

Contents

Preface.....	ix
About the Editor.....	xi
About the Contributors.....	xiii
CHAPTER 1 Challenges in Nanoparticle Risk Assessment	1
1.1 Introduction	1
1.2 The Nature of the Engineered Nanomaterial Challenge.....	6
1.3 The Problem with Definitions	8
1.4 Principles-based Problem Formulation for Engineered Nanomaterials	10
1.4.1 Emergent Risk.....	10
1.4.2 Plausibility	10
1.4.3 Impact	11
1.5 Applying the Principles to Engineered Nanomaterials.....	11
1.5.1 Materials Demonstrating Abrupt Scale- specific Changes in Biological or Environmental Behavior	12
1.5.2 Materials Capable of Penetrating to Normally Inaccessible Places	12
1.5.3 Active Materials.....	13
1.5.4 Materials Exhibiting Scalable Hazard that is Not Captured by Conventional Risk Assessments.....	13
1.6 Looking Forward.....	13
CHAPTER 2 Assessing Exposures to Nanomaterials in the Occupational Environment.....	21
2.1 Nanotechnology and Nanoparticles	22
2.2 Exposure Routes.....	23
2.2.1 Inhalation.....	23
2.2.2 Dermal.....	25
2.2.3 Ingestion	25
2.3 Measurement of Health-related Exposure Metrics.....	26
2.4 Instrumentation.....	31
2.4.1 Real-time Measurements.....	33
2.4.2 Time-integrated Measurements	36
2.5 Exposure Assessment Strategy	37
2.5.1 Basic Characterization.....	39
2.5.2 Exposure Assessment	44

CHAPTER 3 Hazard and Risk Assessment of Workplace Exposure to Engineered Nanoparticles: Methods, Issues, and Carbon Nanotube Case Study	65
3.1 Introduction	65
3.1.1 Risk Assessment Paradigm.....	66
3.1.2 Hazard Assessment.....	67
3.1.3 Dose–Response Assessment.....	71
3.1.4 Temporal Extrapolation	73
3.2 Case Study Example: Carbon Nanotubes.....	74
3.2.1 Data Description.....	74
3.2.2 Severity of Effects	75
3.2.3 Risk Assessment Steps: Benchmark Dose Estimation.....	77
3.3 Discussion	83
3.3.1 Comparison to Other Methods	83
3.3.2 Research Needs	87
3.3.3 Future Directions.....	88
3.4 Appendix: Pulmonary Ventilation Rate Calculations.....	89
3.4.1 Rat Ventilation Rate.....	90
3.4.2 Human Ventilation Rate	90
CHAPTER 4 Pulmonary Bioassay Methods for Evaluating Hazards Following Exposures to Nanoscale or Fine Particulate Materials.....	99
4.1 Introduction and General Background	99
4.2 What Is Postulated About the Lung Hazards of Nanoparticle Exposures.....	100
4.3 Species Differences in Lung Responses to Inhaled Fine and/or Ultrafine TiO ₂ Particles	101
4.4 Pulmonary Bioassay Studies	102
4.4.1 Pulmonary Bioassay Studies of Fine and Nanoscale TiO ₂ Particle-types	103
4.4.2 Pulmonary Bioassay Studies of Fine and Nanoscale α -Quartz Particle-types.....	105
4.4.3 Safe-Handling of Nanoscale Particulates in the Laboratory	106
CHAPTER 5 Using Expert Judgment for Risk Assessment.....	109
5.1 Uncertainties in Risk Assessment	110
5.1.1 Challenges and Uncertainty in Data Collection, Extrapolation, and Modeling	111

Preface

5.2	Limitations of Existing Methodologies for Risk Assessment and Precedents for Using Expert Judgment	112
5.2.1	Traditional Risk Assessment	112
5.2.2	Using Expert Judgment in Risk Assessment	114
5.3	Eliciting Expert Judgment – Selection of Experts, Elicitation Protocols and Best Practices	115
5.3.1	Expert Performance on Elicitation Tasks	115
5.3.2	Elicitation Methods and Best Practices	118
5.4	Arriving at Consensus Risk Estimates	123
5.5	The Use of Expert Judgment for Nanoparticle Risks	124
5.5.1	Uncertainty in Characterizing Health Risks from Nanoparticles	125
5.5.2	Challenges for Expert Judgment with Emerging Nanotechnologies	130
5.6	Conclusions.....	132
CHAPTER 6	Risk Assessment Using Control Banding	139
6.1	Introduction.....	139
6.2	Challenges Related to the Traditional Industrial Hygiene Approach	141
6.3	CB Nanotool	143
6.3.1	Severity Factors	145
6.3.2	Probability Factors	149
6.4	Evaluation of the CB Nanotool	152
6.4.1	Severity.....	153
6.4.2	Probability	154
6.4.3	Addressing Expert Opinion	156
6.5	Considerations for the Nanotechnology Industry.....	160
6.6	Conclusion.....	161
CHAPTER 7	Controlling Nanoparticle Exposures.....	167
7.1	Introduction	167
7.2	The Hierarchy of Control	168
7.3	Criteria for Prioritizing Control Options	170
7.4	Form of Nanomaterials.....	171
7.5	Local Exhaust Ventilation.....	172
7.5.1	Exterior Hoods	172
7.5.2	Ventilated Enclosures	173
7.6	Air Pollution Control Devices.....	176
7.6.1	Electrostatic Precipitators.....	176
7.6.2	Air Filters.....	177
7.6.3	Filter Performance Over Time.....	182

7.7	Work Practices.....	184
7.8	Personal Protective Equipment.....	184
7.8.1	Protective Clothing and Gloves.....	186
7.8.2	Respiratory Protection.....	187
7.9	Summary and Recommendations.....	190
CHAPTER 8 Addressing the Risks of Nanomaterials under United States and European Union Regulatory Frameworks for Chemicals		195
8.1	Introduction	196
8.1.1	Terminology: Nanosciences, Nanotechnologies, and Nanomaterials	197
8.1.2	Different Generations of Nanotechnologies.....	198
8.1.3	Commercial and Economic Dimensions	198
8.1.4	Environment, Health and Safety (EHS) Risks: Scientific Knowledge and Uncertainty	200
8.2	US Chemicals Regulation	202
8.2.1	The Toxic Substances Control Act	202
8.2.2	The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)	212
8.3	European Union Chemicals Regulation	217
8.3.1	Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH)	217
8.3.2	Pesticides	224
8.3.3	REACH and Nanoscale Substances	225
8.3.4	Nanomaterials as “Substances” Under REACH..	228
8.3.5	Quantitative Thresholds.....	229
8.3.6	Inventories and Reporting Requirements	230
8.3.7	Timing of REACH Implementation	231
8.3.8	Bulk versus Nano Forms of Substances	232
8.3.9	Testing Methods	233
8.4	Comparative Analysis.....	234
8.4.1	Key Factors.....	234
8.4.2	Background	236
8.4.3	Premanufacture Review and Registration Requirements.....	238
8.4.4	Information and Data-collection Requirements.....	241
8.4.5	Regulatory Controls	245
8.5	Conclusion.....	248
Index		273