

Regulating Nanotechnology by Information Disclosure

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I. Introduction

Modern science has learned how to design and build “nanotechnology” products with components the size of a virus particle. This explosively growing industry combines great environmental promise with potential, but largely unexplored, environmental dangers.

How should public policy address these concerns? Although some government oversight seems both necessary and inevitable, traditional “command and control” approaches would be far too cumbersome. Instead, I argue, an acceptable intermediate framework could be built around *information disclosure*. Under this approach, a central authority would periodically announce to the public both the nanotechnology products or byproducts that raised some potential health or environmental concern, and (perhaps) the facilities that released them. No further government action would be required. Instead, the disclosure would motivate affected facilities and their local communities to investigate further and perhaps implement controls.

This paper first summarizes the key features of this emerging industry. It then explains why traditional regulation cannot address it effectively. Finally, it describes the information disclosure approach, and outlines its possible application to nanotechnology.²

II. Nanotechnology and the Issues it Raises

Four characteristics of nanotechnology define its regulatory challenges.

A. Nanotechnology promises major environmental benefits as part of its broad economic promise. “Nano-iron” – nanosized iron particles – have been used to good effect in hazardous waste clean-up. Membranes and other materials designed and built at nanoscale may decrease the energy needed to make chemicals, reduce the

¹ This paper develops and applies to nanotechnology ideas expressed more fully in Pedersen, “Regulation and Information Disclosure: Parallel Universes and Beyond”, 25 Harvard Environmental Law Review 152 (2001). I would like to express my appreciation to Leslie Carothers and the Environmental Law Institute for the invitation to take part in a forum on nanotechnology in May 2005 that provided the springboard for this paper.

² This paper does not address whether new legislation would be necessary to establish the disclosure system it recommends. I tentatively think that existing law contains adequate authority to support it.

cost of water purification and desalination, and lead to far more efficient fuel cells, lights, solar photovoltaic cells, and hydrogen storage matrices – all vital elements of any strategy to reduce greenhouse gas emissions.

B. EPA has already concluded that exposure to nano-sized particulates can endanger human health and the environment. Though motor vehicles, power plants, and other sources already produce huge quantities of nanoparticles, nanoparticles built to a specific design might well present unique concerns. Nanotubes, for example, can have troubling similarities to asbestos fibers.

C. We currently know very little about nanotechnology's potential health and environmental dangers. Indeed, there is no scientific consensus on the test methods and analytical protocols to which studies of such matters should conform.

D. U.S. sales of nanotechnology products exceeded \$200 million in 2002 and are rising by 33% a year. The National Science Foundation estimates the world-wide nanotechnology market might reach a trillion dollars a year by 2015. Not surprisingly, the United States, the European Union, and Japan have all identified nanotech as a strategic industry and provide major public support to its development.

III. Currently Debated Approaches to Nanotechnology and the Environment

Most discussion of nanotechnology and the environment has focused on improving the data base, subjecting nanotechnology to traditional regulation, and requiring notice to EPA of new nanotechnology products. These approaches do not add up to a coherent framework either alone or in combination.

A. Creating a Data Base

All stakeholders in the nanotechnology debate - from environmental groups to the chemical industry – accept the pressing need to develop a data base of nanotech studies, to establish standardized test methods and analytical protocols, and to fund research on health and safety issues.

However, such new knowledge will have practical value only if it leads to informed judgments that certain potential risks warrant control, while others do not. Generating more data will promote those decisions only in a general and unfocused way. Some additional mechanism seems needed to bring such questions to the point.

B. Traditional Regulation

Many different provisions of current regulatory law might conceivably apply to nanotechnology. But broad or rapid reliance on these provisions seem entirely unsuited to the nature of this field.

Our regulatory system sometimes requires pre-market approval of sensitive products like drugs or pesticides, or pre-construction permitting of major pollution sources. Almost no-one believes the likely dangers of nanotechnology are big enough to justify the delays in economic and technical progress that would attend the imposition of such requirements.

Regulation of existing activities need not cause such delays. But such regulations take a minimum of three years to issue, measured from the beginning of focused analysis to issuance of the final legal command. Once issued, they can only be amended by the same process. Moreover, they only apply to certain specific “problems”, which they define to the exclusion of other concerns.

Such crude slow tools seem almost perfectly mis-matched to nanotechnology, where very little is known at present, where both the industry and our knowledge of it will change rapidly for the foreseeable future, and where the range of possible problems is both very broad and very ill-defined.

C. Premanufacture Notice

Section 5 of the Toxic Substances Control Act³ requires those who introduce into commerce a “chemical substance” not in use in 1976, or who initiate a “significant new use” of an existing chemical, to give prior notice to EPA. EPA may then forbid or condition the new use. If EPA takes no action, marketing may proceed.

Many have suggested application of these “premanufacture notice” (PMN) provisions to nanotechnology products. That would raise legal questions. However, management issues somewhat analogous to those that make traditional regulation impracticable seem the more pressing deterrent. How similar to each other would two nanotech products need to be in order to be covered by a single PMN? And how would EPA evaluate the notices it would receive? Since nanotech materials often exhibit unique chemical, physical, and other properties, EPA’s current methods of evaluating PMNs would probably be inadequate to determine their potential hazard.

Such concerns have deterred EPA from asserting PMN jurisdiction over nanotech materials to date.

IV. Information Disclosure as a Framework

In our context, “information disclosure” means the release to the public of specific information calculated to flag issues of public concern about a process or material, or about the specific facilities that use or release it. Labeling of drugs and other consumer products is one example. Another, probably more relevant to nanotech, is the disclosure of environmental releases at a particular plant. So, for example, EPA’s “toxic release inventory” required certain facilities to report their releases of “toxic chemicals”, while California’s “Proposition 65” requires similar public disclosure of a facility’s use of cancer-causing materials.

A. Information Disclosure and Nanotechnology Regulation

Information disclosure seems like the only way to address nanotechnology environmental concerns that is intermediate between unfettered self-regulation and traditional command and control. Since these two extremes apparently possess opposite fatal defects, that intermediate position itself suggests that information disclosure may be the right approach.

³ 15 U.S.C. §2604.

Moreover, experience shows that information disclosure, in some important respects, would be well adapted to nanotechnology.

Disclosure approaches, unlike pure research, do not leave the suggestion that a certain activity warrants further analysis and (perhaps) control to emerge by itself from data compiled for other purposes. On the other hand, they do not require regulatory agencies to undertake the exhaustive analysis of issues and control approaches that imposition of mandatory controls requires. Indeed, they do not directly require any controls at all.

An approach that proceeds by flagging issues as the data generates them, rather than by attempting to issue controls, is far better adapted than top-down regulation to address a field in which both the activities of concern, and information concerning them, will be changing rapidly for a long time.

Information disclosure can be expected to address social problems effectively to the extent that companies and communities prove willing and able to take reasonable action in response. That condition, too, seems met for nanotechnology.

The industry will be composed largely of technically sophisticated firms well aware that nanotech's long-term future depends on maintaining public confidence in its safety. These firms will generally be possible to respond at acceptable cost to disclosure concerns, through further research, controls, or some combination of the two.

Similarly, states and local communities will be aware of the potential benefits of nanotechnology, and should therefore be careful not to damage their chances of attracting the industry by over-reacting to disclosures. And where control requirements seemed worth considering, these jurisdictions have long experience in regulating the types of environmental releases and exposures through which any health or environmental harms from nanotechnology might result⁴.

An information disclosure program for nanotechnology would decentralize the job of reacting to potential concerns to the firms and local communities concerned. The result would be quicker decisions that no control was needed, and quicker control decisions, than would ever be possible through a top down regulatory approach. This approach would also allow different approaches to a debatable problem to be tried in different areas, and subjected to the test of experience, thus providing a basis for eventually selecting the best approach in those hopefully rare or nonexistent cases where generic federal regulation might prove necessary.

B. The Problem of Agency Discretion

The framers of existing disclosure programs designed them to minimize any need for the administering agency to make and publicize discretionary judgments about the

⁴ That capacity to regulate where regulation seemed warranted would, in its turn, motivate the industry to address disclosure concerns to ward off regulation.

risk of various activities. Both TRI and Proposition 65 operate through automatic disclosure of information furnished by the regulated entities themselves, according to very precise legislative specifications, without any intervening massaging by government agencies. Moreover, the agencies themselves have been most reluctant to issue risk judgments even when they had clear legal power to do so.

This approach would never work for nanotechnology. The rapid evolution of new knowledge will require a disclosure organization that can change the “disclosure list” of nanomaterials of concern as knowledge advances and new materials come on the market. Such an agency might also need the ability to vary the extent and manner in which specific facilities were described to the public. In short, it would need the ability to distinguish in its disclosures between materials and releases of more and of lesser concern.

There are no fundamental operational or legal barriers to such flexibility. A decision to require disclosure of a given activity requires answering many fewer questions than a decision to regulate it in a particular manner, and should be easier to make for that reason alone. Moreover, since disclosure by itself does not impose any legal obligations, it does not require the detailed procedures and court challenges that attend the actual imposition of federal controls.

Nevertheless, powerful forces might oppose such flexibility as they have in the past. They could include an understandable fear among industry members that technical judgments would be inaccurate, or would be crafted to spread unnecessary public alarm⁵, as well as less legitimate concerns about being “singled out” by disclosure even when the disclosure was objectively phrased and supported by facts. They might also include agency reluctance, based on feelings of political weakness and fears of political retaliation, to make and publicize controversial judgments of whatever nature. Finally, bureaucratic inefficiency and inertia might defeat even good faith agency efforts to master a developing data base and make responsible judgments about disclosure.

On the other hand, all major participants in the nanotechnology debate seem to want a moderate and non-regulatory approach. Industry does not oppose all public oversight, while environmental groups have not supported mandatory regulation. This general desire for a middle ground could provide broad backing for an information disclosure program that would give the administering agency the legitimacy, and therefore (one hopes) the political courage to make it work. Indeed, no other realistic alternative suggests itself.

Any disclosure program could be constructed to affirmatively address stakeholder concerns. It would be presumptuous in this short paper to offer any hard-edged prescription for doing that. Here, however, are some suggestions just to show the types of approaches that might be possible:

⁵ In fact, the framers both of the TRI and of Proposition 65 deliberately required the use of somewhat alarmist language in the required disclosures, presumably to maximize the incentives to reduce the pollution releases being addressed. .

1. The program could prescribe in advance the types of information, or information gaps, that would lead either to disclosure of concerns about a chemical, or to disclosure of the facilities that used or released it, with heightened disclosure keyed to heightened concerns. By defining the “disclosure spectrum” in advance, this would assure consistent treatment of cases, and a degree of scientific support for decisions.
2. The program could prescribe in advance the form of words to be used in characterizing activities of concern, so as to avoid the use of unduly alarmist language.⁶ (That in turn would require limiting to a small number the categories of “activities of concern”, so as to make standard formulas workable. Use of a small number of “disclosure categories” would also tend to give the system predictability and make decisions simpler.)
3. Disclosure requirements could be proposed for public comment, thus providing a forum for correcting technical defects before final action. At the same time, even the proposal of disclosure on a given topic would begin to focus responsive attention on it.
4. Disclosure requirements could be reviewed by a scientific advisory body either before or after they took effect. Alternatively, the entire task of running the disclosure system could be assigned to a new and scientifically literate body created for that purpose.
5. The administering agency could be required to issue an annual report on a specified date fixing the coming year’s disclosure obligations. This in turn would help to force decisions and overcome the forces of bureaucratic inertia, as well as providing a predictable schedule for updating disclosure requirements.
6. Thresholds for disclosure based on levels of production or facility size could be established. (However, because nanotech materials can have very high activity in proportion to their mass, these thresholds might need to be lower than they are when addressing other materials.)

C. Information Disclosure as Part of a Larger Approach

An information disclosure approach would provide a natural overall setting and complement to the three current approaches to nanotechnology summarized earlier.

1. Information disclosure would provide a mechanism for giving real-world significance to the research program that everyone supports, without attempting to use it for regulation prematurely.
2. A disclosure program would defer any need for broad federal regulation, by empowering more flexible and small scale approaches to problems, while simultaneously generating the experience that could serve to make any future regulations more rational, should they prove necessary. Indeed, the **existence** of a

⁶ EPA has adopted such a formulation for required disclosures under the Safe Drinking Water Act.

disclosure program would motivate self-regulation far beyond the significance of any actual disclosures that it might require.

3. Applying PMN requirements to nanotechnology could help provide information for a disclosure program. Indeed, it could do this even in the period before EPA developed analytical tools robust enough to support decisions to keep new chemicals off the market.⁷

V. Conclusion

In recent years information disclosure has emerged as a new and promising method of achieving the same end results as traditional regulation by more flexible and less expensive means. Such disclosure seems ideally adapted in many ways to address the open-ended health and environmental concerns raised by nanotechnology development without stifling its potential benefits. However, actually creating a workable disclosure system would require an agency with the authority and capacity to vary disclosure requirements using its own discretion to keep them current with scientific and economic developments. Creating such a workable power would require overcoming undeniable issues and challenges, but there is no reason to believe this could not be done.

⁷ However, a disclosure program could be set up perfectly well without this extension of PMN requirements. Since there are plenty of other reporting authorities in federal law, and plenty of sources of disc losable information that do not require mandatory reporting, the designers of such a program would also have to decide the extent to which the disclosure authority would base its disclosures on reports required from members of the industry, the extent to which it would rely on other information, and the extent to which the agency would have discretion to make this decision.