Proposal for the MEGA Nano Forum

A Model for an Organization Creating and Reinforcing Mutual Self-Responsibility

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The opinions in this paper are those of the author and should not be taken as official policy determinations made by the agency for which he works.

OTA

- Provides free, confidential technical assistance
- Established as part of the 1989 MA Toxics Use Reduction Act
- Runs a “Safe and Green Nano” listserve
  http://www.internano.org/mailman/listinfo/safe-and-green-nano
- Guidance: *Considerations for Safe Development of Nanotechnology*
  http://www.mass.gov/Elwd/docs/dos/nano/OTA_nanotech_guidance_doc.pdf

PRIMARY PROBLEM THIS TALK ATTEMPTS TO ADDRESS

- *The safe development of nanotechnology is in the interests of both society and those working with nanoparticles. But fear of public scrutiny and interaction with government agencies inhibits progress.*

- Businesses should engage with each other concerning safe development. This will help create the foundation for constructive engagement with agencies, and with the public as well. The MEGA Nano Forum is an example of how this can occur.

RELATED PROBLEM THIS TALK ATTEMPTS TO ADDRESS:

The complexity of the issue inhibits progress and enhances deference to experts, but there are clear principles that can serve the process of democratic resolution.

OFFERED PREMISES:

- Nanotechnology's promise is too great to ignore action that can prevent the stifling of development.
- Risks created by a minority have negative spillover effects on responsible entities.
- Perceived risk can be as politically important as real risk.
- It is not sensible to oppose deliberation concerning regulation on grounds that such discussion reinforces a false idea that there is a risk that needs to be controlled. *There is no longer any realistic question that risks do exist and require control, at least concerning the release of some engineered nanoparticles.*

OFFERED PREMISES, Continued

- Good rules will reduce the risk of the type of harm occurring that could cause widespread fear and suspicion, and backlash against the industry. *Good rules will reduce both health and business risks*.
- Opposing regulation on the grounds that it will have bad economic impacts assumes that it must always be poorly designed. But if expertise and diverse perspectives are engaged in its development this risk is greatly reduced.
- *Rules developed with the active engagement of knowledgeable practitioners committed to regulatory excellence will be better for the industry than the current disorganized state of applicable law, which is prolonged by a failure to constructively engage.*

MORE PREMISES

- **Nanotechnologies are already covered by law, legal liabilities are real.**
- **Current state of law is confusing.**
- **Clarity and certainty are better for the development of nanotechnology.**

Unclear but potentially real legal liabilities

- MSDS doesn’t note hazard created by nanoengineering.
- General Duty clause of OSHA requires actions to address hazards even if no specific requirement.
- When nanoengineering makes a dust reactive: waste may be hazardous, RCRA and fire marshal rules.
- Wastewaters may fail effluent toxicity testing.
- Air emissions may cause nuisance condition.
- Failure to warn concerning hazards in product?
- TSCA, FIFRA, FDA, CPSC, REACh, states, civil action.

Ensuring Main Point is Clear

It is good for business for there to be an open and rich effort to create enforceable standards that help ensure the prevention of harm, and for experts from the nanomaterials-using sector who are committed to doing things properly to be engaged in rule development.

Companies involved in nanotechnologies (and nonprofit, academic researchers using nanomaterials) can work together first to develop a more unified voice concerning safe development, which will aid constructive engagement.

CONTEXTUAL Consideration

Complexity of the topic makes that rich, open democratic exchange difficult.

Societal consensus will be more easily reached if there are commonly accepted guiding principles. Simple, (but not simplistic), understandable concepts will ease the path to sensible regulations.

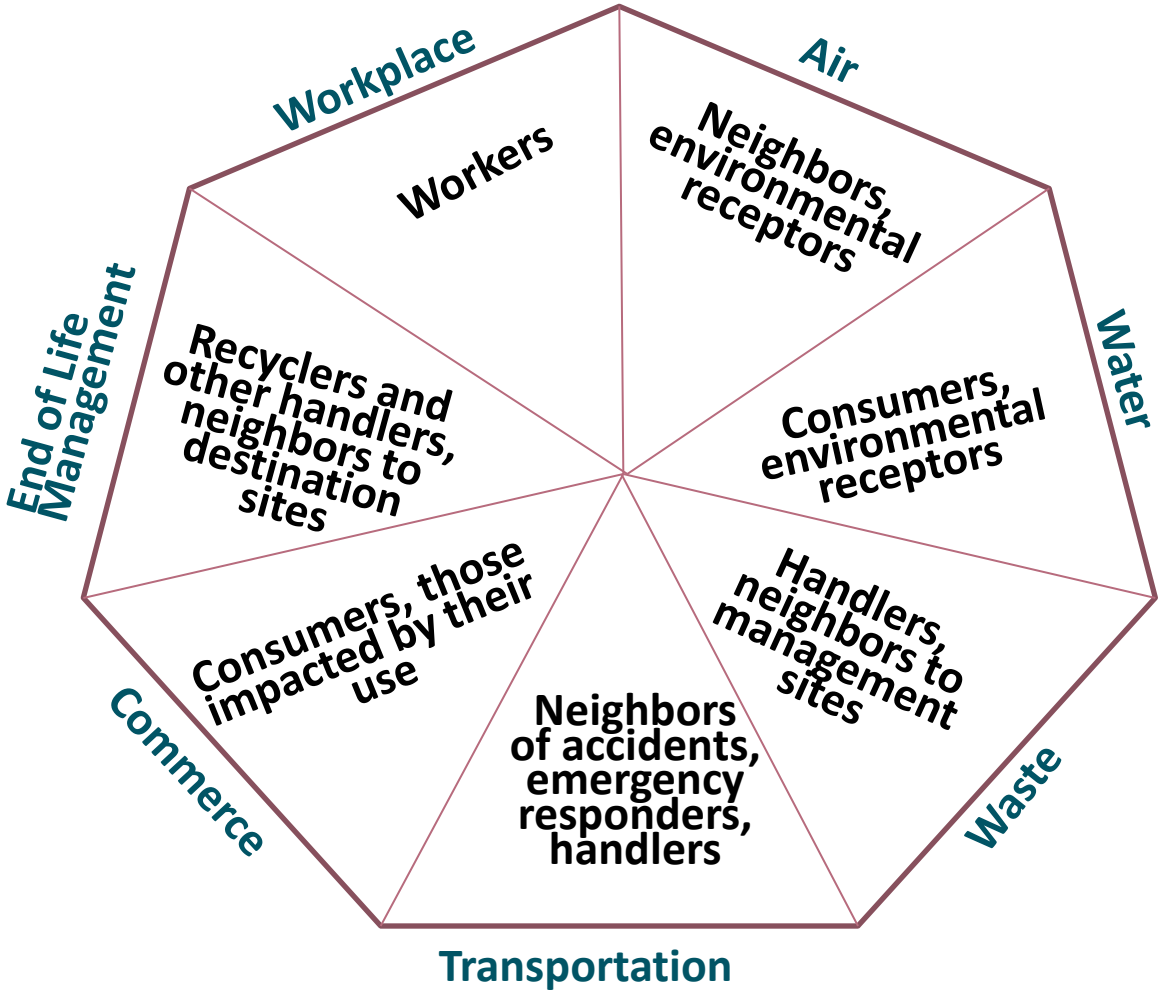
ACCEPT PRECAUTION and APPLY TO FREE PARTICLES FIRST

- *We have more to fear from a lack of precaution than from precaution itself.* Skating on frozen lakes: if the temperature is 50 degrees we ban skating. *We don't wait for visible cracks.*
- *Divide nano-uses into those in which particles become free and available for ingestion, respiration, absorption, or remain contained*. The need for safeguards begins with whether they are free to be taken up by living organisms. Rules organized around this concept make sense.

USE LIFE CYCLE PERSPECTIVE

- Will those who manage wastes, such as used process filters or gloves, be exposed?
- Will releases occur in use, or after an article is used, and is abandoned or disposed?
- Will particles end up in water, affecting micro-organisms?
- Will particles ventilated from the workplace affect neighbors?
- Will downstream manufacturers pass on information you give to them?
- Taking a life-cycle perspective reveals who all the other stakeholders are, and why they have a perspective that needs to be understood.

The Seven-Sided Universe and Stakeholders in each dimension



RTK Principles

- The Rule of Empathy: Would you want to know about it if you were in the place of the one who could be harmed?

  This simple concept remains applicable and powerful despite no matter how complex the topic, and despite the fact that nano has benefits

- The Rule of Safety: Would transmitting the information reduce the risk?
  - Once you accept that others have a right to know, this helps in considering what they would want to know

Avoid inherent toxicity through intelligent design choices.

- To learn them, businesses and researchers must be interested in environmental, health and safety research from the start. Focusing on the design stage is the most economically efficient method of mitigating risks. There are significant barriers to design-stage focus. An active effort to create this focus at the design stage is necessary, else it may be put off.

USE AVAILABLE METHODS

- *NIOSH says that there are workplace safety techniques developed for other sectors (such as for addressing fine pharmaceutical dusts) that should be applied to nanoparticles*. That there are established techniques that can be used NOW to great effect reduces the disabling sense that this is all too difficult to figure out and we need to wait until we know more.

CREATE A SAFE HAVEN

- OTA has established Business Environmental Networks that operate as “safe havens” for businesses to discuss issues among themselves they would not risk discussing in public. Confidential assistance offices from government can facilitate and provide connection to reliable compliance and prevention information. There are many other offices like OTA.

INVITATION to Nano- Practitioners:

- *Be A Founder of the Manufacturers and Researchers Environmental, Health and Safety (EHS) and nano-enabled Green Alternatives Forum (the MEGA Nano Forum).*
- *The Forum is an organization for those who see a common interest in the safe development of nanotechnologies. The purpose of the Forum is for members to work cooperatively to keep each other up to date on needs and opportunities relevant to responsible operation and product development. The guiding spirit of the Forum is that it is better to address EHS issues widely and proactively, than to wait for the issues to become problems, and that the topic is so large and complex that no company or research institution can effectively keep up with all the pertinent information on their own.*

FLEXIBLE Organizational Proposal

- *The MEGA Nano Forum is an informal roundtable or network, with no dues or incorporation. The Office of Technical Assistance (OR APPROPRIATE OFFICE) can help facilitate its meetings. (Consulting with others on the agenda, finding speakers, finding locations, announcing meetings). OTA is a state agency that has provided* ***confidential*** *assistance to companies for twenty years and has created similar groups.*

NEEDS REITERATING!

- *OTA is a safe means of having a relationship with the government. It can help obtain access to official personnel and information and assist participants with regulatory and technical questions. OTA specializes in the prevention of harm through changes in process and materials and has helped hundreds of companies.*

Things Forum members can keep each other up to date on

- The latest National Institute for Occupational Safety and Health guidance
- Affordable, accurate equipment for monitoring nanoparticle releases
- The latest on filters for lab hoods, glove boxes, and other enclosed workspaces
- Practices that ensure waste managers handle the waste safely from cradle to grave
- Contract language to ensure proper disclosure “runs with the product”, to ensure your own liability protection
- The latest on how aspects of toxicity can be designed out

Staying Up to Date

- The weight to give to new evidence of toxicity
- The questions of extrapolating down and scaling up
- Understanding fate and transport, and how the body responds
- The latest Toxic Substances Control Act developments
- How to amend Material Safety Data Sheets, or gather sufficient information from suppliers
- How to embed nanoparticles to prevent releases during product use
- Possible models for product stewardship post-use

Ground Rules for Safety

Although generic information will be permitted to be repeated outside of the confines of the meetings, all specific information considered sensitive to participants must be considered confidential. For example: if a participant reveals that they have determined it is necessary to use nitrile gloves while handling a particular nanomaterial, no one may reveal the fact that this is the procedure now followed by that company. But any attendee may make use of the information that it might make sense to use nitrile gloves in comparable situations.

Benefits to Members

- More eyes looking at your problem, which increases the likelihood that solutions will be identified.
- The nonenforcement agency can take questions for clarification to the regulatory authorities, and get answers for the entire group.
- Efficient and less expensive way to receive training.
- Efficient way to hear from vendors, share contract or bidding documents (on such items as air monitoring equipment or waste management), and perhaps even engage in group purchasing of items necessary for safe operations.

Big benefits

- Group can help increase safety of the sector.
- Group can help coalesce voice of responsible actors. (The forum need not take positions in its own name, but provides space for advocates of responsibility to join together on positions).

GO AHEAD – USE THE IDEA!

You can do this without an OTA, but try finding an appropriate government agency to play that role.

Attribution is nice

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