Nanotechnology - the Next Asbestos?

~~~

Strategies for Surviving an Emerging Regulatory Environment

Legal Publishing Group
of Strafford Publications

Thomas Myers, Esq.
Counsel
Environment, Technology & Regulatory Affairs
U.S. Chamber of Commerce
~~~

What Is Nanotechnology?

- Definition: "It is the manipulation of matter at the molecular level, where unique phenomena enable novel applications." (NNI)
- Nanotechnology is a term used to define the application of materials whose size is measured in billionths of a meter (e.g., a human hair is 80,000 nanometers in diameter)
- At the nanoscale, materials exhibit unique properties, allowing for new manufacturing possibilities in numerous fields such as medicine, textiles, energy, electronics, etc.

WhY is it important?

- Nanotechnology will have an enormous impact on the economy
  - $2.6 Trillion by 2014
  - 20% of all global manufacturing
- Applications in every vital area of the economy
- By the end of the decade, almost every Fortune 500 company will make, buy, or have investments and/or partnerships in nanotechnology

Why Is It Important?

Advent of new technologies always brings with it new legal and regulatory challenges

EHS Benefits-Concerns

- Human health
  - Critics cite both environmental concerns and health problems, such as studies linking nanoscale materials to pulmonary problems and brain damage
- Environment
  - How will nanomaterials impact the water, air, soil?
- Workplace Safety
  - Respiratory safety, hazard communication (MSDS), “general duty clause,” safe handling concerns

Similar to Asbestos?

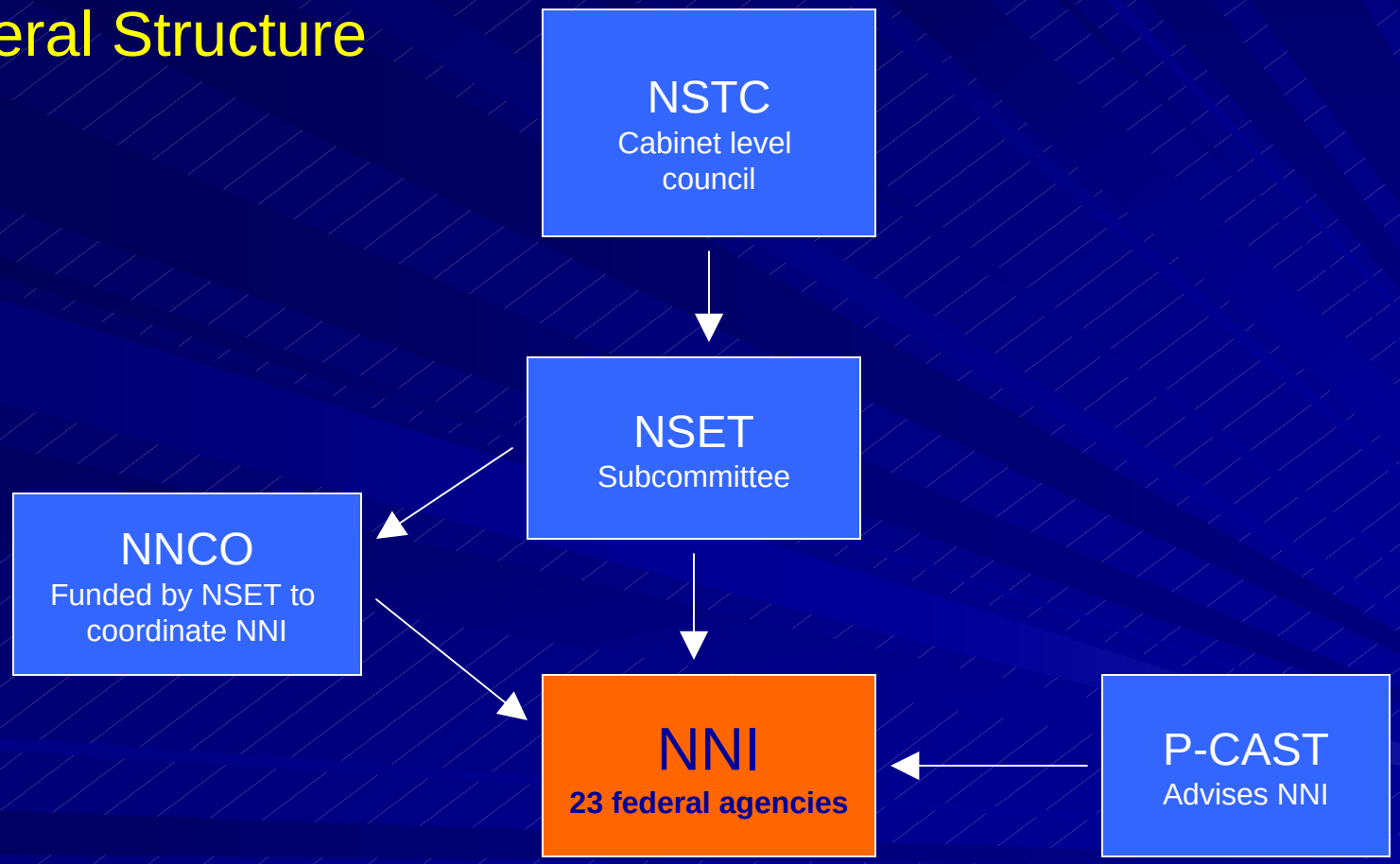
Hazards:

- Asbestos
- PCBs
- DDT
- Peanuts

Trial attorneys **will** make nanotech the next big tobacco (or DDT, or asbestos, or silicone breast implants, etc.)

Government Effort

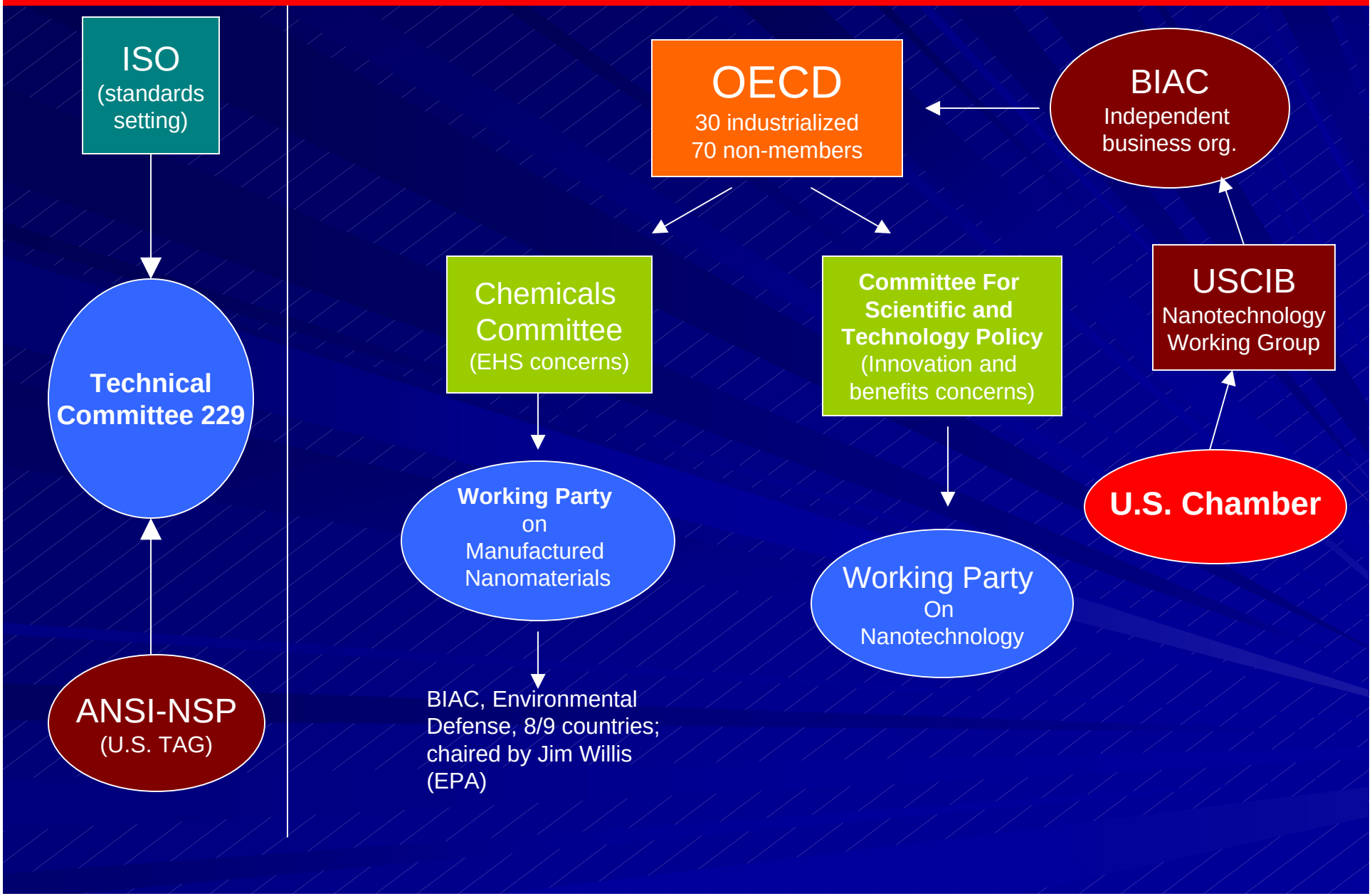
Federal Structure



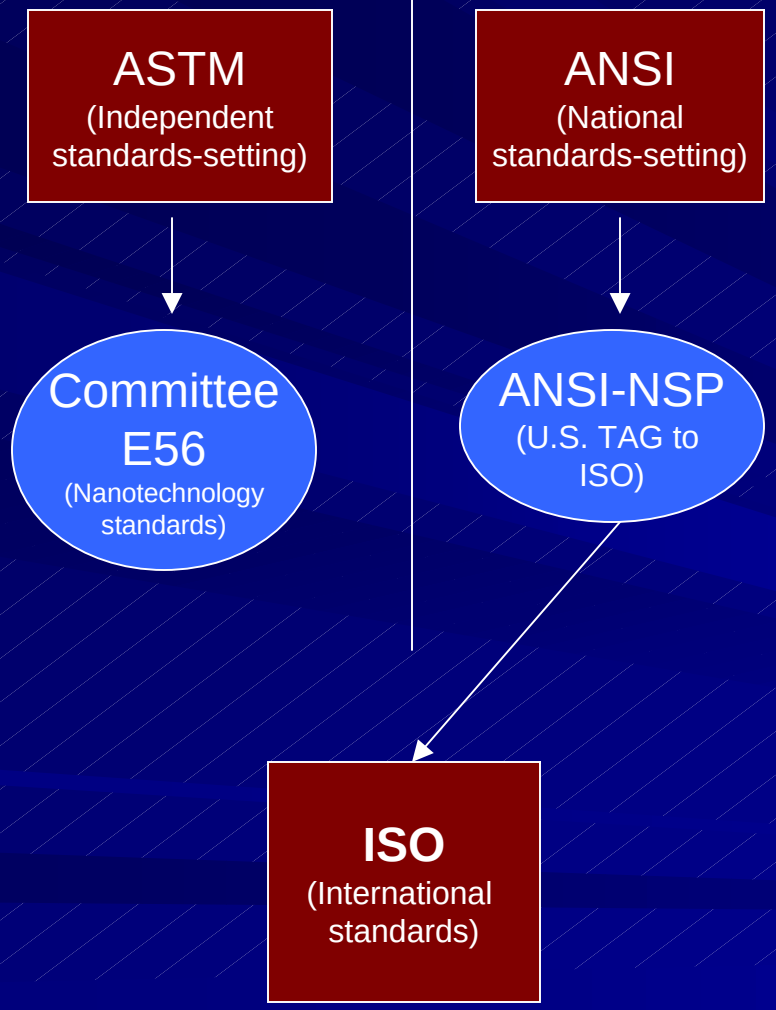
NNI Participants

USDA
NSF
NASA
INTELLIGENCE COMMUNITY
FDA
NATIONAL INSTITUTES OF HEALTH
NIST
NIOSH
EPA

International effort



Standard Setting Domestic Structure



Companies

- R&D
- Applications to market

Academia

- Research (environmental, health and safety concerns, technological developments, etc.)

Venture Capitalists

- Funding, investment

Glossary

- **ANSI** American National Standards Institute
- **ANSI-NSP** ANSI-Nanotechnology Standards Panel (U.S. TAG to ISO)
- **ASTM** (Formerly) American Society for Testing and Materials
- **BIAC** Business and Industry Advisory Committee
- **CSTP** Committee for Science and Technology Policy
- **EHS** Environmental, Health & Safety
- **ISO** International Standards Organization
- **NNCO** National Nanotechnology Coordination Office
- **NNI** National Nanotechnology Initiative
- **NSET** Nanoscale Science Engineering and Technology subcommittee
- **NSTC** National Science and Technology Council
- **OECD** Organization for Co-Operation and Development
- **PCAST** President's Council of Advisors on Science and Technology
- **TAG** Technical Advisory Group
- **USCIB** U.S. Council for International Business

Regulatory Framework

- Currently governed by existing laws
  - ABA imprimatur
  - EPA lead
- Critics are calling for a new law
  - Andrew Maynard, Woodrow Wilson Center

Practitioner Advice

- Frame the debate and you likely win the argument
- By working with agencies before the technology is put into end products, industry can be assured of a balanced approach to regulation while continuing to encourage expansion of the technology
- Industry needs to help government create the initial regulatory regimes—one's with the flexibility to adapt to rapidly advancing technologies—or it will be stuck with whatever regulatory regime results
- If industry can get agencies to agree on appropriate testing protocols, it could significantly reduce costs of compliance and the ultimate scope of the regulations
- Without this, government will regulate in a vacuum—or worse, act upon inflammatory and unsound allegations of nanotech opponents

Regulations Driven By Risk

- Regulations must be based on peer-reviewed science and cost-benefit analysis
  - *The questions is not whether there is any risk, but rather do risks significantly outweigh the net benefits?*
- Fear is not a risk!
  - Must understand real risks are not perceived risks!