International Risk Governance Council

"The Risk Governance of Nanotechnology: Recommendations for Managing a Global Issue"

Session 2: Representative Stakeholder Workshops
Prioritization of Frame 1 Proposals
Parallel Workshop 1: Industry Perspective

July 6, 2006

Terry L Medley,
Global Director Corporate Regulatory Affairs

DuPont Environment and Sustainable Growth Center, USA

Parallel Workshop 1: Industry Perspectives - Objectives

- Evaluate and prioritize the proposed risk governance strategies for Frame 1 nanotechnology products.
- Identify any opportunities for improvement in these strategies.
- Determine any areas of agreement and divergence between and within the represented stakeholder groups.

Key Questions

- Does the separation of potential risks into two frames of reference provide a viable and useful reflection of the current situation? Do you have any suggestions for improvement?

- What is your opinion of the risk management and communication recommendations identified by IRGC for Frame 1 nanostructures? How can they be improved? Do you have any additional recommendations?

- Which Frame 1 recommendations are the most critical and which are the most important? Who should take the lead in developing and implementing these critical risk management strategies?

- How should the most relevant recommendations be implemented? Who would need to initiate what kind of actions at what time?

Question 1: Does the separation of potential risks into two frames of reference provide a viable and useful reflection of the current situation? Do you have any suggestions for improvement?

- Two frames useful as starting point, other factors should be considered

- Improvements
  - Frame one: today, less complex; frame 2: tomorrow, more complex from both technical and societal perspective (start from substance/material, also look at impact (bio-active affect, interactive effect with living systems, disruptive effect for living systems, accumulative effect)
  - Principle of allocating particular type of technology to frame 1/2: suggestion for frame 1 – monitor whether there could be uncertainty in the future; early warning for surprises / continuing 'do-your–obligation' and assess whether there are potential changes so adjustments can be made

Question 2: What is your opinion of the risk management and communication recommendations identified by IRGC for Frame 1 nanostructures? How can they be improved? Do you have any additional recommendations?

- Risk management
  - Risk assessment methodologies
  - Guidelines and best practices available internationally

- Risk communication
  - Information about the benefits and non-intended side effects
  - Risk communication training courses and exercises for scientists

- Improvements
  - Risk communication: what are the objectives of communication – this is most important point which is missing
  - Build up trust through being transparent (on risks and benefit); integrated risk communication / stakeholder dialogue (last recommendation) extremely important for building trust
  - Key scientists should be involved as risk communicators

Question 3: Which Frame 1 recommendations are the most critical and which are the most important? Who should take the lead in developing and implementing these critical risk management strategies?

- Hazard and exposure assessment – more transparency needed
- Improvements
  - Add insurance and financial sector under industry grouping
  - Explore and use international organisations (ISO e.g.)

Question 4: How should the most relevant recommendations be implemented? Who would need to initiate what kind of actions at what time?

- Consultative role of all the groups
- Government should take the lead

Soundbites:

- China
- No one size fits all
- Don’t go through the same process again and again
- Military, military
- Predictability

GENERAL COMMENTS

- Mainly supportive, but a number of questions
- Needed more time – inadequate time allowed to complete task in a really comprehensive manner
- Pre-meeting survey?
- Longer breakout sessions?

Principles for characterizing the potential human health effects from exposure to nanomaterials:elements of a screening strategy– 2005 ILSI report

- Based upon an evaluation f the limited data currently available, the report presents a broad data gathering strategy applicable to this early stage development of a risk assessment process for nanomaterials.
- The report outlines the elements of a toxicological strategy for nanomaterials as the first step – i.e. hazard identification – in the risk assessment process.
- Many current efforts are predominantly focused on using relative simple nanostructured materials such as metal oxide nanoparticles and carbon nanotubes… Research into more complex nanomaterials is anticipated to lead to applications such as cellular-level medical diagnostics and treatment and advanced electronics.

U.S. Environmental Protection Agency Nanotechnology White Paper

For the purpose of this document nanomaterials are organized into four types

- Carbon-based materials
- Metal-based materials
- Dendrimers
- Composites

u.s. Environmental Protection Agency Nanotechnology White Paper

Stages of nanotechnology development;

- First Generation – 2001: Passive nanostructures
- Second Generation – now: Active nanostructures
- Third Generation – 2010: 3-D nanosystems and systems of nanosystems
- Fourth Generation – 2015 Molecular Nanosystems

IRGC Surveys on Nanotechnology Governance

Volume B the role of industry;

- A need to ensure responsible development
- The current state of knowledge is insufficient to set responsible new regulations
- Any changes which are made to regulatory policy should seek responsible development not restrict innovation
- Must prevent long periods of regulatory uncertainty
- New legislation not necessary- assessment of of existing regulations and appropriate adaptations as needed