Nov. 19-21 2008
- 2nd Phase envisioned

		Lead sponsor(s)	Co-sponsor(s)	Contributor
Fullerenes(C60)		Japan, US		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	Canada, Germany	Australia, France, EC, China
Iron nanoparticles		China	BIAC	Canada, US
Carbon black				Germany, US
Titanium dioxide		Germany	Canada, Korea, Spain, US, BIAC	France, China
Aluminium oxide				Germany, US
Cerium oxide		US, UK/BIAC	Netherlands	Australia, Germany, EC
Zinc oxide		UK/BIAC	US, BIAC	Australia, Canada
Silicon dioxide			Korea, BIAC	France, EC
Polystyrene				Korea
Dendrimers			Spain	US
Nanoclays				US



WPMN Project 9: Benefits/Sustainability

OECD conference July 15-17 in Paris

... encouraging development of technologies that can result in environmental gain while avoiding unintended consequences.

Sessions balance technologies, benefits, implications, and policy

Topics:

1. applications to reduce pollution;
2. cleaner production;
3. other benefits including environmental remediation;
4. societal drivers such as policy innovations, and business/NGO leadership.



More information on the OECD

Safety of Manufactured Nanomaterials

<http://www.oecd.org/env/nanosafety>



Contact Info

<http://www.epa.gov/oppt/nano/> and

www.regulations.gov – search on

epa-hq-oppt-2004-0122

markey.kristan@epa.gov

202 564-8716

alwood.jim@epa.gov

202 564-8974