

Table of contents

Introduction: The definition of public health and its position in the European Union.....	19
Section 1: Conceptual and historical background to the research	25
I. Key concepts of the research	25
A. Health	26
B. Public health	27
C. Global health.....	29
II. Evolution of EU public health: political and legal aspects.....	31
A. Early concerns regarding public health.....	31
B. Public health as a justification to barriers to the internal market.....	33
C. Public health as an autonomous field.....	35
Section 2: Research question	41
Section 3: Structure and relevance of the topic	43
PART I: Fragmentation in the EU public health constitutional framework	47
Section 1: Legal bases in EU public health.....	51
I. Asymmetry between EU public health objectives and competences.....	52
A. EU public health objectives	52
B. EU public health competences under Article 168 TFEU.....	54
1. EU internal public health competence	55
2. EU external public health competence.....	56
II. From competence gap to competence creep? Alternative legal bases to legislate in EU public health.....	58
A. The unsuitability of the flexibility clause as a legal basis.....	59
1. Evolution of the conditions in the flexibility clause.....	59
2. Interpretation of the flexibility clause by the CJEU	60
B. The appropriateness of Article 114 TFEU as a legal basis	62
1. Article 114 TFEU and public health protection.....	63
2. Limits to the use of Article 114 TFEU for public health reasons	63
3. The mainstreaming of Article 114 TFEU as an alternative legal basis for public health measures	65
a. Article 114 TFEU in the early case law on tobacco control.....	65

b.	Recent case law on tobacco control	67
c.	Article 114 TFEU as a legal basis for the conclusion of international agreements.....	69
C.	Other legal bases for the adoption of public health measures	71
1.	Common Agricultural Policy	71
2.	EU environmental policy.....	72
III.	Conclusions on Section 1	74
	Section 2: Institutional fragmentation in EU public health.....	75
I.	Internal fragmentation in EU public health.....	76
A.	Inter-institutional and intra-institutional fragmentation	76
1.	Inter-institutional fragmentation	76
a.	The BSE crisis as a turning point in the institutional structure of EU public health.....	77
b.	Role of EU institutions in public health	79
2.	Intra-institutional fragmentation	82
B.	EU agencies in the public health institutional framework.....	83
1.	EU agencies as an additional layer of fragmentation in EU public health.....	83
a.	The increasing number of EU agencies	84
b.	The contested role of EU agencies.....	85
(i)	Nature of EU agencies scientific opinions: from advisory opinions to binding acts.....	85
(ii)	Challenges against EU agencies' scientific opinions.....	86
2.	EU agencies as an opportunity for the global promotion of public health.....	88
a.	Participation-cooperation: agencies' activities beyond the borders of the European Union.....	89
(i)	Cooperation instruments between EU agencies and third parties.....	89
(ii)	Legal nature of cooperation instruments between EU agencies and third parties.....	91
b.	Participation-integration: the integration of third countries in EU agencies ...	93
II.	Heterogeneous participation of the European Union in international organisations and agreements.....	95
A.	Participation in international organisations	96
1.	The European Union as a full member in international organisations and its implications.....	96
a.	The European Union as a full member: the examples of the FAO, the Codex Alimentarius Commission and the WTO.....	96
(i)	Food and Agriculture Organization.....	97
(ii)	Codex Alimentarius Commission.....	98
(iii)	World Trade Organization.....	98

b.	Implications of the full-membership status	99
(i)	The complex exercise of voting rights at the FAO	99
(ii)	The smooth exercise of voting rights at the WTO.....	102
2.	The European Union as an observer: the example of the World Health Organization.....	103
a.	Rights and obligations of the European Union at the World Health Organization.....	103
b.	Can the European Union become a full member to the WHO?	105
B.	Negotiation and conclusion of international agreements	108
1.	The European Union as a contracting party to international agreements	108
2.	Member States as contracting parties to international agreements.....	111
III.	Conclusions on Section 2.....	112
Section 3: Impact of fragmentation on the consistency principle		113
I.	The principle of consistency in EU law	113
A.	Evolution of the principle of consistency in EU law	114
B.	Obligations under the principle of consistency.....	115
1.	Vertical and horizontal consistency	115
2.	Positive and negative consistency	117
II.	The principle of consistency in EU public health.....	118
A.	Horizontal and vertical consistency in EU public health.....	118
1.	Horizontal consistency in EU public health	119
2.	Vertical consistency in EU public health.....	120
B.	Positive and negative consistency in EU public health	121
III.	Adding one more piece to the puzzle: consistency at the global level.....	123
A.	Potential conflicts between the WHO, the WTO and the Codex Alimentarius Commission.....	124
1.	Conflicts between WHO agreements and WTO agreements	124
2.	Conflicts between WTO agreements and international public health standards ..	125
B.	Potential solutions to the conflicts of norms at the global level.....	126
1.	Balancing the different interests at stake	126
2.	Private international law rules of interpretation	127
3.	The 'Bosphorus' solution	127
4.	Other international agreements as international standards	128
5.	Rule of harmonious interpretation.....	128
6.	Cooperation mechanisms between international organisations	129
IV.	Conclusions on Section 3.....	129
General Conclusion on Part I		131

PART II: The promotion of public health in the convergence scenario 135

Section 1: The promotion of public health as a response to security challenges: the case of cross-border health threats 141

I.	Convergence at the EU and at the global levels regarding the protection of public health for security reasons	143
A.	Foundations of the regulation of communicable diseases in Europe.....	143
B.	Internationalisation and securitisation of cross-border health threats control	145
C.	Regulation of cross-border health threats in the European Union	148
1.	Notion of cross-border health threats	149
2.	EU policy on cross-border health threats: from a securitarian to a ‘one-health’ approach	151
a.	A securitarian approach towards cross-border health-threats	151
(i)	The Health Security Committee as the first attempt to link health and security.....	151
(ii)	The European Centre on Disease Prevention and Control: a more formalised approach to health security.....	153
(iii)	The contribution of EU institutions to the promotion of the health-security linkage	154
b.	A ‘one health’ approach towards cross-border health threats	156
3.	Surveillance and response system to cross-border health threats.....	160
a.	Surveillance system to cross-border health threats	160
b.	Response mechanism to cross-border health threats	162
II.	The promotion of public health through the lens of security in bilateral agreements: the example of the European Neighbourhood Policy	165
A.	Goals of the European Neighbourhood Policy: security as a pillar.....	166
B.	EU public health actions in the neighbourhood.....	168
1.	The security-oriented discourse towards cross-border health threats in the European Neighbourhood Policy.....	169
2.	Surveillance systems for cross-border health threats in the European region	171
C.	Is there room for improvement?	172
V.	The promotion of public health security standards at the multilateral level: the negotiation of the International Health Regulations.....	174
A.	The International Health Regulations as a multilateral response to cross-border health threats.....	174
B.	EU participation in the negotiation and implementation of the IHR	177
1.	EU participation in the negotiation of the IHR	178
2.	EU role in the implementation of the IHR.....	180
C.	Prospective role of the European Union at the multilateral level.....	182

IV. The successful promotion of EU standards on cross-border health threats: the case of antimicrobial resistance.....	184
A. Convergence at the EU and at the global levels in the field of antimicrobial resistance.....	184
1. EU actions on antimicrobial resistance: multiple standards for a coherent action plan.....	185
a. EU standards in antimicrobial resistance.....	185
(i) Antimicrobial resistance and the health-security linkage.....	185
(ii) A variety of concerns on antimicrobial resistance.....	186
b. A comprehensive approach towards antimicrobial resistance.....	187
(i) EU competence in the field of antimicrobial resistance.....	188
(ii) Development of a holistic approach towards antimicrobial resistance...	189
2. Global approach on antimicrobial resistance: a strong interest and a patchwork of actions.....	192
a. Priorities on AMR at the World Health Organization.....	192
b. Difficulties to a coherent action on AMR at the global level.....	194
B. Role of the European Union at shaping international standards.....	196
1. The role of the European Union at the global level as an opportunity and a requirement.....	196
2. AMR clauses in bilateral agreements.....	197
3. The European Union as a key actor at the multilateral level.....	199
VI. Conclusions on Section 1.....	202
Section 2: The promotion of public health beyond security: the case of non-communicable diseases.....	205
I. The European Union and the fight against tobacco consumption.....	206
A. Convergence at the EU and at the global levels in tobacco control.....	206
1. EU expertise in tobacco control.....	207
a. Shadows in the EU tobacco-control system.....	207
b. EU tobacco-control legislation.....	210
2. The international momentum for tobacco-control measures.....	214
B. EU role in the negotiation and implementation of the Framework Convention on Tobacco Control.....	217
1. Difficulties in the participation of the European Union in the negotiation of the FCTC.....	217
a. EU competence in the field of tobacco control.....	217
b. Status of Regional Economic Integration Organisations in the negotiation and conclusion of the FCTC.....	218
2. EU leadership during the negotiation of the FCTC.....	219
a. Obstacles to an EU common approach in the FCTC negotiations.....	219

b.	Overcoming the challenges: the European Union as a positive force during the negotiations.....	222
3.	EU commitment in the implementation of the FCTC.....	224
a.	Implementation of the FCTC at the global level.....	224
b.	Implementation of the FCTC at the EU level.....	226
II.	The promotion of healthy diets at the international level: What role for the European Union?.....	229
A.	Convergence at the EU and at the global levels towards the promotion of healthy diets.....	229
1.	EU actions in the fight against obesity.....	229
a.	The promotion of the internal market and the fight against obesity.....	230
b.	Examining the validity of ‘sugar taxes’ under EU law.....	231
c.	Soft law instruments to fight against obesity.....	234
2.	Global actions in the fight against obesity.....	235
a.	Existing measures in the fight against obesity.....	235
b.	The need for a legally binding multilateral convention.....	236
B.	Implications for the promotion of EU standards at the global level in the fight against obesity.....	239
III.	Conclusions on Section 2.....	240
	General Conclusion on Part II.....	243
	PART III: The promotion of public health in the divergence scenario.....	245
	Section 1: The promotion of EU public health standards in the trade of goods.....	251
I.	Divergence between the European Union and third parties in the balance between the trade of goods and public health.....	252
A.	The precautionary principle in EU law.....	253
1.	Genesis of the precautionary principle in the European Union.....	254
2.	Interpretation of the precautionary principle by the CJEU.....	255
a.	Recognition and definition of the precautionary principle.....	255
b.	Conditions for the application of the precautionary principle.....	256
B.	The contested nature of the precautionary principle at the global level.....	258
1.	The precautionary principle in international agreements.....	259
a.	Development of the precautionary principle in multilateral environmental agreements.....	259
b.	Limits to the precautionary principle in WTO agreements.....	261
(i)	SPS Agreement.....	261
(ii)	GATT 1994.....	263
(iii)	TBT Agreement.....	265

2.	The precautionary principle in a comparative perspective	266
C.	Implications of the divergent approaches for trade negotiations.....	269
1.	Risks to public health protection in the procedural features of the EU trade policy	269
2.	The limited promotion of non-trade interests at the World Trade Organization. 270	
a.	The failed incorporation of non-trade interests during the Doha Round negotiations	271
b.	Litigation resulting from divergent regulatory approaches	271
3.	Risks to public health protection in EU bilateral trade and investment agreements.....	272
a.	Regulatory convergence and its impact on the precautionary principle	273
(i)	TBT and SPS chapters: the crystallization of WTO rules.....	273
(ii)	TSD chapters: a weak attempt to preserve non-trade interests.....	274
(iii)	Equivalence of legislation: the circumvention of the obligation to respect regulatory standards.....	277
(iv)	Regulatory cooperation: the development of a unique regulatory approach.....	277
b.	Risks to public health in bilateral investment agreements.....	279
(i)	Status of the right to regulate in investment agreements	279
(ii)	The investor-State arbitration system and its risk to the preservation of public interests.....	281
(iii)	Lack of participation of third parties to the proceedings.....	281
c.	Litigation resulting from the risks of bilateral trade agreements to public health	283
II.	Trade as a tool to promote public health.....	285
A.	EU influence in multilateral negotiations	285
1.	EU influence in the negotiation of trade-related multilateral environmental agreements	286
2.	The right to regulate in the negotiation of a multilateral investment court.....	288
B.	Protecting public health in bilateral trade and investment agreements	289
1.	Public health protection through the procedural features of the Common Commercial Policy.....	290
a.	General principles and the Common Commercial Policy.....	290
b.	Role of the European Parliament at protecting public health in trade negotiations	293
c.	Participation of other actors in the debate on bilateral trade agreements	295
2.	Public health protection in the substantive provisions of EU trade agreements ..	296
a.	The significance of TSD chapters in EU trade agreements.....	296
b.	'Conditional equivalence' as a mechanism to protect public interests.....	298
c.	The right to regulate in a context of regulatory cooperation.....	300

3.	Public health protection in the substantive provisions of EU investment agreements	301
a.	The 'loser pays' principle as an incentive to regulate in the public interest....	301
b.	The 'judicialisation' of arbitration	302
C.	The European Union as a regulatory hegemon and its influence in public health promotion	303
1.	The European Union as a regulatory hegemon	304
2.	The European Union as a global regulator of cosmetic products and its impact on public health protection.....	306
a.	Foreign legislation based on EU rules on cosmetic products.....	306
b.	Role of civil society in the adoption of voluntary rules by private undertakings.....	308
III.	Conclusions on Section 1	309

Section 2: The promotion of EU standards in the balance between intellectual property rights and access to medicines..... 313

I.	Divergence in the debate on intellectual property rights and access to medicines.....	315
A.	Debate on the trade-related aspects of intellectual property rights at the global level	315
1.	International regulation of intellectual property rights: from WIPO to the WTO	316
2.	Debate on public health and intellectual property rights at the WTO.....	317
a.	Divergent views in the negotiating process of the TRIPS Agreement	317
b.	Arrangements to accommodate public health concerns in the TRIPS Agreement.....	319
(i)	Impact of the TRIPS Agreement on public health	319
(ii)	The Doha Declaration on the TRIPS Agreement and Public Health.....	320
B.	The evolutionary approach of the European Union towards intellectual property rights and public health.....	322
1.	Evolution of the EU external capacity to act in the field of intellectual property	322
a.	The European Union in intellectual property international organisations	323
b.	EU external competence in the field of intellectual property rights	324
2.	Evolution of the EU position on the balance between intellectual property rights and public health.....	325
a.	The European Union in the road to Doha: from a strict application of intellectual property rules to the embracement of flexibilities.....	325
(i)	EU position in the pre-Doha period.....	326
(ii)	The Doha Declaration: a turning point in the EU position on intellectual property rights and public health	328
b.	Inconsistencies following the Doha Declaration	329
(i)	The 2005 Strategy for the enforcement of intellectual property rights in third countries	329

(ii) EU legislation facilitating access to essential medicines.....	331
(iii) The 2014 Strategy for the protection of intellectual property rights in third countries.....	333
II. The promotion of EU standards in the balance between intellectual property rights and public health.....	335
A. Role of the European Union in the negotiation of the Doha Declaration.....	335
B. Negotiation and conclusion of bilateral trade agreements and their impact on access to medicines.....	338
1. Bilateral trade agreements with developing countries: the example of the EC- CARIFORUM Agreement.....	339
2. Bilateral trade agreements with developed countries: the EU-Korea Agreement	341
3. Recent trends in the negotiation of bilateral trade agreements.....	342
III. Conclusions on Section 2.....	345
General Conclusion on Part III.....	347
PART IV : Conclusions.....	351
Section 1: Summary of the main findings.....	355
Section 2: Is the European Union successful at promoting public health at the global level?.....	361
I. Factors contributing to public health promotion in EU external relations.....	361
II. Role of the European Union in the global promotion of tobacco-control legislation.....	364
Section 3: Recommendations and further research.....	369
I. A horizontal approach towards public health.....	369
A. Redrafting public health provisions in the Treaties.....	370
1. Expansion of EU public health powers under Article 168 TFEU.....	370
2. Beyond economic health concerns: a human rights approach to public health....	372
3. Addressing current public health challenges.....	373
B. Effective use of the principle of sincere cooperation.....	373
II. What relationship between public health and EU principles and objectives?.....	375
A. Public health protection as a general objective of the European Union.....	375
B. Further research: principles applicable to EU public health.....	377
Bibliography.....	381
Table of legislation.....	383
Primary European Union Law.....	383

International agreements	384
International agreements not yet in force	387
Secondary European Union Law	388
1. Regulations	388
2. Directives	391
3. Decisions	394
4. Recommendations	397
5. Other secondary law	397
National Legislation	398
Soft Law	399
Table of cases	405
Court of Justice of the European Union	405
1. Judgments of the Court	405
2. Judgments of the General Court	411
3. Opinions of the Court	412
4. Orders	412
5. Opinions of Advocates General	413
International Decisions and Awards	413
National Decisions	415
Doctrine	417
Books	417
Contributions to Edited Books	421
Articles	434
PhD Theses	447
Reports, Documents and Articles from Think Tanks	448
Non-Academic News and Websites	451
Institutional sources	453
Documents from EU Institutions	453
1. Communications from the European Commission	453
2. Other Documents from the European Commission	456
3. European Parliament	460
4. Council of the European Union	461
5. European Council	462

6. Court of Auditors.....	463
7. Other EU organs and organisms.....	463
Documents from International Organisations.....	463
1. Resolutions and Decisions	463
2. Reports.....	466
3. Other official documents from international bodies.....	467
Press Releases.....	468
Scientific opinions from EU institutions and international organisations	474
Other documents	475
Institutional Websites	476
Interviews.....	482
Index	483