

Table of Contents

<i>Acknowledgements</i>	v
<i>Table of Cases</i>	xiii
<i>Table of Legislation</i>	xvii
<i>Introduction: Regulating the Invisible</i>	xxix
1. Setting the Scene: Nanotechnologies and their Regulation at the EU Level	1
I. What are Nanotechnologies?	1
II. Between Nanomania and Nanophobia.....	3
III. Risk as a Rationale for Regulatory Intervention.....	5
IV. The EU's Approach to the Regulation of Nanotechnologies:	
A Bird's Eye Perspective.....	7
A. The EU's Incremental Approach to Nanotechnologies.....	7
B. The Legislative Review.....	9
C. Complementary Elements.....	11
V. Conclusion.....	12
2. Regulating in Today's Nano Society	14
I. Embedding the Regulation of Nanotechnologies in Its Societal Context	14
A. Globalisation	15
B. Functional Differentiation	16
C. The Rise of the Risk Society	17
D. Through the Lenses of Nanotechnologies	19
II. Regulating in Today's Nano Society: Two Theoretical Accounts	20
A. A Deliberative Account	20
B. A Reflexive Account.....	23
C. Grasping the 'Procedural Turn'	26
III. Translating the Debate to the EU Level	27
A. The Rise of 'New Modes of Governance'	28
i. The White Paper on European Governance	30
ii. The Concept of 'New (Modes of) Governance'	31
B. The Rise of European Risk Regulation	33
i. Risk Analysis	35
ii. Precaution.....	36
IV. Conclusion and Next Steps.....	38

3. Analysing EU (Risk) Regulation through the Lenses of Regulatory Capacity	40
I. Defining the Object of Analysis: ‘EU Regulation’	40
A. <i>Excursus</i> : Law, Regulation and Governance.....	40
B. Defining ‘Regulation’.....	44
C. The Regulatory Spectrum at the EU Level	45
i. Public–Private.....	45
ii. Legal Effect.....	46
D. The Object of Analysis: ‘EU Regulation’	49
II. Putting on the Analytical Lenses of Regulatory Capacity.....	49
A. First Element: Pooling Knowledge	50
i. Defining ‘Knowledge’	50
ii. The Impact Assessment as a Procedure to Pool Knowledge	51
iii. Extending the Impact Assessment Procedure to Parliament and Council.....	55
B. Second Element: Ensuring Legitimate Regulation.....	57
i. Defining ‘Legitimacy’	57
ii. Participation at the EU Level	59
iii. Holding the EU Regulator to Account.....	64
III. Conclusion.....	70
4. Nanotechnologies in Food	72
I. Nanotechnologies in Food.....	72
A. Innovating Food Production and Processing	72
B. Applications of Nanotechnologies in Food.....	73
i. Nanomania: Exploiting Nanotechnologies for the Food Sector.....	74
ii. Nanophobia: Environmental, Health and Safety Risks of Nanofoods.....	75
C. The EU Food Industry and Nanotechnologies	76
II. The EU Regulatory Framework for Nanotechnologies in Food.....	77
A. EU Legislative Framework for Food: Fit for Nano?.....	77
i. The General Food Law	78
ii. Specific EU Food Law.....	79
iii. State of Play: A Cautious European Commission	85
B. Addressing Nanotechnologies via the Executive Route.....	86
i. Via Comitology: Implementing Acts under the FCM Regulation	87
ii. Via Agency Guidance Documents: EFSA’s Guidance on Risk Assessment of Nanotechnologies in Food and Feed.....	88

iii.	Via Commission Recommendations: Defining the Term ‘Nanomaterial’	89
iv.	Synthesis: Towards Executive Rule Making.....	93
III.	Analysing the EU’s Regulation of Nanofoods through the Lenses of Regulatory Capacity.....	94
A.	Pooling Knowledge.....	94
i.	The Impact Assessment: A Tool to Pool Knowledge?	95
ii.	Knowledge Collection through Commission Expert Groups.....	99
iii.	Knowledge Collection in the Drafting of EFSA’s Guidance Document	101
iv.	Synthesis: Pooling Knowledge in the Drafting of a Regulatory Framework for Nanotechnologies in Food.....	103
B.	Participation.....	106
i.	Political Participation.....	107
ii.	Administrative Participation	108
iii.	Synthesis: Participation in Nano Practice	117
C.	Accountability.....	118
i.	Political Accountability vis-à-vis the European Parliament.....	118
ii.	Legal Accountability: The Role of the EU Courts.....	123
iii.	Administrative Accountability: Making Way for the EU Ombudsman.....	133
iv.	Social Accountability: A Transparent Regulatory Process?	136
v.	Synthesis: Holding the EU Regulator to Account	140
IV.	Conclusion.....	141
5.	Nanotechnologies in Chemicals	144
I.	Nanotechnologies in Chemicals.....	144
A.	Innovating Chemicals.....	144
B.	Applications of Nanotechnologies in the Chemicals Sector.....	145
i.	Nanomania	146
ii.	Nanophobia	147
C.	The EU Chemicals Sector and Nanotechnologies	148
II.	The EU Regulatory Framework for Nanotechnologies in Chemicals.....	148
A.	Reforming the EU Chemicals Policy	148
i.	REACH and Its Main Pillars.....	150
ii.	REACH and Nano	154
iii.	Revising REACH? No But Yes	158
B.	Addressing Nanotechnologies via Comitology	160

C.	Addressing Nanotechnologies via ECHA Guidance Documents.....	160
i.	ECHA Guidance on Information Requirements and Chemical Safety Assessment.....	162
ii.	ECHA Guidance on Nanomaterials in IUCLID 5.....	164
D.	The State of Play: Spotlight on the EU Executive.....	165
III.	Analysing the EU's Regulation of Nanochemicals through the Lenses of Regulatory Capacity.....	166
A.	Pooling Knowledge.....	167
i.	Pooling Knowledge in the Drafting of the REACH Implementing Act(s).....	167
ii.	Pooling Knowledge in the Drafting of ECHA's Guidance Documents.....	170
iii.	Synthesis: Pooling Knowledge.....	179
B.	Participation.....	180
i.	Participation in the Drafting of REACH's Implementing Act(s).....	181
ii.	Participation in the Drafting of ECHA's Guidance Documents.....	184
iii.	Synthesis: From Parliamentary Absence and a Cosy Stakeholder Collaboration.....	188
C.	Accountability.....	190
i.	The Parliament's ex post Scrutiny of ECHA's Guidance Documents.....	190
ii.	In Legal Twilight: The Role of the EU Courts.....	191
iii.	Administrative Accountability: The Expandable Role of the European Ombudsman.....	193
iv.	Social Accountability: Transparency on Paper.....	194
v.	Synthesis: Holding ECHA to Account.....	196
IV.	Conclusion.....	197
6.	Conclusion.....	199
I.	Regulating in Today's Nano Society: The Point of Departure.....	199
II.	Spotlight on the EU Executive.....	200
III.	Main Findings of the Critical Analysis or the Pitfalls of 'New Governance'.....	201
A.	The Impact Assessment: Between Empty Proceduralisation and Strategic Choice.....	201
B.	The Fragmentary Proceduralisation of EU Agency Rule Making.....	202
C.	Depoliticisation: Towards Technocratic Rule?.....	203
i.	The Lack of Parliamentary Involvement.....	203
ii.	The Spectacle of Administrative Participation.....	203

D.	The (Self-)Tied Hands of the EU Courts.....	204
E.	(In)transparency.....	205
IV.	Repercussions for the Meta-Theoretical Level: Is ‘New Governance’ ‘Better Governance’?.....	206
V.	Strengthening Regulatory Capacity: Proposals for Reform at the Micro Level.....	207
A.	Impact Assessment Reloaded.....	207
i.	Clarifying its Scope of Application.....	207
ii.	The Operation of the Impact Assessment: Proportionate Level of Analysis or <i>Carte Blanche</i> ?.....	209
B.	Towards a Structured Proceduralisation in EU Agencies	210
C.	Repoliticising a Depoliticised Political Debate	211
D.	From Lapdog to Watchdog: The Catalyst Function of the EU Courts	213
E.	Taking the EU Ombudsman Seriously.....	215
F.	Fostering a Transparent Regulatory Process.....	216
VI.	Three Facades of EU Risk Regulation	217
A.	The Facade of Participation	218
B.	The Facade of Scientific Truth	220
C.	The Facade of Non-Bindingness.....	222
VII.	Outlook.....	224
	<i>Bibliography</i>	225
	<i>Index</i>	243