A Comprehensive Comparative Regulatory Policy Analysis: U.S. and EU Nano Regulation and Policy Alternatives

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ABSTRACT

Nanoscale science has emerged as a key technology frontier, yet poses new challenges due to our limited understanding of potential risks. Refining the implementation of the existing and politically viable regulatory framework would reduce risks to firms, consumers, workers, and the environment, thereby ensuring continued market growth and innovation. Examining the economic efficiencies associated with a wide range of policy alternatives produces new policy options for reducing risks and improving efficiencies under the existing regulatory regime. Strengthening private risk instruments, incentivizing improved processes, and improving transparency all provide significant benefits to consumers, workers, the environment, and firms.

Keywords: policy, regulation, risk management, economic analysis, insurance.

I. Current Regulatory Frameworks

The emergent nanotechnology industry is at a crossroads, and faces three significant challenges. First, the industry faces economic challenges due to increasing risk uncertainty, inefficient commercialization, and environmental, health, and safety (EHS) externalities. Secondly, legal challenges stem from a legal framework that fails to adequately address unique nanomaterial properties, and a lack of scientific research to adequately define risk and to inform more effective regulation. Finally, the U.S. and the EU have built a strong consensus that current frameworks are sufficient, yet there is a potential for standards disharmonization from various governmental and NGO groups.

Much of the current literature focuses on the applicability of specific regulations to nanotechnology without comprehensively analyzing all existing regulatory tools. Such limited analysis leads to an improper focus on specific regulatory sectors, a failure to recognize private risk management as an important tool, and a call for incremental change to the existing framework. Each of these outcomes fails to leverage maximum efficiency and risk management opportunities.

II. Methodology

This assessment flows from a comprehensive analysis of the existing regulatory framework in the U.S. and the EU. A literature review from a wide range of academic disciplines produced a set of 31 U.S and 40 EU consumer, worker, environmental, intellectual property, and standards and measurements laws cited as *potentially* applicable to regulating nanotechnology. Additionally, all U.S. and EU industry self-regulation in the form of codes of conduct and risk management tools, as well as special interest group calls for increased regulation, are included in this analysis. A systematic comparison of corollary regulations produced a set of common features and significant variations between U.S. and EU law. Subsequently, this comprehensive set of existing policies was subjected to a 1st-

order rudimentary economic analysis. The resulting work creates a clear picture of the current challenges and the need for an *integrated public-private* regulatory framework in order to manage risk efficiently in the face of insufficient scientific data to properly develop new regulation.

III. Current Regulation: Many Tools, Significant Opportunities

A wide range of existing chemical, worker, and environmental regulations can apply to nanotechnology, thereby ensuring a strong regulatory net *if fully implemented as allowed by law* (see figure 1). There are currently no nano-specific regulations (aside from a Berkeley, CA disclosure ordinance, and forthcoming registries from California and Canada). Although this list contains all laws cited as potentially applicable, only a few regulations are frequently cited as likely to be used (noted in italics; regulations not cited in literature yet still corollary or potentially applicable noted in parentheses).

A comprehensive look at these U.S. and EU regulations shows that despite the many tools available, some risks still exist. The U.S. and the EU have comparable regulatory frameworks, although the EU and Member States regulated "human contact and consumption" goods—cosmetics, food, and drugs—with more stringency. There is strong corollary law, with essentially no areas covered by only the U.S. or the EU.

A deeper analysis of the corollary laws indicates generally strong similarities in the implementation level, with some significant differences. Common to both systems are a governmental-level consensus that existing regulatory systems are adequate. Some nano-specific issues, such a volume triggers, could be shifted at the implementation level. Of the noticeable differences, EU regulation is more likely to require industry rather than consumers to bear the costs of ensuring safety through various mechanisms as pre-manufacture notification or requiring a level of proved safety before products can be released to market, but there are important exceptions to this trend in U.S. regulation.

Our current understanding of the physical characteristics and behavior of nanomaterials and their impact on health and environmental safety is limited, and frustrates our ability to design effective regulation today.

For example, particle size (below 20 nm.) is increasingly understood to have significant health and safety impacts, yet early research indicates surface area or structure are potentially more important in determining toxicity. Given the lack of scientific evidence to adequately define risks for at least the next five years, a broader look at regulatory goals could produce better risk management in the near future.

IV. Objectives of a Strong Regulatory Framework

Stepping back from specific existing regulations, we must ask: what is an optimal regulatory framework? An effective framework would achieve three goals: (1) protect consumers, workers, and the environment from harmful substances, (2) provide a stable and predictable business environment to support robust growth and innovation, and (3) provide all stakeholders with information to make informed decisions about use and exposures risks. Such a framework would be built from the ground up, using dose/response curves

to determine risk assessment and risk management structures, which would then inform regulatory standards, triggers, processes and other safety mandates and incentives.

The current system fails to adequately reduce risk; much of this risk is due to the infancy of this emerging technology and the subsequent lack of scientific information to adequately assess risk. Consequently, producers are not well incentivized to actively participate in the assessment and management of risk. To date, the most effective environmental regulations, such as the Toxics Release Inventory (TRI), have focused on enforcing minimum standards and incentivizing the disclosure of information. Such modern regulation focuses on regulatory processes rather than strict standards which produces greater efficiencies and better outcomes.

Ultimately, an effective nanotechnology regulatory structure would increase the efficiency of the market; reduce risk to industry, consumers, workers, and the environment; reduce the *perceived* risk to consumers and industry in order to reduce costs; and set high expectations for safe and responsible development. Critical to the successful implementation of these changes are finding low-cost or no-cost mechanisms which can reside easily within the existing regulatory structures, which improves the likelihood of implementation. To be politically feasible, the changes must respond to the existing consensus in the U.S. and the EU that current regulations are generally adequate, but that that shifts in implementation are tolerable.

Table 1. U.S. and EU Regulation Applicable to Nano (partial iist)

U.S.	Regulation	EU (UK Implemented)
	Consumers	
TSCA	Chemicals	*REACH*
FIFRA (PRIA)		Chemicals (Hazard Information and Packaging for Supply) 2002
		Biocidal Products 2001 (a.a.)*
		Control of Pesticides 1986
FFDCA	Foods, Drugs, Cosmetics	*Food Safety Act 1990 (a.a.)*
FQPA		*Cosmetics Products (Safety) 2004*
DSHEA		Articles in Contact with Food 1987 (a.a.)
		Novel Foods and Novel Food Ingredients 1997 (a.a.)
		Plastic Materials and Articles in Contact with Food 1998 (a.a.)
		EC 178/2002 on General Principles of Food Law
		Colours in Food 1995 (a.a.)
		Miscellaneous Food Additives 1995 (a.a.)
	Biomedical	*Medical Devices 2002 (a.a.)*
		Medicines Act 1968
		Medicines for Human Use (Marketing Authorisations) 1994 (a.a.)
CPSA	Gen. Products	*General Product Safety 2005*
CPSIA		Additives 89/107/EEC
FHSA		Packaging (Essential Requirements) 2003
PHSA		Producer Responsibility Obligations (Packaging Waste) 2005
		Motor Fuel (Composition and Content) 1999 (a.a.)
	Workers:	
OSHA	General	Health and Safety at Work Act 1974
29 C.F.R S		Management of Health & Safety at Work
MSDS	Reporting	*SDS*

VI. STRENGTHENING THE EXISTING REGULATORY FRAMEWORK

A rudimentary 1st-order economic analysis points to a very clear set of policy shifts that can be easily implemented *within the existing regulatory structure* to improve efficiencies and reduce consumer, worker, and environmental risks today. Bolstering the weakening insurance market for nanotechnology is a critical first step in ensuring the continued growth of the emerging market while providing a safe and responsible development of novel materials. The creation of a separate risk market can provide an added incentive for continued innovation. Both of these options provide significant benefits at essentially no costs.

Less easily implemented but still highly effective are the creation of subsidies for clean productions processes and materials registries that can reduce information asymmetry and incentivize higher standards while avoiding inefficiencies. Private-public partnering to provide rigorous third-party certification and the support of voluntary agreements will also ensure a vibrant and responsible market development. By ensuring that risks are managed and reduced, nanotechnology can continue on its very promising path in transforming basic manufacturing processes.

Further work using real data on an industry and sector level is critical to verifying this assessment.

Ultimately, science will provide the necessary answers to develop responsive regulatory shifts. In the interim, we must use the tools available to ensure a robust and responsible industry will can fulfill the remarkable promise of nanotechnology.

Table 2. Weighing Various Policy Options within the Existing Regulatory Framework (partial listing)

Policy Option	More efficient	Lower costs ?	Reduces risk ?	Reduces *perceived* risk ?	Politically feasible?	Overall efficacy
Shift costs to via taxes	Yes	No	Yes	No	Unlikely	Low--Moderate
Optimized Insurance	Yes	Yes	Yes	No	Yes	High, but under threat
Subsidize clean production	Yes	No	Yes	Yes	Likely	Moderate-High
Set standards	Possibly	Possibly	Yes	Yes	Possible	Moderate
Voluntary agreements	No	Possible	Yes	Yes	Likely	Moderate-High
Improved enforcement	Yes	No	Yes	Yes	Somewhat	Moderate
Research database	Yes	No	Yes	Yes	Likely	Moderate-High
Registry	Yes	No	Yes	Yes	Likely	Moderate-High
Certification	Yes	No	Yes	Yes	Somewhat likely	Moderate-High

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