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# NANOTECHNOLOGY ENVIRONMENTAL HEALTH AND SAFETY

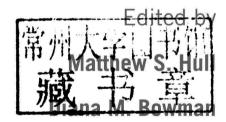
Risks, Regulation, and Management

Second Edition

# Nanotechnology Environmental Health and Safety

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William Andrew is an imprint of Elsevier The Boulevard, Langford Lane, Kidlington, Oxford OX5 1GB, UK 225 Wyman Street, Waltham, MA 02451, USA

First edition 2010 Second edition 2014

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# **British Library Cataloguing-in-Publication Data**

A catalogue record for this book is available from the British Library.

#### Library of Congress Cataloging-in-Publication Data

A catalog record for this book is availabl from the Library of Congress.

ISBN: 978-1-4557-3188-6

For information on all William Andrew publications visit our Web site at www.store.elsevier.com

Printed and bound in the US

14 15 16 17 18 10 9 8 7 6 5 4 3 2 1



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# Foreword

The original idea of a book on *Nanotechnology Environmental Health and Safety: Risks, Regulation, and Management* was conceived 10 years before the publication of this second edition. Back in 2004, many were talking about the innovation power of what is sometimes called a general purpose technology (GPT), such as electricity or information technologies. Even more were talking about the potential risks associated with the giant leap forward that nanotechnologies promised to deliver.

Fast forward by 10 years, and we are now looking at the second edition of a book of the same title. This edition yet again aims to provide a mere "snapshot of perspectives on the potential environmental health and safety (EHS) risks posed [by nanotechnologies]," as was highlighted by the co-editors, Matthew Hull and Diana Bowman, in the preface to the first edition.

On first glance, it looks like not much has changed between the first edition and today's second edition. Some chapters carry the same title, and those speaking of uncertainties of the impact of nanomaterials on environmental and human health are still plentiful, and are thus continuing to fuel the ongoing debate on the potential need for nanospecific regulation. A debate, in itself is as lively as it was 10 years ago. It is in the detail and evidence brought forward to this ongoing debate, however, that progress of the last decade manifests itself. This second edition captures the very essence of the debate's current focus on "applying what we have learned about nanotechnology EHS risks to help realize the promise that nanotechnology offers in achieving a more sustainable future," as highlighted by Hull and Bowman in Chapter 1. Indeed, today's second edition illustrates the progress in understanding the potential ecotoxicological effects of nanomaterials, with a special emphasis on the role of data-mining and informatics tools to ultimately predict the hazard profile of specific types of nanomaterials. Such technological progress is echoed in the change of the labor union perspective since the last edition, supported by vivid descriptions of the careful precautionarydriven practices in some academic institutions and industrial organizations. In doing so, these organizations are contributing vastly to what we know about nanomaterials' EHS issues. Ultimately, the efforts of these leading organizations enable stakeholders to integrate the safety aspects in a more holistic view of nanotechnologies' pivotal role and contribution to more sustainable industrial processes and products.

So, as we are harvesting the fruits of the last decade's tireless research examining the safety of nanomaterials, we have begun to feel confident about working with nanomaterials. This has been achieved while maintaining a level of appropriate precaution that allows us to distinguish that which we know, based on accumulating evidence, from that which we do not yet fully know. In support of this, it is important to note that the very scope and design of regulation allows for uncertainties to be accounted for, so that not every innovative step forward requires a corresponding novel regulation. It is in front of this provision that the highly interdisciplinary research areas of nanotechnologies and nanosciences have steadily progressed, so that we are now looking upon significant advances in the understanding of nanoscale phenomena and the

impact of their applications on the environment and society. We continue to improve the methodologies of measurements and tests to ultimately render them more specific to nanoscale materials—an innovation, which in itself is based on understanding gained through nanotechnologies. Relevant toxicological endpoints for nanomaterials have been confirmed to be identical with those of conventional chemicals. And expert committees around the world have repeatedly, and independently, come to the conclusion that the risk assessment paradigm currently used to assess general chemical safety also holds for the specific cases of nanomaterials.

At the same time—and seemingly in contradiction to the scientific advances described above—the demand for nanospecific regulations, and mandatory reporting schemes and registers, has developed in the opposite direction to the progress achieved in the safety assessment of nanomaterials. A number of regulatory provisions have been implemented since the publication of the first edition: the European Commission has published a regulatory definition of the term "nanomaterial"; several Regulations and Directives of the European Union now contain specific articles on nanomaterials; and manufacturers, importers, and distributors of nanomaterials in France must comply with a mandatory reporting scheme, which many other countries are now considering adapting for their own jurisdictions. By contrast, other jurisdictions have settled for the application of regulatory tools developed for chemicals, such as the Pre-Manufacturing Notices and Significant New Use Rules issued by the United States Environmental Protection Authority, and the addition of industrial nanomaterials to the Australian National Industrial Chemicals Notification and Assessment Scheme.

We have yet to see if the regulatory provisions for nanomaterials launched to date are actually reliably and effectively implementable both from a technical perspective (e.g., the European Commission's regulatory definition of nanomaterials, over three years after its publication, still lacks reference to a reliable method to establish if something is a nanomaterial), and from an economic perspective (e.g., industries estimate that over 50% of all currently produced and used materials are "nanomaterials" according to the European Commission's regulatory definition). Moreover, we have yet to see if these regulatory provisions are ultimately deemed appropriate. The latter question relies on an assessment, which in itself "will depend on past experiences, different views on risk, benefits, innovation, and broader societal considerations, and the degree to which the instruments favorably or unfavorably impact upon [our] behavior or that of others," as Diana Bowman already pointed out in this book's first edition and revisited in an updated chapter in today's second edition. These words (and indeed this book) highlight the pivotal importance of stakeholder perception (in all its culturally biased and individually formed aspects) to this ongoing debate.

Considering the conundrum of interdependent arguments and conclusions, it is not surprising that the differences between this book's first edition and today's second edition are subtle, but none-the-less important: the chapter entitled "Two steps forward, one step back" describes how many of us stakeholders that continue to participate sometimes feel in this debate aimed at maximizing the benefits and minimizing the

often ill-defined risks, as the overarching question of the first edition was described by its authors.

This, however, is a dance, not a sufferer's procession. And the individual steps and movements, not the distance covered since its start, are its most important elements, in that they have resulted in the directionality toward the ultimate innovation challenge that governments, civil society organizations, and industries are now collaboratively addressing for nanotechnologies: "Safe-by-Design." This second edition is an important milestone in the advancements toward this holistic concept of innovation, in that it highlights the progress achieved in the last decade and reflects upon the very elements that form the backbone of the Safe-by-Design concept. This concept is already being adopted by both industry-led initiatives and publically funded projects, as well as several tailor-made public-private partnerships. Collectively, these efforts are now aiming to address the overarching question of this book by minimizing a product's potential risks while designing it to maximize its benefits.

Steffi Friedrichs Director General Nanotechnology Industries Association February 2, 2014

# List of Contributors

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Anders Baun is a professor in risk assessment of nanomaterials at the Department of Environmental Engineering, Technical University of Denmark. He has a M.Sc. in Environmental Engineering (DTU, 1994) and holds a Ph.D. in Environmental Chemistry and Ecotoxicology (DTU, 1998). His main research area is environmental risk assessment of nanomaterials. He is an expert member of several international committees on nanomaterials and risk, e.g., EU's Scientific Committee for New and Emerging Risks (SCENIHR) and the Swiss Research Foundation Programme for Nanotechnology. In 2011, he received the European Research Council's Starting Grants for Excellent European Researchers.

### **Amy Bednar**

Amy Bednar is a research mathematician at the U.S. Army Engineer Research and Development Center (ERDC, Vicksburg, MS). She performs numeric analyses, develops numeric models, utilizes artificial techniques, and develops software application tools. She led the development of NanoExPERT (Nanomaterials Experiment-based Predictor of Environmental Risk and Toxicity). Amy is currently incorporating automated feature detection into the VANE (Virtual Autonomous Navigation Environment). She earned her B.S. in Applied Mathematics (Spring Hill College), M.S. and Ph.D. in Mathematics with an emphasis in Topology (University of Mississispi).

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Richard Berry is the Vice President and Chief Technology Officer of CelluForce. He holds 13 patents, has published over 80 articles and two monographs, and has extensive expertise overseeing the industrial application of his inventions. He received the 2009 Nano-industry award from NanoQuébec for his contributions to position Canada as a global leader in the Nanocrystalline Cellulose industry. He received the 2012 Purvis Memorial Award, and is one of Canada's Clean 50 honorees. He has received numerous Industry awards and is a TAPPI Fellow. He received his Ph.D. in Chemistry from McGill University.

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Robert (Bob) Blaunstein is the past president of Nanotech Risk Management, an advisory service to the insurance and reinsurance industry. He was the Executive Director of the NanoInsurance Forum, a nonprofit organization supporting members on nanotechnology and insurance issues. Previously, Bob was the Director of Environmental Underwriting at Markel Insurance Company, West Coast Regional Office. He was the managing director of Seneca Insurance Company's Environmental Profit Center and vice president for Risk Assessment at AIG Consultants, American International Group. He was a member of the Physics faculty at The University of Tennessee and a consulting scientist to the Oak Ridge National Laboratory.

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#### Diana M. Bowman

Diana Bowman is an assistant professor in the Department of Health Management and Policy and the Risk Science Center, School of Public Health, at the University of Michigan and a visiting scholar at the Faculty of Law, KU Leuven. Her research has focused primarily on legal and policy issues relating to new technologies, including nanotechnologies, and public health law. Diana is the co-editor of five books including *International Handbook on Regulating Nanotechnologies* (2010, with Hodge and Maynard) and *International Handbook on Road Safety* (forthcoming, with Fitzharris and Billingsley). She earned a B.Sc. (Physiology), a LL.B., and a Ph.D. (Law) from Monash University. In August 2011, she was admitted to practice as a Barrister and Solicitor of the Supreme Court of Victoria (Australia).

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Rachael Born is a Masters student in Electrical Engineering at Virginia Tech, where she also serves as a research assistant in the Institute for Critical Technology and Applied Science (ICTAS). She received her Bachelor's degree from the College of William and Mary in a self-designed major, Environmental Physics. Rachael is interested in sustainability as it relates to energy, the environment, and society.

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Mark Chappell is a research physical scientist in the Environmental Laboratory (EL) at the U.S. Army ERDC (Vicksburg, MS). He leads the Soil & Sediment Geochemistry Team (SSGT), which conducts a wide range of basic and applied research on the geochemical fate and transport of environmental contaminants. He holds a Ph.D. in Soil Science from the Iowa State University and has authored over 50 peer-reviewed publications, technical reports, and book chapters, including one book. Mark currently leads the Army's research efforts in the application of environmental life cycle impact assessment models to new materiel acquisitions.

#### Jessica Coleman

Jessica Coleman is a research biologist at the U.S. Army Engineer Research and Development Center (ERDC, Vicksburg, MS). Her research interests include investigating impacts of emerging materials to terrestrial and aquatic environments through evaluation of biological interactions. She is involved in civil and military projects assessing the impact of munitions, nanomaterials, and metal contaminants in the environment. Jessica is serving as task lead to develop validated, scientific methods for the characterization of products incorporating nanomaterials under

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Steve Diamond is the Vice President, Midwest Division, NanoSafe, Inc. where his focus is the safe development and implementation of nanotechnology. Over his 20+year career, he has published peer-reviewed reports describing fate, effects, and risk assessment of a broad range of environmental stressors, including heavy metals, PAHs, petroleum, and ultraviolet radiation, and more recently, on environmental health and safety of manufactured nanomaterials. He was formerly task lead for US EPA's research effort on the ecotoxicology of nanomaterials, has contributed to the work of the Organization for Economic and Cooperative Development (OECD), and has served on review panels for several international research efforts. Steve earned a M.S. and a Ph.D. at Miami University, Ohio.

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Angus Donohoo is a graduate in arts (philosophy of science, University of New South Wales), law and physics (both from the Australian National University). He is currently undertaking a Ph.D. under the ARC Discovery Grant on globalizing artificial photosynthesis and coordinating year 1 in the ANU Medical School Professionalism and Leadership (PAL) program under the mentorship of Prof. Faunce.

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Steffen Foss Hansen is an associate professor in Regulatory Engineering at the Department of Environmental Engineering, Technical University of Denmark. He conducts research into risk analysis, regulation, and governance of nanotechnologies, and the applicability of decision-making tools under uncertainty. He is the project leader at DTU for several national and international research projects, e.g., the FP7 project Sustainable Nanotechnologies. Steffen has several scientific publications including three in Nature Nanotechnology, and he is involved in expert advisory groups on nanotechnology set up by the World Health Organization and the European Chemical Agency.

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Jake Gatof received his B.A. with High Honors from the University of Michigan in Political Science with a minor in International Studies: Global Health & Environment.

He is in his second year at the University of Michigan Law School and anticipates receiving his Juris Doctor (J.D.) in May 2015. Jake is the president of the Michigan Health Law Organization, a Student Attorney in the Entrepreneurship Clinic, and works as a research assistant in the School of Health Management and Policy for Professor Bowman. He will be joining the law firm Goodwin Procter LLP in Boston this summer (2014) as a summer associate.

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Igor Linkov is a focus area lead with the US Army Engineer Research and Development Center and an adjunct professor at CMU and Ca Foscari University of Venice. He is leading projects focused on integration of risk assessment, decision analysis, and life cycle assessment methods for managing nanotechnology risks. He has published widely, including 13 books and over 200 peer-reviewed papers and book chapters. He serves as the US Army Representative in the National Nanotechnology Initiative. Igor was the recipient of the 2005 Society for Risk Analysis (SRA) Chauncey Starr Award for exceptional contribution to Risk Analysis and SRA Fellow Award.

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Karmann Mills is a research engineer with RTI International and has nine years of nanotechnology research experience, specifically, in the areas of cement technologies and nanofiber products for solid-state lighting and air filtration applications. As the task leader for the Nanomaterial Registry project, she supervises the curation process. She also maintains the website content and leads outreach activities to extend awareness of the Registry as a tool for the community. Karmann holds a B.S. in Polymer and Color Chemistry from North Carolina State University and a M.S. in Fiber Science from Cornell University.

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John Monica is a partner in the Washington, DC Office of Porter Wright Morris & Arthur LLP where he leads the firm's multidisciplinary nanotechnology practice group. He was named as one of the top 10 experts in environmental, health, and safety issues related to engineered nanoscale materials by Nanotechnology Law

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Brian O'Connor is a program manager in charge of environmental research at FPInnovations (Pointe Claire, Quebec, Canada). He received his Ph.D. in organic chemistry from McGill University and held a postdoctoral fellowship at Purdue University. His expertise encompasses issues relevant to the pulp and paper industry such as environmental assessment of new products, environmental impact in receiving waters, best management practices for effluent treatment performance, and energy/resource recovery from solid residues. Brian also leads regulatory efforts at FPInnovations related to the commercialization of nanocrystalline cellulose (NCC) in the United States and Canada.

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