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Matthew Hull
Diana Bowman

NANOTECHNOLOGY ENVIRONMENTAL HEALTH AND SAFETY

Risks, Regulation and Management

Micro & Nano Technologies Series

Nanotechnology Environmental Health and Safety:

Risks, Regulation and Management

Edited by

Matthew Hull
Diana Bowman

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Micro- and Nanotechnologies

Series Editor: Jeremy Ramsden

Professor of Nanotechnology, Microsystems and Nanotechnology Centre, Department of Materials, Cranfield University, United Kingdom

The aim of this book series is to disseminate the latest developments in small-scale technologies, with a particular emphasis on accessible and practical contents. These books will appeal to engineers from industry, academia, and government sectors.

Foreword

Andrew D. Maynard

Back in 2001, I had the privilege of visiting Richard Smalley's laboratory at Rice University. I was working with a team measuring the airborne release of single walled carbon nanotubes as they were produced and handled. The work led to some of the first published data on possible inhalation exposures to nanotubes, but my abiding memories of that visit are of Rick's overwhelming enthusiasm for this innovative new material, and a rather relaxed attitude among his research team to prevent exposure. Wipe your finger along any surface in the lab it seemed, and it would come away black.

Carbon nanotubes epitomize the tension between realizing the promise of emerging engineered nanomaterials and avoiding possible new risks. Carbon nanotubes are quite unlike anything else we have had in our materials construction set—strong, lightweight, highly conductive of heat and electricity, and able to be combined with other materials in innovative new ways. They have uses as wide ranging as better batteries to stronger materials and transparent conductors to anti-radiation sickness drugs. Yet there are hints that they could be uniquely harmful to humans and the environment if they get to the wrong place, in the wrong form. Successful and much-needed carbon nanotube-based applications will depend on identifying and managing these possible risks.

Carbon nanotubes are just one of countless new engineered nanomaterials being developed though. And while the tension between benefits and risks may not be as pronounced in many cases, using these new materials successfully will still depend on understanding how to handle them safely.

In *Nanotechnology Environmental Health and Safety: Risks, Perspectives and Management*, Matthew Hull and Diana Bowman have succeeded in bringing together a strong cast of authors with a variety of perspectives to shed light on uncertainties currently being faced by an expanding nanomaterial community. By outlining the issues confronting researchers and manufacturers, as well as some of the nascent risk management options available, they have produced a practical resource for anyone grappling with the challenge of using engineered nanomaterials as safely as possible.

Following that first visit to Richard Smalley's lab, there was a marked change in attitudes. Enthusiasm for the potential uses of carbon nanotubes remained unabated. But work practices were tightened up beyond all recognition. Using knowledge on possible risks together with advice on good hygiene practices, the team successfully slashed the chances of potentially harmful exposures occurring.

My sense is that this book is set to have the same impact, but on a broader audience. It won't tell you everything you need to know on how to use engineered nanomaterials safely—that would be an impossible task, given all that we still don't know. But it will help researchers, producers, and users of these materials take steps toward significantly reducing the chances of harm occurring.

Andrew D. Maynard
July 12, 2009

Series Editor's Preface

Whereas, formerly, societies stumbled upon their consensuses seemingly through a series of accidents with much backtracking, in our present globalized society we feel that they should be reached through a much more rational process, informed by reliable and comprehensive knowledge. This book has been assembled very much in that spirit of promoting such rational decision-making. The object of discussion is the impact, focusing on health and safety aspects, of nanotechnology on the human environment. Uniquely, it combines technological aspects (i.e., the toxicology of nano objects) with issues of regulation (i.e., legal aspects, covering both the USA and the European Union) and management of the risks. As is customary in the series, there is a strong emphasis on practical matters rooted in reality—for example, the book includes several case studies in the section on risk management.

The authors point out that in some situations current knowledge is too scanty to be able to make a fully rational decision. Indeed, with a technology as new as nanotechnology, this situation is rather common. Individual inventors and companies will nevertheless press ahead, without waiting for the rationally designed regulatory framework to be in place. This somewhat chaotic reality must be encompassed in any practically useful risk assessment, making it a much more complex matter than in well-established industries.

It is sobering, even alarming, to realize that although Strabo the Greek and Pliny the Elder documented the health dangers arising through contact with asbestos about 2000 years ago, this knowledge was not sufficient to prevent the ghastly diseases resulting from exposure to amphibole asbestos that became such a prominent part of occupational medicine in the latter part of the twentieth century. In fact, formal risk assessment is a relatively new area, the first one being carried out by the US Environmental Protection Agency in 1975. This inability, or unwillingness, to learn from knowledge accumulated in the past intrudes, seemingly irrationally, into the orderly vision of the knowledge-based economy. Before the invention of printing, knowledge was indeed a rare commodity that could only be shared with difficulty. Nowadays, in principle at least one can conveniently access a vast quantity of scientific and technical literature from a desktop computer, thanks to the World Wide Web. Yet, paradoxically, citation patterns in the primary research literature increasingly provide evidence that researchers read less, and are generally less aware of past and even contemporary knowledge. This problem will also need to be addressed, if it is not to become a real barrier to the responsible development and use of advanced technology in the twenty-first century.

As the authors point out, the overarching question is how to maximize the benefits of nanotechnology while minimizing the risks. The contributions in this book provide a wealth of information and analysis that will be of immense value to companies, government departments, and other organizations involved in insurance, developing regulatory and legal frameworks, and in guarding their workforces against undue hazards. It will also serve as an important milestone in the further development of the theoretical basis of the subject.

Jeremy Ramsden
September 2009

Preface

Matthew S. Hull, Diana M. Bowman and Steffi Friedrichs

Risk is a reality. And while innovative management frameworks, policies, protective strategies, and regulation can do much to reduce the risks associated with certain products or activities, seldom can they eliminate those risks entirely. Technological advancements in a modern age, ranging from the introduction of the automobile through to, for example, biotechnology and the comforts that accompany them, are no different. Such advancements come pre-packaged with their own unique set of risks and trade-offs.

Indeed, *progress has never been a bargain; you have to pay for it*.[1] Exactly how much we are willing to "pay" for progress—new technologies and the products derived from them—is usually established through risk tolerance thresholds that materialize through society's perceptions (factual or otherwise) of the technology. While this will vary over time and between jurisdictions, it will nevertheless involve a complex interplay between social attitudes and culture, economics, politics, history and science. What is acceptable to some in terms of risk may not therefore be acceptable to all.

Some thresholds, usually those that have developed over time and with input from practical experience or hard data, can be quite clear and well established. Such thresholds readily lend themselves to translation into legislative instruments, regulations (state or non-state based), or standards. Other thresholds, however, particularly those still in their formative stages, can be remarkably amorphous and dynamic. In these latter situations, there is simply too little information available to fully assess the actual risks or even the benefits to society, and the decision of whether or not to proceed is likely to become increasingly clouded and complex.

It is the inseparable nature of risk and reward that underlies the current debate surrounding the emergence of nanotechnologies. And it is the manner in which stakeholders in different jurisdictions have risen to address this issue that motivates the present work. The aim of this book is to provide

[1] Quote from 'Inherit the Wind', 1960, Stanley Kramer Productions.

readers with a snapshot of perspectives on the potential environmental health and safety (EHS) risk, posed by some facets of the technology and risk management strategies from individuals who have helped shape the evolving nanotechnology EHS landscape.

According to an oft-cited definition, nanotechnology is the study of phenomena governed by novel properties arising from the diminutive size of an object, which includes at least one dimension of 1–100 nm (National Nanotechnology Initiative, 2001). For reference, the common flu virus is 40 nm in diameter, while the width of a human hair is typically more than a thousand times larger. From nano-scale size and control arise extraordinary new properties not found at other size scales; for example, carbon nanotubes (a cylindrical shape with a diameter of up to 100 nm, and a lengths of up to several microns) possess tensile strength many times that of steel, but with only a fraction of the weight; nanoscale titanium particles offer novel photocatalytic properties; and nanoscale quantum dots possess tunable fluorescent properties attributable to quantum confinement effects.

Over the last two decades, and during a period that many would suggest represents only its infancy, the field of nanotechnology has spurred some of the most exciting advancements in science, engineering, and manufacturing since the industrial revolution. According to some commentators we are in the midst of a 'Nano Revolution' (see, for example, Merkle, 2000; Drexler, Peterson and Pergamit, 2003; Sparrow, 2008). This so-called [r]evolution has 'erupted' or 'evolved'—depending on one's view—from the development of new instruments and the subsequent convergence of enhanced capabilities to visualize and manipulate materials at the molecular scale with large-scale investment by the public and private sectors on nanotechnology initiatives.

Given the current rate of progress, it is difficult to predict precisely what nanotechnology-enabled innovations will emerge in the years ahead. However, as evidenced by talk of space elevators (Appell, 2002; Pugno, 2006) and Crichton's (2002) shape-shifting nanoassemblers, the absence of a clear development trajectory certainly has not stifled imaginations. For curious readers seeking a more pragmatic perspective on forthcoming nanotechnologies, Roco (2004) has described four distinct generations of nanotechnology-enabled structures and devices whose emergence coincides to some degree with the acquisition of the scientific and engineering capabilities necessary to actually produce them. Of course, technology is disruptive by nature and sometimes imaginations rule the day!

Amidst the excitement over undeniable progress in nanoscale science and engineering, one fact remains: *in the past, society has been taught some cruel and lasting lessons by the promise of new technologies*. Such lessons have been comparatively frequent and hard-learned for new classes of chemicals or materials and examples abound in recent history: while extremely effective at controlling insect-borne disease, DDT and similar pesticides had unintended negative effects on reproduction of avian predators; although regarded as exceptional coolants and aerosol propellants, chlorofluorocarbons (CFCs) have been linked to depletion of the earth's protective ozone layer; and finally, while once hailed as a miracle mineral of natural origin, with applications in myriad products ranging from building materials to automotive products, asbestos—as discussed by Mullins in his chapter – has become synonymous with a legacy of chronic respiratory disease and class-action litigation.

What is perhaps most interesting about these cases is that they are all relatively recent and their effects are still rippling through society. Unlike previous generations, it would appear that modern society has been conditioned to question not only the acute risks of emerging technologies, but also those potential risks that may lie just beyond the grasp of current scientific understanding. We have become highly sensitized to the societal risks of new technologies, and while this new-found sensitivity is accompanied rightly or wrongly by a degree of cynicism, it also fosters a level of *techno-trepidation* that can be put to good use to usher in advancements in science and engineering in a safe and responsible manner.

It would be unbalanced, however, to consider in this discussion only those examples or aspects of technologies that had unintended negative consequences on society. Just as the past century has highlighted the potential dangers of new technologies, they have also demonstrated technology's extraordinary utility in overcoming many of humankind's greatest challenges. DDT, for example, has been credited with saving millions of lives in developing countries ravaged by malaria. Such facts cannot be ignored. But what if those lives could be saved without potentially catastrophic consequences to ecosystems? What if advanced materials could be created without compromising the health of millions of workers who manufacture them? These are the questions that must be considered when weighing the potential benefits and risks of any new technology.

As remarkable as recent advancements in nanotechnology have been, the world's proactive engagement of emerging nanotechnology EHS risks—both known and unknown—has been remarkable in its own right. Internationally, governments have included in national nanotechnology research initiatives language specifically mandating funding of risk-related research. While the adequacy, effectiveness, and legitimacy of many of these activities have been questioned (see, for example, Powell and Colin, 2008; Friends of the Earth Australia, 2009), they nevertheless represent a dramatic shift from the development-focused paradigm of the past. Along with government-led programs, a number of corporations, non-profit organizations and academic research institutions have developed their own nanotechnology-specific risk management initiatives. While not completely altruistic in nature, some of these initiatives demonstrate industry's recognition of the fact that when it comes to the risks of new technologies and products, a sound business case can be made for behaving proactively rather than reactively. Trade organizations, international standards committees, and professional services providers have also weighed in on the nanotechnology EHS debate, expressing both concerns about risk and potential measures to mitigate them.

Nanotechnologies are no longer confined to the laboratory, and industrial-scale nanomanufacturing is a commercial reality around the globe. In Africa, the South African Nanotechnology Initiative (SANi) (2009) includes efforts to synthesize nanoscale particles for applications in solar cells, catalysis, fuel cells, and composite materials. In Asia, companies are now manufacturing multi-ton quantities of carbonaceous fullerenes and nanoscale silver particles. Firms in Australia manufacture nanotechnology-enabled products ranging from metal oxide nanoparticle sunscreens to highly branched, nanoscale materials known as dendrimers. In North America and the European Union, a diverse and robust nanomanufacturing industry has emerged, with the capability of producing anything from semiconducting quantum dots to multi-ton quantities of metallic oxide nanoparticles and carbon nanotubes. And in South America, an extensive network of government and industry supported nanotechnology research centers has emerged, along with strong nanotechnology-focused collaborations with international partners in India, Africa, and the European Union.

To conclude, the question before us is this: *How do we extract and ensure the benefits of nanotechnology, while minimizing potential and often ill-defined risks?* The chapters that follow consider this question through the experiences of representatives from academia, trade unions, Fortune 500 corporations, entrepreneurs, insurers, nanotechnology facility managers, and experts in product liability and environmental law. The result, we trust, is a balanced discussion of the emerging nanotechnology EHS landscape, coupled with practical strategies developed to manage these risks in nanotechnology facilities of varying size and complexity.

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List of Contributors

Robert Blaunstein

Dr Blaunstein is the past President of Nanotech Risk Management, providing technical, underwriting, and risk management advisory services. Clients include the insurance and reinsurance industry, financial entities, and technology developers to identify and implement risk management solutions to the EHS, product liability, and general liability risks associated with nanotechnologies. Dr Blaunstein is currently the Director of Environmental Underwriting at Markel Insurance Company, West Coast Regional Office. Previous positions have included Vice President for Risk Assessment at AIG Consultants, American International Group, and Managing Director for Seneca Insurance Company's Environmental Casualty Profit Center. Dr Blaunstein was an Assistant Professor of Physics at the University of Tennessee and a Consulting Scientist to the Oak Ridge National Laboratory where he lectured and conducted research in the area of atomic and molecular physics. He is a frequent lecturer at nanotechnology conferences and has published extensively in the area of nanotechnology risk management.

Diana M. Bowman

Diana M. Bowman is a Senior Research Fellow in the Center for Regulatory Studies, Faculty of Law, Monash University. Diana is also a Visiting Scholar in the Faculty of Law, K.U. Leuven, and the Center for Technology, Ethics, and Law in Society, King's College, London. Diana's research has focused primarily on legal and regulatory and public health policy issues relating to new technologies, with a particular focus on nanotechnologies. She is a co-editor (along with Graeme Hodge and Andrew Maynard) on the forthcoming book *International Handbook on Regulating*

Nanotechnologies. Diana has published widely in the area of regulating new technologies, with over 50 articles and book chapters in this field.

Steffi Friedrichs

Dr Steffi Friedrichs is the Director of the Nanotechnology Industries Association (NIA), globally the only industries-focused trade association in nanotechnology, providing a sector-independent, responsible voice for the industrial nanotechnologies supply chains. In this capacity, she has given evidence to numerous expert committees and regulatory organizations; she initiated in-depth programs in support of the ongoing advancement of nanotechnologies and participated in many stakeholder debates and citizen's engagement panels. Steffi joined the NIA from The Technology Partnership, where, as a Senior Nanotechnology Consultant, she was responsible for the development of nanotechnology innovations and contributed to the tendering and due diligence processes for the MNT Network (Department of Trade and Industry, UK Government).

Steffi started her scientific career with an undergraduate degree in "Diplom-Chemie" at the Technical University of Braunschweig (Germany), before taking a DPhil at the University of Oxford (UK), specializing in single-walled carbon nanotubes (both synthesis and toxicology). She subsequently held a Fellowship at Oxford University and a Lectureship in Nanotechnology at Cambridge University.

Matthew S. Hull

Matthew S. Hull is the President of NanoSafe, Inc., a nanotechnology environmental health and safety services company headquartered in Blacksburg, Virginia (US). He is also a doctoral student and National Science Foundation IGERT Fellow in the Virginia Tech Department of Civil and Environmental Engineering. Prior to returning to Virginia Tech, Matthew directed and participated in research programs exploring applications and implications of nanotechnology for agencies ranging from the US Department of Defense to the UK Department of Environment, Food, and Rural Affairs (DEFRA). In 2005, while working with a commercial nanomanufacturer, Hull developed the NANOSAFE™ risk management framework for commercial nanotechnology companies. That framework would go on to spin-off programs focused on web-enabled nanotechnology EHS management systems, nanotechnology waste recovery and recycling processes, and life-cycle ecotoxicological studies of nanomanufacturing.

Igor Linkov

Dr Igor Linkov is an Adjunct Professor of Engineering and Public Policy at Carnegie Mellon University and a Research Scientist with the US Army Engineer Research and Development Center. Dr Linkov has managed multiple ecological and human health risk assessments and risk management projects. Many of his projects have included application of the state-of-the-science modeling and software tools to highly complex sites and projects (e.g., restoration and remediation planning, insuring emerging risks, risk-based prioritization of engineering projects). He has published widely on environmental policy, environmental modeling, and risk analysis, including 10 books and over 100 peer-reviewed papers and book chapters. Dr Linkov has served on many review and advisory panels for DHS, EPA, NSF, EU and other US and international agencies. He is DOD representative at the Interagency Working Group on Nanotechnology Environmental and Health Implications (NEHI). The Governor of Massachusetts has appointed Dr Linkov to serve as a Scientific Advisor to the Toxic Use Reduction Institute. He is the recipient of the 2005 SRA Chauncey Starr Award for exceptional contribution to risk analysis.

John C. Monica, Jr.

John C. Monica, Jr has considerable litigation experience in defending national and international products liability claims for Fortune 500 companies. He is a nationally recognized authority on nanotechnology product liability issues. As a member of American National Standards Institute and American Society for Testing and Materials, John participates in the development of voluntary international nomenclature and EHS standard for the nanotechnology industry. Additionally, he has successfully represented numerous clients in a variety of general commercial litigation matters in state and federal courts. John is the Associate Editor for legislative/regulatory affairs, *Nanotechnology Law & Business*, and has authored numerous articles on nanotechnology. John has a JD with honours from George Washington University School of Law and a BA from Northwestern University.

Steve Mullins

Steve started in the union movement 10 years ago as an Industrial Officer at the Actors and Journalist Union. For the past 7 years he has worked at the

Australian Council of Trade Unions in the ACTU's commercial arm and then filling the Acting International Officer role before taking up the ACTU's OH&S Policy Officer position in 2004. Steve represents the interests of working people on Safe Work Australia and on other government and non-government bodies. Steve is also an Al Gore-trained Climate Project presenter.

Michele L. Ostraat

Dr Michele L. Ostraat, Senior Director for the Center for Aerosol Technology at RTI International, has expertise in aerosol technology, nanoparticle applications, submicron particle processing, micro- and nanofiber filtration, portable nanoparticle detection, occupational safety and health of nanoparticles, and inhalation toxicology. Before joining RTI, Dr Ostraat worked at DuPont's Experimental Station with primary responsibilities in the aerosol synthesis and characterization of submicron and nanoparticles for a variety of electronic and materials applications. She earned her PhD (2001) and MS (1998) degrees in Chemical Engineering from the California Institute of Technology. Dr Ostraat has authored numerous research publications in the areas of aerosol nanoparticle synthesis, characterization, and electrical properties, holds six patents, and has given over 45 conference presentations and invited talks.

Annette B. Santamaria

Dr Annette B. Santamaria is a Senior Manager in the Health Sciences Practice of ENVIRON International Corporation and is located in Houston, Texas. She is a board-certified toxicologist and has extensive experience evaluating human health risks associated with exposure to a variety of consumer products, pharmaceuticals, medical devices, food additives, personal care products, nanomaterials, and industrial chemicals. She developed the Nanotoxicology Specialty Section of the Society of Toxicology. Dr Santamaria has an MPH from the Johns Hopkins School of Public Health and Hygiene and a PhD in toxicology from the University of Texas School of Public Health.

Christie M. Sayes

Dr Christie M. Sayes is an Assistant Professor at Texas A&M University with appointments in Veterinary Physiology and Pharmacology, Biomedical