



The evolving regulatory landscape for nanomaterials

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Nano-EHS Regulation

Regulatory change
is happening



But policy is uncertain

EPA regulatory change

- Toxic Substances Control Act (TSCA)
 - Carbon nanotube and fullerene trial balloons (and graphene)
 - New regulation promised for mandatory data generation
 - Specification of “new” (use or material) under TSCA
- Pesticides (FIFRA)
 - Exploring definitions and regulatory tools, starting with silver biocides
- Risk assessment....
 - OECD data generation, and ESH research
 - Consideration of “life cycle” and risk extrapolation issues

FDA regulatory change

- Nanotechnology Task Force report still stands
 - <http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/default.htm>
 - being codified to guidance
- Food additive guidance in development (started with specification of size; now manufacturing and GRAS; next is toxicity testing)
- Cosmetics (how to respond to EU labeling interest)
 - working within International Cooperation on Cosmetic Regulation (ICCR)
- Devices
 - What is a predicate device, considering nanoscale material innovation?
 - National Academy of Sciences, Institute of Medicine report in progress, generally on 510k revision but will also affect nanomaterial determinations.
- Drugs
 - What data will CDER need for manufacturing consistency?
 - Validated test methods? (Guidance re: Uptake by immune system?)

Mandatory data call-ins

California, and soon EPA and Environment Canada

Two general kinds of data have been requested:

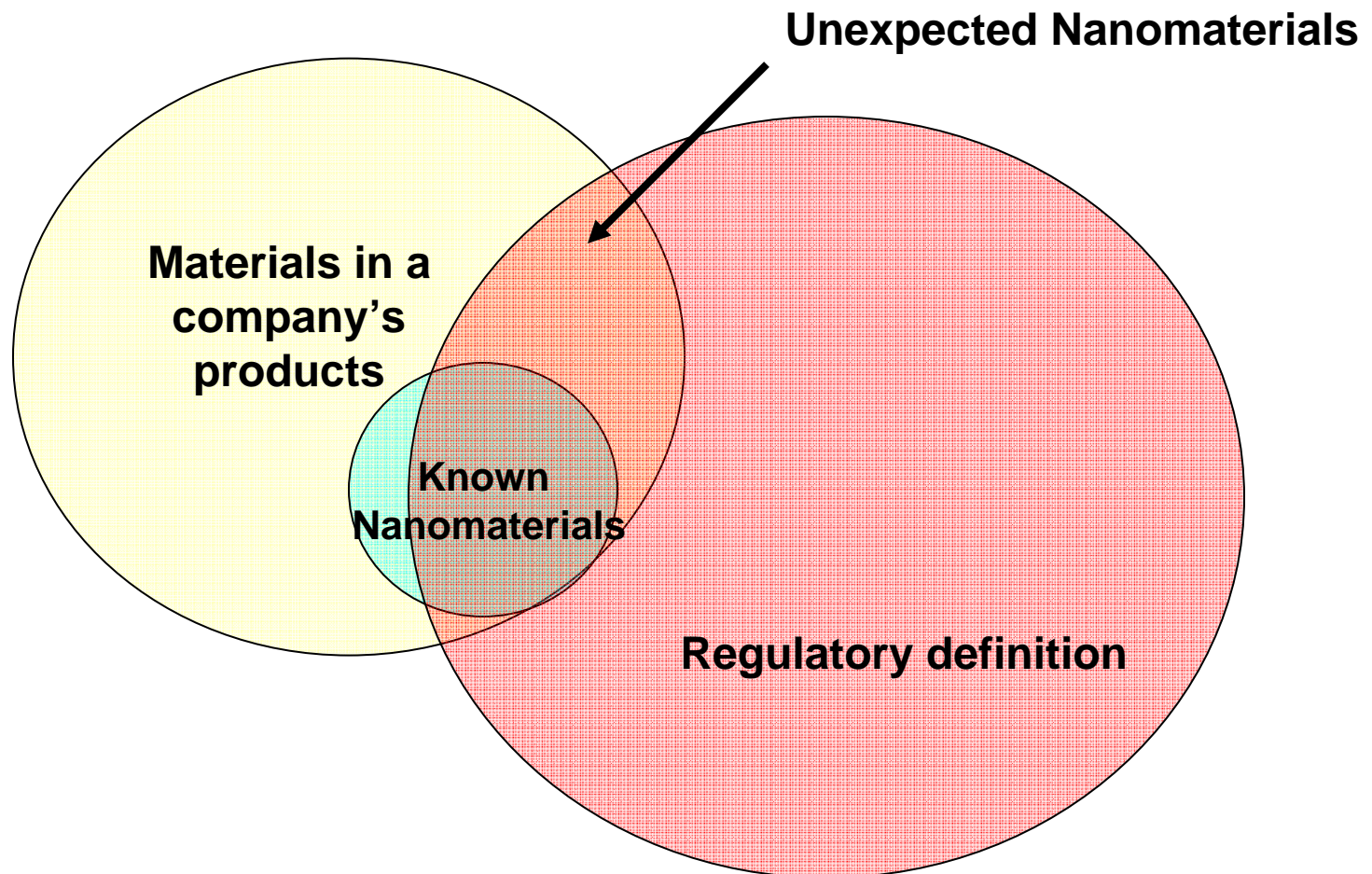
1. Data to assess presence in market and knowledge of properties
 - Getting our arms around the problem
 - Where to draw lines or specify
2. “Data” regarding understanding of safety
 - Risk communication?
 - Liability line - no government assessment of safety

Jury is out on what the California data call-in accomplished.

Regulation while policy is uncertain

- Definitions are all over the map
 - Reality will be determined by the practical interpretations
- Forest vs. trees
 - Some policy mistakes “nano” for a discrete entity rather than a range of technologies
 - European Parliament labeling for “nanomaterial”
 - SAICM African-Region resolution on “nanomaterial” in waste
 - But there is hope - some policy is specific to the characteristics and materials
 - FDA’s product-specificity and attention to size data rather than discrete boundaries
 - EPA focusing on specific materials in a TSCA Section 4 rule
- But how will EPA do a general SNUR?
 - Based on processes?
 - Based on lines in the sand? (Corralling angels on the head of a pin)

Unintended effects of broad regulatory definitions



European Parliament definitions

Novel foods

“any intentionally produced material that has one or more dimensions of the order of 100 nm or less or is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic to the nanoscale”

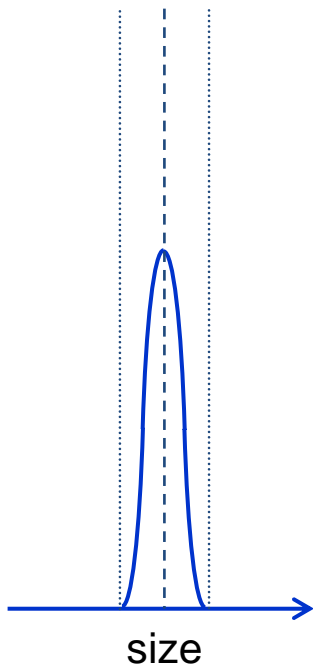
Cosmetics

“an insoluble or bio-resistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm”

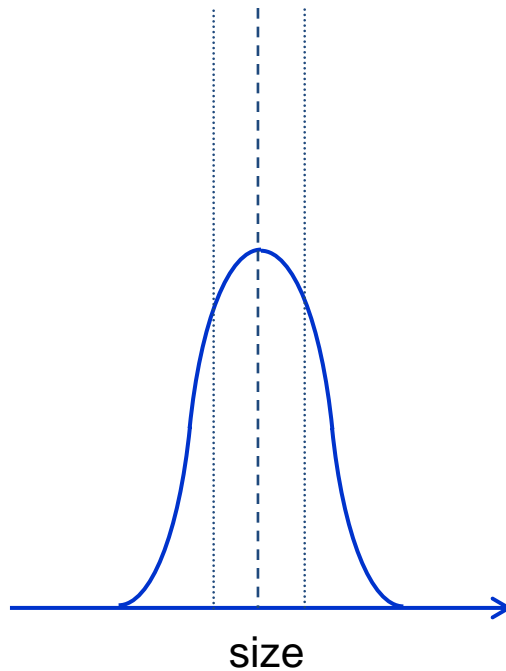
Practical interpretations

- The nanomaterial definitions include an infinity of products, a large proportion of which *will have no appreciable risk*
- Practical interpretations by agencies will be the key to the meanings
 - When is processing raw minerals intentional manufacture?
 - What about proteins?
 - What proportions? e.g., TiO₂ in paint with 0.1% free particles in nanoscale, or 1% agglomerated of nanoscale materials, or?
- Practical interpretations can be biased and unpredictable and lead to differences of opinion

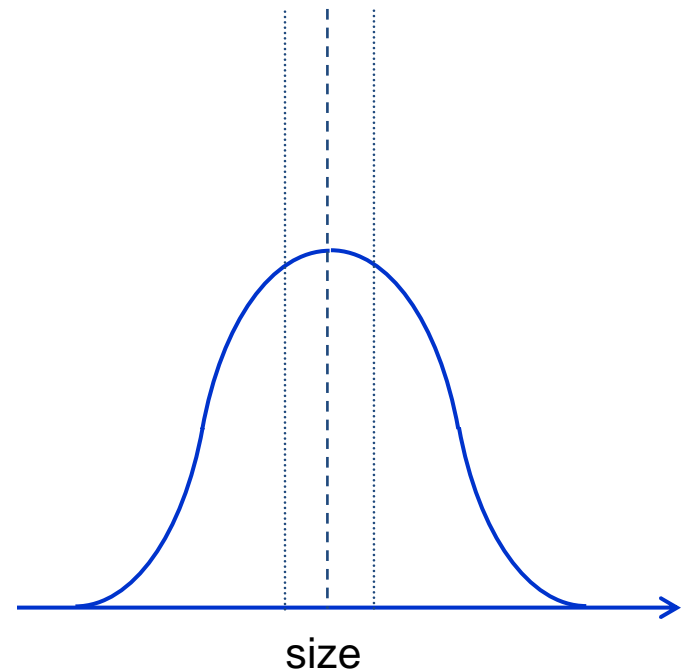
What does “impurity” mean for a nanomaterial when size determines properties?



100% within range



50% within range
50% impurity?



10% within range
90% impurity?

US Government Coordination Efforts

Regulatory policy

- Renewed White House Policy Coordination Group
- Agency-specific groups at FDA and EPA
- Government Accountability Office report

Science (supporting risk management in some cases)

- President's National Science and Technology Council Committees and Work Groups
- President's Council of Advisors on Science and Technology
- National Academy of Sciences report

International coordination

- Why do we care?
 - Inefficient regulation
 - Differing risk-acceptance – TRADE
- What is happening?
 - Agency bilaterals (FDA, EPA, USDA)
 - US EU-Mission group?
 - Perhaps a White House to European Commission connection?
 - OECD on data and risk assessment approaches
 - ISO on definitions, reference documents, etc
- Are ISO and OECD working, and are they enough?

What does it mean for business?

- Higher risk due to regulatory and risk uncertainty requires higher payoff
 - Dampening investment and innovation
- There is an information premium
 - Knowing the likely regulatory and guidance boundaries helps you make the right choices
 - Evolving “risk science” will drive decisions

What should you do?

- Choose wisely in consideration of knowledge of regulatory and risk management likelihoods
 - Don't avoid exploration, but don't wait too long in the process to determine your risk
- Push for guidance
 - Work with regulators to shape the boundaries of inquiry
 - Clarify the data needed for decisions early in the planning
 - Take advantage of early consultation from NIOSH, FDA, and EPA
- Affect policy now
 - Develop the data and analysis to set the record straight
 - Release and environmental transport monitoring
 - Risk assessment for specified real-world conditions
 - Set the standards for what is measured and how it is assessed