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Getting Nanotechnology Right the First Time

Environmental Defense's perspective on responsible nanotechnology development
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Nanotechnology has great potential to deliver environmental (as well as other) benefits. The novel properties that emerge as materials reach the nano-scale – changes in surface chemistry, reactivity, electrical conductivity, etc. – open the door to innovations in cleaner energy production, energy efficiency, water treatment, environmental remediation, lightweighting of materials, among other applications, that will provide direct environmental improvements.

At the same time, these novel properties may pose new risks to workers, consumers, the public and the environment. The limited data now available demonstrate the potential for some nanomaterials to be both persistent and mobile in the environment and in living organisms; to cross the blood-brain barrier; and to be capable of damaging brain, lung and skin tissue. This trickle of data only highlights the fact that we know so little about the environmental and health effects of engineered nanomaterials.

As illustrated by asbestos, CFCs, DDT, leaded gasoline, PCBs, and numerous other substances, the fact that a product is useful does not ensure it is benign to health or the environment. And if it proves harmful after widely entering commerce, the consequences go beyond human suffering and environmental harm to include lengthy regulatory battles, costly clean-up efforts, expensive litigation quagmires, and painful public-relation debacles.

In our view, both the public and private sectors' best interests are served by an investment to identify and manage potential nanotechnology risks now, rather than to pay later to remediate resulting harms. Yet the rapid development and commercial introduction of nanomaterial applications is outpacing our efforts to understand their implications – let alone ensure their safety. Thousands of tons of nanomaterials are already being produced each year, and hundreds of products incorporating nanomaterials are already on the market. The global market for nanotechnology products is expected to reach at least $1 trillion over the next decade. Given the length of time it will take to develop an adequate understanding of the potential risks posed by a wide variety of nanomaterials, and to apply this knowledge to inform appropriate regulation, it is imperative that substantial funding is dedicated to comprehensive risk research programs *now*.

The *risks* at issue here are not only those related to health and the environment, but also risks to the very success of this promising set of technologies: If the public is not convinced that nanotechnology and nanomaterials are being developed in a way that identifies and minimizes the risks to human health and the environment, we can be virtually assured of a backlash that will delay, reduce, or even prevent the realization of many of the potential benefits of nanotechnology.

Complexity of defining nanomaterial risks

There is broad agreement among stakeholders that addressing the potential risks of nanotechnology will be an unusually complex task. Despite its name, nanotechnology is anything but *singular*; it is a potentially limitless collection of technologies and associated materials. The sheer diversity of potential materials and applications – which is a source of nanotechnology's enormous promise – also poses major challenges with respect to characterizing potential risks. Nanotechnology entails:

- many fundamentally different types of materials (e.g., metal oxides, quantum dots, carbon nanotubes), and hundreds or thousands of potential variants of each;
- many novel properties potentially relevant to risk (e.g., size, structure, reactivity, surface chemistry, electrical and magnetic properties)
- many potential types of applications (e.g., fixed in a matrix vs. freely available, captive vs. dispersive use);
- many categories and types of uses (e.g., medical devices, pharmaceuticals, environmental remediation, and consumer products ranging from cosmetics to electronics);
- multiple points of potential release and exposure over the full lifecycle of a given material/application (e.g., during production, use, disposal);
- multiple potential means of release (e.g., in emissions, in wastes, from products);
- multiple potential routes of exposure (e.g., inhalation, dermal, oral);
- multiple potentially exposed populations (e.g., workers, consumers as well as public); and
- potential to cause environmental as well as human health-related impacts.

Scope of needed research

Even before the research that will allow hazards and exposures to be quantified, a number of more fundamental needs must be addressed. We currently lack a good understanding of which specific properties will determine or are otherwise relevant to nanomaterials' risk potential. Many of the methods, protocols and tools needed to *characterize* nanomaterials, or to *detect and measure* their presence in a variety of settings (e.g., workplace environment, human body, environmental media) are still in a very early stage of development.

Nor is it clear the extent to which we can rely on our existing knowledge about conventional chemicals to predict risks of nanomaterials. The defining character of nanotechnology – the emergence of wholly *novel* properties when materials are reduced to or assembled at the nano-scale – carries with it the potential for novel risks and even novel mechanisms of toxicity that cannot be predicted from the properties and behavior of their bulk counterparts. By their very nature many nanomaterials are more reactive per unit mass than their conventional counterparts. For example, aluminum in the form used in many applications, such as the ubiquitous soda can, is prized because of its lack of reactivity, but it becomes highly explosive in nano-form – hence its potential use as a rocket fuel catalyst.

Moreover, we already know that even extremely subtle manipulations of a nanomaterial can dramatically alter its properties and behavior: Tiny differences in the diameters of otherwise identical quantum dots can alter the wavelength of the light they fluoresce; slight changes in the degree of twist in a carbon nanotube can affect its electrical transmission properties. We have yet to develop the means to sufficiently characterize or systematically describe such subtle structural changes – a clear prerequisite to being able to consistently and rigorously apply and interpret the results of toxicological testing. And only then can we begin to assess the extent to which such subtle structural changes may affect the toxicity of a material – or the extent to which such a property is stable or may be transformed in the environment or the human body.

Until these threshold questions about nanomaterials' potential risks are answered, it is unclear whether or to what extent we will be able to rely on methods widely used to reduce the amount of traditional toxicological testing needed to characterize conventional chemicals: the ability to identify "model" materials, which upon characterization could serve as a basis for extrapolation to "like" materials.

Among the types of risk research needed are the following:

- Material characterization (in manufactured form(s), during use, in emissions, in wastes, in products; in environmental media, in organisms)
- Biological fate (extent and rate of absorption, distribution, metabolism, elimination)
- Environmental fate and transport (persistence, distribution among media, transformation)
- Acute and chronic toxicity (related to both human and ecological health)

For each of these areas, existing testing and assessment methods and protocols need to be re-examined to determine the extent to which they can be modified to account for nanomaterials' novel characteristics or need to be supplemented with new methods. Similar challenges will arise with respect to methods and technologies for sampling, analysis and monitoring, all of which will be needed to detect nanomaterials and their transformation products in living systems and in various environmental media.

What needs to be done?

We believe that there is a real opportunity to advance nanotechnology in a responsible manner that acknowledges risks, takes the steps necessary to address them, and meaningfully engages the full array of stakeholders to help shape this technology's trajectory – in short, the opportunity to "get it right the first time."

We see four key needs:

- First, government needs to use its existing capabilities and authorities, or develop new ones as needed, to ensure that the risks of nanomaterials are identified <u>before</u> they are incorporated into products for commercial production. Far more government research dollars need to be spent on health and environmental implications of nanotechnology, to ensure that the critical research needed to identify potential risks is done, and done expeditiously. Of the roughly $1 billion that the U.S. federal government is spending annually on nanotechnology, we are calling for at least $100 million annually to be dedicated over at least the next several years specifically to nanomaterial risk identification.

- Second, government needs to provide for the comprehensive management of those risks that are identified – from a full life-cycle perspective, taking into account worker safety, manufacturing waste, product use, and product disposal. An objective assessment is needed of the capacities and regulatory authorities of the various government agencies – one that clarifies roles and responsibilities and identifies changes needed to address current gaps and uncertainties that may create "nano-loopholes" in regulatory oversight. In our view, serious gaps appear to be constraining the ability of U.S. federal agencies to give more than limited scrutiny to nanomaterials, especially those that have conventional, previously approved bulk counterparts.

- Third, because we do not expect government action to happen overnight, industry itself needs to develop and drive widespread adoption of "standards of care" for responsible nanotechnology development. Such standards should employ a comprehensive risk identification and management process both prior to and following commercialization of nanomaterial-containing products.

- Lastly, both government and industry needs to do a far better job engaging the broad array of stakeholders outside government and industry – labor, health organizations, consumer advocates and environmental NGOs – whose constituencies stand to be both beneficiaries of this technology and those most likely to bear any risks that arise. All too often, "stakeholder involvement" translates in practice into either communicating the end result of a process to those who have been excluded (whether intentionally or by default) from participating in it, or seeking to "educate" the public in order to promote a technology and allay fears or concerns believed by the proponents to be unfounded or irrational.

  Engagement is NOT simply top-down communication, whether about benefits or risks or before or after the fact. It means involving stakeholders from the outset in helping to identify their expectations and concerns, and providing a role for them in helping to set research priorities and agendas. And many of these stakeholders not only have a stake or interest in nanotechnology, they also have relevant perspective, experience and expertise to offer.

These steps can help to ensure that nanotechnology is developed in a safe and responsible manner, such that its benefits are realized while appropriately identifying and managing its potential risks.

Conclusion

The rapid commercialization of nanotechnology, coupled with the clear risk potential of at least certain nanomaterials demonstrated in initial studies, lends urgency to the need for governments to direct more of their major investments in nanotechnology development toward research aimed at identifying the potential risks and the means to address them. There is a remarkable degree of agreement among experts and stakeholders from a range of perspectives on both the need and the urgency. There is also considerable agreement that assessing these risks will be a complex task, given the range of materials and potential applications involved and the current lack of knowledge and experience with such materials. A broad scope of research will be needed, first to identify the key characteristics of nanomaterials relating to hazard and exposure; second, to adapt existing or develop new testing methods; and third, to actually assess the magnitude of hazard and exposure potential of specific nanomaterials.

Government initiatives on nanotechnology to date have done a great job in accentuating and accelerating the enormous potential benefits of nanomaterials. To date, however, governments have yet to come to terms with their equally critical role in identifying, managing and ideally avoiding the potential downsides. A far better balance between these two roles must be struck if nanotechnology is to deliver on its promise without delivering unintended and unforeseen adverse consequences.

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