Forensic Environmental Analysis of Nanotechnology Regulation

C. Scher and D. Caputo
Quest Consulting, Inc.
Bellaire, Texas, USA, cscher@questehs.com

ABSTRACT

Some considerable effort has recently been displayed by manufacturers, researchers, regulatory bodies, professional organizations, NGOs, and other interested parties addressing how nano-particles and their manufacture should be environmentally regulated. The term environment here is used in a very broad context; it also refers to health and safety and extends from manufacture through consumer use to the nano-particle's ultimate disposition. This issue is not solely the USA's; it extends to all countries currently and potentially fielding a nanotechnology industry. In the USA, everyone including EPA, FDA, ABA, universities and a host of other entities are trying to voice an opinion. The executive branch of the federal government with congress's approval and funding has created an investigatory group examining the regulatory potential.
Considerable amounts of money are at stake; the nanotechnology industry is projected to reach $2-3 trillion worldwide in 10-15 years. Industry would prefer to enjoy a wide open regulatory arena, one that doesn't impose unnecessary laws on top of those it already must comply with. Others are not so sure. They are suspect either because of ignorance, feeling steamrolled by proponents of the technology, or wanting a piece of the action. Here is an opportunity to get involved while the technology is immature, developing, financially attractive and potentially unregulated. There is room for everyone; but how to best meet the technical challenges of everything nano, making it economically attractive, and yet minimizing potential risk to human health and the environment.

There is a body of thought within science and engineering termed forensics. Forensic environmental engineering and science is becoming popular among professionals and more frequently used in environmental thought and investigation. In fact, the pure definition of forensic according to Webster's Collegiate Dictionary, 10th edition, is "1; belonging to, used in, or suitable to courts of judicature or to public discussion and debate 2: Argumentative, rhetorical 3: Relating to or dealing with the application of scientific knowledge to legal problems." All three parts of the definition are applicable to the issue at hand – the application of forensics to the environmental regulation of nanotechnology.

It is the authors' contention that use of environmental forensics to encompass scientific investigative methods, in this case including as a minimum analytical chemistry, atmospheric chemistry, environmental fate assessment, environmental law, environmental fate and transport, computer modeling, geochemistry, toxicology, hydrogeology, and health risk assessment, will provide the answer to what level of regulation is required. Forensic environmental science and engineering is a state of mind; an analytical approach to solving this problem. And it need not be complicated, just complete and scientifically defensible.

PROBLEM

New chemicals are now regulated by the Toxic Substances Control Act (TSCA). The process is cumbersome, expensive, lengthy, and restrictive. A new approach is needed and it must be scientifically transparent and defensible. The challenge is that the range of nan0-sized chemicals may have different properties than presently known and tested chemicals. Therefore, the question is the following:

1. Should nano-materials be regulated by TSCA?
2. Should nano0materials be regulated at all?
3. Should nano-materials be regulated by a new methodology, structure, and system?

The realities of nano-materials are the following:

1. Nano-sized chemicals frequently have different properties than large sized materials.
2. The present regulatory structure is slow and cumbersome.
3. A new multi-trillion economic "machine" is about to enter the market.
4. Public perception of nanotechnology is shown as having a neutral benefit vs. risk (Figure 1)[1].
5. There is an opportunity to regulate or not regulate a new technology from its inception.

METHODOLOGY

Environmental forensics actually began a long time ago with the discovery and pronouncement of the precursor to

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the scientific method by Aristotle in ancient Greece. The scientific method was updated and reformatted as we now know and use it by René Descartes of France in 1637. His pamphlet entitled *Discourse on the Method for Conducting One's Reason Well and for Seeking the Truth in the Sciences* or simply a *Discourse on Method* sets the stage on **how science should be conducted.** Within his treatise are four rules for problem solving. Note that problem solving is the objective in this exercise – what regulatory structure should encompass the manufacture, use and disposition of nano-materials. The four rules are stated as thus:

1. Never accept anything as true that is not plainly known to be such; that is to say, carefully avoid hasty judgments and prejudice. In other word, be doubtful;
2. Divide each of the difficulties into as many parts as possible in order to better resolve them;
3. Conduct these thoughts in an orderly fashion, commencing with the simplest and ascending little by little to the more complex, and
4. Everywhere make enumerations so complete and reviews so general assuring to have omitted nothing.

We will seek to perform a forensic analysis of the problem to determine the optimum regulatory process for nano-materials.

ANALYSIS

The analysis of regulating nano-materials proceeds as follows:

1. Use a bottom-up approach, not top-down. Start fresh, assume no TSCA.
2. Involve all crucial elements required - use the most successful entities in existence.
3. Devise safeguards to protect human health and environment (ecology).
4. Create mechanisms to move forward through pinch-points or over hurdles.
5. Make assumptions specific and relevant.
6. Be aware of the lack of any data and the full range of probabilities.
7. Involve the public early and often in the decision making process.
8. Create a blue-ribbon independent agency (separate from EPA) to administer the program.
   - Employ the best scientific, engineering, and legal minds available.
   - Re-evaluate and streamline the existing risk assessment methodology.
   - Provide funds for constructive and applied research leading to decision making.
   - Use the framework for environmental health risk management (Figure 2)[2] which includes the following elements:

1. Define the problem and put it into context.
2. Analyze the risks associated with the problem in context.
3. Examine options for addressing the risks.
4. Make decisions about which options to implement.
5. Take actions to implement the decisions.
6. Conduct an evaluation of the actions.
7. **Engage stakeholders from the beginning**.

Employ constructive and applied research leading to a multi-tiered risk analysis.

- Research must be more focused.
- Employ some function/structure relationship to toxicity as a criteria for filtering risk decisions.
- Ensure scientific information is understandable, credible, usable and relevant.
- Provide the information so that decisions can be made quicker.
- Decisions should be re-evaluated more often if new information becomes available.
- Consider all reasonable options
- Use multiple criteria decision analysis for decision making (MCDA-Figure 3)[3]

CONCLUSION

The result of this analysis is a new nanotechnology environmental regulation based upon some combination of the following:

- Focused research
- Reasonable risk
- Technical achievability
- Economics of implementation
- Enforceability of regulations

REFERENCES

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2. Framework for Environmental Health Risk Management, 1997
3. MCDA, An Integrated Approach, V. Belton and T.J. Stewart. 2002

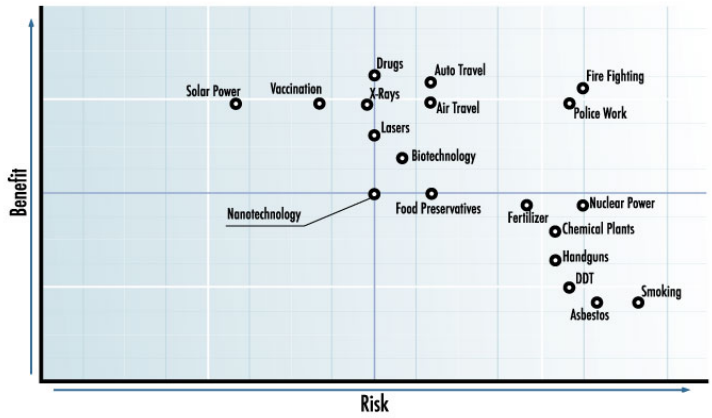

Figure 1

Figure 2

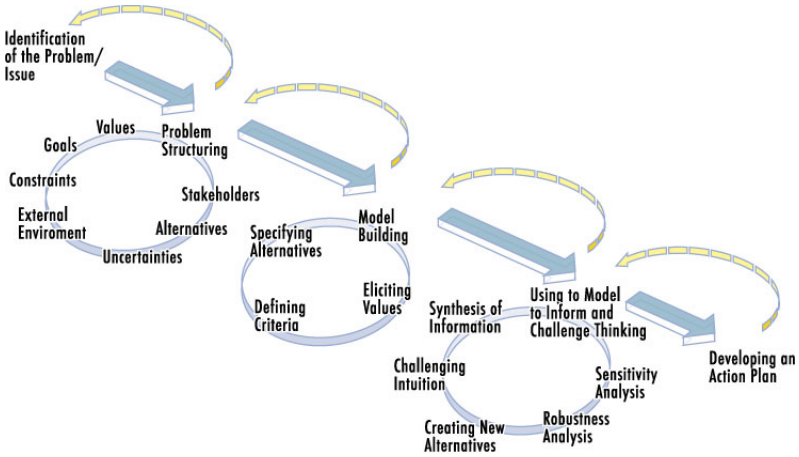

Figure 3

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