

REGULATING BERKELEY'S NANOTECH FUTURE

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Nanotechnology offers the promise of revolutionizing the material sciences, but it may also pose substantial threats to public health and the environment. At present, there is a dearth of related toxicology research and there is no consistent regulatory framework for illuminating and articulating the risks and uncertainties of nanotechnology. Javiera Barandiaran examines the City of Berkeley's new public nanotechnology disclosure ordinance, providing suggestions for its improvement as well as recommendations for other governments looking to develop their own policies.

Nanomaterials provide exciting opportunities for new applications because their physical and chemical behavior is very different from that of larger materials. As initial toxicity research shows, their biological behavior is also different, exhibiting the ability to cross biological barriers that previously seemed impermeable and accumulating and dispersing through the environment in ways still little understood. These reasons, together with the likelihood for long-term risks derived from chronic exposure, make the potential threats posed by nanomaterials far too severe to ignore. Looking back at the history of toxic substance regulation, it is precisely these types of risks that have been hardest to manage. Prominent examples are asbestos and lead, as opposed to nuclear power that has the potential for a high level of damage from just one exposure.

Nanotechnology's Growing Economic and Research Impact

Nanotechnology refers to scientific and commercial research and development that takes place at the atomic or molecular levels. This is smaller than a human cell: on the scale of proteins and DNA or, put in terms of size, at a scale of approximately one to one hundred nanometers in any dimension. To be considered nanotechnology, the technology must create and use "structures, devices and systems that have novel properties and functions because of their small

size," with emphasis on our new technical capacity to control and manipulate matter at this scale.¹ The importance of nanotechnology lies not in the scale or size alone, but on the potential to apply size-dependent qualities innovatively and functionally—that is, leveraging the effects of nanotechnology's minute scale for some new, useful purpose.

At least two key factors differentiate nanoscale materials from the same materials at a larger scale. Because of their size, and certain chemical properties that come from such a small size, nanomaterials are more chemically reactive than larger materials. The other important factor that separates nanomaterials from their larger counterparts is that nanomaterials are subject to visible quantum effects.

As a result, nanomaterials behave differently from what we know and expect of larger materials. These differences allow us to use conventional materials in new ways, bringing improvements to currently available technologies for application in areas such as drug testing and delivery, environmental remediation, sensors, manufacturing, energy production and delivery, optics, and many others.² Examples of research efforts underway include: cheaper methods for cleaning arsenic from water; food wrapping that can detect spoiling, thereby reducing both the disposal of still good food and the consumption of spoiled food; solar panels that require less material and that are more efficient and cost-effective; and drugs that can be more

accurately delivered to the area in need of treatment, meaning less damage to surrounding healthy tissues and more effective therapeutics in a smaller dose.

Aggressive commercial research and development is not the only bellwether for nanotechnology's growing importance. In February 2007 the EPA published its second Nanotechnology White Paper, laying out a list of priorities for toxicology research as well as recommendations for which government agencies should participate in this process. The EPA estimates that global nanotechnology research and development spending in 2006 was around \$9 billion.³ Last year, the National Science Foundation invested \$5.4 million in ethical, legal, and social research and education related to nanotechnology.⁴ The Woodrow Wilson Center has created a consumer products inventory that currently catalogues almost 500 consumer products which use nanotechnology in some way.

Amidst all of the excitement about the potential economic and social benefits of nanotechnology, it is increasingly believed that nanotechnology has the potential to pose serious toxicity risks to human health and the environment. While a small amount of toxicology research has been conducted, a general consensus exists that these efforts need to be greatly increased.⁵ Some examples of the dangers that nanomaterials pose include:

- Health hazards

- o Researchers have observed that inhaled nanoparticles can reach sensitive areas of the human body, such as bone marrow, lymph nodes, the heart, or the central nervous system. Similarly, they can penetrate the skin and absorb into lymphatic channels.⁶
- o Other potentially hazardous health effects involve a kind of molecule, called a dendrimer, used for drug delivery. Research indicates that certain characteristics of the surface of a dendrimer can lead it to cross or upset the blood-brain barrier, a particularly sensitive part of the human body that is normally impermeable to external bodies.⁷

- Environmental Hazards

- o Very little is known about the potential environmental impacts of nanomaterials, but it does appear that nanomaterials cross cell membrane barriers of plant and animal species. They also accumulate in the natural environment and absorb into plants and animals if deposited in the environment. However, some mitigating effects may exist and these processes are little understood.⁸

Nanotoxicity is a complex phenomenon because not all nanomaterials are toxic nor are those that are toxic all toxic in the same way. For example, two common types of nanomaterials, quantum dots and fullerenes, have been found to have both toxic effects and beneficial antioxidant effects for human health.⁹ A significant amount of research is focused on identifying the key characteristics of nanomaterials that are associated with toxicity. Some recent findings, as summarized at a recent conference on the state of nanotoxicity, include:¹⁰

- A large surface area compared to the mass of a nanoparticle (surface-to-mass ratio) is associated with toxicity in the case of poorly soluble particles, like titanium dioxide.
- Small size is associated with toxicity in the case of airborne nanoparticles. For instance, airborne nanoparticles of carbon appear to interfere with the immune system, potentially increasing susceptibility to infections.
- Pre-existing conditions may sometimes be necessary for nanomaterials to pose a particular hazard. For example, asthma sufferers that inhale nanoparticles accumulate more in the lungs than among non-asthma sufferers.
- Carbon nanotubes are among the most common nanomaterials. Research indicates the degree to which they pose a health threat to the lungs depends on the amount inhaled or the use of different chemical coatings on the nanotube, among other factors. Scientists find that metal coatings such as iron pose the health threat earlier than the carbon nanotubes themselves.

- Translocation is a particular type of health effect, and refers to the ability of nanoparticles to cross from one organ or tissue to another. Again, not all nanomaterials behave in a similar fashion. While gold nanoparticles appear to be able to cross the blood-air barrier of the lungs, the nanomaterial technegas is now found to translocate to a lesser degree than previously thought.

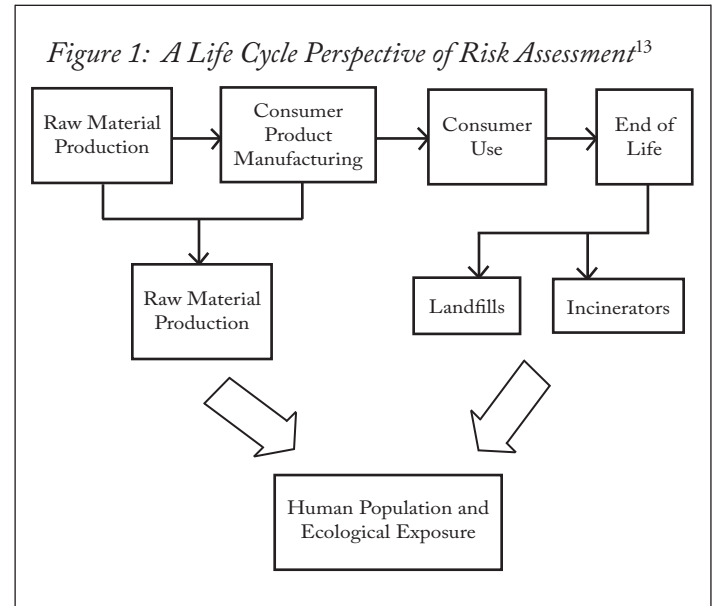
Research about toxicity needs to be greatly increased. It may be erroneous to assume that no evidence of toxicity means there is no risk. Given current knowledge, toxicity should be assessed for each nanomaterial.¹¹ There is sufficient reason to believe that at least some nanoparticles will have adverse environmental and health effects. Our understanding of when nanomaterials are toxic, how they disperse in the body and the environment, and why they have the effects that they do, is insufficient. We must develop a set of standards for toxicity testing and risk management.

In addition, the common measures used to regulate chemicals, such as weight, volume and mass, do not capture all the relevant variables that effect the potential for toxicity of nanomaterials. Currently, hazardous substances are regulated if more than a certain quantity is handled. Because of their scale, nanomaterials would fall outside these quantities in all cases. Therefore the current regulatory framework may be inadequate for managing nanomaterials.

Given what we know now, the main risks of nanomaterials derive from the potential for chronic exposure. Because of their small size, the total quantities of nanomaterials handled at any one site are likely to be very small. A spill or nanomaterial disaster is therefore unlikely. Rather, adverse effects from chronic exposure over time, (as in the case of asbestos) is the most likely risk scenario regulators should consider.

Third, other chemical properties of nanomaterials are more important in determining the potential for toxicity. For example, because nanomaterials are so small, they have a very high surface-to-mass ratio (a large surface with little filling). In addition, different chemicals can be used to coat nanomaterials. Both of

these properties make nanomaterials very chemically reactive compared to bulk chemicals.¹²



Regulating Nanotechnology

Regulation will be required to facilitate the transfer of nanotechnologies from the laboratory to the market, and to ensure that the potential hazards of nanomaterials are adequately addressed. This regulation will need to work toward sufficient labeling and classification standards. There is also a need for regulations that define nanotechnology, create incentives for toxicity research, and disseminate accurate information to consumers, researchers, and communities.¹⁴

Letting present trends continue or calling for a research moratorium—as some advocacy interests, such as the ETC Group, have done—are impractical and undesirable options. Present trends are seeing far too low a level of toxicity research into nanomaterials, and the potential economic and social benefits of nanotechnology are far too great to abandon. It is not within society's interests to ban or impede nanotechnological research, nor is it in society's interest to ignore the serious health and environmental risks nanotechnology poses.

Currently, the regulatory debate centers on whether nanomaterials should be regulated using existing frameworks—for example, the Toxic Substances Control Act (TSCA), the Occupational Safety and Health Act (OSHA), the Food and Drug Administration (FDA) and a collection of other laws ranging from the FIFRA act regulating pesticides to pollution control legislation— or through a new, nano-specific framework.¹⁵

This debate focuses on at least three distinct issues. First, it is open to interpretation whether or not nanomaterials are new chemicals as defined in TSCA

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or hazardous materials as defined in the Health and Safety Code. The Health and Safety Code defines a hazardous material as “any material that because of its quantity, concentration, or physical or chemical characteristics, poses a significant present or potential hazard to

human health and safety or the environment if released into the workplace or the environment.”¹⁶ For the moment, groups pushing to regulate nanomaterials tend to interpret that nanomaterials are hazardous materials in order to apply existing laws. However, this view could easily be contested legally and, given the stakes, a clearer legal mandate with which to manage nanomaterials is desirable in the long run.

Second, there is growing consensus that the current regulatory framework not only inadequately addresses the potential hazards of nanotechnology,¹⁶ but also inadequately addresses the hazards of chemicals generally. In particular, extensive research by federal agencies and academic institutions points to the failures of TSCA to “assess the hazards of chemicals in commerce or control those of greatest concern.”¹⁷

Given these failures, the argument for a new and improved nano-specific framework gains force. Society and long-term economic development would benefit from a more comprehensive reform of TSCA. The recent efforts in the European Union to strengthening

chemical regulation is increasingly seen as an example to follow.¹⁸

Finally, as explained above, nanomaterials differ from chemicals in that toxicity is more a function of their physical and chemical properties than of the quantity being handled. This difference shifts the focus of regulation from emergency preparedness to exposure control and should be reflected in the type of data collected under ‘right to know’ frameworks.

Berkeley, California

The City of Berkeley, California recently adopted a nanotechnology disclosure ordinance, embedded within the hazardous materials business plan (HMBP) and subject to the same definitions and conditions as other chemical substances.¹⁹ Any facility that produces or handles manufactured nanoscale materials—defined as “manufactured nanomaterials that are engineered and which have a dimension less than 100 nanometers”²⁰—must submit a yearly report. The aim is to provide a flexible mechanism by which local groups inform the City government of the potential toxicity of the nanomaterials being used and, if the user determines there is a risk, what measures they have taken to minimize exposure and hazard to workers and the community.²¹

As the first of its kind, the Berkeley ordinance will no doubt serve as a model for further local disclosure initiatives. Cambridge, Massachusetts has already expressed interest in mimicking this ordinance.²² Furthermore, the Berkeley ordinance could make collecting a large amount of specific information on nanomaterials possible; it is one of the cities with the highest concentrations of nanoscale research being conducted due to the presence of the University of California and Lawrence Berkeley National Laboratory.

The ordinance establishes a matrix combining a nanomaterial’s degree of toxicity and the public’s risk of exposure to guide decisions on how to manage certain classes of nanomaterials.²³ The ordinance describes four possible control bands, from low risk (low toxicity, no exposure) to high risk (high or unknown toxicity, high exposure). Materials falling into the 3rd or 4th control band are subject to a ‘high level of control measures.’ In this way, while the ordinance does not exempt any material from the reporting require-

ment, it does allow that some materials be subject to a higher management standard than others.

The aim of the Berkeley ordinance is to compel laboratories using nanomaterials to inform local government and the community of the materials they are using, how much they know of their potential toxicity, and the measures they are implementing to contain potential risks, with the objective of contributing to a wider debate on nano-regulation.²⁴ While this is a valuable first step – toxicity tends to go unmonitored unless there is a requirement to do so²⁵ – the City of Berkeley will have great difficulty enforcing the ordinance and evaluating the claims of laboratories.

Recommendations for Improving the Berkeley Ordinance

To evaluate the claims of laboratories working with and producing nanomaterials, greater information on toxicity needs to be available. This requires not only a significant expansion of the amount of toxicity research being conducted but also an improved dissemination mechanism for this information. This is a shared responsibility of researchers, industry and government that is largely beyond the means of local government. Nonetheless, in the current political context and given the large gaps in information that now exist, introducing certain improvements in the disclosure form now being used by the City of Berkeley could help further these aims.

A streamlined disclosure format facilitates compliance;²⁶ however the ordinance's disclosure form was published as a text document with open questions. Laboratories are more accustomed to reporting chemicals using a closed, questionnaire style document. Although laboratories can choose to report using a closed format,²⁷ the use of the open format has produced information that is difficult to analyze and process, especially for a city government with limited human and financial resources.

This format will negatively affect the process of linking specific nanomaterials to particular characteristics that pose health or ecological hazards. Furthermore, the lack of clear data to be recorded hinders efforts at comparative research and the cross-referencing of other databases or regulations. For example, a questionnaire style reporting form could ask for specific quantities of nanomaterials being used as

well as information on the surface-to-mass ratio, use of coatings, shape, and other details of nanomaterials.

The requirements of the ordinance fail to capture some key characteristics of nanomaterials considered to be important for their potential toxicity. Among other things, the ordinance asks for the "average and maximum daily amount of the material stored (in metric units), chemical form (solid, liquid), particle dimensions and approximate mass." While this information is considered sufficient to manage the risks of bulk materials, it is known to be insufficient to characterize the risks of nanomaterials because the potential for toxicity depends also on factors like shape, surface-to-mass ratio, surface coatings, surface characteristics and reactivity potential. The ordinance does not specifically ask for critical data on these or other relevant factors for nanotoxicity. While the information collected by the ordinance fits well with the needs of the hazardous materials business plan, the debate on how to regulate nanomaterials would benefit more from the development of a reporting form that begins to get at the key factors of nanotoxicity.

We recommend the design of a closed format for the reporting of nanomaterials that incorporates more variables considered critical in determining the toxicity of nanomaterials. The development of this tool should (1) be based on recent efforts to create a standardized nomenclature of nanomaterials, (2) be conducted with help of professionals and (3) aim to provide useful information on nanotechnology for the protection of public and worker safety.

Nanomaterials Nomenclature

In December 2006 ASTM International (originally known as the American Society for Testing and Materials) published the first nano-specific nomenclature.²⁸ In February 2007 Dupont and Environmental Defense published a nano-risk framework that outlines in great detail what factors of nanotoxicity should be recorded at each stage of a material's life cycle;²⁹ ISO International has set up a working group on nanomaterials with a subgroup on environmental and health effects commissioned to develop standard definitions and metrics. Finally, the Berkeley Nanotechnology Exchange (BNE) is developing a nanomaterials database to facilitate

commercialization. The development of a standard nomenclature would facilitate the process of integrating information gathered from different sources and the pairing of data on nanomaterials with potential environmental and health effects. Although the development of standards is a slow process that will not be completed for possibly several years, government entities should begin to use these classifications in order to test their adequacy for public reporting.

Collecting more information on the physical and chemical properties of nanomaterials using the standardized formats being developed by industry and researchers can contribute to the development of categories of materials subject to stronger control bands. Developing a more complex matrix of control bands with better defined standards of management – including the possibility of identifying classes of nanomaterials which should be exempt from regulation – should be a key objective of government as a means to implementing and enforcing standards that better protect public health and the environment.

Disclosure regulation based on nanomaterials standards, like those being developed by ASTM or ISO, can help test whether the data necessary for effective regulation is being covered by these evolving standards before they become finalized. Once a definition or set of parameters are adopted as the industry standard, changes to this framework become more difficult to pursue. For this reason, government entities seeking to manage nanomaterials should seek to influence this process by adopting ordinances that test the concepts and assumptions adopted by industry before a standard is adopted.

Working with both Scientists and Environmental, Health and Safety Specialists

While local government has a very limited capacity to influence how toxicity research is done, it could play a greater role in promoting the exchange and accumulation of data on toxics research. In addition to written reports, government could host government-industry-university meetings in which these actors provide some information on the toxicity of nanomaterials in exchange for access to other information which is costly and difficult to produce. In this way, an inventory of data on toxicity that aggregates

the research efforts of industry and academics can be developed. This inventory would need to be compiled in a standardized format, as described above.

The Berkeley nanomaterials ordinance is an example of an information-based regulatory mechanism. Following the public goods theory of government, information on nanotoxicity is very likely to be underprovided by unregulated market mechanisms, and could be particularly well-suited to government efforts to aggregate, process and distribute the information. Not only is this the result of the character of information itself (competing firms have few incentives to create and share information that is costly for them to produce but practically free to distribute) but it is also critical for building trust among citizens and for leveling the field of competition among firms. Only large firms are likely to be able to afford the costs of toxicity testing for nanomaterials, placing small firms such as start-ups at a clear disadvantage. However, from the public's point of view, large firms alone may not have the necessary credibility to assure a concerned citizenry.

The collaboration of research scientists and government in the production, validation and distribution of publicly available information is important for achieving both ends. Such meetings can take many forms, from a permanent advisory panel to an annual conference. The greatest difficulty is developing specific methods to encourage industry and academy participation. An ideal type of collaboration would aim towards a mechanism in which commercial and non-commercial research facilities freely exchange information based on the expected benefits derived from learning about the toxicity of nanomaterials they have not tested, from participating in the crafting of government regulations, and hopefully from resulting increases in public confidence. The end product would be a nanomaterials toxicity inventory that is accessible to laboratories, government agencies and the public.

Working Toward Useful Public Information

The final step in the process described above regards public access to nanotoxicity information. Right-to-know legislation, which the Berkeley ordinance is, operates under the belief that citizens

and consumers have a right to know about potential risks and that they will use such information to make better decisions about their behavior. Mechanisms which allow consumers to distinguish product safety can contribute to the creation of long-term, market-based incentives for toxicity research.³⁰ Market-based incentives of this sort are seen by many to be more effective than command and control mechanisms—a category into which disclosure ordinances could fall—for the long-term management of the risks of nanomaterials.

For this reason, some sectors are calling for the introduction of a consumer nanotechnology label.³¹ While this may eventually be desirable, it needs to be considered more carefully. Currently it is unclear what consumers understand about nanotechnology³² and it may be unreasonable to expect consumers to base their decisions on complex scientific information and terms that are difficult for non-specialists to understand. Given the range of materials and applications of nanotechnology, it seems desirable to begin to differentiate, in the public perception, specific applications of nanotechnology.

This is difficult to do in the absence of clear standards and definitions for nanomaterials because different stakeholders have no criteria on which to organize and evaluate information.³³ This ambiguity contributes to a false perception of nanotechnology as a single, monolithic body of research, when it is best characterized as an “enabling technology” with direct impact on a vast range of materials, processes and applications.³⁴ Several negative effects develop from this ambiguity. For example, the Woodrow Wilson Center’s Consumer Products Inventory relies on manufacturers’ or some other source’s claims about whether a product uses nanotechnology.³⁵ In this context, consumers are unable to choose safer products, and market-based incentives for toxicology research are foregone. Finally, this lack of clarity can foster feelings of distrust in government institutions that can be projected on the whole of nanotechnology rather than on the specific materials or applications that pose hazards.³⁶

Based on these factors, it is worth considering alternatives to a consumer product label. One possibility is to develop a company certification standard

for laboratories that meet the government’s disclosure requirements and participate in a nanomaterials toxicity inventory as described above. The purpose of the certificate would be to signal to both the public and workers that efforts are being made to develop nanotechnology responsibly. Not only would such a certification program avoid the need to assess each individual product (it is much simpler to assess companies), it would also initially send a signal to workers who currently face the most risks from exposure to nanomaterials. The knowledge that some companies do more than others to develop nanomaterials responsibly may influence researchers when they are choosing between potential employers.

Conclusion

The above recommendations aim to build an inventory of data on the toxicity of nanomaterials in order to stimulate further debate on nanotechnology regulation and improve the data on which future regulation is based. Clearly, the debate on nanotechnology regulation is much broader than the challenges involved in collecting information. The information collected would contribute forcefully to many of the pending state and national legal and political debates on nanotechnology regulation. Because nanomaterials are so varied, an inventory on toxicity would greatly clarify the issue. Such a framework would both facilitate and add transparency to the decisions regarding when to apply higher standards of exposure control and containment, how to legally define nanomaterials and structures and what information on safety consumers need to know.

As the first government-led effort to collect data on toxicity, how the information assembled by the Berkeley ordinance is used and organized could have important consequences for the regulation of nanomaterials. In addition, the Berkeley ordinance is likely to be replicated over the next several years by other local governments. In this scenario, it would be extremely useful to be able to integrate different data sets of nanomaterial information. Furthermore, it is critical that local government initiatives test the adequacy of the standardized categories and variables for the protection of public health and the environment.

Endnotes

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