Nanotechnology Regulation

### Background

Nanotechnology represents a significant scientific breakthrough across numerous sectors of the 21st century landscape. These machines or micro particles (nanos), built at the molecular level, can address a myriad of challenges within the sectors of healthcare, energy independence and industry. Nanotechnology has the potential to influence humans, our environment and industry in the next decade. Yet because it is such a new science, its long-term effects and policy implications regarding its regulation are unclear.

In healthcare, nano-delivery systems can administer medicine at super targeted locations within the body and offer the potential of improved treatment and restorative advances. Diagnostic tests, imaging agents and gene therapy are areas where the technology can be used. In the energy field, nanos can increase the efficiency of solar panels and other alternative energy sources. In industry, consumer goods enhanced with “smart electronic” capabilities can improve durability and within a military application, help to improve soldier survivability.

With all their possible benefits to society, it is easy to understand why the scientific community has propelled nanotechnology research to its highest priority. Yet, despite all the promise, nanotechnology development and implementation presents significant human risks. Some reports compare nanoparticles to asbestos and suggest that the scientific community is ignoring early warning signs of the danger to human health. The International Center for Technology Assessment (ICTA) in its *Principles for the Oversight of Nanotechnologies and Nanomaterials,* puts it best; *“Due to their size, nanoparticles can cross biological membranes, cells, tissues, and organs more readily than larger particles… Once inside cells, they may interfere with normal cellular function, cause oxidative damage and even cell death”*

Related to the environment, nanotechnology could serve to eliminate some of our existing pollutants, but they can also create new unplanned and potentially dangerous by-products. New forms of pollution (the remains of nanoparticles discarded as waste) may be unleashed into our environment. As nanotechnology does not occur in nature, plant and animal life will have no biological methods for filtering these complex contaminates. Our fragile ecosystems may suffer under the impact of nano pollution.

Failing to acknowledge the impact of nanotechnology through weak or non-existent regulations would represent a failure of both science and policy makers to acknowledge the fragility of our environment.

### Policy Analysis

From the policy perspective, there are three central concerns with this technology that both demonstrates and defies the need for regulations and controls. First, as a new field of study, the long-term risks of exposure to nanotechnology, for both humans and the environment are unknown. The field has no like predecessor, so federal or state entities have no background or experience in applying relevant regulations. Finally, insufficient controls on the handling of this technology could represent a new global terrorism weapon.

Unlike advances in other fields or industries, built upon previous frameworks of rules, research and understanding, nanotechnology is a scientific green field. Scientists are gaining familiarity with the effects of these particles at the molecular level, but much ground work remains to be completed. The combination of incomplete scientific understanding and the lack of comparable policy initiatives has disadvantaged policymakers in their analysis. In the wrong hands, nanotechnology can be manipulated to damage industry, business, and humanity itself. In a dire scenario, nanotechnology can turn from useful technology advancement to devastating military platform.

Two U.S. cities, Berkeley, CA and Cambridge, MA, have launched, or are currently evaluating policies addressing the issue of nanotechnology regulation. Berkeley’s policy model addresses the regulation and monitoring of nanotechnology materials, and the safe handling and disposal requirements of these materials by their manufacturers. Cambridge, MA, considered Berkeley’s regulations for its own use, but concluded that it is still too early for regulation of this technology. “In recognition of the limited health effects data and the absence of a clear consensus on best practices and standards for engineered nanomaterials, the Cambridge Public Health Department …does not recommend that the City Council enact a new ordinance regulating nanotechnology…”

The EU has also initiated discussions on building a nanotechnology regulation portfolio. It addresses the regulation of nanotechnology by repurposing current chemical and workers protection laws to incorporate new technologies. Redefining the EU’s current legislative framework, however, has fundamental issues. Representative nations have already acknowledged the differences between nanotechnology and previous technologies, especially in the areas of test and risk assessment methods. This represents a dangerous separation between current health testing standards and the standards necessary for nanotechnology. Additionally by not developing nanotechnology specific legislation, the EU risks inviting erroneous interpretation into the enforcement of their portfolio.

In both the Berkeley and EU strategies, precaution and preventative measures are prominent. Any successful solution will integrate these concepts into a broader legislative package that allows for the simultaneous development of the science and the necessary security precautions.

### Recommendation

A balanced policy of incremental regulation will promote scientific growth and protect public health. Preliminary regulations, including both the legislative mechanism for policy updates and the recommended assessment intervals, are fundamentals in the policy. These regulations allow for the essential re-evaluation of new information, effectively allowing research to progress while protecting long and short-term safety concerns. Whether this re-evaluation mechanism manifests itself as a governing body or policy framework, the ability to respond to the latest research is vital.

While the incremental approach to the regulation of nanotechnology is the best-suited policy approach, because of the evolutionary state of the technology, it is not a perfect solution. The slowdowns imposed by regulatory guidelines will potentially hinder the developmental efforts of scientists and researchers. Regulation will also represent a high economic cost to manufacturers, consumers and the federal government.

Hampering the speed of nanotechnology research may seem like a prudent approach, but a longer-term outlook suggests that this type of slowdown may produce serious setbacks. Prominent researchers and program developers will look to more accommodating nations to pursue these initiatives, particularly if funding grants are tightly tied to policy regulations. Economic costs, both in terms of developing regulatory initiatives and enforcement of those initiatives will be high. Regulations will directly increase the cost of technology development and will be viewed as a deterrent.

As an example, the U.S. was once the dominant leader in the area of nuclear research. Today, the U.S. has fallen second in its position, due to slowdowns and funding shortages. While a multinational group, led by France, has now taken the lead in this area, clearly a U.S. advantage has been lost. Falling behind in nanotechnology research could represent a significant risk to our global leadership particularly related to technology innovation.

### Conclusion

While challenges to nanotechnology regulations may appear daunting, the impact that this technology may have on our future is equally significant. At the center of our socio-political concerns today, health, industry and energy challenge our resources. These concerns require new solutions, which nanotechnology can potentially offer. Antiquated models of regulations will not keep pace with these rapidly evolving technologies. Prudent planning to form responsible, adaptable policy for 21st century nanotechnology will protect and advance U.S. interests in our world.