

A close-up photograph of a microscope, showing the objective lenses and the eyepiece. The image is in blue and white tones, with a soft focus on the background.

STEPTOE & JOHNSON ^{LLP}

EuroNanoForum 2011

Bilateral EU – US Cooperation

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NANO: OPPORTUNITIES

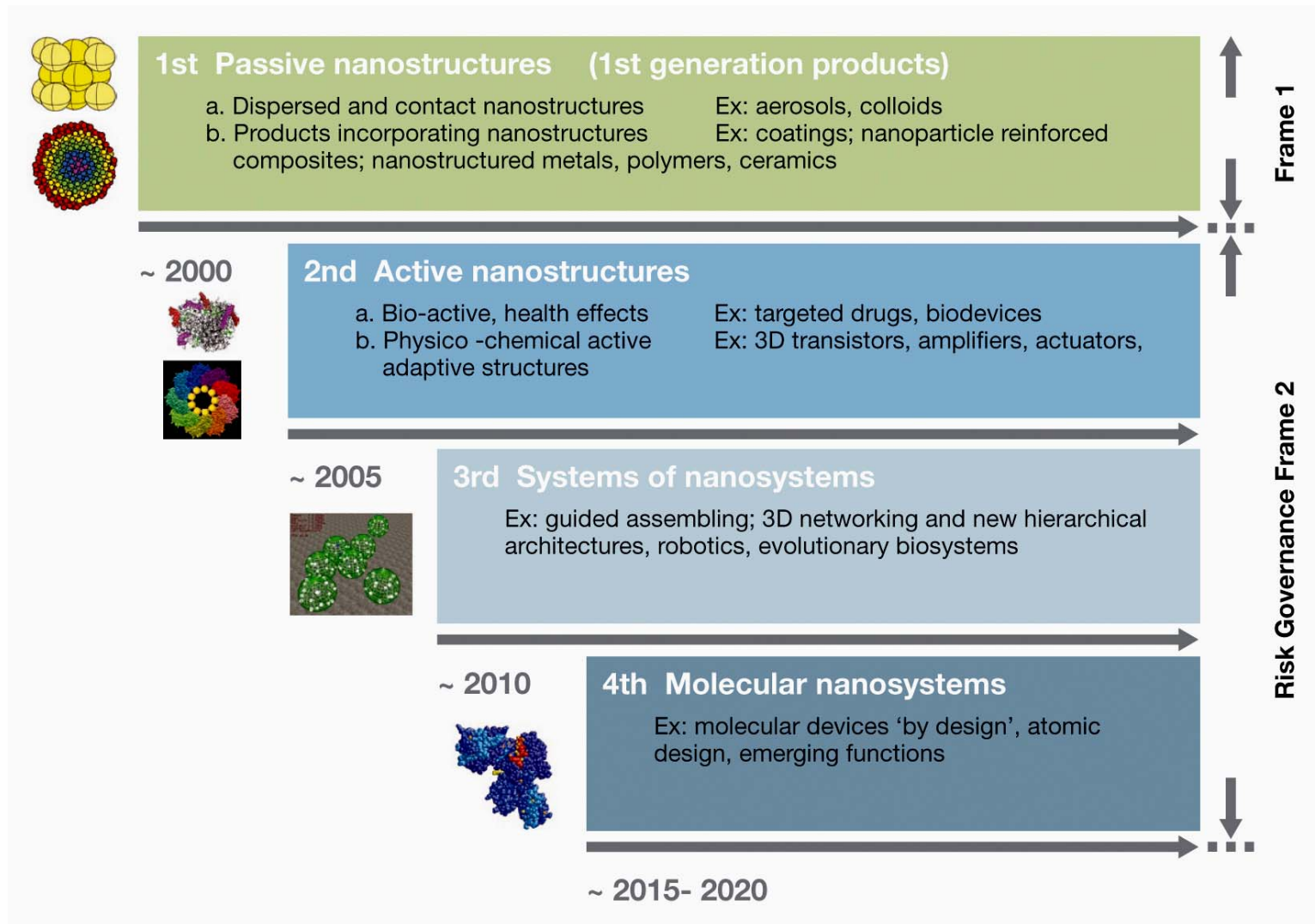
- Promise of advanced new materials and new applications in key areas such as electronics, pharmaceuticals, chemicals, engineering, aerospace, defence
- Promise of improved human health, extended lifespan, enhanced physical capabilities
- Promise of sustainability by cleaner energy, environmental remediation, water purification, improved food production
- Promise of economic growth and job creation
- ▶ **Global opportunities require coordinated approach**

NANO: CHALLENGES

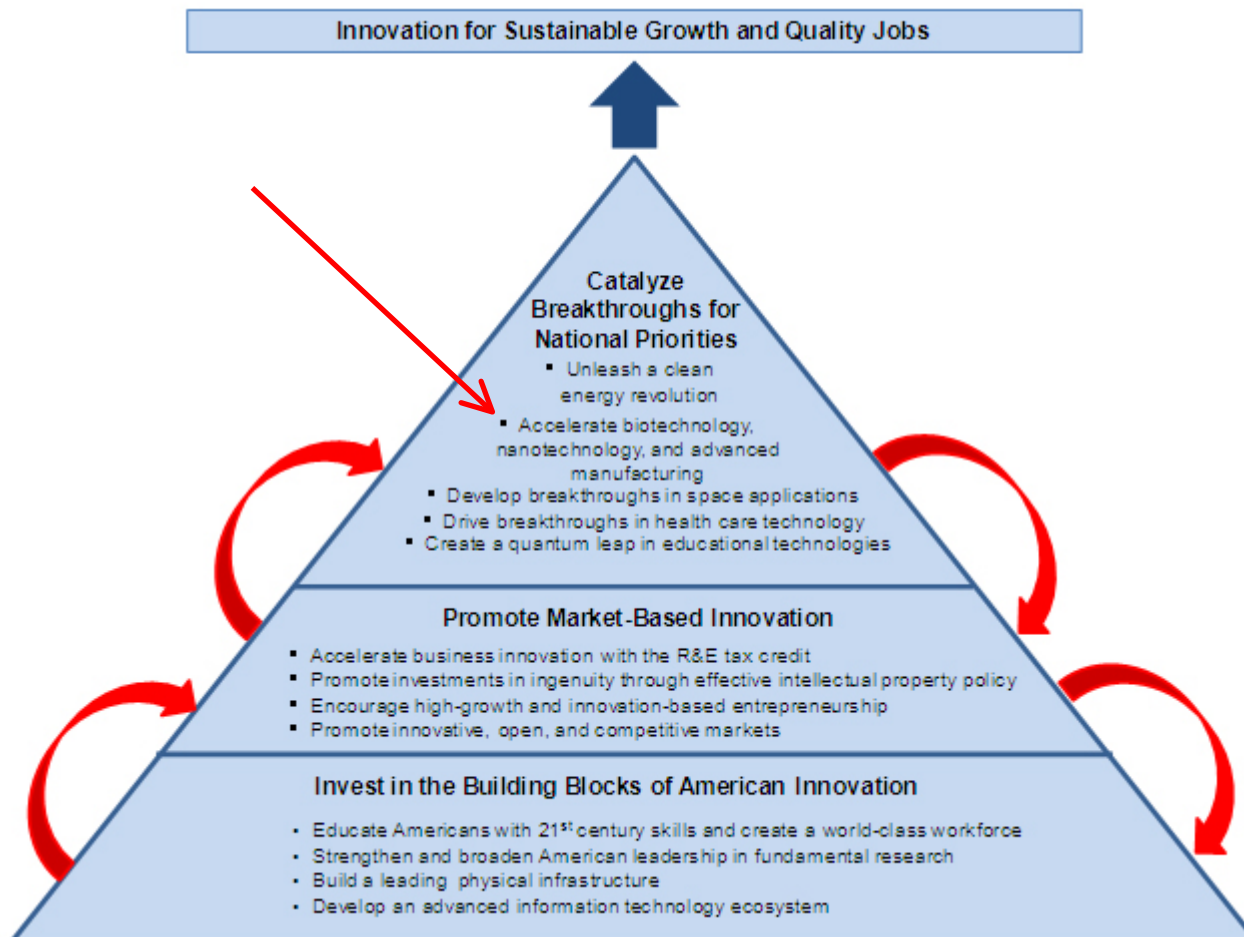
- Human health (workers' and consumers' safety)
- Environment (potential immediate and long term effects)
- Disruptive nature of the technology (potential new industries; new economical powers; changes in labour markets)
- Responsibilities and Liabilities (regulatory oversight; accountability)
- Civil Liberties (privacy issues; right for individual choice)
- ▶ **Challenges also need to be addressed globally**

FOUR GENERATIONS OF NANOTECHNOLOGY

(Courtesy: International Risk Governance Council, 2009)



STRATEGY FOR AMERICAN INNOVATION (PRESIDENT OBAMA, FEBRUARY 2011)



“The President is committed to investments in innovation that promise to drive better health, future economic growth, and quality jobs in America... the FY 2012 Budget is making substantial investments to accelerate breakthroughs in advanced manufacturing technologies that can provide foundations for private sector investment and growth.”

EU INNOVATION UNION

- Europe 2020 Flagship Initiative: Innovation Union (Communication from the Commission October 2010)
- EU 2020 Strategy on Sustainable Consumption and Production with sustainable resource efficiency and management of materials

STRUCTURE OF US FEDERAL OVERSIGHT

- Overlying structure: National Nanotechnology Initiative (NNI)
 - ✓ Managed through National Science and Technology Council (Executive Office of President, Office of Science and Technology Policy)
 - ✓ Launched in 2000 by President Clinton; composed currently of 25 Agencies
 - ✓ NNI “megabudget” composed of the 15 Agencies with individual nano R&D budgets
 - 2012 NNI budget: ~\$2.1 billion (requested)
 - ✓ Strategic plan released in 2011

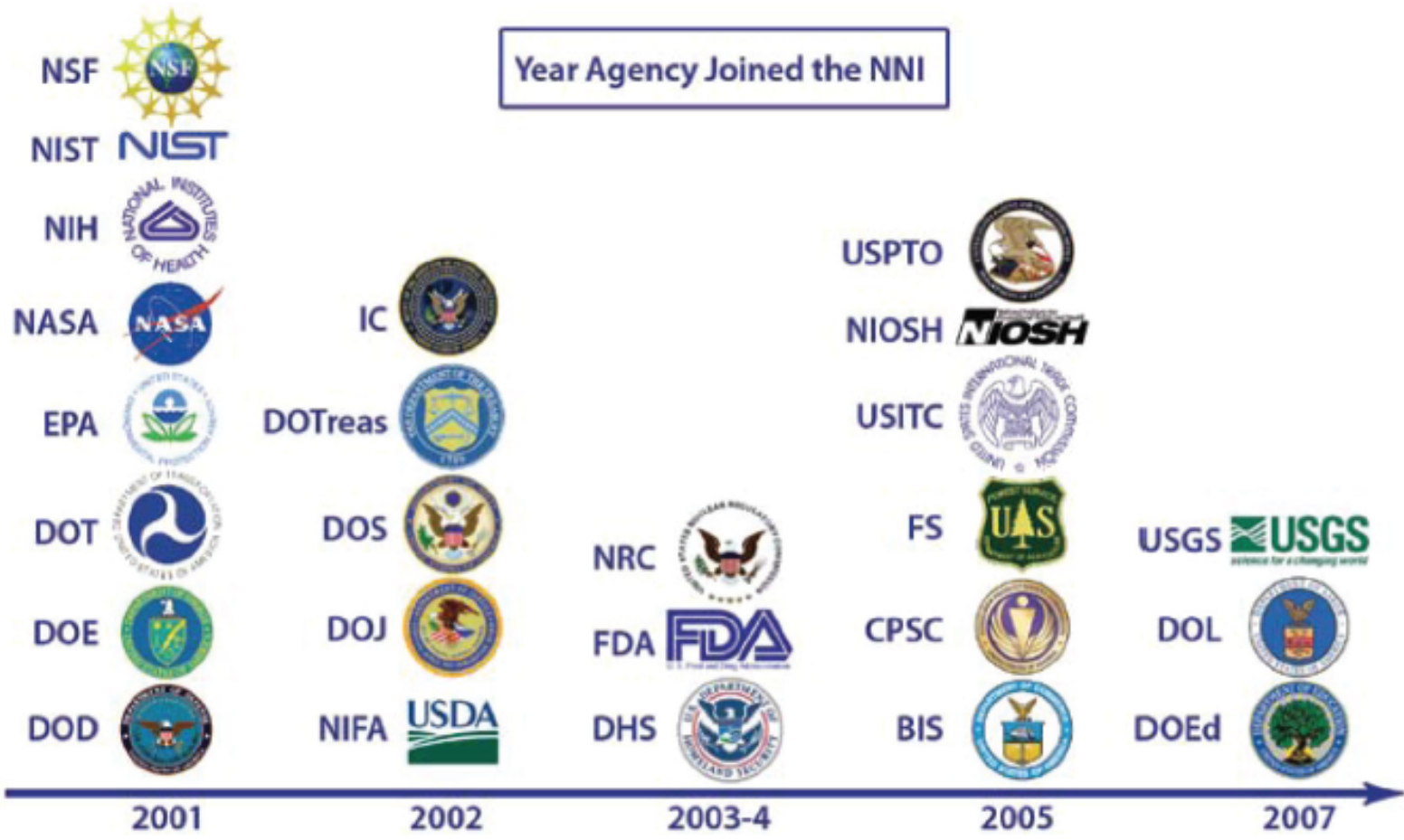


Figure 1. NNI Participating Agencies by Year Joined

Taken from the 2011 NNI Strategic Plan

NNI OBJECTIVES

- *“NNI expedites the discovery, development and deployment of nanoscale science and technology to serve the public good”*
- Oversees work of member agencies to accomplish four primary goals:
 - ✓ To advance world-class nanotechnology research and development;
 - ✓ To foster the transfer of new technologies into products for commercial and public benefit;
 - ✓ To develop and sustain educational resources, a skilled workforce and the supporting infrastructure and tools to advance nanotechnology;
 - ✓ To support the responsible development of nanotechnology.



EU REGULATORY STRUCTURE

➤ **European Commission:**

Horizontal Legislation: (applicable, but pre-nano)

General Product Safety and Product Liability Legislation
Chemicals Legislation (REACH and CLP)

Vertical Legislation: (application and nano-specific)

Food / Novel Food / Food-contact / Cosmetics / Biocides/
RoHS/ Medical Devices etc.

➤ **European Parliament:** Resolution of 24 April 2009 requesting the Commission to review all relevant legislation within two years to ensure safety

➤ **Member States:** National initiatives either on voluntary (Germany, UK) or mandatory (France) basis

INTERNATIONAL HARMONIZATION ISSUES

- Regulatory definition
- Global definition of pre-competitive material
- Harmonized Test Guidelines
- Standard reference materials
- Trade barriers due to lack of regulatory harmony

SAME GOALS - DIFFERENT APPROACHES?



US – EU

Bridging nano - EHS Research Efforts

10-11 March 2011, Washington DC

**Joint Workshop on Research for
Regulatory Decision Making**

Purpose of the Workshop

- **Create a more informal, multidisciplinary, multi-stakeholder research-based process to understanding US-EU programs and perspectives on nanoEHS and regulatory data needs.**
 - Stakeholders such as material scientists, measurement scientists, physicists, biologists, those with regulatory and policy responsibilities and ethicists, social scientists, and representatives from NGOs, industry, and the general public
- **Grapple with recurring scientific issues for the field and pose bilateral solutions.**
 - Issues such as dose metrics, the role of surface modifications and chemical transformation on toxicity, and critical parameters for understanding the behavior of nanomaterials in environmental media, consumer goods, and general population.
- **Identify barriers to dialogue and collaboration and mechanisms to overcome them.**

Goals of the Workshop

- Develop a new common understandings of the breadth of EHS research that is currently underway in the US and EU, and fundamental research needs on which we can collaborate and leverage investment.
- Advance the dialogue on critical scientific issues that will benefit from consensus among our scientific communities.
- Establish mechanisms for ongoing scientific exchange.

Agenda

- PART 1: Understanding Perspectives and Programs
 - US and EU speakers on their respective nano EHS research programs
- PART 2: Data needs for regulatory decision making
 - Subject matter experts
- PART 3: Tackling the Challenges of Producing Reliable and Reproducible Data for Nanomaterials Assessment and Risk Management
 - Breakout Sessions
- PART 4: Getting It Done Together
 - EC, NNI, AAAS

Breakout Session One: Human and Environmental Data Needs

Questions

- What are the research data needs to address regulatory challenges?
- What do these data needs imply for networking and data management?
- What are the barriers to producing the data in support of regulation?
- How can we integrate US-EU research to maximize research time and efficiency?
- What are potential areas for US-EU collaboration?

PART 4: Getting It Done Together

- **Enhancing Cooperation between EU and U.S. Scientists through the BILAT-USA and Link2US Projects**

(These programs are helpful to structure and support the US-EU research efforts.)

- **Developing Communities of Research (Practice)**

(Communities of practice are groups of people who **share a concern or a passion** for something, do **not** necessarily work together on a **daily** basis, and who develop a shared repertoire of resources: experiences, stories, tools, ways of addressing recurring problems)

- **Identifying Technical Platforms for Collaboration**

(Joint Calls for Research, funding common projects, developing shared public-private partnerships)

Path Forward

- Workshop Report
 - ✓ All breakout session summaries collected
- Website up soon
 - ✓ Agenda, participant list, slide presentations
- Several Communities of Research in planning stage

Nanofutures



- “Nano-Hub”: Industry-driven initiative for the sustainable development of nanotechnologies via cooperation for addressing horizontal issues (safety, regulation communication, etc.)
- Multi-sectoral, cross-ETP integrating platform
- Objective: Co-ordinate research efforts, address all horizontal issues, ensure societal acceptance
- Openness: open to EU industry, SMEs, NGOs, financial institutions, research institutions, universities, civil society
- Close co-ordination with European Commission (DG Research)

Further information at <http://www.minamwebportal.eu/index.php?m1=Public-Area>



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THANK YOU

<http://www.step toe.com/nanoresourcecenter>

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