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Regulating the Impacts of Nanomaterials: Identifying Gaps in Characterizing Risk

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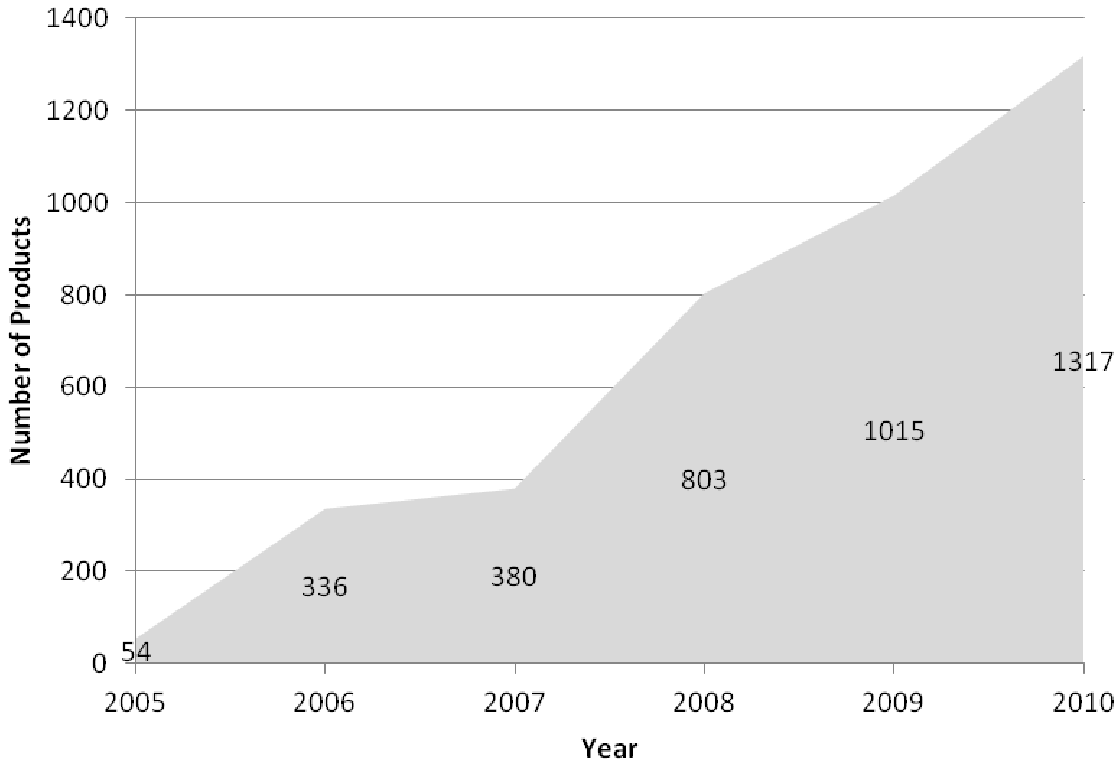
November 5, 2012

Research questions

- What are the challenges to regulating nanomaterials and nanoproducts?
- Can we use batteries with nanomaterials as a case study for identifying and addressing these challenges?

Why regulate?

- In a growing number of products



Project on Emerging Nanotechnologies, 2012

Why regulate?

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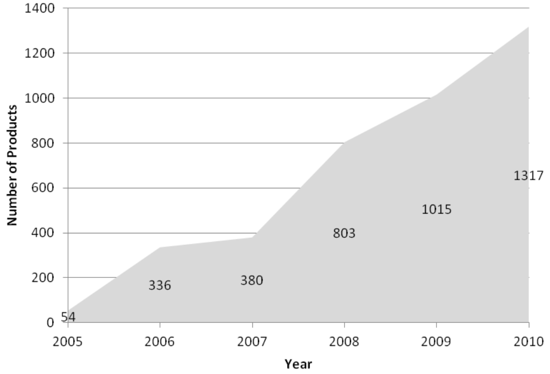
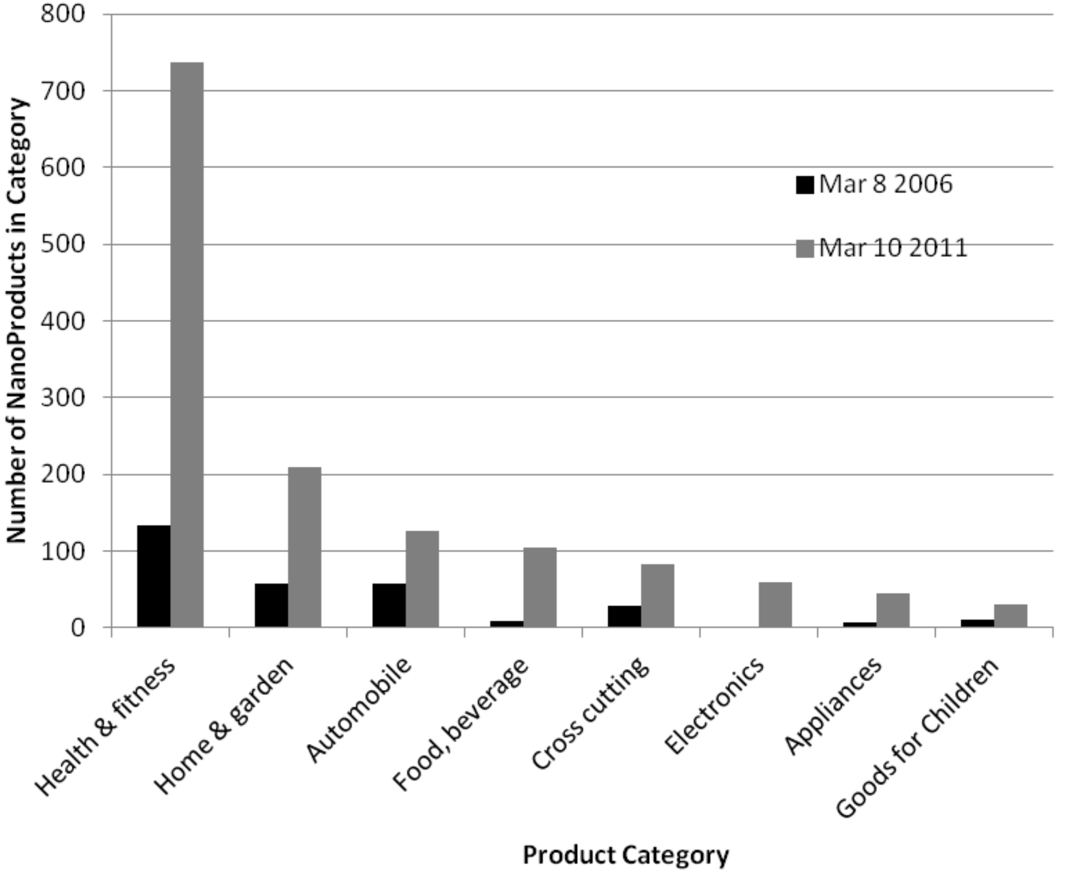
- Present in diverse products





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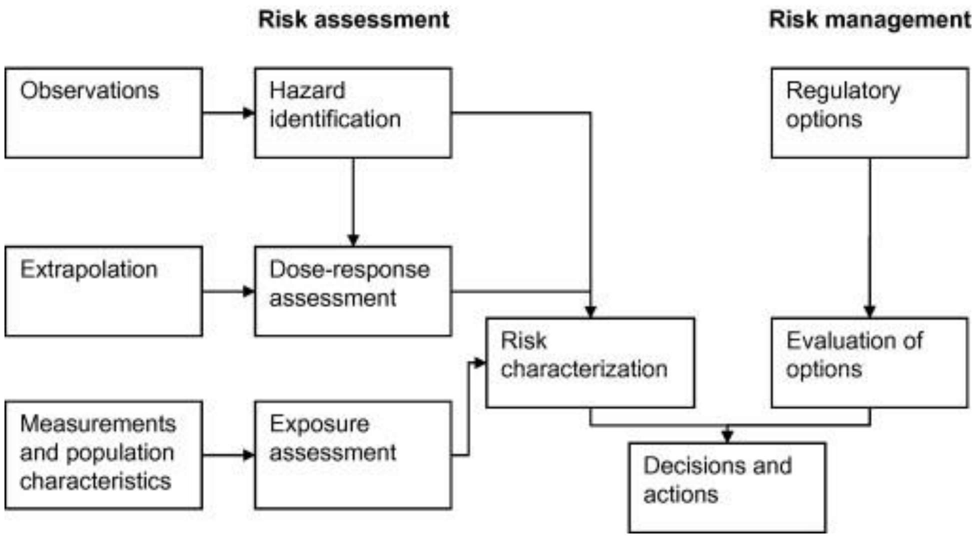
- Evidence that exposure will have significant health and environmental impacts



Red Book Risk Assessment procedure

	FY 2006		*FY 2009*	
Category	**Number of Projects**	**Million $ Invested**	**Number of Projects**	**Million $ Invested**
Instrumentation, Metrology, and Analytical Methods	78	26.5	42	11.3
Human Health	**100**	**24**	**117**	**41.6**
Environment	**49**	**11.7**	**54**	**43.7**
Human and Environmental Exposure Assessment	5	1.1	14	3.3
Risk Management Methods	14	3.3	21	3.5
TOTAL	**246**	**66.6**	**248**	**103.4**

Nanotechnology, Environmental and Health Implications Working Group, 2011

Impact Assessment

- Impact studies are very common
  - Methodology taken from toxicology
- What do they tell us?
  - Relationship of physicochemical properties to likelihood of an adverse effect in a given medium

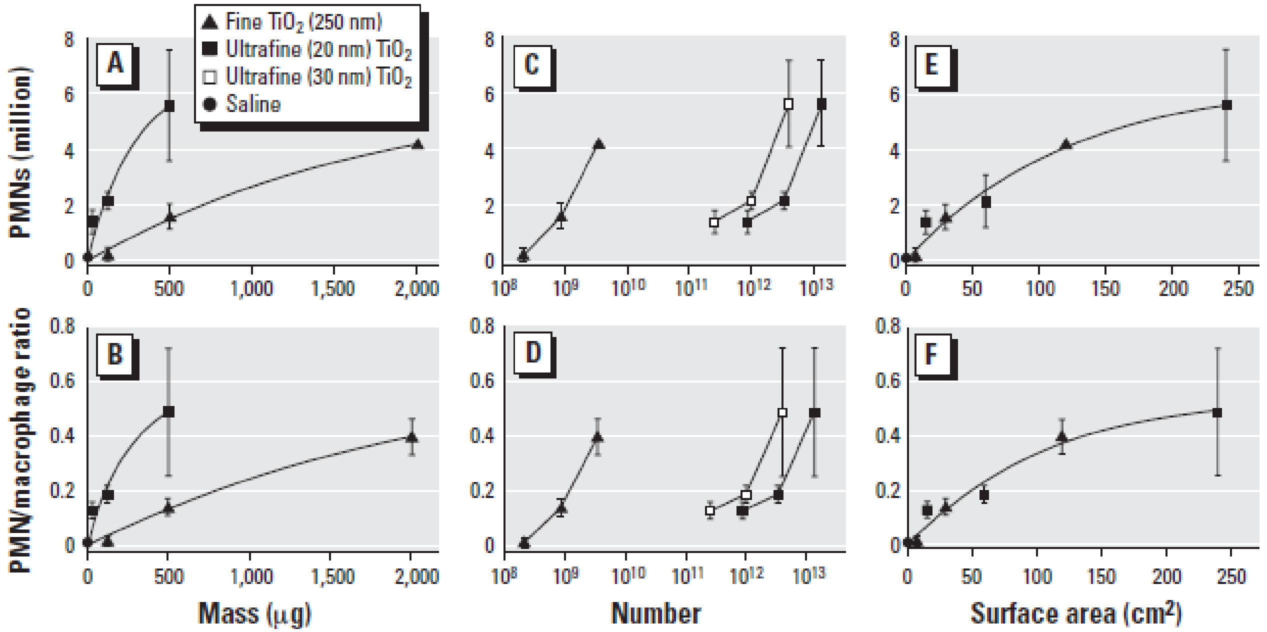


Figure 1. Inflammatory cell response in lung lavage 24 hr after intratracheal instillation of fine (~ 250 nm) and ultrafine (20–30 nm) TiO_2 expressed by different dose metrics [particle mass (*A,B*), number (*C,D*), and surface area (*E,F*)] and different response metrics [number of PMNs (*A,C,E*) and PMN/macrophage ratio (*B,D,F*)].

Oberdorster G, Oberdorster E, Oberdorster J, 2007

Impact Assessment

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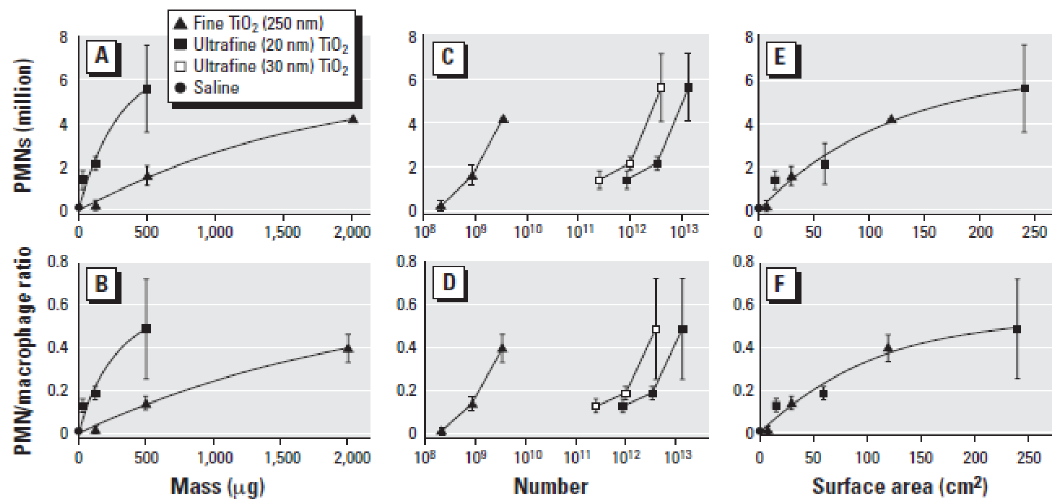
- What do they tell us?
  - Relationship of physicochemical properties to likelihood of an adverse effect in a given medium
    - Properties: Mass, surface area, shape, surface chemistry
    - Media: Small animals, human and animal cells, and organic material
    - Impacts: Damage to respiratory system such as asthma, damage to other organs, oxidative stress, pulmonary fibrosis and cancer after prolonged exposures

  - Results
    - Metrics needs to be examined
    - Inhalation is important
    - Other pathways are less well understood



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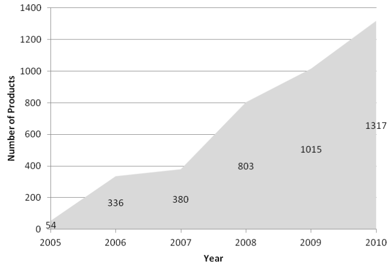

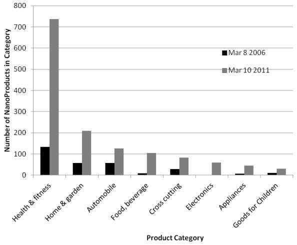

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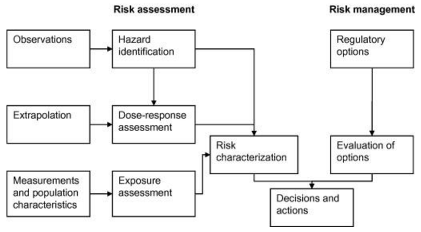
- Evidence that exposure will have significant health and environmental impacts
- Uncertainty about exposure
  - Lifecycle



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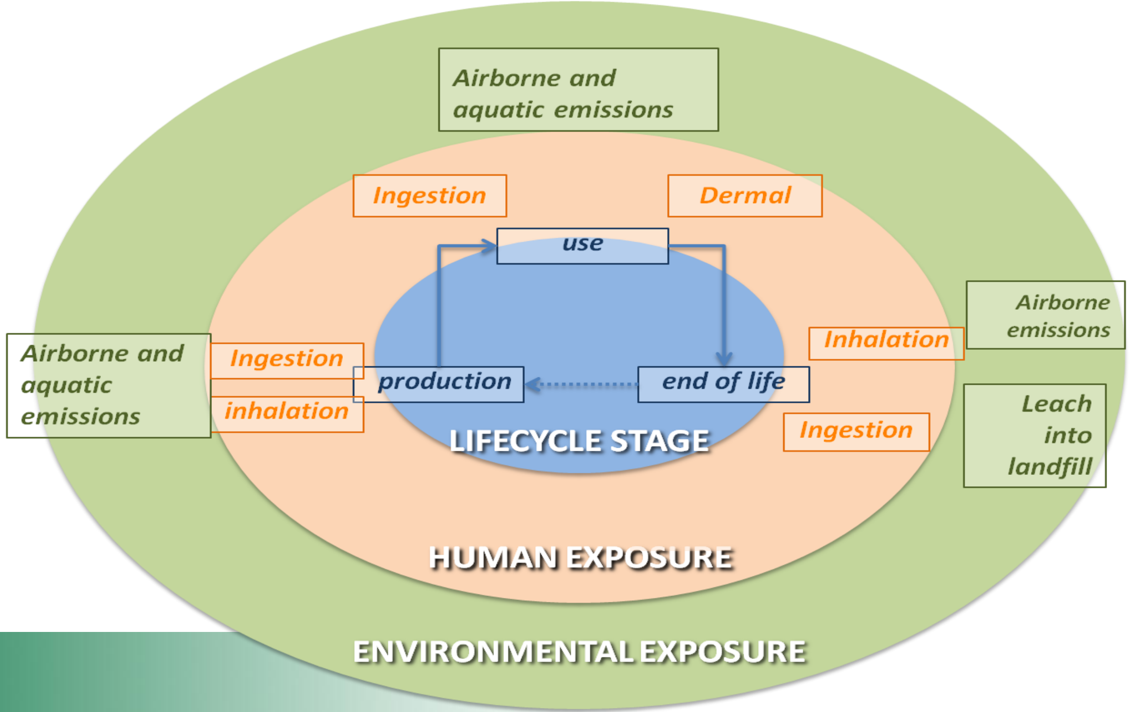
Exposure Studies

- Exposure studies determine the relevant pathways, time, and degradation of nanomaterials in the environment

- Exposure is less well characterized
    - Methodologies (modeling, data collection, and simulation) are less well established and replicable
    - Metrics



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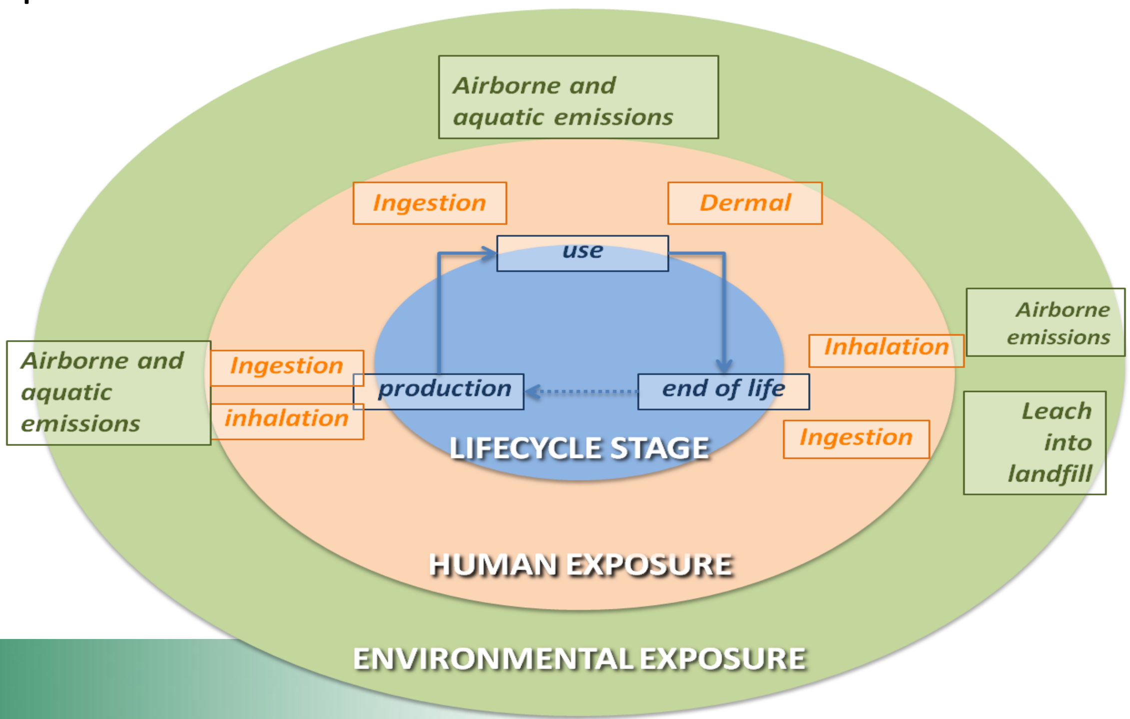
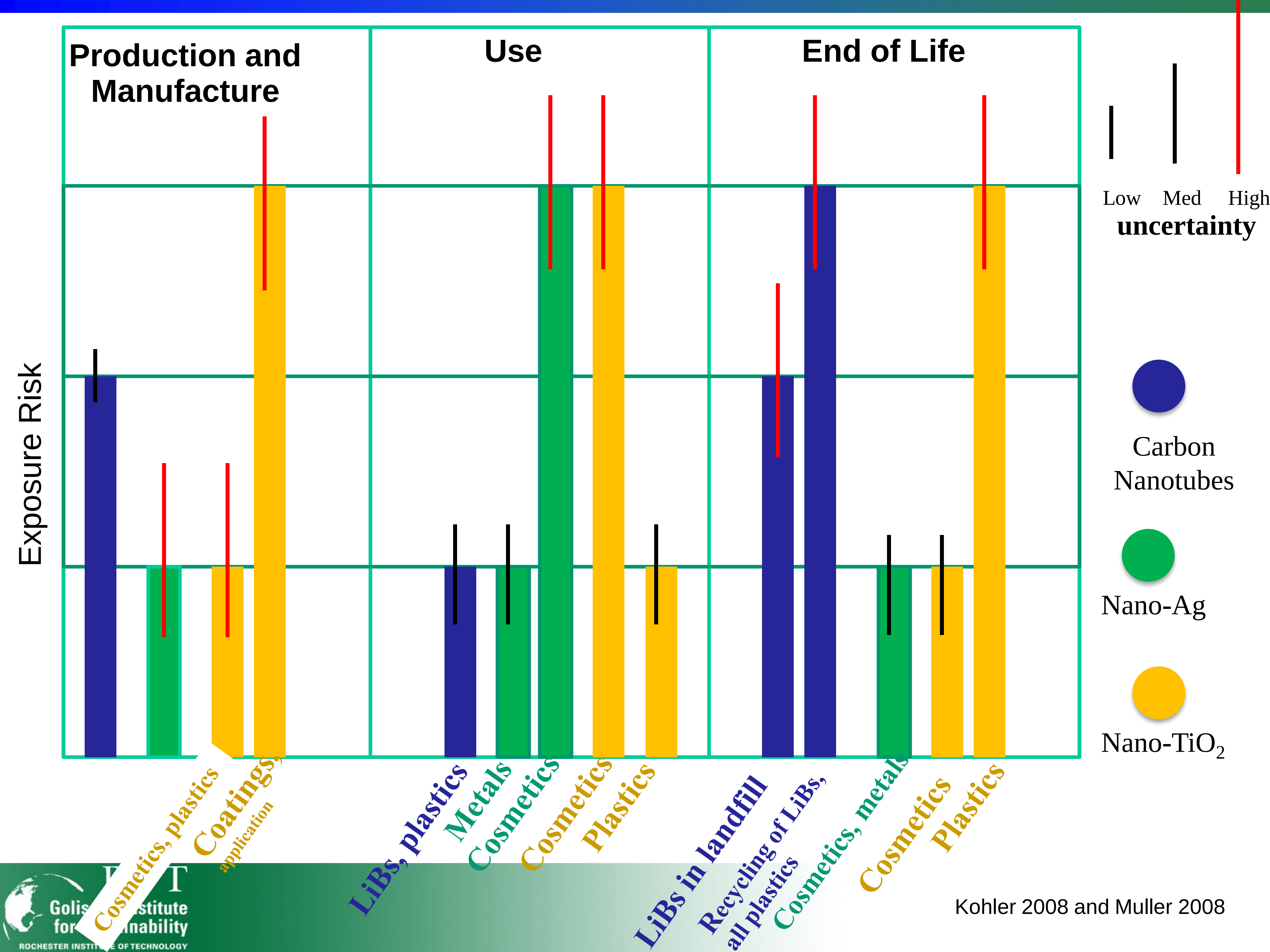
- Gap at EoL





Kohler 2008 and Muller 2008

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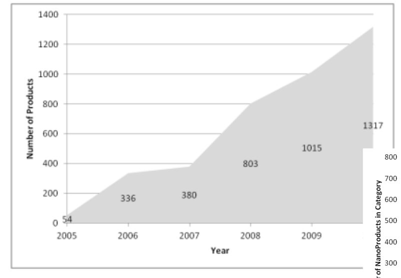

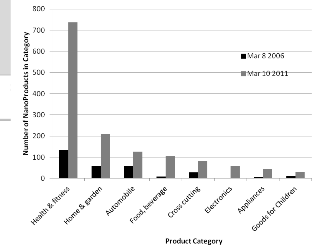

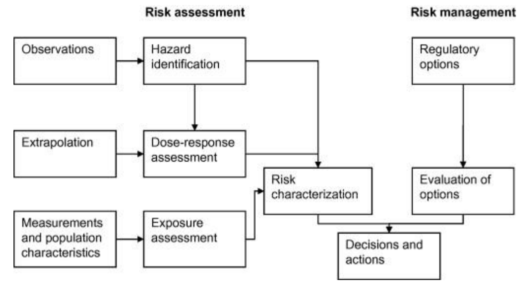

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Mismatch between Research and Regulation

What can we learn from other regulation?

Nano Research	Research Category	Regulation	Metrics
Assays of Interaction between nanomaterials and organic matter (TiO2, Heavy metals, Natural Organic matter; soil: change in bacterial growth)	Hazard identification	EPA Clean Air, Clean Water Acts	Total Maximum Daily Load (TMDL), Wasteload Allocation (WLA) , Load Allocation (LA), Margin of Safety (MOS), etc.
In vitro assays (daphnia, rainbow trout, green algae)			
In vitro assays (human brain, lung, human dermal fibroblasts, gingival fibroblasts, renal cells, bronchial epithelial cells, lung epithelial cells, pulmonary cells, etc)	Dose response assessment	OSHA Health and Safety standards	Permissible Exposure Limits (PEL), Recommended Exposure Limits (REL), Lethal Dose (LD)
In vitro assays (Rats lung tissue, rabbits dermal and mice lymph node, hamster ovary cells, daphnia, rainbow trout, green algae)			
Particle, Substance Flow Analyses	Exposure assessment	EPA Toxic Substances Control Act	Maximum number of workers exposed; Number of workers exposed to acute inhalation; substantial environmental release (volume)
Simulation			
Probabilistic Models (MFA)			
Column modeling/ numerical modeling, Video Exposure Modeling			
Clinical Detection			
Quantitative Exposure Assessment			
Risk Assessment Framework			

OSHA Exposure Limits

OSHA/NIOSH regulatory tools:
Permissible Exposure Limit/
Recommended Exposure Limit

- Particulate Not Otherwise Regulated
- Respirators required

Material	NIOSH REL	OSHA PEL	Exp. Route	Target Organ
Ammonium chloride fume	TWA 10 mg/m^3 ST 20 mg/m^3	--	Inh, Con	Eyes, skin, resp sys
Cadmium fume	**Carcinogenic**	**TWA .005 mg/m^3**	**Inh**	**resp sys, kidneys, blood [prostatic & lung cancer]**
Copper Fume	TWA 0.1 mg/m3	TWA 0.1 mg/m3	Inh, Con	eyes, skin, resp sys
Ferrovanadium dust	TWA 1 mg/m3	TWA 1 mg/m^3	Inh, Con	Eyes, resp sys
Particulates not otherwise regulated	**See Appendix**	**TWA 15 mg/m3 (total)**	**Inhalation, Skin and/or eye contact**	**Eyes, skin, resp. system**
Perlite	TWA 10 mg/m3 (total) TWA 5 mg/m3 (resp)	TWA 15 mg/m3 (total), TWA 5 mg/m3 (resp)	Inh, Con	Eyes, skin, resp sys
Vanadium fume	C 0.05 mg V/m3 [15-minute]	C 0.1 mg V2O5/m3	Inh, Con	Eyes, skin, resp sys

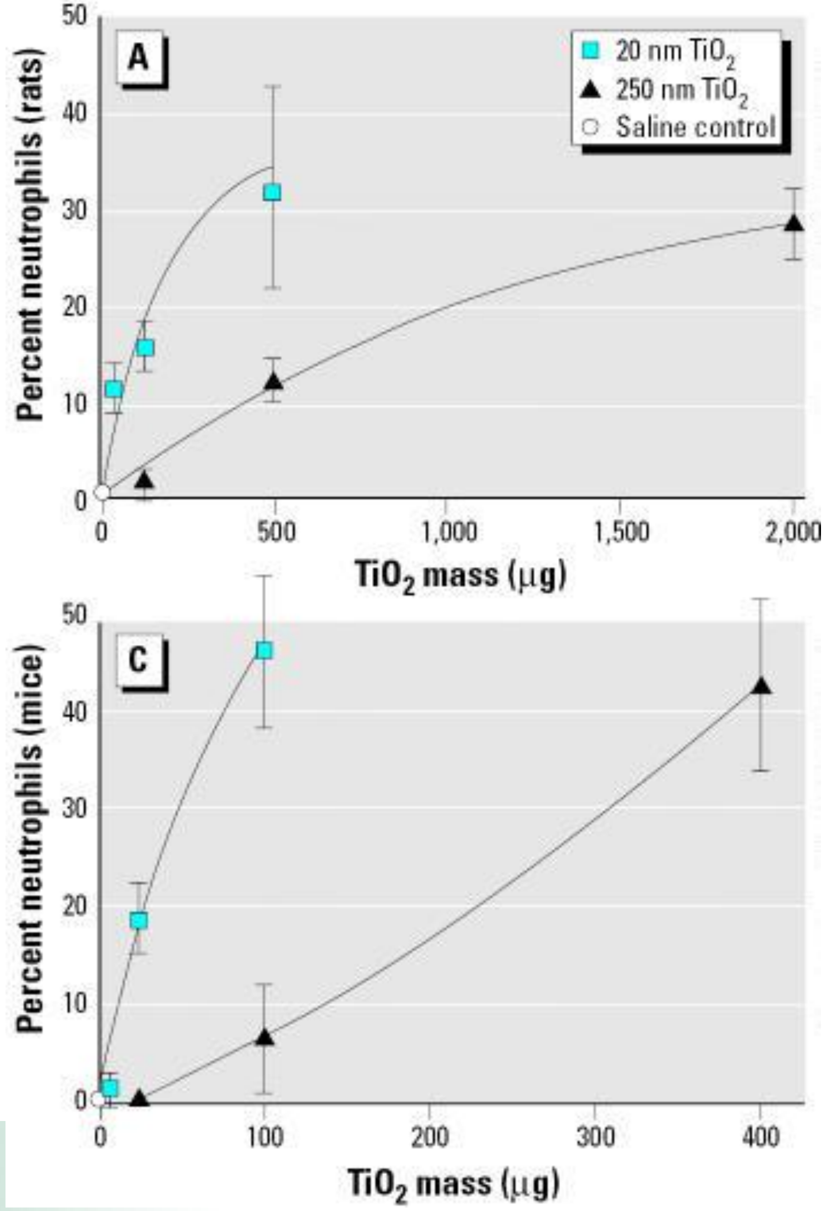
NIOSH pocket guide 2011

Establishing a PEL for Nanomaterials

•PEL for Particulates not otherwise regulated:
15 mg/m^3 for 8-hour period

•For nanomaterials much smaller doses have been shown to have high probability of impact

=>Need more stringent PEL for nanomaterials



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OSHA Exposure Limits

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Pros and Cons

- **Pros:**
  - Single score metric
  - Widely accepted
  - Has basis for enforcement
- **Cons:**
  - Doesn't protect consumer
  - Doesn't cover end-of-life except WM workers
  - takes a long time to get legislate
  - **companies may not have sensors sensitive enough**
  - **expensive to monitor**

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NIOSH pocket guide 2011

Landfill Ban

State or local statutes banning products/ materials from entering a landfill

- Product-specific ban

Pros and cons:

- **Pros:**
  - reduce landfill volumes,
  - improve soil and groundwater health,
  - Requires recovery
- **Cons:**
  - Difficult and costly to enforce without clear economic incentive
  - reduces exposure *only* at EoL
  - Product-based
  - **Nano-specific:** Uncertainty about ability to leach in landfills and the impact
  - Diverse array of products

Air Quality Standards

Clean Air Act's National Ambient Air Quality Standards

- Use of primary and secondary standards to protect 1) vulnerable populations and 2) public welfare protection

Pros and cons:

- **Pros:**
  - Covers all lifecycle stages
  - Spans all products
  - Particulate matter already monitored
- **Cons:**
  - Long time to legislate and updated infrequently
  - Only covers inhalation exposure

Pollutant [final rule cite]		Primary/ Secondary	Averaging Time	Level	Form
Carbon Monoxide [76 FR 54294, Aug 31, 2011]		primary	8-hour	9 ppm	Not to be exceeded more than once per year
			1-hour	35 ppm	
Lead [73 FR 66964, Nov 12, 2008]		primary and secondary	Rolling 3 month average	0.15 μg/m^3 [(1)]	Not to be exceeded
Nitrogen Dioxide [75 FR 6474, Feb 9, 2010] [61 FR 52852, Oct 8, 1996]		primary	1-hour	100 ppb	98th percentile, averaged over 3 years
		primary and secondary	Annual	53 ppb [(2)]	Annual Mean
Ozone [73 FR 16436, Mar 27, 2008]		primary and secondary	8-hour	0.075 ppm [(3)]	Annual fourth-highest daily maximum 8-hr concentration, averaged over 3 years
Particle Pollution [71 FR 61144, Oct 17, 2006]	$PM_{2.5}$	primary and secondary	Annual	15 μg/m^3	annual mean, averaged over 3 years
			24-hour	35 μg/m^3	98th percentile, averaged over 3 years
	PM_{10}	primary and secondary	24-hour	150 μg/m^3	Not to be exceeded more than once per year on average over 3 years
Sulfur Dioxide [75 FR 35520, Jun 22, 2010] [38 FR 25678, Sept 14, 1973]		primary	1-hour	75 ppb [(4)]	99th percentile of 1-hour daily maximum concentrations, averaged over 3 years
		secondary	3-hour	0.5 ppm	Not to be exceeded more than once per year

as of October 2011

EPA 2012

Conclusions Moving Forward

Gaps:

- Developing appropriate impact methodology
- Exposure uncertainty and at EoL
- Metrics development to bridge the gap between research and regulation

Future work:

- Quantifying the tradeoffs of different types of regulation through BCA
- Exploring hybrid regulation
- Applying these lessons to batteries