



Nanomaterials: Environmental Risks and Benefits and Emerging Consumer Products



COPPER

International Copper Association, Ltd.

ICON™ INTERNATIONAL COUNCIL
ON NANOTECHNOLOGY
A partnership for nanotechnology stewardship and sustainability



CEGEST
Centro de Estudos de Gestão

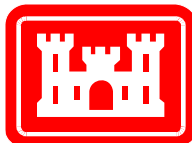


- **Co-Directors**
 - Jeff Steevens and Mahmud Haraza
- **Chair**
 - Igor Linkov
- **Organizing Committee Members**
 - Vicki Colvin, Saber Hussain, Delara Karkan, Jeff Morris, Boris Yatsalo, Abou Ramadan
- **Local Organizers**
 - Carlos Fonseca, Jose Figueira, Jose Palma Oliveira, Carlos Palmeira



ARW Goals

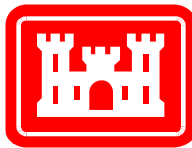
- **Summarize state-of-the-science in areas related to Nano EHS**
 - Summary presentation during the workshop
 - Summary Chapters after the workshop
 - Book based on the workshop
- **Identify problems and propose solutions/ analytical methods**
 - Focus on Consumer Products - Technology and Policy
 - Risk Assessment (ecological and human health)
 - Decision Analysis
- **Establish collaborative teams and possible projects (including NATO ARWs)**
- **Have Fun!**





Previous Meetings

- **2000 – Lisbon, Portugal**
 - Risk Assessment and Management; Application in developing countries
 - RA methods, RA tools, Environmental Management
- **2002 – Anzio (Rome), Italy**
 - Comparative risk assessment (CRA); Applying CRA to Middle Eastern environmental problems
 - CRA, CRA and Decision making
- **April, 2004 – Eilat, Israel**
 - Environmental Security and Risk Assessment, applications in Middle East
 - Environmental Security, Risk Assessment and Decision Analysis
- **June, 2004 – Palm Beach, Florida USA**
 - Decision-making for contaminated sediments
 - Comparative risk assessment; MCDA; Technology innovation
- **2005 – Thessaloniki, Greece**
 - Environmental security in coastal areas
 - Risk assessment & security; navigation/contaminated sediments; invasive species & coastal restoration
- **2006 - Venice, Italy**
 - Environmental security at ports and harbors
 - Critical Infrastructure, Decision Analysis, Environmental Security
- **2007 - Lisbon, Portugal**
 - Non-chemical Risks
 - Decision Making and Risk Assessment tools and applications to emerging threats
- **2008 – Carvoeiro, Portugal**
 - Nanotechnology EHS

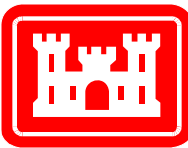




Overview

- **Why Nano?**
- **Why Environmental Health and Safety**
- **Why Risk Assessment?**
- **Why Decision Analysis?**
- **Why Us and Why Now?**

- **Agenda**





Why Nano?

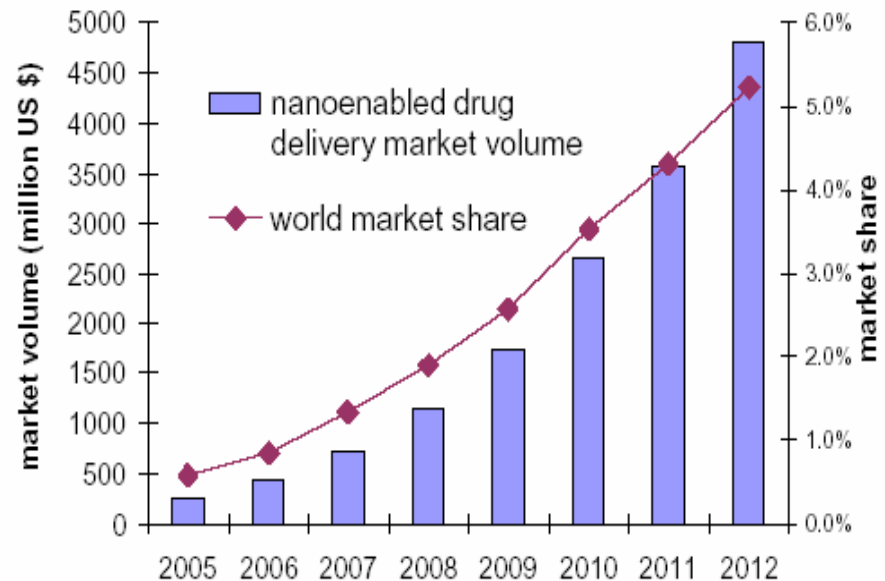
- **Current State**

- R&D Surging – Global Nano R&D \$9 billion
- Nano Patents to Date – 4,000 US Patents
- Over \$50 Billion in Nano-products Sold in 2006

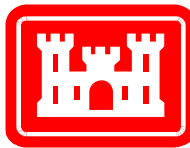
- **Near Future**

- Estimated market of \$2.6 trillion by 2014
- 2015 – 15% of Global Manufacturing will use nano

Nano-enabled drug delivery market



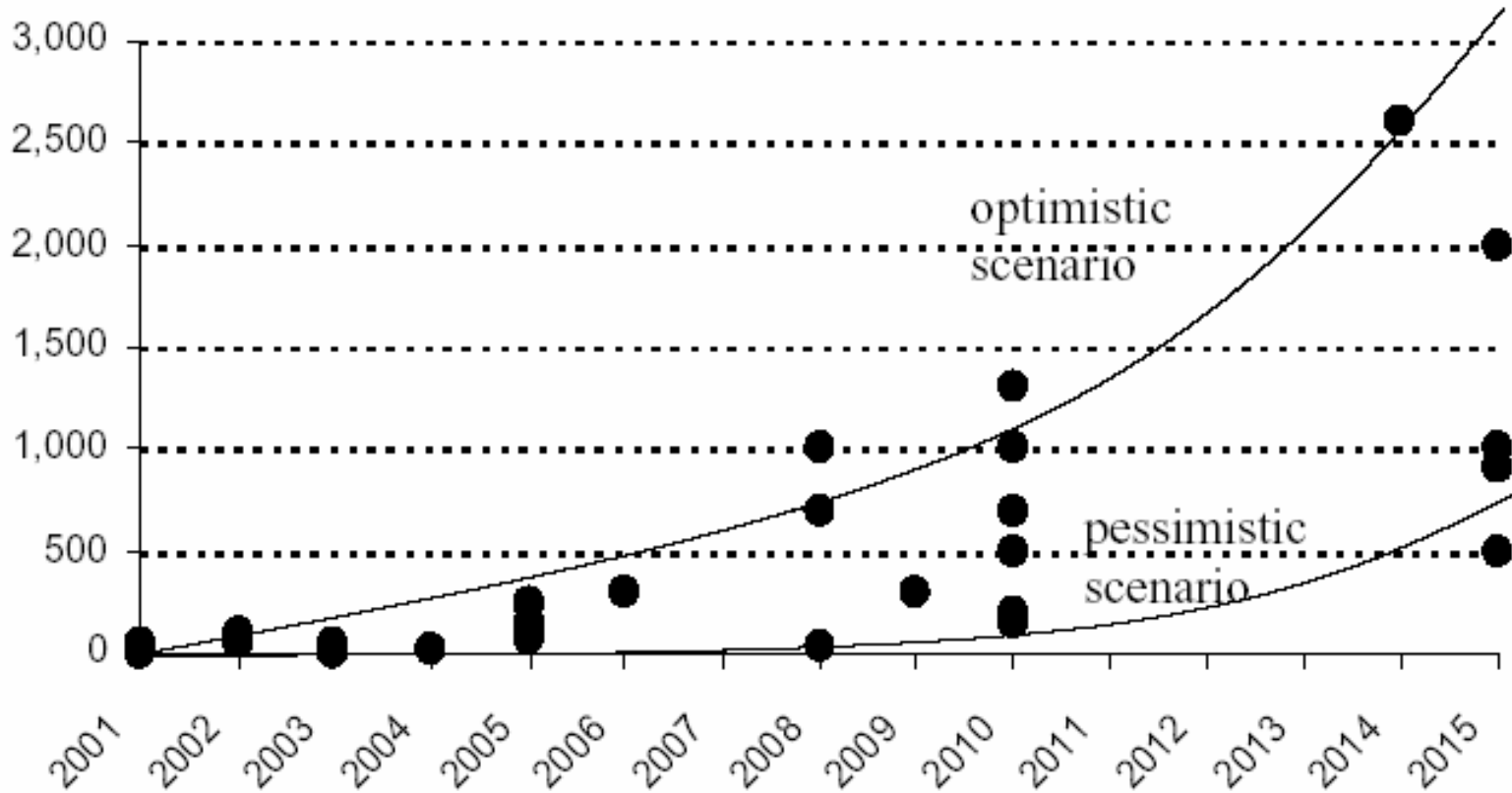
Source: Moradi, 2005



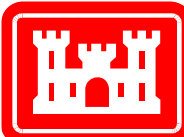


Why Nano? Significant Growth

Nanotechnology Market
(Billions US \$)

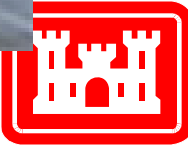


Compiled by Hullman (2006), based on data from German Government, Evolution Capital, NSF, Sal. Oppenheim, DG Bank, DTI, US Nanobusiness Alliance, Cientifica, In Realis, Mitsubishi Research Institute, Deutsche Bank, Nomura Research Institute, BCC, GEMZ corp., Helmut Kaiser Consultancy, and Lux Research





About 600 products, example: LifeStraw
Reduces bacteria by at least 6 log₁₀ (99.9999%) and
viruses by about 2.0 log₁₀ (99%)
Cost: ~\$2, Good for 1yr (700 L of water)



Why EHS?

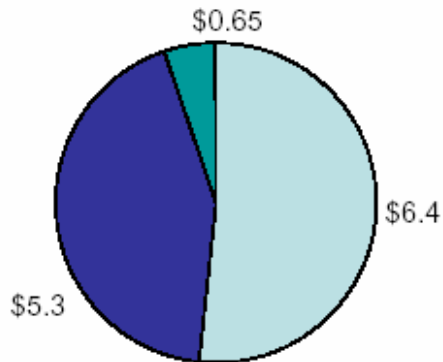
Nanotech Funding and EHS component

US Government -- \$1.3B for all Nano in FY 2007

\$44.1M (3.5%) for EHS

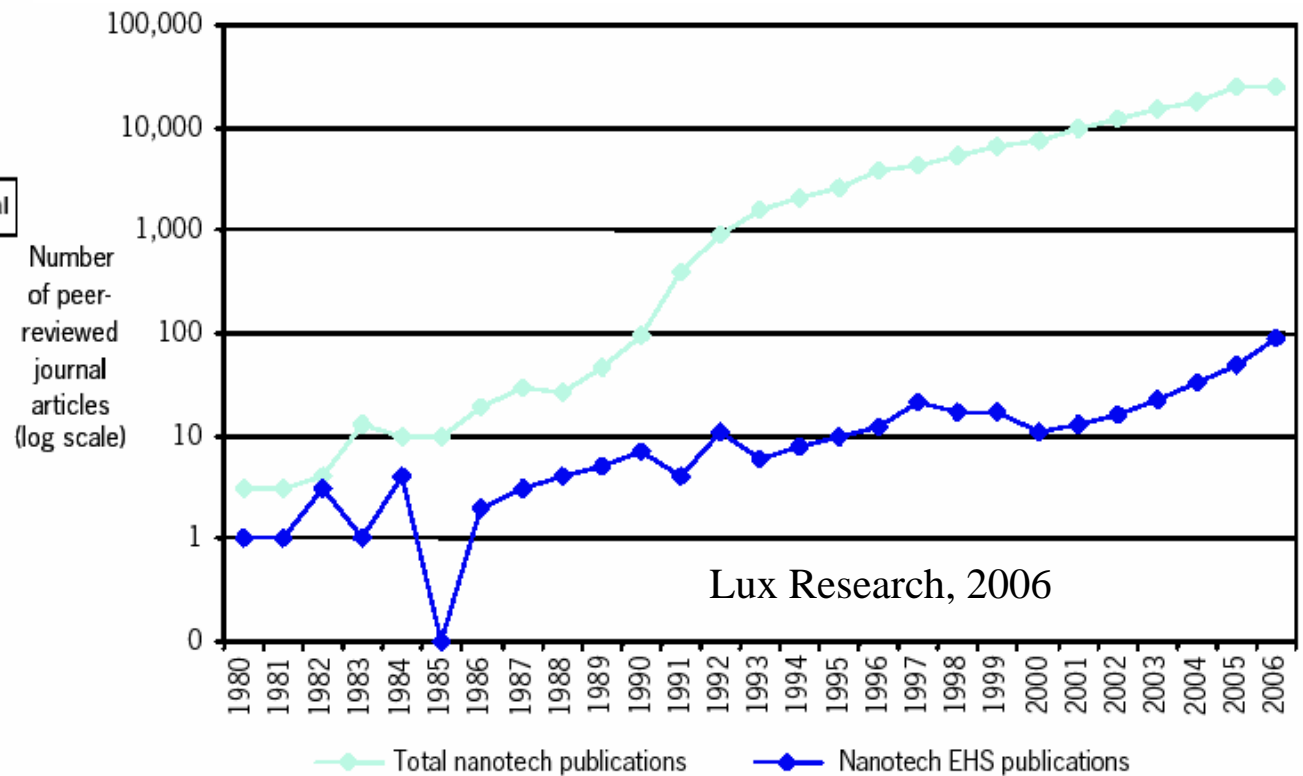
\$3.3M for Risk Management

By source



US\$ billions

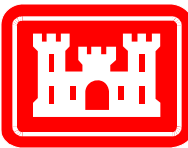
Government Corporate Venture capital





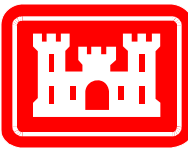
Why EHS?

- **It is important for environmental health and safety to keep up with the rapid growth of the nanotechnology industry. This will involve the integration and resolution of questions asked by toxicologists, the community, regulators, and the industry.**



Why Risk Assessment?

- **Goal: Will exposure to a contaminant cause adverse health effects?**
- **Based on data (often limited and imprecise) regarding toxic effects of materials on people and animals**
- **State-of-the-science risk assessment is not very far advanced**
 - Two general bodies of data
 - Toxicity studies in animals
 - Epidemiologic studies in humans
 - Uncertainties can be tremendously large
- **Often handled as a “bright line” approach, but typically plagued with uncertainties**





Why Risk Assessment?

Risk Assessment/Comparative RA - Planning Tool to Evaluate Environmental Problems and Choices

←

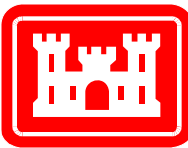
Specific Applications

- Hazard Identification
- Exposure Assessment
- Toxicity Assessment
- Risk Characterization
-
- Risk Management

→

Participatory Process to incorporate Stakeholder Views

- Priority Setting
- Incorporation of stakeholder opinions
 - Cross-industry comparisons
 - Nation-wide ranking



Why RA?

Public Concerns are Increasing

Two types of “correct” risk assessment:

Expert: Risk = Hazard · Exposure · Magnit · Probab

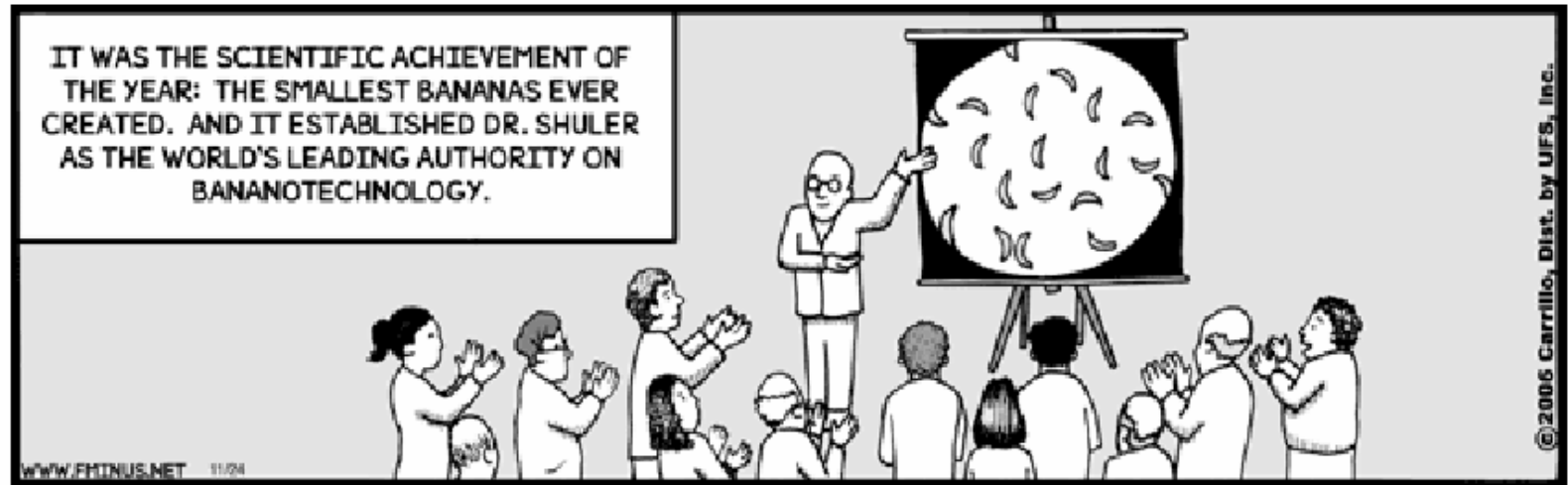
Layperson: Risk = Hazard · Perception

For stakeholders, the root issue is:

fear of becoming a victim to (uncompensated) loss

Core concerns tend to be:

trust, control, process, information and timing.



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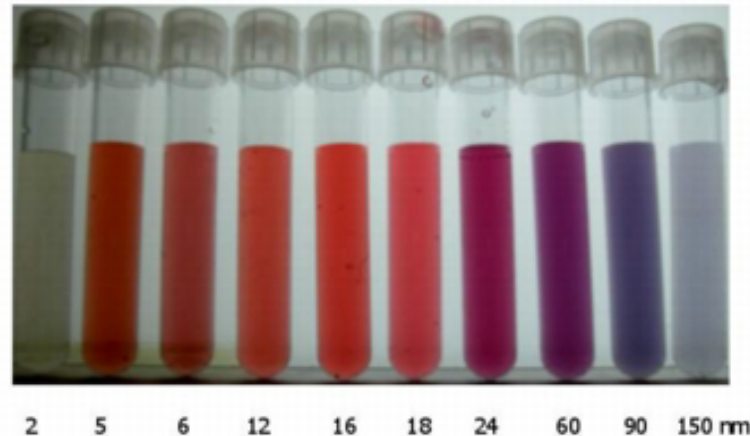
LifeStraw Risk Assessment: Silver or NanoSilver?

“Silver is present in LifeStraw-treated water at concentrations ranging from low (<25 ppm) to high (up to 200 ppm) in effluents collected over the intended lifetime of the device (700 L). The average effluent silver concentrations ... are below the WHO guideline value and the US EPA MCL of 100 ppb.”

www.lifestraw.com

Are Bulk Material Standards Appropriate for Nano?

Different sizes of colloidal gold particles



The first is a textile pre-filter. The tiny openings in the mesh of the filter measure 100 microns in diameter. A micron is a millionth of a meter, so 100 microns is a tenth of a millimeter. If you're still trying to picture the actual size, look at a strand of hair. That's about 100 microns in diameter. This filters out bigger particles, like dirt and sediment.

Next, the water passes through a polyester filter. The holes in the mesh of this filter are much smaller — only 15 microns. Reportedly, this filters out clusters of bacteria.

From there, the water moves through a chamber of beads that are impregnated (saturated) with iodine. The iodine kills parasites and 99.3 percent of bacteria and viruses.

And finally, the water passes through a chamber of granulated active carbon. Not only does the carbon improve the taste and smell of the water, it should also filter out any remaining parasites.

From the leader in colloidal products

MesoSilver® - True colloidal silver

Highest particle surface area for maximum effectiveness.



[Enter the website](#)

“Because of the potency of Nano-Silver, one can take less than the 350 mcg/day allowed by EPA as a maximum daily reference dose and **still maintain a robust component of bio-available silver in the bloodstream.** We have experienced very effective prophylactic benefit from 1-2 teaspoons/day of Nano-Silver over several years of usage by **10's of thousands of customers.** That equates to 100-200 mcg/day, well **under the amount referenced by EPA** for public water supplies in the US. That enables users to be as secure with daily use of Nano-Silver as a dietary supplement as one can be with EPA approved drinking water. **The properties of Nano-Silver, then, completely put to rest any concern with Argyria** or other perceived toxicity concerns.”

www.nano-silver.com

NanoSilver – Risk or Benefit?

Product Name Click on product name for complete lab analysis report	Particle Surface Area cm ² /mL	Efficiency Index	Price Cents/mL	Price Cents/cm ²	Normalized mL	cm ² /\$
Health & Herbs Col. Silver 10	0.001	5.9	4.22	4216	104,700	0.024
Trace Minerals Col. Silver 30	0.022	0.7	7.08	321.7	4,759	0.31
home brewed w/ SG-7	0.024	1.64	na	na	4,362	na
Silver Shield Col. Silver	0.027	0.19	6.34	234.8	3,878	0.43
Silver Biotics 10	0.035	3.2	11.39	325.4	2,991	0.31
Tri Silver Colloidal Silver 10	0.052	5.5	5.49	105.6	2,013	0.95
Silver Lightning 5	0.078	17	1.05	13.44	1,342	7.44
Daily Mfg. Col. Silver 20 ppm	0.080	3.8	10.10	126.3	1,309	0.79
Silver Wain Water 3	0.083	34.2	2.64	31.8	1,261	3.14
Wonder Water 10	0.096	9.6	4.67	48.60	1,090	2.06
ASAP 10	0.112	10.2	10.99	98.11	935	1.02
Sovereign Silver 10	0.217	22.3	25.36	116.9	482.5	0.86
Ultra Pure Colloidal Silver 35	0.225	13.6	7.80	34.68	465.3	2.88
Vitol Super Col. Silver 5 ppm	0.286	54.6	13.39	46.82	366	2.14
High Energy Lab Col. Sil. 15 ppm	0.319	15.1	4.22	13.22	328	7.56
Argentyn 23 ppm	0.355	22.6	20.12	56.67	294.9	1.76
ASAP 22	0.587	26.3	15.22	25.92	178.4	3.85
Futurebiotics Adv. Col. Silver	0.591	61.6	28.65	48.48	177.2	2.06
Int. Pharm. Invive 50 ppm	0.621	4.4	7.61	12.25	168.6	8.16
Electra Clear Col. Sil. 10 ppm	0.662	25.1	3.16	4.77	158.2	20.9
Source Naturals Col. Silver 30	0.881	24.3	13.94	15.83	118.8	6.32
Kelly Colloidal Silver 20	1.420	122	6.34	4.46	73.7	22.4
Herbal Healer Col. Sil. 500 ppm	2.513	3.80	30.43	12.11	41.66	8.25
Utopia Advanced Col. Sil. 20	12.20	924	12.24	1.003	8.58	99.7
Innovative Natural Prod. 500	12.39	20.5	33.77	2.725	8.45	36.7
Mesosilver 20	104.7	5235	11.97	0.1143	1.0	874.7

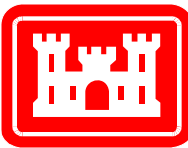
Higher values are better.

Lower values are better.

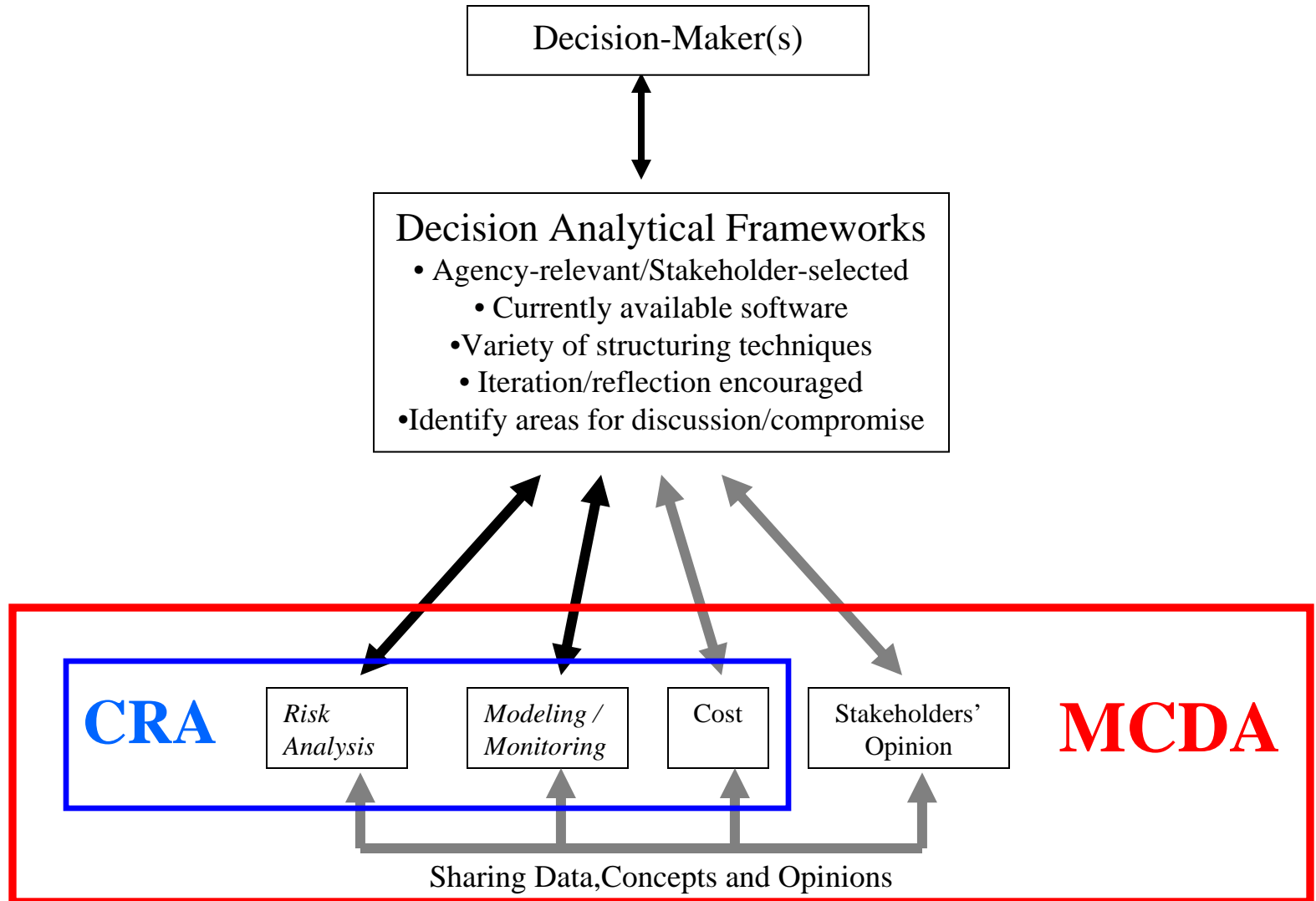


Why Decision Analysis?

- Environmental evaluations and decisions for nano are complex and information is very uncertain, traditional risk assessment may not be sufficient
- Provide a means of integrating various **inputs** with stakeholder **values**
- Provide a means of communicating model/monitoring **outputs** for scenario planning and stakeholder understanding

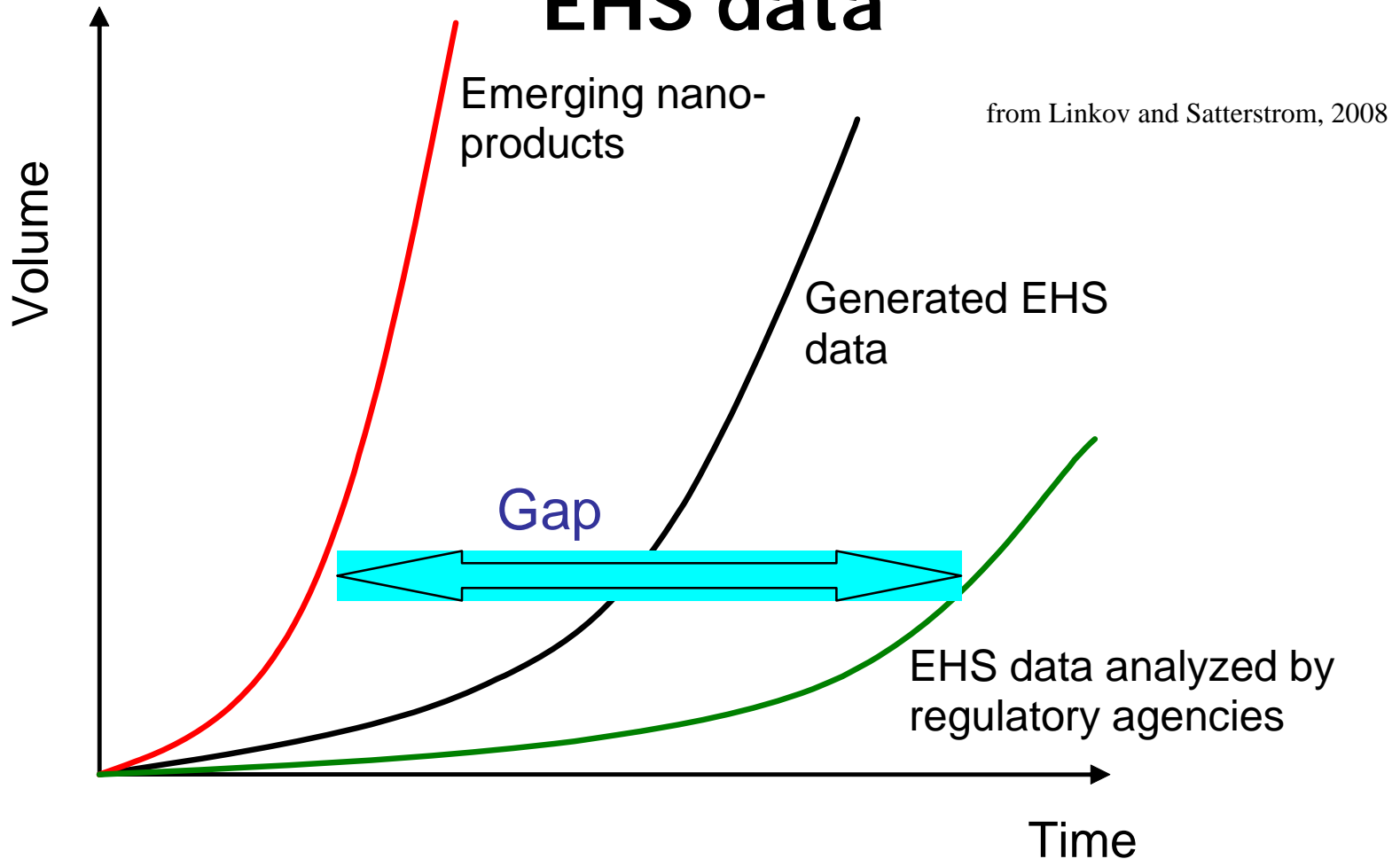


Evolving Decision-Making Processes



Emergence of Nanotechnology Products in Comparison to Generated

EHS data

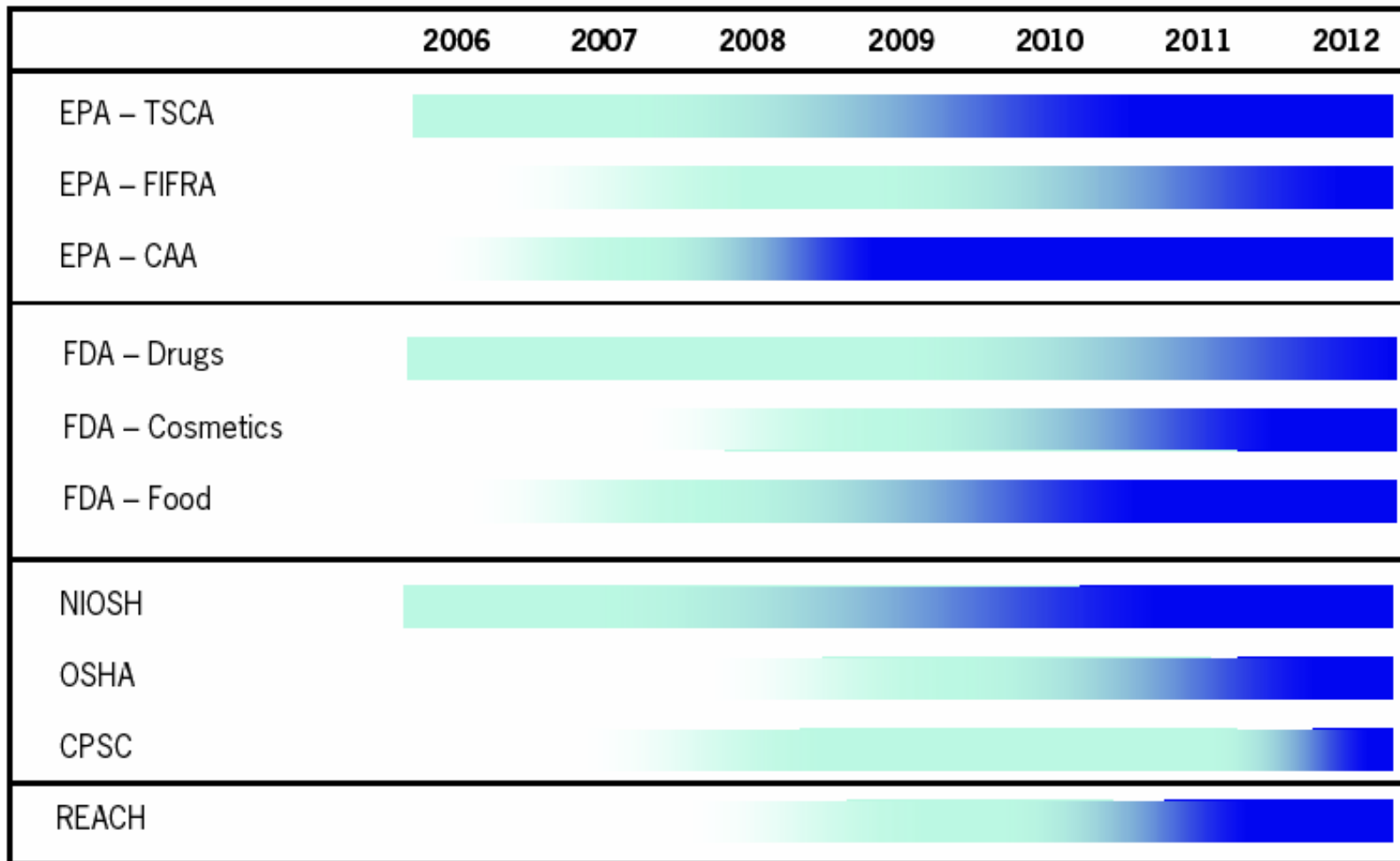


Increasing gap requires innovative risk management



Why Now?

Regulatory Developments



Nanotech-specific regulations begin to appear

Nanotech-specific regulations are well established



Comparison of Framework Documents

	Science and Research Aspects				Legal and Regulatory Aspects				Social Engagement and Partnerships				Leadership and Governance			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
EPA White Paper	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
FDA	■		■			■	■		■	■	■		■			
Woodrow Wilson Center	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■
ED-DuPont	■	■	■	■	■	■			■	■			■	■	■	■
Québec Commission	■	■	■	■	■	■			■	■	■	■	■	■	■	■
Royal Society	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
DEFRA	■	■	■	■	■				■	■	■					
Responsible NanoCode			■		■				■	■	■					
EC SCENIHR	■	■	■	■												
EC Action Plan	■	■	■	■		■			■	■	■	■		■	■	
IRGC Policy Brief	■	■	■	■	■	■			■	■	■	■	■	■	■	■
IRGC White Paper 1	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
IRGC White Paper 2	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■

Sub-criteria for the table are as follows:

- **Science and Research Aspects**
 1. Development of methods for detection / characterization / data collection
 2. Assessment of environmental fate & transport / impacts
 3. Assessment of toxicology / human health impacts
 4. Assessment of health and environmental exposure
- **Legal and Regulatory Aspects**
 1. Voluntary regulatory and best-practices measures
 2. Information-based regulatory tools (*e.g.*, labeling)
 3. Economic-based regulatory tools (*e.g.*, tax or fee for safety testing)
 4. Liability-based regulatory tools (*e.g.*, penalty for pollution)
- **Category 3: Social Engagement and Partnerships**
 1. Promotion of education and distribution of information / use of risk communication tools
 2. Use of stakeholder engagement tools
 3. Development of partnerships with academia, industry, public organizations, provinces, and international regulators
 4. Emphasis of ethical conduct
- **Category 4: Leadership and Governance**
 1. Transparency in nanotechnology-related decisions
 2. Consideration of benefits of nanotechnology
 3. Adaptive modification of existing or development of new legislation
 4. Consideration of precautionary principle

from Linkov and Satterstrom, 2008



Agenda - Monday

1. Workshop Introduction and Goals

8.00 **Linkov, Haraza & Fonseca: Introduction**

8.30 **Linkov & Steevens: Scientific Background, Goals and Workshop Overview**

2. Emerging Consumer Products: Medical, Food, Industrial and Environmental Applications

9.00 **Colvin: Environmental Applications and Implications**

9.20 **Gulledge: State of the Industry**

9.40 **Korenstein: TBA**

10:00 **Coffee Break**

3. Nanotechnology Benefits: Panel Discussion

10:30 **Brief Presentations: Figovsky, Danzeisen, Abdel Mottaleb, Adlakha-Hutcheon, Varma**

11:00 **Discussion**

4. Formation Of Working Groups And Review Of Charge

The following WG are currently planned:

WG1: Policy and Society

WG2: Technology and Benefits

WG3: Human Health Risks

WG4: Environmental Risks

12.00 – 1.00 **Working Lunch (Sandwiches and Appetizers)**

PM

5. Nanotechnology Implications and Risks: Human Health

1.30 **Lynch and Elder: Nanoparticle interaction with Living Matter**

2:00 **Shvedova: Toxicology of Nanomaterials (inhalation)**

2.20 **Monteiro-Riviere: Toxicology of Nanomaterials (dermal)**

2:40 **Savolainen: Occupational**

6. US EPA: Nanotechnology Knowledge Gaps

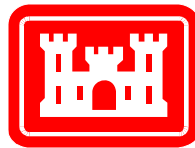
3:00 **Davis and Linkov: Discussion and Brief Survey**

7. Coffee Break and Interactive Poster Session

3:30 **Poster Presentations: 3 min Presentations; Posters will be on display during all three days**

8. 5pm **WG Meeting #1: WG organization and planning**

7pm **SOCIAL HOUR & DINNER (Hotel)**





Agenda - Tuesday

AM

8.00 *Linkov & Steevens: Brief Review of Day 1 Discussions & Working Group Activities*

7. *Regulatory Landscape*

8:15 *Kadeli: US EPA*

8:35 *Owen: UK DEFRA and OECD*

8:55 *Karkan: Canada*

9:15 *Stamm: EU*

8. *Nanotechnology Risks: Panel Discussion*

9:35 *Depledge, Haruvy, Kenawy, Melkonyan*

10:00 *Coffee Break*

9. *Work Group Meetings #2: Challenges and Issue Identification*

12.00 – 1.00 *Working Lunch (sandwiches and appetizers)*

PM

10. *Work Group Meetings #3: Preparation of Summary Paper*

2:30 *Coffee Break*

11. *Summary Presentations from WG Chairs, WG Coordination*

12. *Nanomaterials Measurement and Characterization Tools*

3:30 *Foss Hansen: Categorization Framework to Aid Exposure Assessment of Nanomaterials in Consumer Products*

3:50 *Kuhlbusch: Nanoparticles and Exposure: Measurement Technologies and Strategies*

4:10 *Gatti: Nanofood or nanocontamination: the impact of the nanotechnologies on humans and animals..*

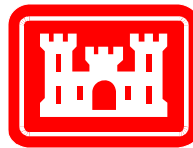
13. *Social Implications and Communication*

4:30 *Palma: Risk Perception of Nanotechnology: implications for risk assessment and communication*

4:50 *Monica: Legal Implications*

5:10 *Discussion (Vaseashta)*

6.00 *CONFERENCE DINNER (Monchique Village, Bus departs at 6:15)*





Agenda - Wednesday

AM

8.00 *Linkov & Figueira: Brief Review of Day 2*

14. Nanotechnology Implications and Risks: Ecological

8:20 *Steevens: Nano Ecotoxicology: Bioaccumulation and Fate and Transport*

8:40 *Kapustka: Developing an ecological risk framework to assess environmental safety of nanoscale products*

Risk Assessment and Decision Analysis Methods and Tools

9:00 *Figueira Figueira, Greco, Slowinsky: GRIP: a Generalized Regression method with Intensities of Preference for ranking alternatives evaluated on multiple criteria*

9:20 *Tervonen: MCDA: Application to Nanomaterials Characterization and Risk Management*

9:40 *Davis: Risk Assessment: Discussion of Survey and Case Studies*

10:00 *Coffee Break*

16. Work Group Meetings #4: Preparation of Presentation

12.30 – 2:00 *Lunch*

PM

17. Work Group Meetings #5: Finalize Presentation and Summary Paper Draft, Plan for paper Completion

18. Work Group Reports

3.15 *WG#1 Representative*

3.30 *WG#2 Representative*

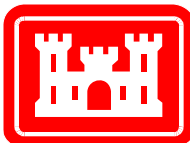
3.45 *WG#3 Representative*

4.00 *WG #4 Representative*

19. Plenary Summary of Workshop & Next Steps

4.15 *Steevens: Summary of Key Results and Research Needs*

4.45 *Linkov & Haraza: Schedule for Publication of Proceedings & Next Steps for Workshop*



Working Groups

Here

POLICY

Abdel-Mottaleb	EGYPT
Arcuri	BRAZIL
Davis T	Canada
Figueira	PORTUGAL
Foss Hansen	DENMARK
Gulledge	USA
Hakkinen	ITALY
Kadeli	USA
Karkan	CANADA
Kearns	FRANCE
Kondratyev	RUSSIA
McQuaid	UK
Monica	USA
Palma	PORTUGAL
Satterstrom	USA
Srdjevic	SERBIA
Stamm	ITALY

Alfa

TECHNOLOGY

Adlakha-Hutcheon	CANADA
Bayramov	AZERBAIJAN
Colvin	USA
Figovskiy	ISRAEL
Fonseca	PORTUGAL
Gatti	ITALY
Gnewush	UK
Haraza	EGYPT
Haruvy	Israel
Kenawy	EGYPT
Khaydarov	UZBEKISTAN
Korenstein	Israel
Palmeira	PORTUGAL
Shalhevet	Israel
Steevens	USA
Vaseashta	USA
Vieira T	Portugal

Sala

HUMAN HEALTH

Davis M	USA
Elder	USA
Grieger	DENMARK
Kaczmar	USA
Kuhlbusch	GERMANY
Linker	Netherlands
Lynch	IRELAND
Matias S	
Monteiro-Riviere	USA
Pinto	
Rudnitskiy	USA
Savolainen	FINLAND
Shvedova	USA
Tervonnen	FINLAND
Vieira M.	PORTUGAL

Vila

ENVIRONMENTAL HEALT

Bennett	CANADA
Chan-Remillard	CANADA
Chappel	USA
Depledge	UK
Goss	CANADA
Goudey	CANADA
Grossi	Brazil
Kapustka	CANADA
Melkonyan	RUSSIA
Metcalfe	CANADA
O'Brien	IRELAND
Owen	UK
Picado	Portugal
Ramadan	EGYPT