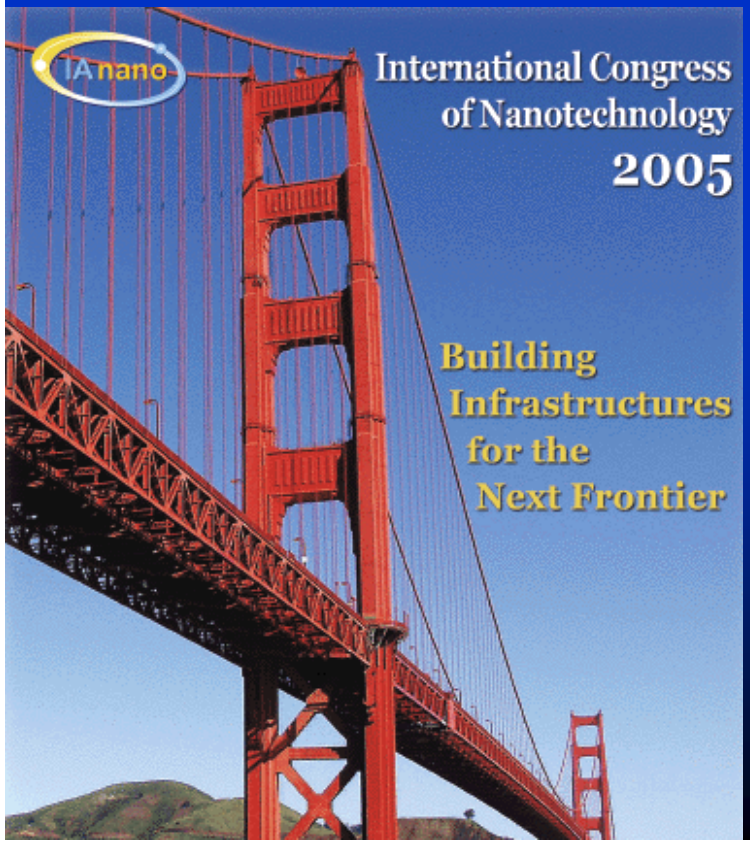
International Nomenclature and Standards in Nanotechnology:

Ethics, Societal, Environmental and Safety implications



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http://www.ianano.org

Why International Nanotechnology Standards are needed ?

- The Standard Project will develop interoperability specifications for nanomaterials, devices and nanoscale structures and systems.

- To set international standards for testing methods and processes so data is reported uniformly and results can be compared and verified

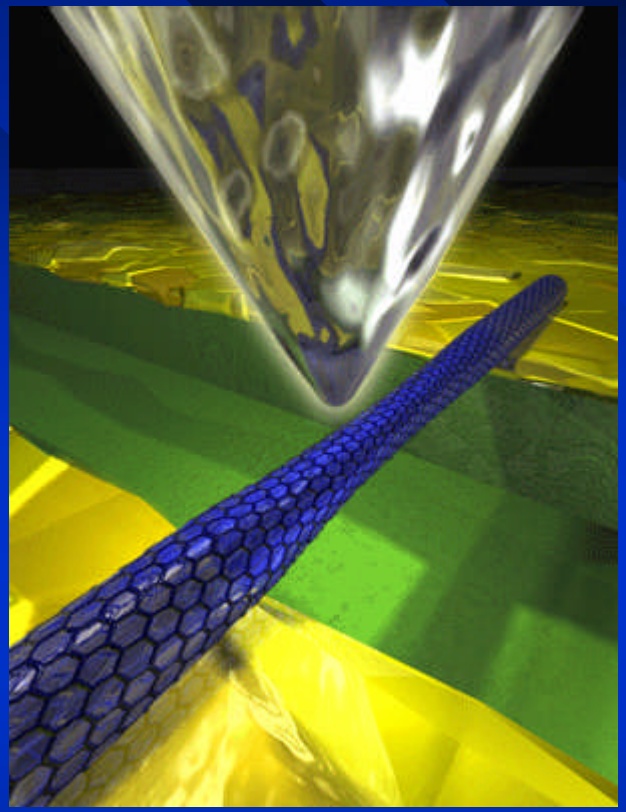
- This will help researchers, designers, manufacturers and suppliers as well as customers to communicate effectively and harmonize best practices worldwide.

- To optimize the manufacturing processes while ensure the trust and confidence of customers and public at large

- Without standards the emerging field cannot grow to become an major industry.

International nomenclature and standards in Nanotechnology are urgently needed for

- Research laboratory
- Publication
- Patent Protection
- Communication
- Clinical study
- Manufacturing
- Commercialization



http://www.mb.tn.tudelft.nl/images/AnimatedTube.gif

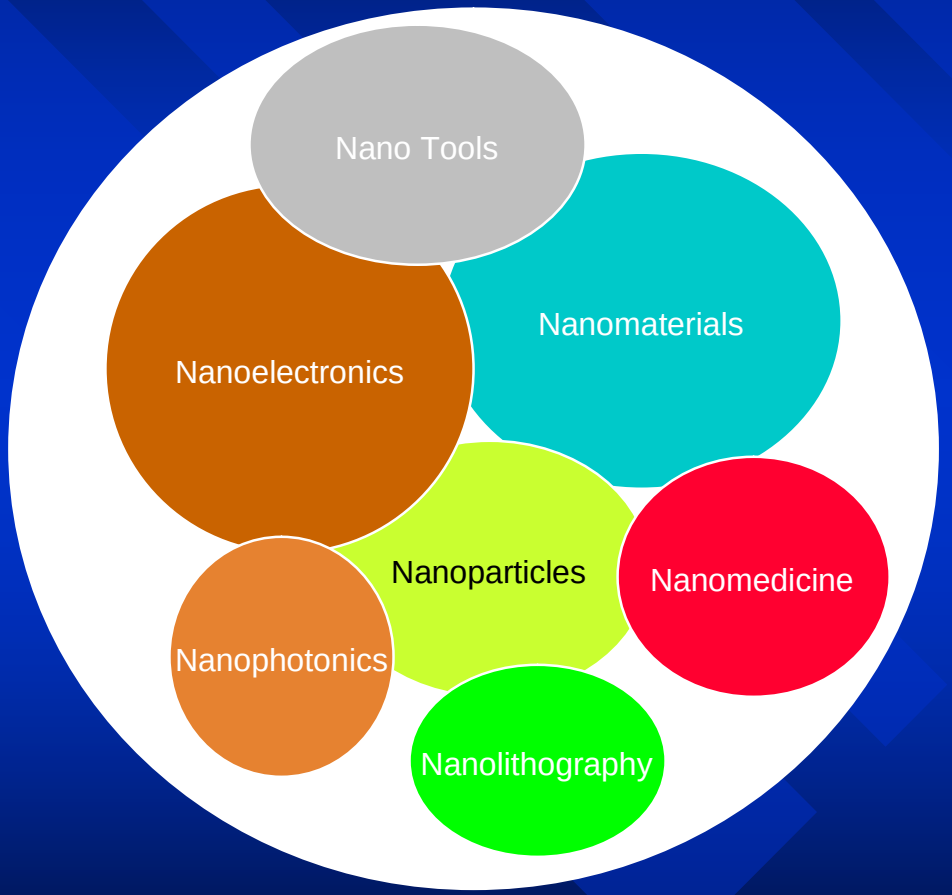
Example of some nanotechnology terms:

- "Bottom-up"
- "Top-down"
- "Wet/wet", "wet/dry", "dry/dry"
- Nano-scale hybrid materials
- Taxonomy of carbon nanostructured:

  carbon black, diesel exhaust, filtration carbon, $C^{60,}$ fullerene, single-wall carbon nanotubes, multiwall carbon nanotubes

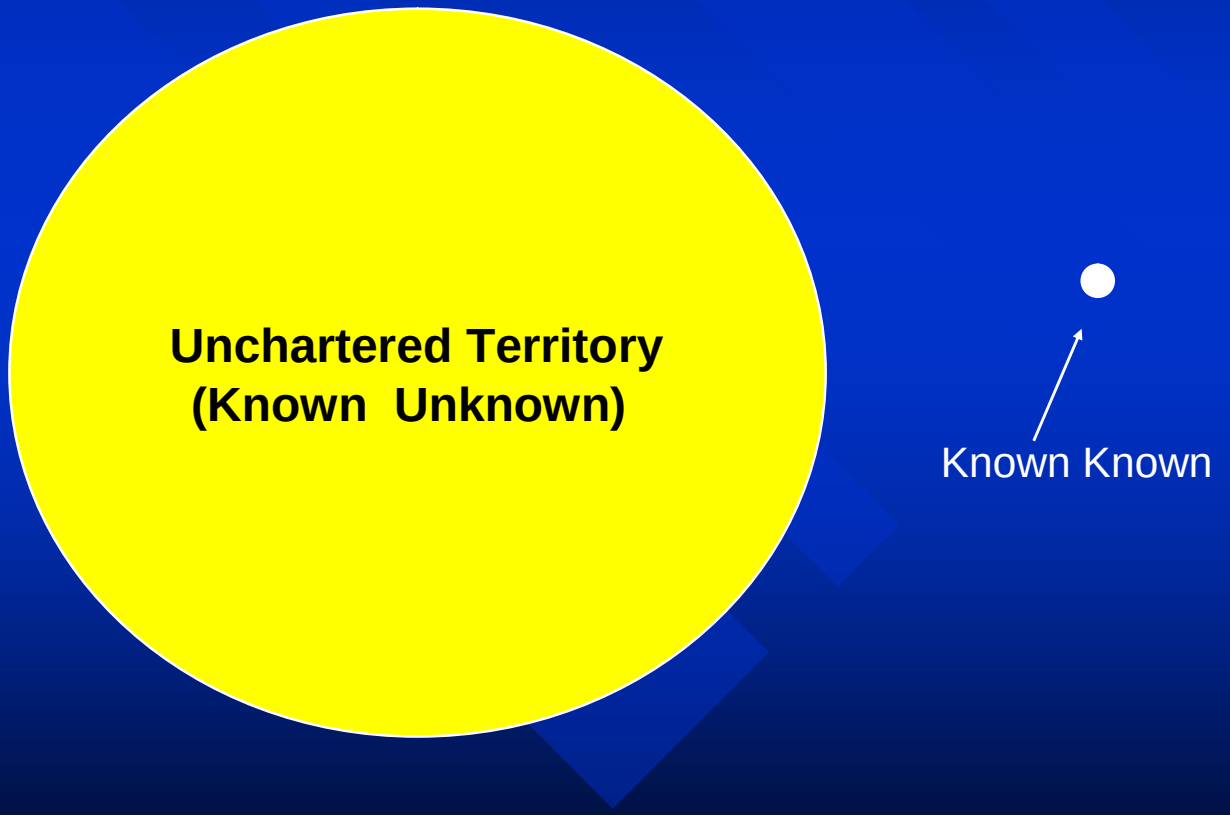
Scientific landscape in Nanotechnology

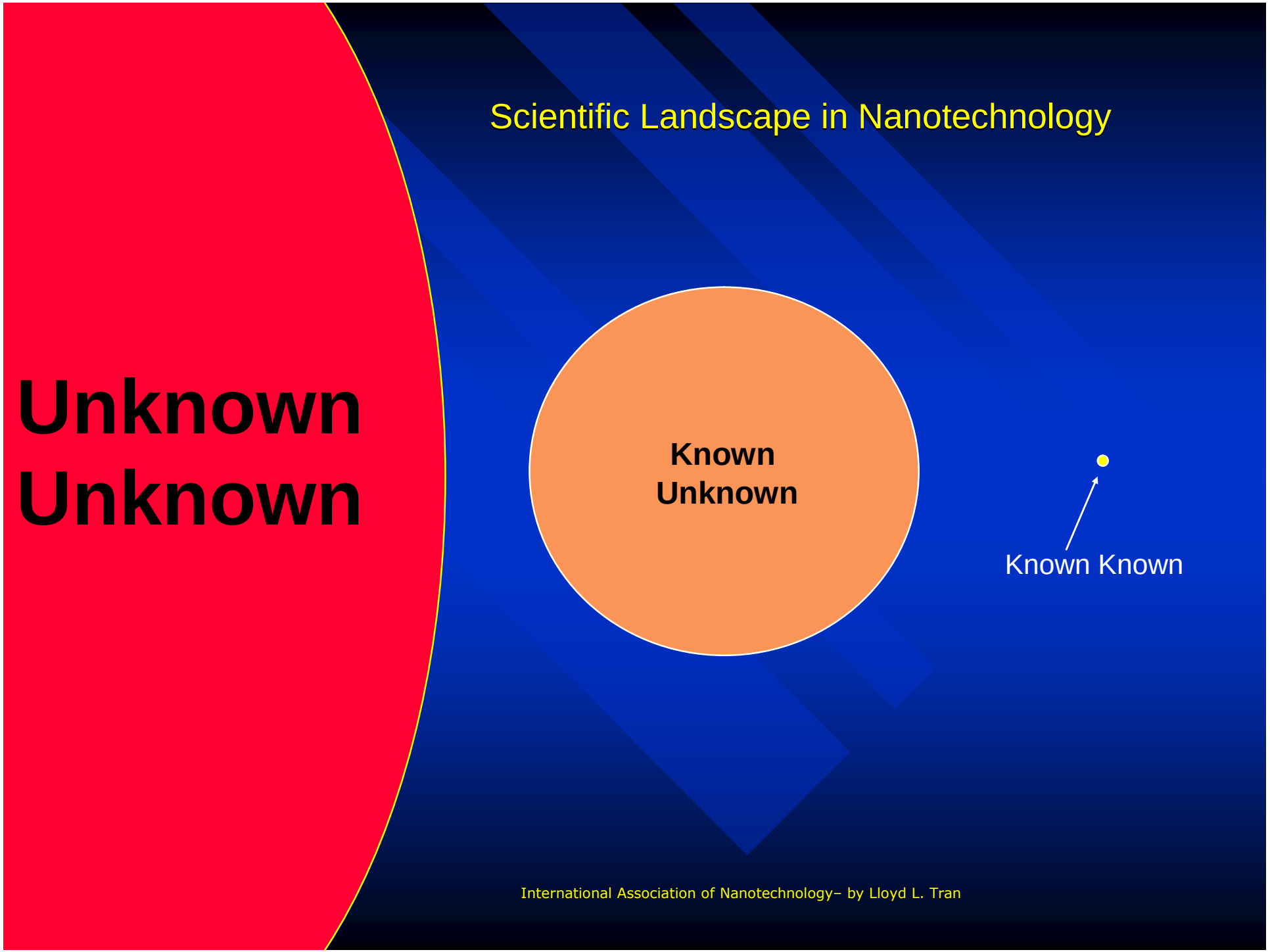
Knowledge based Nanoscience and Nanotechnology (known-known)



Scientific Landscape in Nanotechnology

Un-chartered Territory : great opportunities in exploring the unknown




Scientific Landscape in Nanotechnology
Unknown
Unknown
Known
Unknown
Known Known
International Association of Nanotechnology– by Lloyd L. Tran

Current Nomenclature & Standards Development Effort

- IEEE has had standard for electrical characteristics of carbon nanotubes
- IUPAC and CAS have had some nomenclature frameworks for fullerene
- American National Standard Institute (ANSI) initiated a Nanotech panel 11/04
- ASTM and ASME has recently begun metrology effort
- ISO has begun development of international standards in nanotechnology

Nanotechnology Standard Development:

1. Metrology and test Methods:
2. Properties and characteristics of nanomaterials
3. Risk assessment and management
4. Toxicology study
5. Environmental impact

Nanotechnology Standards

1. Metrology and test methods:

- Aggregation
- Agglomeration
- Airborn concentration
- Aspect ratio
- Dispersivity
- Hydroxylation
- Zeta potential
- Light scattering absorbance
- Mass concentration
- Surface area/ concentration
- Standards for calibration
- Statistical significance

and others…

Nanotechnology Standard Development:

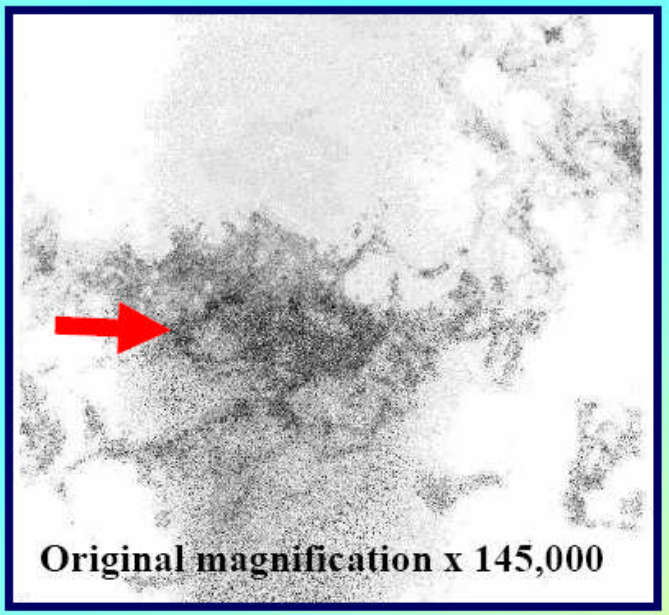
1. Metrology/measurement test methods
2. Properties and characteristics of nanomaterials
   - naturally occurring vs. engineered particles
   - size, shape, morphology
   - surface area
   - porosity
   - solubility
   - magnetic
   - electrical
   - bioactive
   - composite, etc…

Single Wall Carbon Nanotube contains Redox-Active Iron

Metal Components of SWCNT

Component	(μg/gram)	Component	(μg/gram)
Aluminum	233	Molybdenum	1070
Calcium	164	Sodium	8750
Cadmium	23.4	Nickel	8,750
Chromium	13.1	Palladium	28
Copper	2,530	Selenium	<2.001
Iron	239, 000	Titanium	6.92
		Zinc	85.9

Transmission Electron Microscopy of SWCNT



Source: Valerie E. Kagan, Dept. Environmental & Occupational Health, University of Pittsburgh

Nanotechnology Standard Development:

1. Metrology/measurement test methods:
2. Properties and characteristics
3. Risk Assessment and management

   - exposure assessment
   - hazard identification
   - dose-response assessment
   - risk characterization
   - containment procedures
   - threshold levels
   - adverse effect report
   - etc.…

Nanotechnology Standard Development:

1. Metrology/measurement test methods:
2. Properties and characteristics
3. Risk Assessment and management
4. Toxicology study

- bioavailability
- bioaccumulation
- bio-interaction
- pathogenicity
- toxic levels: ppm, ppb
- acute vs chronic
- in vitro vs. in vivo
- by-products, metabolites, degradation products
- exposure route: external, ingestion and inhalation,
- animal toxicity vs. human toxicity
- susceptibility: children vs. adult exposure
- short-term and long term toxicity

Etc…

Nanotechnology Standard Development:

1. Metrology/measurement test methods:
2. Properties and characteristics
3. Risk Assessment and management
4. Toxicology study
5. Environmental impact
   - water and air quality
   - land and soil quality
   - energy conservation
   - pollution and life cycle
   - waste disposal
   - route of exposure
   - measures of exposure
   - distribution of hazardous waste
   - balanced risk/benefit evaluation
   - pollution prevention

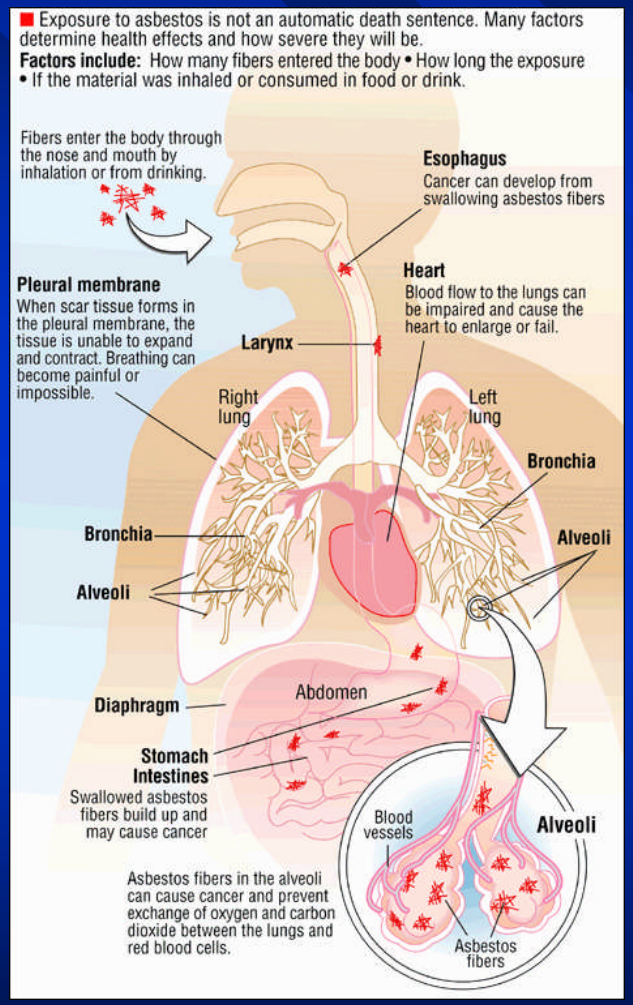
   Etc…

Developing “Gold Standards “ in Nanotechnology?

Nanoparticle Characterization :

1. What are the forms in which particles are presented to host, cells and organelles?
2. What are residual solvents, processing variables, impurities and excipients?
3. What are validated assays to detect and quantify nanoparticles in in vitro and in vivo?
4. How do we determine long and short-term stability of nanomaterials?
5. How do you analyze the degradation of nanoparticles
6. How to maintain quality assurance in scaling-up to mass production.
7. What are the reference materials and manufacturing standardization

Nanoparticle Safety



- What are the nanoparticle' pathways inside the human body?
- How long do the nanoparticles remain in the tissues and how are they cleared?
- What effects do nanoparticles have on cellular and tissue functions?
- Can nanoparticles gain access to the systemic circulation from dermal exposure? If nanoparticles enter skin cells, is there an effect on cellular functions?
- What are unanticipated reactions in vivo?

Nanomaterial Environmental Issues:

- How to protect workers from exposure to nanoparticles?
- Following human and animal use, can nanoparticles be released or excreted into the environment
- How to determine the extent of quantity of nanoparticle release in the environment?
- What might the nanoparticles effect on the environment?

FDA Standard Test Methods for Biological Responses

- Guidelines for evaluating biological safety for pharmaceutical products
- Guidelines for nanoparticles are in development

Toxic Substances Control Act

15 U.S.C. s/s 2601 et seq. (1976)

- The Toxic Substances Control Act (TSCA) of 1976 was enacted by Congress to give EPA the ability to track the 75,000 industrial chemicals currently produced or imported into the United States.

- EPA repeatedly screens these chemicals and can require reporting or testing of those that may pose an environmental or human-health hazard.

- EPA can ban the manufacture and import of those chemicals that pose an unreasonable risk.

European Union's REACH

Registration Evaluation Authorization of Chemicals

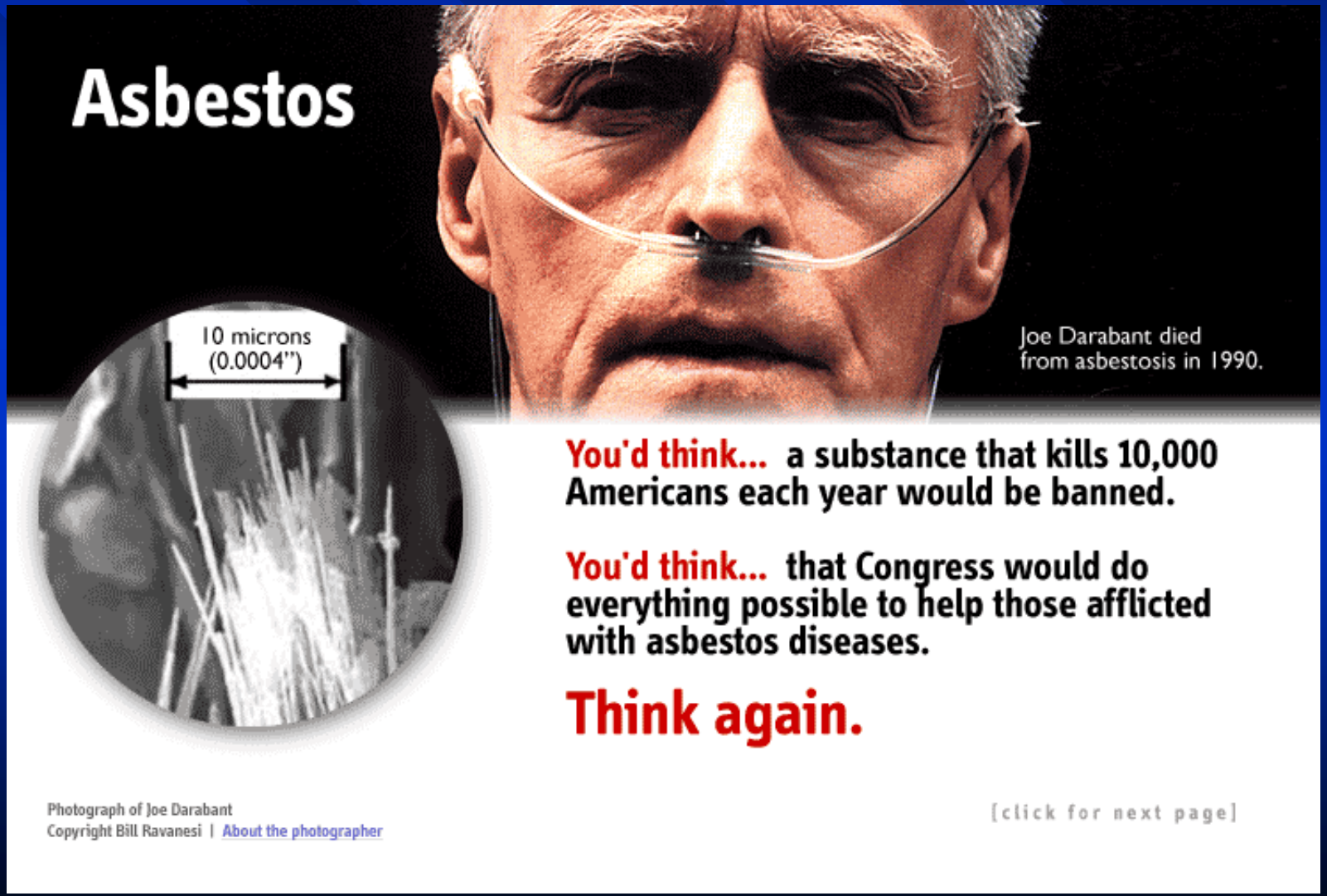
❑· New chemicals. A new chemical is defined as one that does not appear on the EINECS (European Inventory of Existing Commercial Substances) inventory. When a new chemical is produced, before introduction to the market, the producer of that chemical is required to conduct testing, and in the meantime take such precautions as are practicable. The level of testing required is determined by the mass produced, with the lowest mass trigger currently set at 10kg per annum. Only changes in chemical structure constitute a new substance, whereas changes in form (for example size or shape) do not. An exception is made for polymers: those produced entirely from EINECS listed monomers are exempt from notification.

❑· Mass (tonnage) triggers: Essentially, the more of an existing substance that is produced, the more data on its properties are required by regulators.

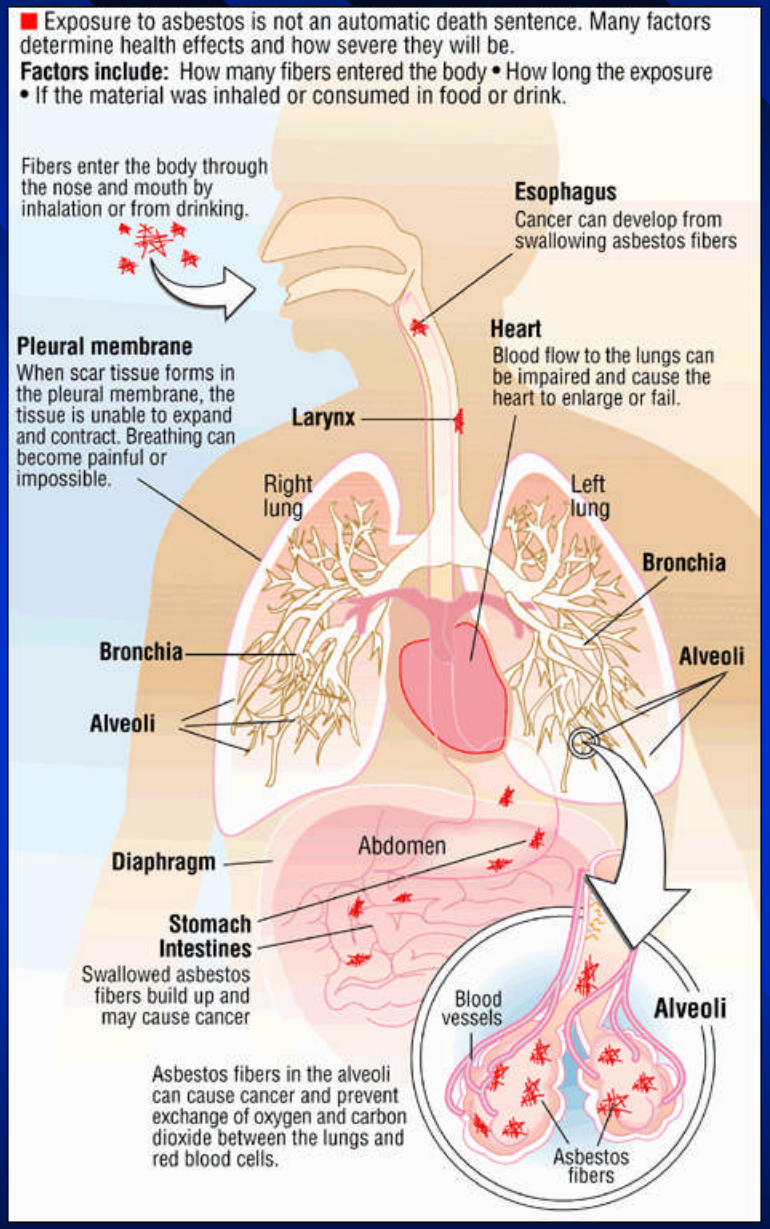
A case study: Asbestos

Scanning electron micrograph of asbestiform amphibole from a former vermiculite mining site near Libby, Montana. Source: U.S. Geological Survey and U.S. Environmental Protection Agency, Region 8, Denver, Colorado.

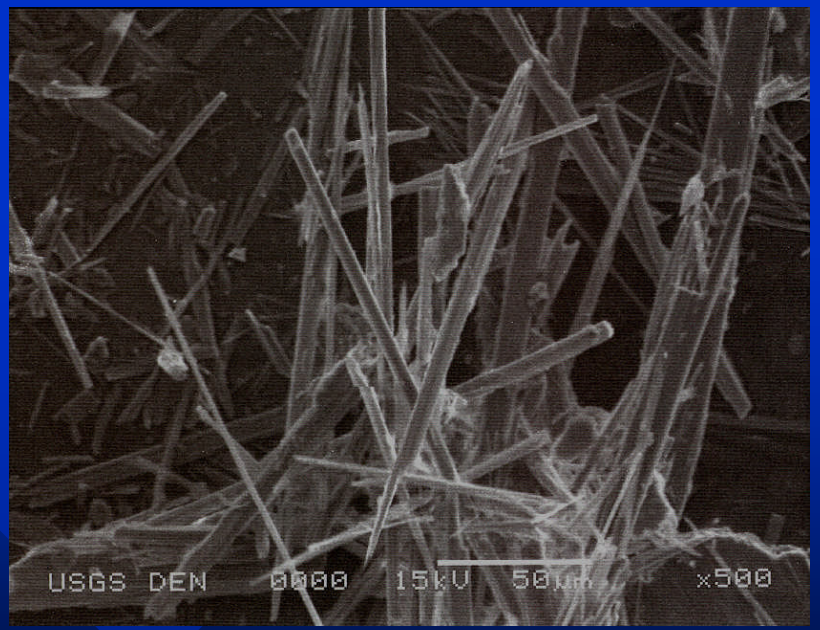
Asbestos: over the past century has caused millions of deaths and asbestos toll exceeds 100,000 per year around the world



Health Effects of Asbestos

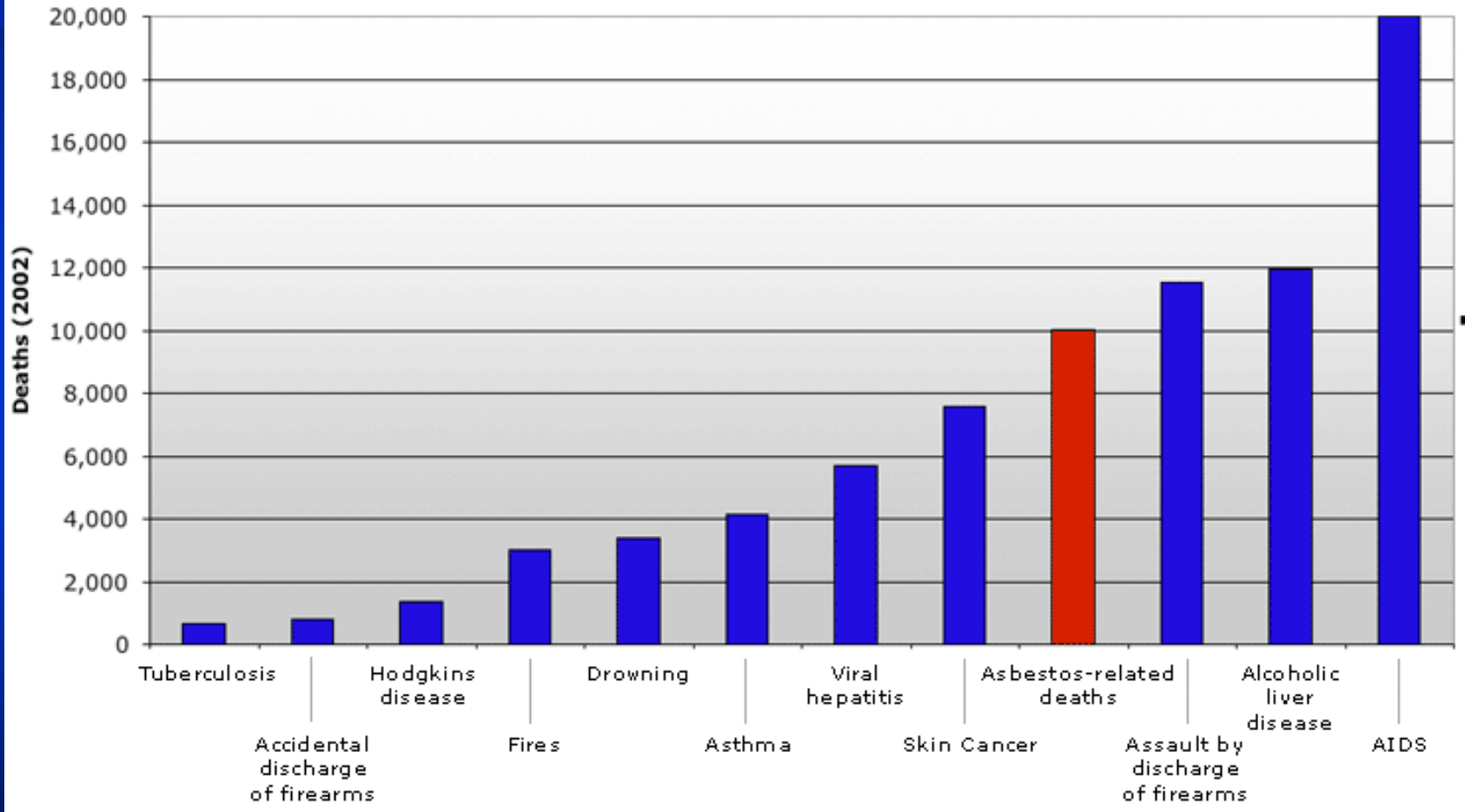


After asbestos are inhaled, they can remain and accumulate in the lungs. Asbestos can cause lung cancer, mesothelioma (a cancer of the chest and abdominal linings), and asbestosis (irreversible lung scarring that can be fatal). Symptoms of these diseases do not show up until many years after exposure began.



http://www.ohiotoxicmold.com/images/IAQ%20Images/exposure.gif

Asbestos-related deaths are at an epidemic scale in the United States



Source: EWG Action Fund estimate for asbestos deaths (2002). Center for Disease Control and Prevention, NCHS, National Vital Statistics Reports, Deaths: Preliminary Data for 2002, Volume 52, Number 13, February 2004.

CURRENT ASBESTOS BANS AND RESTRICTIONS

(Revised January 4, 2005)

National Asbestos Bans:

Argentina
Australia
Austria
Belgium
Chile
Cyprus*
Czech Republic*
Denmark
Estonia*
Finland
France
Gabon
Germany
Greece*
Honduras
Hungary*
Iceland
Ireland
Italy
Japan
[Major restrictions on asbestos use were introduced in October, 2004;
Japanese asbestos consumption has fallen by more than 90%]

Kuwait
Latvia
Lithuania*
Luxembourg
Malta*
Netherlands
Norway
Poland
Portugal*
Saudi Arabia
Seychelles
Slovakia*
Slovenia
Spain
Sweden
Switzerland
United Kingdom (including England, Scotland, Wales and Northern Ireland)
Uruguay
South Africa (Planning Major Restrictions on Chrysotile Use)

(Source: compiled by Laurie Kazan-Allen)

The USA, Canada and Russia are 3 major developed countries that have not banned Asbestos

Asbestos with its known toxicity has killed millions people over the past 100 years.

Yet, asbestos is still not banned in the USA.

What about any new toxic nanoparticles?

Failed effort to ban asbestos in the USA

- In 1979 EPA issued a notice of its intent to regulate asbestos under the authority of Section 6 of the Toxic Substances Control Act (TSCA).

- Asbestos producers and the Canadian government began to pressure the Reagan Administration to halt EPA's efforts. Canada took a particular interest in the matter because 95 percent of the 85,000 tons of asbestos used in the US came from Canada, primarily Quebec.

- In 1989, after conducting a ten year study, EPA announced that it would phase out and ban virtually all products containing asbestos.

- EPA's stated rationale for the ban was simple: "*asbestos is a human carcinogen and is one of the most hazardous substances to which humans are exposed in both occupational and non-occupational settings*."

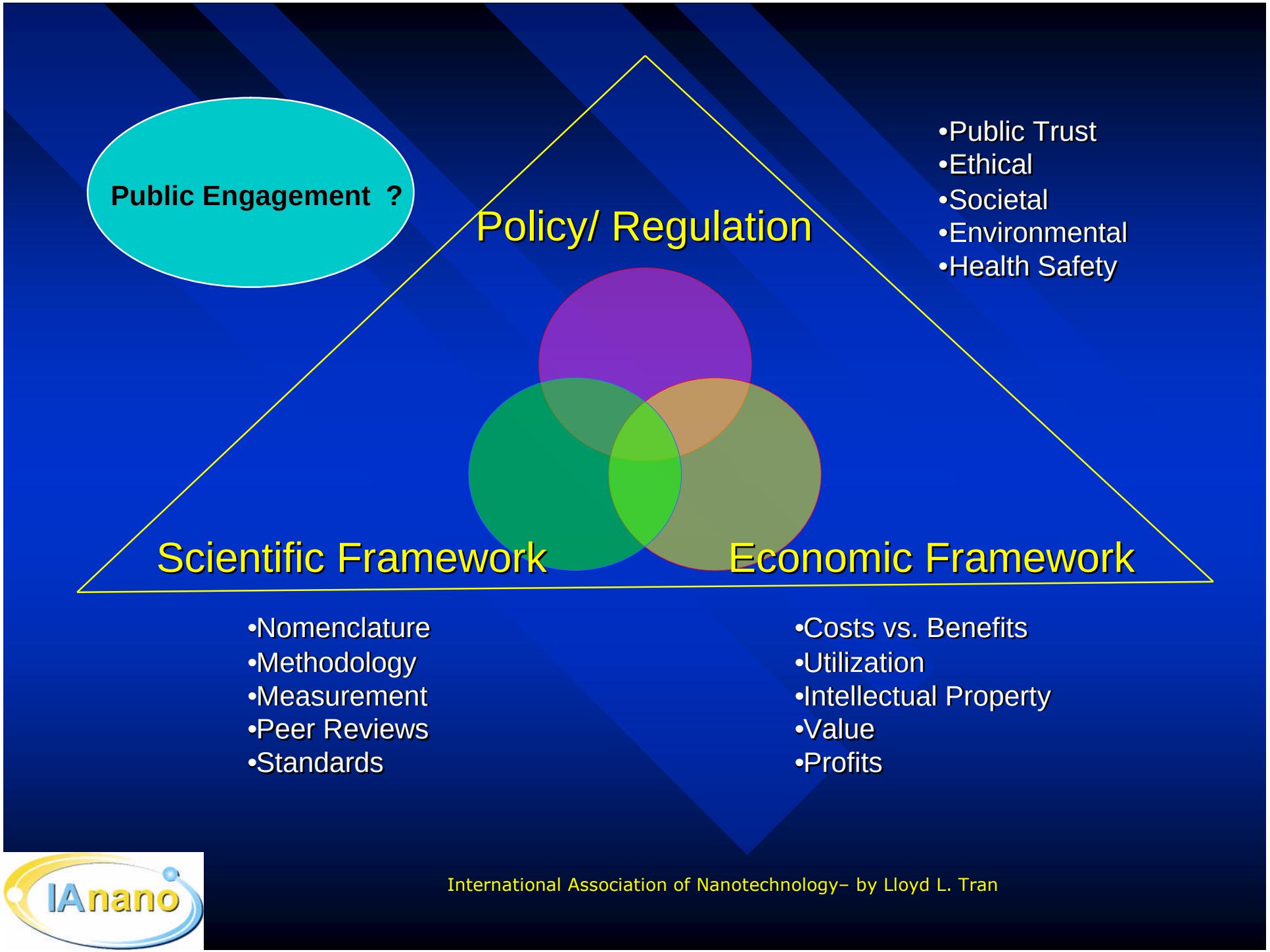
- Proposals to ban asbestos in the United States were announced on June 18, 2002 by Senator Patty Murray

- Asbestos product manufacturers and industry organizations swiftly filed a lawsuit challenging the ban's validity under TSCA in Corrosion Proof Fittings v. EPA.

- The Fifth Circuit vacated the ban, finding that EPA failed to present "substantial evidence" to justify the ban under TSCA.

- The administration of George Bush chose not to appeal the decision to the Supreme Court.

- Many Americans are unaware that the use of asbestos is still permitted in the USA.


Public Engagement ?
Policy/ Regulation
•Public Trust
•Ethical
•Societal
•Environmental
•Health Safety
Scientific Framework
Economic Framework
•Nomenclature
•Methodology
•Measurement
•Peer Reviews
•Standards
•Costs vs. Benefits
•Utilization
•Intellectual Property
•Value
•Profits

It is difficult to assess the risk factors of nanomaterials without internationally adopted standards

Challenges in developing international nomenclature/ standards:

- Communication across multi-disciplines
- National and international geo-political differences
- Intellectual Property protection
- Confidential business information
- Lack of funding for this long term endeavor
- Concern about speeding up government regulation and public policy

Conclusion

- Recognize the known-unknown and unknown-unknown
- International nomenclature and standards are urgently needed
- Societal, environmental and safety are to be part of the priority & criteria
- Pro-active risk management to prevent abuse and unintended misuse
- Public engagement should be part of the decision making process

THANK YOU !

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